

# CareManagement

JOURNAL OF THE COMMISSION FOR CASE MANAGER CERTIFICATION | THE CASE MANAGEMENT SOCIETY OF AMERICA | THE ACADEMY OF CERTIFIED CASE MANAGERS

Vol. 26, No. 3 June/July 2020

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##### A Frank Conversation **CE**

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The National Academy of Medicine estimates that over 100 million people have chronic pain in the United States and estimates the cost of chronic pain at \$600 billion annually. Chronic pain, which is often a component of disability claims, is the not-so-hidden trigger for the opioid epidemic: opioid abuse most often starts with trying to find something to help with the pain. Fixing the opioid crisis requires a multipronged approach.

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Gary S. Wolfe

## From the Publisher and Editor-In-Chief

**W**e are pleased to announce the appointment of Catherine M. Mullahy, RN, BS, CRRN, CCM, as the Executive Editor of the journal *CareManagement*. Mullahy has had a distinguished career in case management. She has shaped the course of case management in advocating for higher credentialing standards, certification, ethics, and performance monitoring.

In 1983, following her clinical work, she founded Options Unlimited, a full-service case management firm providing utilization, case management, and disease management along with employee risk reviews to businesses, insurers, municipalities, and third-party administrators. In 2003, the firm was acquired by Matria Health, Inc. and became its Case Management Division. She later founded Mullahy and Associates, LLC, with the sole purpose of educating and training case managers to deliver the highest standards of case management. She developed the premier course for the foundational preparation of case managers and their successful certification.

Mullahy has assumed key leadership roles within the profession and has served as the National President of the Case Management Society of America. She has also served as Commissioner and then Chair for the Commission for Case Manager Certification, during which time she led the development of its Code of Professional Conduct. She has served on numerous boards and committees that

provide leadership in health care.

Mullahy is a frequent presenter and author in leading health care and case management publications. She is the author of the profession's definitive textbook, *The Case Manager's Handbook*, now in its 6th edition. This book is used widely in graduate and undergraduate nursing and health management courses throughout the United States and Canada as well as 18 other countries.

In recognition of her major contributions to case management, Mullahy received CMSA's 2010 "Lifetime Achievement Award," CMSA's 1999 "Distinguished Case Manager of the Year" Award, and the professional Rehabilitation Association's 1997 "Rehabilitation Professional of the Year."

Mullahy joins the editorial staff of *CareManagement* as the publication celebrates 25 years of publishing and will continue to support the mission of improving case management practice through education.

Please join us in welcoming Cathy to the editorial team!

Gary S. Wolfe, RN, CCM  
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*CareManagement*

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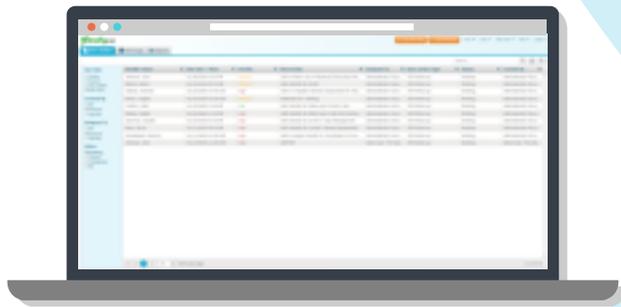
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Catherine M. Mullahy

# A New Chapter in Case Management for All of Us!

**A**s this journal begins its 26th year, I am excited about beginning yet another chapter in my case management journey. When Jennifer Maybin, the extremely talented individual who preceded me, announced her retirement a few months ago, I was asked to join the staff of *CareManagement*. The journal has been a familiar and valued resource for me since its creation by Publisher Howard Mason, RPh, MS. As I join him and long-term friend and colleague, Editor-in-Chief Gary Wolfe, RN, CCM, as well as the journal's terrific staff, I wonder just what is in front of us? My association with this publication has been a long one, as a reader, contributing author, and member of the editorial board. In my new role, I will have the opportunity to listen to our readers, share valuable insights from our contributors, and advance a platform committed to the highest standards of case management.

As I considered my first column, I reflected on our world in turmoil; we are experiencing so many challenges, some exciting and others very sobering. I wondered just where to begin. We continue toward an unknown destination along a path that, to say the very least, has been a bumpy one. With everchanging rules and regulations that attempt to provide guidance during the COVID-19 pandemic, yet pose their own conflicts, the world of health care is more challenging than

ever. Nothing today is even remotely the same as it was months ago, and the future is uncertain. Who would have thought that we would still be debating how COVID-19 is diagnosed, treated, and prevented? We know so much, yet so little. Just as we get closer to uncovering and resolving one problem, another one appears and presents still more challenges. We talk of returning to normal but recognize it will likely be a "new normal." Our nation's health care system is faced with an unprecedented challenge—one for which it is clearly unprepared in terms of vital equipment and facilities—and we now struggle with the consequences. Social determinants of health, which were previously recognized as having a critical impact on health and wellness, are now front and center. It is evident that the "one-size-fits-all" approach will not work and that case management can and will be a viable solution.

Where will case management be during this chaotic state of affairs? Right where it has always been...on the front line! As strategic leaders, case managers have a more important role than ever before. We have a unique opportunity to find creative solutions rooted in our standards of practice, codes of conduct, and the evidence-based guidelines that are continuing to evolve for our patients across the growing continuum of care and practice settings.

We will be busy preparing new content for the journal, mentoring

new authors, and adding to the well-regarded CE content that will prepare you to meet the challenges ahead. We look forward to embarking on this journey with you! As always, your suggestions, comments, and support are welcomed.

*Catherine M. Mullahy*

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# Case Managers on the Front Lines of COVID-19

MaryBeth Kurland, CAE

**T**he COVID-19 pandemic has impacted many case managers, both personally and professionally, as evidenced in a [recent survey](#) with nearly 7,000 responses from board-certified case managers (CCMs).

Based on the preliminary results, more than half (57%) of respondents said they were working remotely, which meant having limited in-person contact with clients and patients (55%). Not surprising, many (40%) were fielding more questions than ever from the clients and patients.

Some case managers have been called to work on the frontlines, including to provide case management

COVID-19 patients can access lifesaving treatment without compromising public health objectives and the safety of health workers.”

While the demands being placed on case managers have escalated, some have been facing difficulties. For example, a significant percentage of survey respondents reported dealing with staff shortages (15%) and a lack of supplies (28%).

Case managers have also been personally affected. Income loss is a concern among a significant percentage of the case managers who answered the survey (30.5%), while food scarcity is also a concern for a notable percentage

we do this is by providing access to webinars and training, particularly related to COVID-19 as well as other educational programs. Many are free.

A variety of resources can be found on the [CCMC website](#). Examples include:

- [The National Association of Social Workers'](#) (NASW) COVID-19 webpage includes educational and advocacy resources, broken down by category (eg, ethics, workforce). It also has links to webinars that are free to NASW members.
- The [Alliance for Health Policy](#) has produced a series of COVID-19 webinars. The focus is on public

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**The Commission for Case Manager Certification (CCMC) is committed to supporting the professional case management community. One way we do this is by providing access to webinars and training, particularly related to COVID-19 as well as other educational programs.**

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for individuals with COVID-19. For these case managers, in particular, the stakes are high. According to a recent World Health Organization (WHO) report, “[Operational Considerations for Case Management of COVID-19 in Health Facility and Community](#),” the primary importance is to “ensure that

*MaryBeth Kurland, CAE, is CEO of the Commission for Case Manager Certification, the first and largest nationally accredited organization that certifies over 48,000 professional case managers and nearly 2,300 disability management specialists. The Commission is a nonprofit volunteer organization that oversees the process of case manager certification with its CCM credential and the process of disability management specialist certification with its CDMS credential.*

(16.6%). Nearly one-quarter (21%) of respondents report clinical health issues, and approximately 5% of those responding say the practice or organization they work for has shut down completely.

Most distressing of all, many more than we anticipated—5.3% of responding case managers—report losing loved ones to COVID-19. Despite their heavy burdens, case managers demonstrate admirable resilience. In addition, there is a real hunger among case managers to learn more about the coronavirus. They want to be trusted resources for clients and patients, colleagues, friends, and family.

The Commission for Case Manager Certification (CCMC) is committed to supporting the professional case management community. One way

health, but some have direct application for case managers, including [COVID-19 Webinar Series Session 9 – Social Isolation and Loneliness](#).

- [Nurse.org](#) has curated 5 online training resources for nurses.
- [The Institute for Health Improvement](#) has curated a collection of COVID-19 guidance and resources, including a link to its Virtual Learning Hour Special Series.
- [The National Academy of Medicine](#) provides an array of coronavirus resources, including webinars and videos.
- [American Academy of Ambulatory Care Nursing's](#) site features links *continues on page 32*

# Latest CDMS Role and Function Study Underway

MaryBeth Kurland, CAE

**T**he practice of [disability management](#) has evolved over the years from its roots in insurance-based rehabilitation.

Today, it covers a wide range of services and solutions to help people with illnesses, injuries, and disabilities return to or stay at work.

As board-certified practitioners in this dynamic field, Certified Disability Management Specialists® (CDMSs) must have the knowledge and skills required to analyze workplace health and safety risks, recommend

prevention strategies, and alleviate both the personal and professional impacts of disability. The role of the [CDMS](#) can be described as getting

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**The research-based role and function study is undertaken regularly to identify the essential activities performed by disability managers as well as the important knowledge statements of what is needed to effectively perform this role.**

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employees “back to well, back to work, and back to life.”

To keep up with this evolution in disability management practice, a job

analysis, known as a role and function study, is conducted every 5 years. The latest CDMS role and function study is currently underway. Results of the

study will ensure that eligibility criteria and the certification examination content remain up to date and relevant for the CDMS credential, which is administered and governed by

the Commission for Case Manager Certification (the Commission).

The research-based role and

[continues on page 31](#)



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# Case Managers in the COVID-19 Environment: Resist, Recharge, Regroup

Melanie A. Prince, MSN, BSN, NE-BC, CCM

October 11–17, 2020, is National Case Management Week, and this year’s recognition is one for the record books as the world copes with and recovers from the COVID-19 pandemic. As with most health care professionals, case managers have found themselves adapting to the challenges of the impact of coronavirus disease on “care management as usual.” Case managers are uniquely equipped to tackle the most complex problems, but the added pressures of keeping one’s self safe, juggling family and social disruptions, and coordinating care in overwhelmed or conversely, closed facilities, have turned up the pressure valve. Many case managers continue to manage significant caseloads while simultaneously dealing with home schooling, child care, and head of household responsibilities as well as being the family medical advisor and teleworking. It’s a lot!

It is critically important for case managers to pause and devote

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*Melanie A. Prince, MSN, BSN, NE-BC, CCM, is incoming president of the Case Management Society of America 2020. Recently retired as an Air Force Colonel, she is chief executive officer, Care Associates Consulting, and is frequently asked to deliver presentations, editorials, and training on various case management and leadership topics. Melanie is a certified professional case manager and nurse executive, and she has master’s degrees in nursing case management and military strategic studies.*

deliberate time to **resist, recharge,** and **regroup.** Case managers are celebrated for the outstanding care provided to patients, families, and clients. Case managers are also notorious for acting above and beyond, often neglecting (unintentionally) their own needs. However, the COVID-19 environment shines a light on the many demands and pressures on case managers, professionally and personally. **Resist** operating from a

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**The COVID-19 environment has produced drastic changes in the way we live, work, and play, but these changes can be shaped to produce new roles for case managers.**

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place of fear or anxiety. **Resist** the urge to conquer it all...whatever the “it” may be. America demonstrates its compassion and generosity for others during times of crises and this is the moment when asking for help may be the easiest. There are many people who are looking for ways to support others or give back to the community in small and large ways. Have the courage to let someone know you can use a hand. **Resist** the status quo of managing it all.

Find ways to **recharge** and find your center. Today’s stressors, in some ways, are unprecedented. Some case managers have lost a loved one and are struggling to maintain a caseload while grieving. They may have friends or relatives who are ill from COVID-19 or other illnesses but are having difficulty accessing the health care system because of the increased demand.

A job loss for the case manager or a family member who contributed to the household income may place a drain on the family finances. If you are reassigned to a new clinical area that is unfamiliar but critical to meeting the COVID-19 cyclical surges, be deliberate about scheduling time to **recharge** every day in some small way. I made a list of activities that puts me in a “happy place.” From gardening and trying new recipes

to contacting a different acquaintance or taking photos of interesting things that I had never stopped to notice before gives me a boost. I exhaust a new list every week for

my “**recharge** moment.” My mood and energy have sustained a level of positivity despite these trying times.

Finally, case managers should use this time to **regroup.** Crises birth opportunities. Problems fuel solutions. The COVID-19 environment has produced drastic changes in the way we live, work, and play, but these changes can be shaped to produce new roles for case managers. For example, occupational case management has typically functioned in the context of injury recovery. The COVID-19 workplace has different concerns such as a renewed emphasis on Occupational Safety and Health Administration compliance, employee screening, contact tracing, and safety monitoring. Occupational case managers can transition to a population health approach and manage a cohort of

*[continues on page 32](#)*



# CARF Update

Chris MacDonell, FACRM

**A**s this article is being written, the world is in the midst of a pandemic that has had an enormous impact on the world of rehabilitation and health and human services. As an international accreditation system with over 1400 peer review surveyors and more than 3200 surveys occurring per year, everything has come to a standstill. One of the outcomes of this focusing event is that innovation and creativity along with empathy and recognition of the uniqueness of all the fields CARF International works in has created a quick response to keep the over 14 million people served in our accredited programs safe. As of June 1, 2020, a few organizations will participate in a pilot to explore options if they are due for a CARF survey. The pilot will include a Digitally Enhanced Site Survey (DESS), which is one of the options, as well as other extensions with submission of important information to discern ongoing conformance for a period of time. We know that CARF-accredited programs have a strong foundation in health, safety, emergent conditions, and risk management that assists them in providing quality services during this difficult time. Many of our organizations/programs/services have been accredited for a number of years and have done well in following

*Christine M. MacDonell, FACRM, is the Managing Director of Medical Rehabilitation and International Aging Services/Medical Rehabilitation in Tucson, Arizona.*

their country's guidelines and have protected the individuals who are in their programs as well as their workforce. Information coming from countries about the long-term effects of COVID-19 would lead us to believe that quality rehabilitation programs, throughout the continuum of services, will be needed since cognitive, behavioral, mental, and physical issues

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**CARF-accredited programs have a strong foundation in health, safety, emergent conditions, and risk management that assists them in providing quality services during this difficult time.**

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seem to remain long after "recovery." One of the first rehabilitation recovery COVID units recently graduated their first patient. [Here is a link](#) to see this program at Mary Free Bed Hospital in Grand Rapids Michigan.

We will not detail any of the new accreditation options in this article since it is a pilot. We will have many lessons to be learned. We plan to determine whether these options are good for our providers and whether they will ensure that the lives of persons served are enhanced, and we will determine whether to continue with these new options after the threat of COVID-19 has decreased and a vaccine is available. We want to express our pride in all health and human service employees around the world who have done such an incredible job. During these difficult times, case managers are critical to shepherd individuals, families, essential workers, and stakeholders. As regulations are waived in medical rehabilitation, telerehabilitation becomes

a new way to deliver services because many of the most vulnerable patients are isolated.

There are many resources to assist individuals working in health and human services. It has been amazing to see the willingness of providers in the field of medical rehabilitation around the world share lessons learned from their interaction with COVID-19. We

know that CMSA has kept their membership current. CARF International is working with many of our International Advisory Council members to get information out to the

field, so CMSA is welcome to send information that they think would benefit an audience of organizations on the front lines and those dealing with vulnerable populations. What we have learned and seen in these difficult times is that barriers are removed and everyone wants to be able to assist others. We hope you all remain safe, well, and healthy. **CM**

## Readers

Have an idea for an article?  
Send your suggestions for editorial topics to:  
[cmullahy@academyccm.org](mailto:cmullahy@academyccm.org).

# Running Toward the Fire

Elizabeth Hogue, Esq.

**M**uch of the focus thus far in the treatment of COVID-19 patients has been on hospitals and rightfully so. Practitioners on the front lines of treatment of COVID-19 patients and policy makers are now beginning to advocate for the treatment of COVID-19 patients at home instead of in hospitals. Are home care providers ready to run toward the fire?

Italian physicians led the way, as reported in an article, “A Plea From Doctors in Italy: To Avoid COVID-19 Disaster, Treat More Patients at Home,” by Sharon Begley that appeared in STAT on March 21, 2020. The article says:

A dozen physicians at the epicenter of Italy’s COVID-19 outbreak issued a plea to the rest of the world..., going beyond the heartbreaking reports of overwhelmed health care workers there and a seemingly uncontrollable death toll to warn that medical practice during a pandemic may need to be turned on its head with care delivered to many patients at home.

Fearful that major hospitals and ambulances transporting sick patients to hospitals became major sources of transmission of COVID-19, physicians said:

Managing patients at home is a brilliant thing...and one that could be augmented by mobile clinics and telemedicine. Bring them nutrition, measure their oxygen levels, even bring them oxygen, and you probably keep many of them at home... That change would decrease transmission and protect other patients as well as health care workers.

Then, in “Will 2020 Be the Year That Medicine Was Saved?” that appeared in *The New York Times* on April 14, 2020, Ezekiel J. Emanuel and Amol S. Navathe, who direct the Healthcare Transformation Institute at the

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**Practitioners on the front lines of treatment of COVID-19 patients and policy makers are now beginning to advocate for the treatment of COVID-19 patients at home instead of in hospitals. Are home care providers ready to run toward the fire?**

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University of Pennsylvania, pointed out that treatment of chronic conditions has been slowly moving from hospitals to home care. The authors said:

In general, patients treated at home recover faster, with fewer tests, fewer readmissions, and high satisfaction. And care in the home typically costs less than care in hospitals. COVID-19 has shown that even more patients can be treated well without being hospitalized.

Among the authors’ recommendations in the article is that: “hospitals should be required to offer all low-risk patients a care-at-home option, so they can stay out of the hospital...”

Finally, in “Senior Care Innovator Bill Thomas: COVID-19 Rewriting Health Care Rules, Pushing Home Care into the Spotlight,” by Joyce Famakinwa that appeared in *Home Health Care News* on April 20, 2020, Mr. Thomas characterized the COVID-19 virus as a “home- and community-based emergency.”

Thomas went on to say:

Let’s say that the intense focus on hospitals, ventilators, and ICU beds was the right thing in the early weeks of the outbreak. Maintaining that focus, going forward, is actually counterproductive. If we’re going to control the virus in the months before we have a vaccine, it’s not the hospitals that are going to get control of the virus, it’s the home. That’s where we will hold the virus at bay.

Thomas closed with this prediction:

First, we’re going to finally see an awareness from health care systems that home care is an essential part of the equation and not just someone to call at the end of a hospitalization. Home care providers need to be at the table, working side-by-side with health care systems to design responses...In order to manage the second, third and fourth wave of this COVID virus, we’re going to need a really powerful, well organized, well-resourced home care system nationally.

Yes! Yes! Yes!

The focus on home care providers as first responders, however, means that they must be prepared to “run toward the fire” as first responders do instead of “mopping up” after patients are discharged from hospitals. Scary as this idea may seem to some, there is no doubt that home care providers are up to challenge. As a longtime friend to home care, I know it’s so! Make it so! **CM**

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# Hospital Discharge Planners Risk Disciplinary Action by State Licensure Boards

Elizabeth Hogue, Esq.

**A** key manager at a home health agency (HHA) recently related an instance that seems like a clear failure to comply with applicable standards for discharge planning from hospitals. The manager said that the Agency received a referral from a hospital and subsequently admitted the patient. Two days after the patient was admitted to the Agency, the hospital notified the Agency that the patient was positive for COVID-19!

So, the staff members who visited this patient were then quarantined. The Agency notified the state health department whose staff contacted all of the patients seen by staff members who also visited the patient who tested positive for COVID-19. All of the patients were quarantined.

Apart from the significant facts that the Agency now has fewer staff members to care for patients, patients are inconvenienced, and patients and caregivers may contract the virus with possibly dire results, this conduct is a clear violation of applicable standards of care for discharge planning for hospitals.

The Centers for Medicare and Medicaid Services (CMS) recently issued new Conditions of Participation (COPs) for hospitals. These new rules were effective on November 29, 2019. New COPs for hospitals are applicable to acute care hospitals, long-term

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*Elizabeth Hogue, Esquire, is an attorney who represents health care providers. She has published 11 books, hundreds of articles, and has spoken at conferences all over the country.*

care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), inpatient psychiatric facilities, children's hospitals, cancer hospitals, and critical access hospitals (CAHs). COPs for hospitals now generally require the discharge planning process to include:

Transfer and referrals of patients along with necessary medical information at the time of discharge to appropriate post-acute (PAC) services providers and suppliers, facilities, and agencies and to other patient service providers and practitioners responsible for patients' follow-up or ancillary care

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**Hospital discharge planners/case managers must now be meticulous about providing essential information to postacute providers when patients are discharged. The stakes are high for patients, caregivers, and for hospital discharge planners/case managers themselves!**

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Provision of necessary medical information to receiving facilities or appropriate PAC providers and practitioners responsible for patients' follow up care after patients are discharged from hospitals or transferred to other PACs or, for HHAs, other HHAs.

A diagnosis of COVID-19 surely qualifies as "necessary medical information" that must be provided by discharge planners/case managers

to PAC providers when patients are discharged from hospitals. Anecdotally, PAC providers; including HHAs, hospices, private duty agencies HME companies, skilled nursing facilities (SNFs), and assisted living facilities (ALFs); have complained for many years that hospital discharge planners/case managers do not provide essential information when patients are referred to them. This instance certainly seems to be an egregious example of these complaints!

Hospital discharge planners/case managers may be disciplined for their failure to meet applicable standards. Most hospital discharge planners/case managers are licensed nurses or social workers. They are subject to discipline by state licensure boards. Provided with the facts described above, it seems highly likely that state licensure boards will discipline hospital discharge planners/case managers for these types of lapses.

Hospital discharge planners/case managers must now be meticulous about providing essential information to PAC providers when patients are discharged. The stakes are high for patients, caregivers, and for hospital discharge planners/case managers themselves! [CM](#)

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# Care Transitions: Understanding Challenges/Identifying Solutions

Lecia Snell-Kinen, MSN, APRN-CNS, CCCTM

*This interactive sponsor-supported satellite symposium, presented by Lecia Snell-Kinen, MSN, APRN-CNS, CCCTM, Care Transition Director, Option Care Health, was attended by over 90 RN case managers. The learning outcomes for the symposium were:*

- Summarize the challenges of case managers as they select and coordinate care with postacute providers
- Identify solutions to common barriers resulting in an efficient transition plan
- Define strategies to ensure effective collaboration throughout the patient transition

## Introduction

Health care spending continues to increase in the United States (US). The annual US healthcare expenditure exceeded \$3.65 trillion, making it 17.8% of GDP in 2018.<sup>1</sup> Value-based reimbursement continues to drive changes to reduce overall cost and improve the quality of care. With these changes, case managers are on the front line to identify at-risk patients and transition them to the most cost-effective site for care.

## Validating the challenges: case management focus group

To better understand the needs of case managers, Option Care Health engaged an independent focus group to identify what influences both patient and referral source satisfaction. The key objective of the focus group was to gain

insight about the challenges of their role and decision factors in selecting an infusion provider. The challenges identified by the case managers in this focus group include factors related to patients, payers, providers, and hospital systems (Table 1).

During the presentation, participants had the opportunity to identify any additional challenges they face. In addition, during the CCMC conference, COVID-19 had just been declared a global pandemic. The need for quick discharges, lack of resources, and continual policy changes related to the crisis were a common theme for many who participated.

The focus group also identified what factors influence the choice of an infusion provider. Health care regulations require that patients are

given a choice in providers based on quality metrics. In addition, some health systems have preferred provider agreements that are driven by quality care metrics. Other factors identified by the group included:

- Response time to acceptance and discharge of patient
- Having a positive working relationship while working toward common goals
- Having an in-person liaison
- Using preferred communication such as secure texting or phone call
- Availability of pharmacists to assist with drug recommendations as needed
- The ability to provide the patient with estimated out-of-pocket expenses

*[continues on page 32](#)*

**TABLE 1** CHALLENGES IDENTIFIED BY THE FOCUS GROUP

Related Factors	Example
Provider	Finding a provider that can accept the patient based on payer, geography, and staff/medication availability
Patient	Psychosocial barriers including lack of housing or caregiver or known risk behaviors
Payer	Underinsured or have no coverage, finding a contracted provider
Health care provider	Delays in discharge related to having multiple physician involvement as well as late rounding patterns and getting final order
Hospital system	Case manager to patient staffing ratio, lack of consistent discharge planning processes

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CE I

# Chronic Pain, Opioids, and Disability: A Frank Conversation

Michael Lacroix, PhD

**T**he National Academy of Medicine estimates that over 100 million people have chronic pain in the United States and estimates the cost of chronic pain at \$600 billion annually.<sup>1</sup> Chronic pain is often a component of disability claims. Chronic pain is the not-so-hidden trigger for the opioid epidemic: opioid abuse most often starts with trying to find something to help with the pain. On an individual basis, opioid abuse adds about \$15,000 per patient per year in incremental health care costs.<sup>2</sup> There are now about 2.7 million Americans addicted to prescription opioids,<sup>3</sup> which is larger than the population of 16 of the 50 states. And in 2015, of the more than 50,000 Americans who died from a drug overdose, 17,536 were from an overdose of prescription opioids. Over 22,000 others died of overdoses from either synthetic opioid or heroin, which are often taken illegally by patients whose doctors have cut off their prescriptions.<sup>4</sup> It is estimated that the overall number of drug-related deaths has gone up since 2015.<sup>5</sup>

The alarm has sounded. In a recent article in *CareManagement*, Drs. Doug Kalunian and Laurent Tao published an excellent essay on the history of the opioid crisis as well as potentially useful medical strategies for physicians and medical case managers to address this crisis.<sup>6</sup> Medical journals such as *JAMA*<sup>7</sup> as well as the U.S. Department of Health and Human Services<sup>8</sup> and state public health departments<sup>9</sup> have also heard the clarion call for action.

To date, putative solutions to the opioid epidemic have mostly involved educating both physicians and dentists, who often prescribe opioids after dental surgery. Education is obviously a good start, but some states are also combining regulation, law enforcement, public health initiatives, and other initiatives to ensure success. In most cases, however, the emphasis has been on punishing physicians for doing the “wrong” thing rather than rewarding them for doing the

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“right” thing. Florida, for example, has placed significant restrictions on physicians' ability to prescribe opioids and increased oversight. This has led to the intended changes in doctors' prescribing behavior.<sup>10</sup> But many patients' behaviors have also changed—and not in a good way. Many shifted to illegal drugs—heroin in particular.<sup>11</sup> If their doctors won't help them with their chronic pain, they start looking elsewhere for relief. Simply taking drugs away often kicks the can down the road, as illustrated by this letter to the editor of the *Sarasota Herald-Tribune* (5/28/18):

I am a 76-year-old woman who got hit by a car 40 years ago. I have had three knee replacements, two hip replacements, three spine fusions, and an ankle so broken and fused that it cannot be operated on. I have neuropathy due to the spine, gout, and severe pain even after taking Lyrica and allopurinol. So why can't I have my half-tablet of Vicodin? I have to find a new “pain management” doctor or a marijuana doctor to see if I qualify for something to help with the pain in my feet. Am I going to have to find a drug dealer to “upgrade” to heroin? Give me a break: half a pill?

## A three-pronged approach

Fixing the opioid crisis requires a multipronged approach.<sup>12</sup> We need to deal simultaneously with:

1. The opioid issue on the front end (ie, preventing new patients from getting addicted)
2. The 2.7 million people in the United States now addicted to opioids
3. The root cause—chronic pain—that is driving people to opioids (both prescribers and patients). We need to provide patients with effective alternatives to handle their pain.

In a more perfect world in which we could address the opioid epidemic in its much broader context, or if we could start all over again, we would focus on the socioeconomic determinants because addressing health issues at that level has been shown to have the greatest impact.<sup>13</sup> Addressing health issues at the level of the individual doctor or the individual patient is much less effective. Still, and in keeping with the biopsychosocial model that guides our practice of medicine,<sup>14</sup> success in addressing the opioid epidemic will require more than simply a change of prescriptions.

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**Chronic pain is the not-so-hidden trigger for the opioid epidemic: opioid abuse most often starts with trying to find something to help with the pain. On an individual basis, opioid abuse adds about \$15,000 per patient per year in incremental health care costs.**

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The education strategy is likely to be most effective in terms of prevention, so that people do not start taking opioids and therefore do not become addicted in the first place. But this cannot take place in a vacuum. Patients ask for medication, and physicians supply them with medication because they're having difficulty dealing with their pain. And thus those patients trying not to get addicted in the first place—as well as those struggling to get off drugs—need more than admonitions about the dangers of opioids: they need to be given alternative options to deal with their pain. There are many such options, but we sometimes forget that, especially in the United States, what is available to patients often depends on who is picking up the tab. For example, the nature and frequency/duration of covered treatments may be quite different for claimants with workers' compensation claims in California than for those in Florida. Outside the world of workers' compensation, treatment can vary even more broadly, given how many Americans do not have health insurance or have high-deductible plans.

If the experience of Florida is any guide, stopping people from taking opioids is more complicated than just getting doctors to stop prescribing. Achieving success typically requires a range of interventions. People are not widgets, and so while some will relate well to 12-step programs, for example, others will not. Getting off drugs is fundamentally a behavioral problem, which therefore requires behavioral solutions. And because drug-taking behavior is embedded in a family/environmental context, it's not just the patient but also the patient's environment that needs to be "reprogrammed."<sup>15</sup> Successful treatment will, therefore, usually involve a combination of interventions.<sup>8, 12</sup>

From a biopsychosocial perspective, there are a number of behaviorally focused intervention strategies that are effective in managing chronic pain. Perhaps the most common among the behavioral strategies is cognitive-behavioral therapy. Cognitive-behavioral therapy refers to a family of techniques that emphasize changing how patients think about their pain and that increase patients' enjoyable activities in an attempt to shift attention from the pain to more "normal," functional, and adaptive behaviors. Many well-controlled studies have found these techniques to be effective in managing chronic pain.<sup>16</sup> Exercise, sometimes supervised by a physical therapist,

has also been found to be useful, as has the combination of cognitive-behavioral therapy, increased physical activity, and medical management.<sup>17</sup> Motivational interviewing (to find the right lever to motivate behavior change) and couples/family therapy also have a place.<sup>8, 12</sup>

The fundamental problem with these therapeutic avenues, especially when used in combination, is not that they don't work, it's that they're expensive, particularly in a health system where billings are still, by and large, on a "per-procedure" basis rather than on the basis of outcomes. That is changing, but the change is happening slowly; there are a lot of stakeholders involved, and nobody is volunteering to reduce their income.

More recently and in part driven by a search for cheaper yet successful alternatives, we have seen an interest in therapeutic modalities that a few years ago would have been considered "on the fringe" of acceptable treatment options. While some "fringe" modalities deserve to remain there, history has shown that others can become mainstream when the data start coming in (perhaps the most famous example of a fringe theory becoming mainstream is germ theory, which predicated that physicians/surgeons should wash their hands and which was considered ludicrous until the 1890s in the United States). One alternative option that is clearly on its way to the mainstream is mindfulness meditation training. Initially associated with Buddhist practices, mindfulness-based therapy is now used to alleviate stress, depression, anxiety, and chronic pain.<sup>18, 19</sup> Even the US military has now begun to adopt those strategies.<sup>20</sup> Acupuncture, massage, and certain forms of chiropractic manipulations have also had some success.<sup>21</sup>

Recent developments, albeit along different lines, also include innovations in delivery methods to provide effective treatments to patients. For some time now, the practice of medicine has made use of "physician extenders" (nurses and physician assistants) to provide first and second levels of assessment and treatment, with the physician coming in on the more difficult cases. While mental health service delivery involves clinicians with various levels of training to provide "counseling," "psychotherapy" has typically been the province of psychologists and psychiatrists providing services in their offices and clinics. Evidence suggests that specially

trained nurses and new models of treatment delivery, such as telepsychology and web-based behavior-change programs, can also be effective in some cases.<sup>22</sup> These new approaches may keep costs more manageable. We must consider that effectiveness is intimately intertwined with cost—who is paying the bill and what are they willing to pay for which interventions and for which outcomes?

In the world of health care, there are deductibles, coinsurance, and health savings accounts. Since most patients probably have little to no idea which nonpharmacological assistance they may be entitled to that could prevent the development of chronic pain, their treatment is based on their doctors’ recommendations and what their insurance plan will pay for/what they can afford. There is an obvious role here for case managers to provide advice, and in some cases to direct care appropriately.

In the world of workers’ compensation, where every state follows different rules, the type of assistance employees can receive after a work-related injury with the potential to develop chronic pain will depend on their doctors’ recommendations and their state’s workers’ compensation laws and regulations. Some employers may also offer access to additional services, particularly if they have a formal return-to-work program coordinated either directly by the payer or through a vendor. In addition, some insurers are also stepping into the breach. For example, The Hartford’s iRECOVER program provides 10 weeks of individual coaching, tools, and techniques to help workers injured on the job maneuver the many hurdles (including pain) that may prevent them from returning to functionality and to work.

The state of Ohio has developed a particularly successful opioid/chronic pain management program for their workers’ compensation claimants. The Ohio Bureau of Workers’ Compensation has mandated the following:

- Checkpoints for physicians, for appropriate dosages after different time periods
- No reimbursement for physicians who do not comply with these “best practices”
- Reimbursement for medication-assisted treatment, behavioral and psychological counseling, and inpatient detoxification
- For up to 18 months as long as injured worker and their physicians follow the plan

As a result, the number of patients dependent on opioids has fallen by 60% over the last 5 years in Ohio. Similarly, there may be employer-based services for employees who develop nonoccupational injuries, but in most cases treatment options will be entirely dependent on the vagaries of their health plan since disability insurers have no responsibility to pay for treatment.

**Prevention is the ultimate key**

We recently completed a pilot project with United Parcel Service (UPS). We wanted to see if we could prevent the development of chronic pain in claimants at risk for chronic pain. While this is a difficult goal in a clinical setting where patients are interacting with their own physicians, it is even more challenging in a disability insurance environment where claimants are interacting with what are often perceived as “insurance company nurses or case managers” and where the clinicians are at the disadvantage of being legally prevented from directing care and are only allowed to educate.

Eligible employees who were on short-term disability based on one of a dozen musculoskeletal diagnoses were recruited into the project. Disability durations for diagnoses often exceeded guidelines and were correlated with the development of chronic pain; diagnoses were selected on the basis of these disability durations.

Claimants were given the opportunity to evaluate the basis for their pain via a web-based test that they could complete on their smartphones or tablets, after which they were routed to web-based disease management programs specific to their pain profiles. The *PainCAS*<sup>23</sup> instrument and associated *PainAction*<sup>23</sup> programs were developed through grants from the National Institutes of Health and have been validated on patient populations recruited in medical offices and hospitals<sup>24</sup> but never with disability claimants. Would disability insurance claimants access such web-based evaluation and educational tools provided at arm’s length from the insurer and, if so, would this facilitate discussions with their health care providers, leading to enhanced patient engagement sufficient to alter disability outcomes?

A notable proportion of claimants (34%) refused to participate outright, reflecting the trust deficit noted above. However, those who did participate benefited significantly. Disability durations for claimants who participated fully

TABLE 1

**COMPARISON OF OUTCOMES FOR PARTICIPANTS WHO COMPLETED VS WHO DID NOT COMPLETE A WEB-BASED DISEASE MANAGEMENT PROGRAM SPECIFIC TO THEIR PAIN PROFILES.**

Participant group	Average no. of short-term disability days	Percent who returned to work at study end	Percent who migrated to long-term disability	Percent of claims still active at study end
Did not complete	128.9	36.1%	19.4%	22.9%
Full participants	100.9	72.7%	13.6%	4.5%

**There are now about 2.7 million Americans addicted to prescription opioids, which is larger than the population of 16 of the 50 states. And in 2015, of the more than 50,000 Americans who died from a drug overdose, 17,536 were from an overdose of prescription opioids.**

were significantly shorter than for claimants who did not participate fully and for previous-year controls matched for employer, primary diagnosis, age, gender, and the presence or absence of secondary diagnoses (Table 1). Return-to-work rates 30 days after the end of the program were 50% higher for claimants who participated fully, and their migration rate from short-term to long-term disability averaged 30% lower. Age, gender, and the physical demands of the occupations were similar between the groups. Clearly, these results are not only impressive statistically but they also reflect win-win outcomes for all involved and especially for the employees and their employer.<sup>25</sup>

### Conclusions

Our opioid crisis is finally being recognized for what it is—an epidemic that will take away more American lives this year than the entire Vietnam conflict. To solve this crisis, we need to recognize that there are 3 separate problems requiring different solutions. 1) For individuals who are not yet addicted, addiction can be prevented by physician education and state regulation and oversight of physician prescription behaviors (many states have started doing this). 2) For individuals who are already addicted, limiting prescriptions will not solve their underlying pain, and doing so often leads them to seek alternative drugs for pain relief (including fentanyl and heroin), creating an even worse problem. 3) Chronic pain is an underlying root cause of the opioid epidemic, which therefore needs to be addressed for all patients, but restricting prescriptions will not resolve patients' pain. We need to be able to provide them with alternatives. The biopsychosocial model, which guides our practice of medicine, directs us to behaviorally focused interventions. These have proven successful, but they are generally more expensive in the short term than medications, although there are ways to bring the costs down. There are many pathways for accessing possible interventions through the health, disability, and workers' compensation systems. Case managers' multidisciplinary vantage point in the health recovery process puts them in a unique position to impact the chronic pain–opioid crisis faced by many of their clients. **CE I**

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# CE II Marijuana and Opiates

**Teaera Roland, FNP-BC, MSN, RN, CCM, CARN-AP**

If you have turned on the television or opened a social media page, I am sure you have heard discussions about medical marijuana and the opioid epidemic. As a health care provider working in the mental health/addiction/holistic and functional medicine world, both topics are a part of typical conversation.

Though early uses of hemp (cousin of marijuana) dates back over 10,000 years ago, the first record of medicinal uses of the plant dates to the 28th century B.C. with Chinese emperor Shen-Yung. Shen-Yung completed his writing in a collection called Pen Ts'ao, a herbal medicine book now referred to as a Materia Medica. The earliest version of the Pen Ts'ao contains multiple references of "ma," the Chinese word for cannabis. Ma was used for treatment of pain, wasting, rheumatism, and infection through the 10th century

migraine headache, pain, involuntary twitching, excessive coughing, and treatment of withdrawal symptoms associated with morphine and alcohol addiction.<sup>1</sup>

The most notable medical uses of cannabis are the conditions listed in the 1854 US Dispensatory: "It is asserted also to act as a decided aphrodisiac, to increase the appetite... In morbid states of the system, it has been found to produce sleep, to allay spasm, to compose nervous inquietude, and to relieve pain. In these respects it resembles opium in its operation; but it differs from that narcotic in not diminishing the appetite, checking the secretions, or constipating the bowels... The complaints to which it has been specially recommended are neuralgia, gout, tetanus, hydrophobia, epidemic cholera, convulsions, chorea, hysteria, mental depression, insanity, and uterine hemorrhage."<sup>2</sup>

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## Cannabis has been used for thousands of years for the treatment of many types of pain.

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A.D. Pedacius Dioscorides, a Greek physician born in Asia Minor in the 1st century A.D., published a materia medica that became to the western world what the Pen Ts'ao was to the Chinese. This book became one of the most referenced medical books for nearly 1500 years. Dioscorides references cannabis over 600 times, and the medicinal uses of cannabis became household remedies.

When and how did cannabis officially become a medication in the United States? Credit is mostly attributed to an Irish born physician, Dr. William Brooke O'Shaughnessy. Dr. O'Shaughnessy was amazed at the medical benefits of the cannabis that he witnessed as a surgeon for the British East India Company. Once he published his findings, English physicians began to promote the use of cannabis for most every ailment. Cannabis was a successful treatment used for child birth, menorrhagia, loss of appetite, inability to sleep,

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*Teaera Roland, FNP-BC, MSN, RN, CCM, CARN-AP, founded Lotus Health, LLC, because of the overwhelming need for patient-centered and holistic treatment in the community. Teaera is certified in addiction as well as cannabinoid medicine and serves on the Board of Directors for the American Academy of Cannabinoid Medicine.*

### Endogenous Cannabinoid System

The endogenous cannabinoid system (ECS) was discovered well after the cannabinoid THC (tetrahydrocannabinol) was isolated in 1964 by Raphael Mechoulam and Yechiel Gaoni at the Weizmann Institute of Science in Israel.<sup>3</sup> The ECS was discovered in 1992 along with the discovery of our own naturally occurring endocannabinoid, anandamide (N-arachidonoyl ethanolamine). The ECS is an extremely complex retrograde system functioning post- to presynapse. This unique function allows the system to be the regulator of the other major systems including the immune system, the endocrine system, and the nervous system. Although it is a complex system with multiple variables, the end goal of the ECS is homeostasis of the body. There are cannabinoid receptors throughout the body, including the brain, glands, and immune system. The two major receptors are cannabinoid 1 (CB1) and cannabinoid 2 (CB2). Cannabinoid 1 receptors are more abundant in the brain, spinal cord, organs, and connective tissues and throughout the nervous system. Cannabinoid 2 receptors are mostly attached to the immune system. Some parts of the body contain both CB1 and the CB2 receptor sites. This overarching system

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**In 2011, a systematic review of the literature was published in the *British Journal of Clinical Pharmacology*. Seven studies demonstrated that cannabinoids exhibited an analgesic effect that was significantly better than controls. A total of 22 of 29 randomized controlled trials demonstrated that cannabinoids have a modest analgesic effect and are safe in the management of chronic pain.**

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of balance helps to explain the endless claims of seemingly unrelated medical uses.

Phytocannabinoids, present in the cannabis plant, help our body stimulate our own ECS to produce endocannabinoids naturally. 2-archidonyl glycerol (2-AG) is a second naturally occurring cannabinoid in the body. Aside from CB1 and CB2, there is a third less researched cannabinoid receptor as well.<sup>4</sup> The CB1 receptor is the one of the most abundant G protein-coupled receptors in the brain. THC actually works directly on the CB1 receptors while cannibal works directly on the CB2 receptors. Cannabinoids go against the typical flow of signaling and act as communication traffic directors. The therapeutic effects of both the endocannabinoids and the phytocannabinoids is dependent upon either the stimulation or blocking of these receptors. Another variable is the stimulation of non-ECS receptors by multiple cannabinoids.

What does this complex system have to do with the opiate epidemic? If the ECS controls homeostasis and communication signaling, the ECS would obviously be involved in the perception of pain, which is typically the genesis of opiate use. The ECS would also be involved in neurotransmitter regulation in addiction, the symptoms associated with opiate withdrawal, and overall mental health and stability.

In 2014 alone, US retail pharmacies dispensed 245 million prescriptions for opioid pain relievers, and over 2 million individuals became addicted.<sup>5</sup> Withdrawal symptoms can develop upon cessation of opioid treatment within days of regular and uninterrupted opioid use. Also, when a person uses an opiate, the body will create more pain receptors and a higher perception of pain.

Cannabis has been used for thousands of years for the treatment of many types of pain.<sup>7</sup> In 2011, a systematic review of the literature was published in the *British Journal of Clinical Pharmacology*. Seven studies demonstrated that cannabinoids exhibited an analgesic effect that was significantly better than the control. A total of 22 of 29 randomized controlled trials demonstrated that cannabinoids have a modest analgesic effect and are safe in the management of chronic pain.<sup>8</sup>

The question that we need to answer is why do we use opiates as first-line pain control when there is no evidence of efficacy? Any of the currently approved drugs have a very modest effect (approximately 30% pain reduction) in only

a subpopulation of chronic pain patients (approximately 50%) with or without improvements in function. Every day of opiate use increases the probability of dependence. Given the dangers, these figures are astounding considering lack of efficacy. Opioids are recommended as an option for the treatment of chronic pain, despite their lack of superiority to non-opioid options and high potential for dependence.<sup>9</sup>

Cannabis has been shown to decrease the need for opiates while increasing quality of life. According to review of Medicare D patient data, medical cannabis laws are associated with significantly lower opioid prescribing practices. Bradford et al. controlled for the type of medical cannabis laws and found a 14.4% reduction in use of any opioid associated with medical cannabis dispensaries and a 6.9% reduction in any opioid prescribing with home cultivation only-based medical cannabis laws.<sup>9</sup>

The endocannabinoid system is known for playing an important role in the brain's reward system. Endocannabinoid signaling is involved in reward, which raises the possibility that drugs targeting this system could be used to treat substance use disorders.<sup>10</sup> Despite cannabis having a significantly higher safety profile than buprenorphine and methadone, some individuals are still reluctant to use cannabis in place of (or even in conjunction with) traditional medications. The risk of addiction increases with every dose of an opiate-based medication, while than 30,000 patients taking the FDA-approved cannabis based nabiximols showed no evidence of abuse or diversion.<sup>11</sup>

When Columbia University completed a double-blind placebo-controlled clinical trial of a cannabinoid agonist for opioid-dependent patients undergoing treatment with XR naltrexone, dronabinol (30 mg per day) reduced opioid withdrawal symptoms during the acute inpatient phase of withdrawal and naltrexone initiation.<sup>11</sup> The THC derivative not only reduced withdrawal symptoms, it also significantly increased adherence to the injectable naltrexone program. All patients using the cannabis derivative were able to make it to the second injection appointment compared with 46% of the control group. Further, when cannabis was smoked by the patients, significantly less anxiety and insomnia were reported.<sup>11</sup>

THC has been widely studied. There are over 150 other cannabinoids, all of which have medicinal uses and are

## In a survey of Lotus Health LLC patients, cannabis increased quality of life for 95% of patients.

important. One of the other main cannabinoids is cannabidiol (CBD). A recent study published in the *American Journal of Psychiatry* reported that acute CBD administration, in contrast with placebo, significantly reduced both craving and anxiety induced by the presentation of salient drug cues compared with neutral cues. CBD also showed significant protracted effects on these measures 7 days after the final short-term (3-day) CBD exposure. In addition, CBD reduced the drug cue-induced physiological measures of heart rate and salivary cortisol levels. There were no significant effects on cognition, and there were no serious adverse effects.<sup>12</sup>

### What are the experts saying?

Dr. David Bearman, one of the major contributors to modern cannabis medicine with 50 years of experience in addiction treatment, has a clear scientifically based opinion. According to Dr. Bearman, cannabis has been used for years by patients both as an illicit and as a licit substance to routinely, safely, and successfully reduce, if not eliminate, opioid use.

I am blessed to work with amazing and established providers. Rev. Dr. R. Lee Tyson DNP, DMin, APRN-CNP, PMHNP-BC, ANP-BC, CARN-AP, Founder/Owner, Lee Side Wellness, Assistant Professor at University of Cincinnati College of Nursing, Director, Psychiatric-Mental Health NP Program, serves as a Director of the Addictions Nursing Certification Board. According to Rev. Dr. Tyson, there is a burgeoning of evidence that continues to emerge which suggests that using cannabis therapy in persons with opioid use disorder is a safe, appropriate, and efficacious treatment modality. While admittedly there is controversy among various factions across the political and big pharma spectrum, there is markedly little reason to be skeptical that this form of treatment is a viable option when considering things from a purely clinical vantage.

Barriers to treatment inclusive of cannabis are broad. One barrier is fear of payment consequences. Since 1996, when California became a medical cannabis state, not one facility has been denied payment or been prosecuted for allowing cannabis within the organization. This is currently attributed to the Rohrabacher-Farr amendment. According to Brian Higgins, a healthcare attorney at Frost Brown Todd, LLC, research indicates that no healthcare providers have lost their Medicare enrollment (and thereby, federal funding) for conduct that strictly complied with their state's medical marijuana law.

A barrier to decreased stigma associated with cannabis use is not just lack of knowledge by the general public but the lack of knowledge or desire for that knowledge by a significant number of healthcare providers. With already FDA-approved drugs containing synthetic cannabinoids and the mere rumor of a system controlling homeostasis, there is no excuse for the healthcare community to refuse to do research. More concerning is the unwillingness of higher learning institutions to teach about the ECS or to allow students to learn about the ECS at their own request. I've encountered countless students, all competing for precious clinical hours, being denied so much as shadowing experiences despite the opportunity to learn from a practice owned by a nurse practitioner.

The same rhetoric can be applied to medical cannabis supporters. There is an abundance of lobbyist-produced propaganda in circulation, and there now are extremely intelligent neuroscientists refusing to entertain the possibility that the plant has any negative effects.

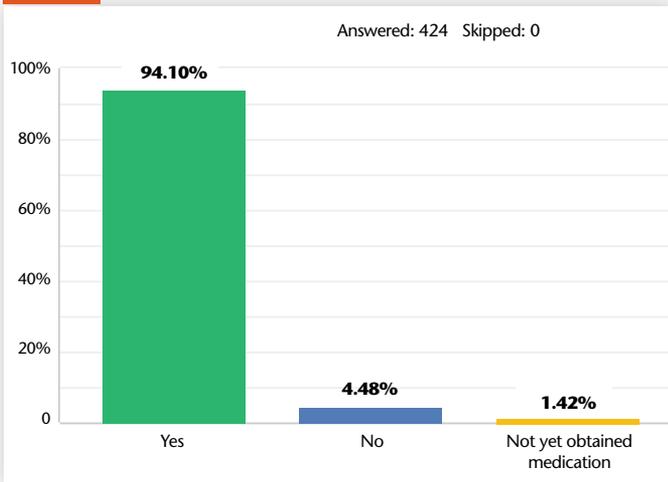
Dr. Peter Grinspoon, contributing editor to Harvard Medical School's Harvard Health Blog, puts some ideas into perspective: "My advice for doctors is that whether you are pro, neutral, or against medical marijuana, patients are embracing it, and although we don't have rigorous studies and 'gold standard' proof of the benefits and risks of medical marijuana, we need to learn about it, be open-minded, and above all, be non-judgmental. Otherwise, our patients will seek out other, less reliable sources of information; they will continue to use it, they just won't tell us, and there will be that much less trust and strength in our doctor-patient relationship. I often hear complaints from other doctors that there isn't adequate evidence to recommend medical marijuana, but there is even less scientific evidence for sticking our heads in the sand."<sup>13</sup>

There is a system in the human body that controls homeostasis and is involved with almost every disease process. This affects all of us. We are case managers. By nature, we do not accept things at face value and walk away with disappointment. We find the answer. We find a solution that will work. We accept the challenge.

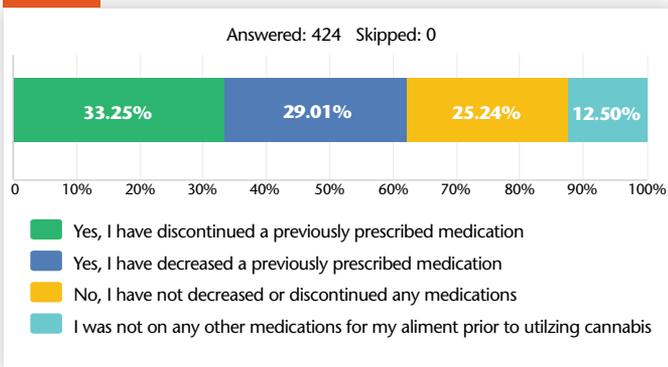
### My Own Observations:

I have to see things and understand things before optimally using the information in day-to-day practice. I own a small holistic practice in Mason, Ohio. Ohio is newer than other states to medicinal cannabis laws, and for political reasons

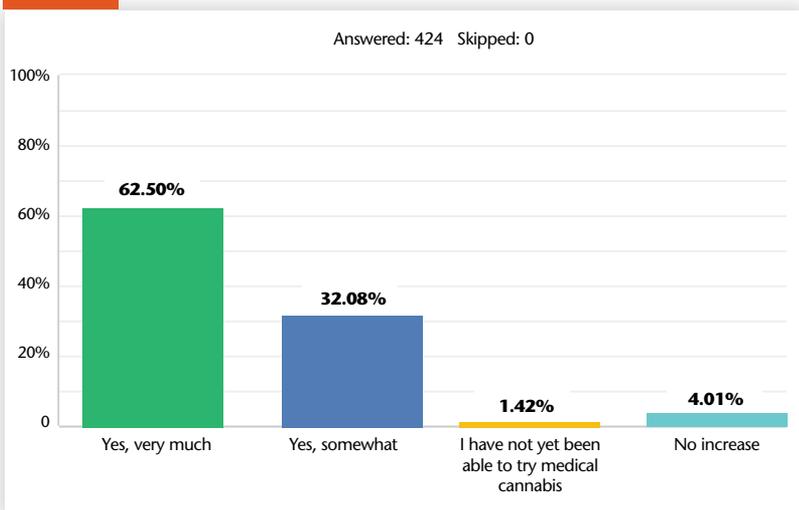
**FIGURE 1 Q6 QUALIFYING CONDITION TREATMENT SUCCESS**



**FIGURE 2 Q7 STOPPED OR DECREASED TRADITIONAL MEDICATIONS**



**FIGURE 1 Q10 HAS CANNABIS INCREASED OVERALL QUALITY OF LIFE?**



Ohio is way behind. Over the past 13+ years, I have studied the science, laws, uses, and implications of the cannabis plant. My practice currently offers specialized treatment plans for people wanting to incorporate cannabis. In a world of what I like to call “Green Box Docs,” basically the “pill mill” of the legal cannabis world, I believed it was important to offer the option of science-based treatment vs the one-size-fits-all approach. Would this make a difference? Would I be able to help my community obtain safer and more effective options for treatment? I am certified as an advance practice additions provider as well as a cannabinoid medicine specialist. In conjunction, I offer continuing education units for nurses, social workers, and therapists pertaining to the endocannabinoid system, science, law, and uses. I felt prepared to assist clients with their treatment planning.

First, let’s get rid of the stigma. My office is in the middle of red country. I wanted to have an education- and science-oriented practice, taking away from the stoner and sex-crazed industry we have come to know and (not) love today. I personally saw over 500 patients during the past 18 months for the purpose of cannabis treatment incorporation aside from the other clients that I usually see. Surprisingly, my clients are usually older than 65. Because of my geographic location, most of my clients are middle class, Caucasian, and conservative. Ironically, in the cannabis world, these are people with the most questions and the most fear of stigma. I wanted to not only examine simple outcomes but also to look for variables explaining the variations in outcomes.

Even though my actual patient panel is older than 65, the results of the survey are based on the respondents. Some of the patient population I see is not in the position to answer these questions in the manner in which the survey was presented. They were followed up with verbally and were not included in these results. I did not want to add bias, which could result from verbal vs electronic methods. This did, however, create a bias result in age. Many respondents were younger. Of 454 patients, 352 patients completed the survey, 44.8% were over age 50, with only 28% of those being over the age of 65. Sixty-six percent of patients were seen for chronic pain inclusive ailments, which is consistent with state and national averages. This does not mean they were not also seen for another qualifying diagnosis as well. Some people who were treated had multiple diagnoses.

At the time of the initial survey, 50% of patients had been able to use an Ohio dispensary. When questioned why they were not able to use the dispensary, over 35% of patients listed

*continued on page 33*

# PharmaFacts for Case Managers



## Ongentys® (opicapone) capsules, for oral use

### INDICATIONS AND USAGE

Ongentys is indicated as adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes.

### DOSAGE AND ADMINISTRATION

#### *Dosing and Administration Information:*

The recommended dosage of Ongentys is 50 mg administered orally once daily at bedtime. Patients should not eat food for 1 hour before and for at least 1 hour after intake of Ongentys.

#### *Dosage Recommendations for Patients with Hepatic Impairment:*

In patients with moderate hepatic impairment (Child-Pugh B), the recommended dose of Ongentys is 25 mg orally once daily at bedtime. Avoid use of Ongentys in patients with severe (Child-Pugh C) hepatic impairment.

**Discontinuation and Missed Dose:** When discontinuing Ongentys, monitor patients and consider adjustment of other dopaminergic therapies as needed. If a dose of Ongentys is missed, the next dose should be taken at the scheduled time the next day.

### DOSAGE FORMS AND STRENGTHS

Ongentys capsules are available in the following strengths:

- 50 mg capsules with a dark blue opaque cap and dark pink opaque body; axially printed with "OPC" over "50" in white ink, on both the cap and body.
- 25 mg capsules with a light blue opaque cap and light pink opaque body; axially printed with "OPC" over "25" in blue ink, on both the cap and body.

### CONTRAINDICATIONS

Ongentys is contraindicated in patients with:

- Concomitant use of nonselective monoamine oxidase (MAO) inhibitors.
- Pheochromocytoma, paraganglioma, or other catecholamine-secreting neoplasms.

### WARNINGS AND PRECAUTIONS

#### *Cardiovascular Effects with Concomitant Use of Drugs Metabolized by Catechol-O-Methyltransferase (COMT):*

Possible arrhythmias, increased heart rate, and excessive changes in blood pressure may occur with concomitant use of Ongentys and drugs metabolized by COMT (e.g., isoproterenol, epinephrine, norepinephrine, dopamine, and dobutamine), regardless of the route of administration (including inhalation). Monitor patients treated concomitantly with Ongentys and drugs metabolized by COMT.

#### *Falling Asleep During Activities of Daily Living and Somnolence:*

Patients treated with dopaminergic medications and medications that increase levodopa exposure, including Ongentys, have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes has resulted in accidents. Patients may not perceive warning signs, such as excessive drowsiness, or they may report feeling alert immediately prior to the event. Before initiating treatment with Ongentys, advise patients of the potential to develop drowsiness and specifically ask about factors that may increase the risk for somnolence with dopaminergic therapy, such as concomitant sedating medications or the presence of a sleep disorder. If a patient develops daytime sleepiness or episodes of falling asleep during activities that require full attention (e.g., driving a motor vehicle, conversations, eating), consider discontinuing Ongentys or adjusting other dopaminergic or sedating medications. If a decision is made to continue Ongentys, patients should be advised not to drive and to avoid other potentially dangerous activities.

#### *Hypotension/Syncope:*

In Study 1 and Study 2, hypotension (orthostatic and nonorthostatic), syncope, and presyncope occurred in 5% of patients treated with Ongentys 50 mg compared to 1% of patients who received placebo. Monitor patients for hypotension (orthostatic and nonorthostatic) and advise patients about the risk for syncope and presyncope. If these adverse reactions occur, consider discontinuing Ongentys or adjusting the dosage of other medications that can lower blood pressure.



### **Dyskinesia:**

Ongentys potentiates the effects of levodopa and may cause dyskinesia or exacerbate pre-existing dyskinesia. In controlled clinical trials (Study 1 and Study 2), dyskinesia occurred in 20% of patients treated with Ongentys 50 mg compared to 6% of patients who received placebo. Dyskinesia was also the most common adverse reaction leading to discontinuation of Ongentys. Reducing the patient's daily levodopa dosage or the dosage of another dopaminergic drug may mitigate dyskinesia that occurs during treatment with Ongentys.

### **Hallucinations and Psychosis:**

In Study 1 and Study 2, hallucinations (hallucinations, auditory hallucinations, visual hallucinations, mixed hallucinations) occurred in 3% of patients treated with Ongentys 50 mg compared to 1% of patients who received placebo. Delusions, agitation, or aggressive behavior occurred in 1% of patients treated with Ongentys 50 mg and in no patient who received placebo. Consider stopping Ongentys if hallucinations or psychotic-like behaviors occur.

Patients with a major psychotic disorder should ordinarily not be treated with Ongentys because of the risk of exacerbating the psychosis with an increase in central dopaminergic tone. In addition, treatments for psychosis that antagonize the effects of dopaminergic medications may exacerbate the symptoms of PD.

### **Impulse Control/Compulsive Disorders:**

Patients treated with Ongentys can experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge eating, and/or other intense urges, and the inability to control these urges while taking one or more dopaminergic therapies that increase central dopaminergic tone. In some cases, these urges were reported to have stopped when the dose was reduced or the medication was discontinued. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to specifically ask patients or their caregivers about the development of new or increased gambling urges, sexual urges, uncontrolled spending, or other urges while being treated with Ongentys. In Study 1 and Study 2, impulse control disorders occurred in 1% of patients treated with Ongentys 50 mg and in no patient who received placebo. Reevaluate the patient's current therapy(ies) for PD and consider stopping Ongentys if a patient develops such urges while taking Ongentys. Use with caution in Parkinson's patients with suspected or diagnosed dopamine dysregulation syndrome.

### **Withdrawal-Emergent Hyperpyrexia and Confusion**

A symptom complex resembling neuroleptic malignant syndrome (characterized by elevated temperature, muscular rigidity, altered consciousness, and autonomic instability), with no other obvious etiology, has been reported in association with rapid

dose reduction, withdrawal of, or changes in drugs that increase central dopaminergic tone. In the controlled clinical studies of Ongentys, patients discontinued Ongentys treatment without dose tapering or gradual withdrawal. There were no reports of neuroleptic malignant syndrome in Ongentys controlled clinical studies. When discontinuing Ongentys, monitor patients and consider adjustment of other dopaminergic therapies as needed

### **ADVERSE REACTIONS**

The following are clinically significant adverse reactions:

- Cardiovascular Effects with Concomitant Use of Drugs Metabolized by Catechol-O-Methyltransferase (COMT)
- Falling Asleep During Activities of Daily Living and Somnolence
- Hypotension/Syncope
- Dyskinesia
- Hallucinations and Psychosis
- Impulse Control/Compulsive Disorders
- Withdrawal-Emergent Hyperpyrexia and Confusion

### **CLINICAL STUDIES**

The efficacy of Ongentys for the adjunctive treatment to levodopa/carbidopa in patients with PD experiencing "off" episodes was evaluated in two double-blind, randomized, parallel-group, placebo- and active-controlled (Study 1, NCT01568073) or placebo-controlled (Study 2, NCT01227655) studies of 14- to 15-week duration. All patients were treated with levodopa/DOPA decarboxylase inhibitor (DDCI) (alone or in combination with other PD medications). The double-blind period for each study began with a period for levodopa/DDCI dose adjustment (up to 3 weeks), followed by a stable maintenance period of 12 weeks.

#### **Study 1:**

In Study 1, patients (n=600) were randomized to treatment with one of 3 doses of Ongentys. The intention to treat (ITT) population included patients treated with Ongentys 50 mg once daily (n=115) or placebo (n=120). Baseline demographic characteristics were similar across all treatment groups: approximately 60% of patients were male, mean age was 64 years, and all patients were Caucasian. Baseline PD characteristics in the treatment groups were as follows: mean duration of PD of 7 years for Ongentys 50 mg compared to 7.7 years for placebo and mean onset of motor fluctuations of 2.2 years prior to study enrollment. Eighty-two percent of patients in both groups used concomitant PD medications in addition to levodopa; the most commonly used were dopamine agonists (68%), amantadine (23%), MAO-B inhibitors (20%), and anticholinergics (5%). The primary efficacy endpoint was the change in mean absolute OFF-time based on 24-hour patient diaries completed 3 days prior to each of the scheduled visits. Ongentys 50 mg significantly reduced mean absolute OFF-time compared to placebo.



### Study 2:

In Study 2, patients (n=427) were randomized to treatment with either one of two doses of Ongentys once daily (n=283) or placebo (n=144). The intention to treat (ITT) study population included patients treated with Ongentys 50 mg once daily (n=147) or placebo (n=135). Baseline demographic characteristics (Ongentys 50 mg vs. placebo) were as follows: mean age (66 years vs. 62 years), male (61% vs. 53%), Caucasian (78% vs. 66%) and Asian (21% vs. 31%). Baseline PD characteristics were generally similar across treatment groups with a mean duration of PD of 8.2 years and a mean onset of motor fluctuations of 3.2 years prior to study enrollment. Eighty-five percent of patients treated with Ongentys 50 mg compared to 81% of patients who received placebo used concomitant PD medications in addition to levodopa; the most commonly used were dopamine agonists (70%), amantadine (21%), MAO-B inhibitors (20%), and anticholinergics (12%).

The primary efficacy endpoint was the change in mean absolute OFF-time based on 24-hour patient diaries completed 3 days prior to each of the scheduled visits. Ongentys 50 mg significantly reduced mean absolute OFF-time compared to placebo.

### HOW SUPPLIED/STORAGE AND HANDLING

How Supplied Ongentys (opicapone) capsules are available as:

- 50 mg hard gelatin capsules, Size 1; dark blue opaque cap and dark pink opaque body; axially printed with “OPC” over “50” in white ink, on both the cap and body – Bottle of 30 with child-resistant closure.
- 25 mg hard gelatin capsules, Size 1; light blue opaque cap and light pink opaque body; axially printed with “OPC” over “25” in blue ink, on both the cap and body – Bottle of 30 with child-resistant closure.

### Storage and Handling

Store at a temperature below 30°C (86°F).

See Product Insert for full prescribing information.

Ongentys is distributed by Neurocrine Biosciences, Inc., San Diego, CA

## Zeposia® (ozanimod) capsules, for oral use

### INDICATIONS AND USAGE

Zeposia is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

### DOSAGE AND ADMINISTRATION

#### Assessments Prior to First Dose of Zeposia:

Before initiation of treatment with Zeposia, assess the following:

- Complete Blood Count:
  - Obtain a recent (i.e., within the last 6 months or after

discontinuation of prior MS therapy) complete blood count (CBC), including lymphocyte count.

- Cardiac Evaluation:
  - Obtain an electrocardiogram (ECG) to determine whether preexisting conduction abnormalities are present. In patients with certain preexisting conditions, advice from a cardiologist should be sought.
- Liver Function Tests
  - Obtain recent (i.e., within the last 6 months) transaminase and bilirubin levels.
- Ophthalmic Assessment:
  - In patients with a history of uveitis or macular edema, obtain an evaluation of the fundus, including the macula.

### Current or Prior Medications

- If patients are taking anti-neoplastic, immunosuppressive, or immune-modulating therapies, or if there is a history of prior use of these drugs, consider possible unintended additive immunosuppressive effects before initiating treatment with Zeposia.
- Determine if patients are taking drugs that could slow heart rate or atrioventricular conduction.

### Vaccinations:

Test patients for antibodies to varicella zoster virus (VZV) before initiating Zeposia; VZV vaccination of antibody-negative patients is recommended prior to commencing treatment with Zeposia. If live attenuated vaccine immunizations are required, administer at least 1 month prior to initiation of Zeposia.

### Dosing Information

- Maintenance Dosage:
  - After initial titration, the recommended maintenance dosage of Zeposia is 0.92 mg taken orally once daily starting on Day 8.
  - Zeposia capsules should be swallowed whole and can be administered with or without food.
- Treatment Initiation:
  - Initiate Zeposia with a 7-day titration.
  - Days 1-4 0.23 mg once daily
  - Days 5-7 0.46 mg once daily
  - Day 8 and thereafter 0.92 mg once daily

### CONTRAINDICATIONS

Zeposia is contraindicated in patients who:

- In the last 6 months, have experienced a myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III or IV heart failure
- Have the presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sinoatrial block, unless the patient has a functioning pacemaker



- Have severe untreated sleep apnea
- Are taking a monoamine oxidase (MAO) Inhibitor

#### ADVERSE REACTIONS

The following serious adverse reactions were observed in clinical trials:

- Infections
- Bradyarrhythmia and Atrioventricular Conduction Delays
- Liver Injury
- Fetal Risk
- Increased Blood Pressure
- Respiratory Effects
- Macular Edema
- Posterior Reversible Encephalopathy Syndrome
- Unintended Additive Immunosuppressive Effects From Prior Treatment With Immunosuppressive or Immune-Modulating Drugs
- Severe Increase in Disability After Stopping Zeposia
- Immune System Effects After Stopping Zeposia

#### CLINICAL STUDIES

The efficacy of Zeposia was demonstrated in 2 randomized, double-blind, double-dummy, parallel-group, active comparator-controlled clinical trials of similar design, in patients with relapsing forms of MS [Study 1 (NCT02294058) and Study 2 (NCT02047734)]. Patients in Study 1 were treated until the last enrolled patient completed 1 year of treatment. Patients in Study 2 were treated for 24 months. Both studies included patients who had experienced at least 1 relapse within the prior year or 1 relapse within the prior 2 years with evidence of at least a gadolinium-enhancing (GdE) lesion in the prior year, and had an Expanded Disability Status Scale (EDSS) score from 0 to 5.0 at baseline. Patients with primary progressive MS were excluded.

Patients were randomized to receive either Zeposia 0.92 mg given orally once daily, beginning with a dose titration, or interferon (IFN) beta-1a, the active comparator, 30 mcg given intramuscularly once weekly. Neurological evaluations were performed at baseline, every 3 months, and at the time of a suspected relapse. Brain MRI scans were performed at baseline, 6 months (Study 1), 1 year (Studies 1 and 2), and 2 years (Study 2).

The primary endpoint of both Study 1 and Study 2 was the annualized relapse rate (ARR) over the treatment period (Study 1) and 24 months (Study 2). Additional outcome measures included: 1) the number of new or enlarging MRI T2 hyperintense lesions over 12 and 24 months, 2) the number of MRI T1 Gadolinium-enhancing (Gd+) lesions at 12 and 24 months, and 3) the time to confirmed disability progression, defined as at least a 1-point increase from baseline EDSS confirmed after 3 months and after 6 months. Confirmed disability progression was evaluated in a pooled analysis of Studies 1 and 2.

In Study 1, a total of 895 patients were randomized to receive

Zeposia (n=447) or IFN beta-1a (n=448); of these patients, 94% who received Zeposia and 92% who received IFN beta-1a completed the study. The mean age was 35.4 years, 99.8% were White, and 65% were female. The mean time since MS symptom-onset was 6.9 years, and the median EDSS score at baseline was 2.5; 31% had been treated with a non-steroid therapy for MS. At baseline, the mean number of relapses in the prior year was 1.3 and 48% of patients had one or more T1 Gd-enhancing lesions (mean 1.8) on their baseline MRI scan.

In Study 2, a total of 874 patients were randomized to receive Zeposia (n=433) or IFN beta-1a (n=441); of these patients, 90% who received Zeposia and 85% who received IFN beta-1a completed the study. The mean age was 35.6 years, 98% were White, and 68% were female. The mean time since MS symptom onset was 6.6 years, and the median EDSS score at baseline was 2.5; 29% of 16 patients had been treated with a non-steroid therapy for MS. At baseline, the mean number of relapses in the prior year was 1.3 and 43% of patients had one or more T1 Gd-enhancing lesions (mean 1.7).

The ARR was statistically significantly lower in patients treated with Zeposia 0.92 mg than in patients who received IFN beta-1a 30 mcg IM. The number of new or enlarging T2 lesions and the number of GdE lesions were statistically significantly lower in patients treated with Zeposia 0.92 mg than in patients who received IFN beta-1a.

There was no statistically significant difference in the 3-month and 6-month confirmed disability progression between Zeposia and IFN beta-1a-treated patients over 2 years.

#### HOW SUPPLIED/STORAGE AND HANDLING

##### How Supplied

Zeposia is available as capsules in the following dosage strengths:

- Ozanimod 0.23 mg: light grey opaque body/light grey opaque cap imprinted with black ink “OZA” on the cap and “0.23 mg” on the body
- Ozanimod 0.46 mg: light grey opaque body/orange opaque cap imprinted with black ink “OZA” on the cap and “0.46 mg” on the body.
- Ozanimod 0.92 mg: orange opaque body/orange opaque cap imprinted with black ink “OZA” on the cap and “0.92 mg” on the body

##### Storage

Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C to 30°C (59°F to 86°F)

See product insert for full prescribing information.

Zeposia is manufactured for the Celgene Corporation. 



*LitScan for Case Managers* reviews medical literature and reports abstracts that are of particular interest to case managers in an easy-to-read format. Each abstract includes information to locate the full-text article if there is an interest. This member benefit is designed to assist case managers in keeping current with clinical breakthroughs in a time-effective manner.

*JAMA*. 2020 May 11. doi: 10.1001/jama.2020.8630.  
[Epub ahead of print]

[Association of treatment with hydroxychloroquine or azithromycin with in-hospital mortality in patients with COVID-19 in New York State.](#)

Rosenberg ES, Dufort EM, Udo T, et al.

IMPORTANCE: Hydroxychloroquine, with or without azithromycin, has been considered as a possible therapeutic agent for patients with coronavirus disease 2019 (COVID-19). However, there are limited data on efficacy and associated adverse events.

OBJECTIVE: To describe the association between use of hydroxychloroquine, with or without azithromycin, and clinical outcomes among hospital inpatients diagnosed with COVID-19.

DESIGN, SETTING, AND PARTICIPANTS: Retrospective multicenter cohort study of patients from a random sample of all admitted patients with laboratory-confirmed COVID-19 in 25 hospitals, representing 88.2% of patients with COVID-19 in the New York metropolitan region. Eligible patients were admitted for at least 24 hours between March 15 and 28, 2020. Medications, preexisting conditions, clinical measures on admission, outcomes, and adverse events were abstracted from medical records. The date of final follow-up was April 24, 2020.

EXPOSURES: Receipt of both hydroxychloroquine and azithromycin, hydroxychloroquine alone, azithromycin alone, or neither.

MAIN OUTCOMES AND MEASURES: Primary outcome was in-hospital mortality. Secondary outcomes were cardiac arrest and abnormal electrocardiogram findings (arrhythmia or QT prolongation).

RESULTS: Among 1438 hospitalized patients with a diagnosis of COVID-19 (858 [59.7%] male, median age, 63 years), those receiving hydroxychloroquine, azithromycin, or both were more likely than those not receiving either drug to have diabetes, respiratory rate >22/min, abnormal chest imaging findings, O<sub>2</sub> saturation lower than 90%, and aspartate aminotransferase greater than 40 U/L. Overall in-hospital mortality was 20.3% (95% CI, 18.2%-22.4%). The probability of death for patients receiving hydroxychloroquine+azithromycin was 189/735 (25.7% [95% CI, 22.3%-28.9%]), hydroxychloroquine alone, 54/271 (19.9%

[95% CI, 15.2%-24.7%]), azithromycin alone, 21/211 (10.0% [95% CI, 5.9%-14.0%]), and neither drug, 28/221 (12.7% [95% CI, 8.3%-17.1%]). In adjusted Cox proportional hazards models, compared with patients receiving neither drug, there were no significant differences in mortality for patients receiving hydroxychloroquine+azithromycin (HR, 1.35 [95% CI, 0.76-2.40]), hydroxychloroquine alone (HR, 1.08 [95% CI, 0.63-1.85]), or azithromycin alone (HR, 0.56 [95% CI, 0.26-1.21]). In logistic models, compared with patients receiving neither drug cardiac arrest was significantly more likely in patients receiving hydroxychloroquine+azithromycin (adjusted OR, 2.13 [95% CI, 1.12-4.05]), but not hydroxychloroquine alone (adjusted OR, 1.91 [95% CI, 0.96-3.81]) or azithromycin alone (adjusted OR, 0.64 [95% CI, 0.27-1.56]). In adjusted logistic regression models, there were no significant differences in the relative likelihood of abnormal electrocardiogram findings.

CONCLUSIONS AND RELEVANCE: Among patients hospitalized in metropolitan New York with COVID-19, treatment with hydroxychloroquine, azithromycin, or both, compared with neither treatment, was not significantly associated with differences in in-hospital mortality. However, the interpretation of these findings may be limited by the observational design.

*Acad Emerg Med*. 2020 May 12. doi: 10.1111/acem.14009.  
[Epub ahead of print]

[Symptom criteria for COVID-19 testing of health care workers.](#)

Clemency BM, Varughese R, Scheafer DK, et al.

BACKGROUND: Limitations on testing availability has been a challenge during the COVID-19 pandemic. An evidence based symptom criteria for identifying health care workers (HCW) for testing, based on the probability of positive COVID-19 test results, would allow for a more appropriate use of testing resources.

METHODS: This was an observational study of outpatient COVID-19 testing of HCW. Prior to testing, HCW were asked about the presence of 10 symptoms. Their responses were then compared to their subsequent pharyngeal swab COVID-19

Polymerase Chain Reaction test results. These data were used to derive and evaluate a symptom based testing criteria.

**RESULTS:** 961 HCW were included in the analysis, of which 225 (23%) had positive test results. Loss of taste or smell was the symptom with the largest positive likelihood ratio (3.33). Dry cough, regardless of the presence or absence of other symptoms, was the most sensitive (74%) and the least specific (32%) symptom. The existing testing criteria consisting of any combination of one or more of three symptoms (fever, shortness of breath, dry cough) was 93% sensitive and 9% specific (AUC = 0.63, 95% CI: 0.59 - 0.67). The derived testing criteria consisting of any combination of one or more of two symptoms (fever, loss of taste or smell) was 89% sensitive and 48% specific (AUC = 0.75, 95% CI: 0.71 - 0.78). The hybrid testing criteria consisting of any combination of one or more of four symptoms (fever, shortness of breath, dry cough, loss of taste or smell) was 98% sensitive and 8% specific (AUC = 0.77, 95% CI: 0.73 - 0.80).

**CONCLUSION:** An evidence based approach to COVID-19 testing which at least includes fever and loss of taste or smell should be utilized when determining which HCW should be tested.

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*J Infect.* 2020 Apr 30. pii: S0163-4453(20)30260-7. doi: 10.1016/j.jinf.2020.04.034. [Epub ahead of print]

### [Environmental contamination of SARS-CoV-2 in healthcare premises.](#)

Ye G, Lin H, Chen S, et al.

**OBJECTIVES:** A large number of healthcare workers (HCWs) were infected by SARS-CoV-2 during the ongoing outbreak of COVID-19 in Wuhan, China. Hospitals are significant epicenters for the human-to-human transmission of the SARS-CoV-2 for HCWs, patients, and visitors. No data has been reported on the details of hospital environmental contamination status in the epicenter of Wuhan.

**METHODS:** We collected 626 surface swabs within the Zhongnan Medical Center in Wuhan in the midst of the COVID-19 outbreak between February 7–February 27, 2020. Dacron swabs were aseptically collected from the surfaces of 13 hospital function zones, five major objects, and three major PPE. The SARS-CoV-2 RNAs were detected by reverse transcription-PCR.

**RESULTS:** The most contaminated zones were the intensive care unit specialized for taking care of novel coronavirus pneumonia (NCP) (31.9%), Obstetric Isolation Ward specialized for pregnant women with NCP (28.1%), and Isolation Ward for NCP (19.6%). We classified the 13 zones into four contamination levels. The most contaminated objects were self-service printers (20.0%), desktop/keyboard (16.8%), and doorknob (16.0%). Both hand sanitizer dispensers

(20.3%) and gloves (15.4%) were the most contaminated PPE.

**CONCLUSION:** Our findings emphasize the urgent need to ensure adequate environmental cleaning, strengthen infection prevention training, and improve infection prevention among HCWs during the outbreak of COVID-19.

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*Lancet Gastroenterol Hepatol.* 2020 May 12. doi: 10.1016/S2468-1253(20)30126-6. [Epub ahead of print]

### [Manifestations and prognosis of gastrointestinal and liver involvement in patients with COVID-19: a systematic review and meta-analysis.](#)

Mao R, Qiu Y, He JS, et al.

**BACKGROUND:** The prevalence and prognosis of digestive system involvement, including gastrointestinal symptoms and liver injury, in patients with COVID-19 remains largely unknown. We aimed to quantify the effects of COVID-19 on the digestive system.

**METHODS:** In this systematic review and meta-analysis, we systematically searched PubMed, Embase, and Web of Science for studies published between Jan 1, 2020, and April 4, 2020. The websites of WHO, CDC, and major journals were also searched. We included studies that reported the epidemiological and clinical features of COVID-19 and the prevalence of gastrointestinal findings in infected patients, and excluded preprints, duplicate publications, reviews, editorials, single case reports, studies pertaining to other coronavirus-related illnesses, and small case series (<10 cases). Extracted data included author; date; study design; country; patient demographics; number of participants in severe and non-severe disease groups; prevalence of clinical gastrointestinal symptoms such as vomiting, nausea, diarrhoea, loss of appetite, abdominal pain, and belching; and digestive system comorbidities including liver disease and gastrointestinal diseases. Raw data from studies were pooled to determine effect estimates.

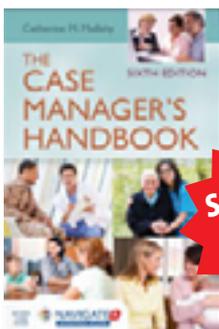
**FINDINGS:** We analysed findings from 35 studies, including 6686 patients with COVID-19, that met inclusion criteria. 29 studies (n=6064) reported gastrointestinal symptoms in patients with COVID-19 at diagnosis, and the pooled prevalence of digestive system comorbidities was 4% (95% CI 2-5; range 0-15;  $I^2=74\%$ ). The pooled prevalence of digestive symptoms was 15% (10-21; range: 2-57;  $I^2=96\%$ ) with nausea or vomiting, diarrhoea, and loss of appetite being the three most common symptoms. The pooled prevalence of abnormal liver functions (12 studies, n=1267) was 19% (9-32; range 1-53;  $I^2=96\%$ ). Subgroup analysis showed patients with severe COVID-19 had higher rates of gastrointestinal symptoms (odds ratio [OR] 1.60 [95% CI 1.09-2.36];  $p=0.0020$ ;  $I^2=44\%$ ) and liver injury (2.20 [1.60-3.02];  $p<0.00001$ ;  $I^2=36\%$ ) compared



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with those with non-severe disease. Patients in Hubei province, where the initial COVID-19 outbreak occurred, were more likely to present with abnormal liver functions ( $p < 0.0001$ ) compared with those outside of Hubei. Paediatric patients with COVID-19 had a similar prevalence of gastrointestinal symptoms to those of adult patients. 10% (95% CI 4-19; range 3-23;  $I^2=97\%$ ) of patients presented with gastrointestinal symptoms alone without respiratory features. Patients who presented with gastrointestinal system involvement had delayed diagnosis (standardised mean difference 2.85 [95% CI 0.22-5.48];  $p=0.030$ ;  $I^2=73\%$ ). Patients with gastrointestinal involvement had a higher prevalence of complication (OR 2.51 [95% CI 1.62-3.89];  $p < 0.0001$ ;  $I^2=0\%$ ).

**INTERPRETATION:** Our study showed that digestive symptoms and liver injury are not uncommon in patients with COVID-19. Increased attention should be paid to the care of this unique group of patients.

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**Radiology.** 2020 May 14:201754. doi: 10.1148/radiol.2020201754. [Epub ahead of print]

[Clinical and chest radiography features determine patient outcomes in young and middle age adults with COVID-19.](#)

Toussie D, Voutsinas N, Finkelstein M, et al.

**Background:** Chest radiography (CXR) has not been validated for its prognostic utility in evaluating patients with coronavirus disease 2019 (COVID-19). **Purpose:** The purpose of this study was to analyze the prognostic value of a CXR severity scoring system for younger (non-elderly) patients with COVID-19 upon initial presentation to the emergency department (ED). Outcomes of interest included hospitalization, intubation, prolonged stay, sepsis, and death. **Materials & Methods.** In this retrospective study, patients between the ages of 21 and 50 years who presented to EDs of an urban multicenter health system from March 10 - 26, 2020 with COVID-19 confirmation on real-time reverse transcriptase polymerase chain reaction (RT-PCR) were identified. Each patient's ED CXR was divided into 6 zones and examined for opacities by two cardiothoracic radiologists with scores collated into a total concordant lung zone severity score. Clinical and laboratory variables were collected. Multivariable logistic regression was utilized to evaluate the relationship between clinical parameters, CXR scores, and patient outcomes. **Results.** The study included 338 patients: 210 males (62%), median age 39 [31-45]. After adjustment for demographics and co-morbidities, independent predictors of hospital admission ( $n=145$ , 43%) were CXR severity score  $\geq 2$  (OR: 6.2, 95% CI 3.5-11,  $p < 0.001$ ) and obesity (OR 2.4 (1.1-5.4) or morbid

obesity. Of patients who were admitted, a CXR score  $\geq 3$  was an independent predictor of intubation ( $n=28$ ) (OR: 4.7, 95% CI 1.8-13,  $p=0.002$ ) as was hospital site. We found no significant difference in primary outcomes across race/ethnicity, those with a history of tobacco use, asthma or diabetes mellitus type II. **Conclusion.** For patients aged 21-50 with COVID-19 presenting to the emergency department, a chest x-ray severity score was predictive of risk for hospital admission and intubation.

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**Ann Intern Med.** 2020 May 5. doi: 10.7326/M20-1632. [Epub ahead of print]

[Epidemiology of and risk factors for coronavirus infection in health care workers: a living rapid review.](#)

Chou R, Dana T, Buckley DI, et al.

**BACKGROUND:** Health care workers (HCWs) are at risk for severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2) infection.

**PURPOSE:** To examine the burden of SARS-CoV-2, SARS-CoV-1, and Middle Eastern respiratory syndrome (MERS)-CoV on HCWs and risk factors for infection, using rapid and living review methods.

**DATA SOURCES:** Multiple electronic databases including the WHO Database of Publications on Coronavirus Disease and medRxiv preprint server (2003 through 27 March 2020, with ongoing surveillance through 24 April 2020), and reference lists.

**STUDY SELECTION:** Studies published in any language reporting incidence of or outcomes associated with coronavirus infections in HCWs and studies on the association between risk factors (demographic characteristics, role, exposures, environmental and administrative factors, and personal protective equipment [PPE] use) and HCW infections. New evidence will be incorporated on an ongoing basis by using living review methods.

**DATA EXTRACTION:** One reviewer abstracted data and assessed methodological limitations; verification was done by a second reviewer.

**DATA SYNTHESIS:** 64 studies met inclusion criteria; 43 studies addressed burden of HCW infections (15 on SARS-CoV-2), and 34 studies addressed risk factors (3 on SARS-CoV-2). Health care workers accounted for a significant proportion of coronavirus infections and may experience particularly high infection incidence after unprotected exposures. Illness severity was lower than in non-HCWs. Depression, anxiety, and psychological distress were common in HCWs during the coronavirus disease 2019 outbreak. The strongest evidence on risk factors was on PPE use and decreased infection risk. The association was most consistent for masks but was

also observed for gloves, gowns, eye protection, and handwashing; evidence suggested a dose-response relationship. No study evaluated PPE reuse. Certain exposures (such as involvement in intubations, direct patient contact, or contact with bodily secretions) were associated with increased infection risk. Infection control training was associated with decreased risk.

**LIMITATION:** There were few studies on risk factors for SARS-CoV-2, the studies had methodological limitations, and streamlined rapid review methods were used.

**CONCLUSION:** Health care workers experience significant burdens from coronavirus infections, including SARS-CoV-2. Use of PPE and infection control training are associated with decreased infection risk, and certain exposures are associated with increased risk.

*N Engl J Med.* 2020 May 7. doi: 10.1056/NEJMoa2012410. [Epub ahead of print]

**Observational study of hydroxychloroquine in hospitalized patients with Covid-19.**

Geleris J, Sun Y, Platt J, et al.

**BACKGROUND:** Hydroxychloroquine has been widely administered to patients with Covid-19 without robust evidence supporting its use.

**METHODS:** We examined the association between hydroxychloroquine use and intubation or death at a large medical center in New York City. Data were obtained regarding consecutive patients hospitalized with Covid-19, excluding those who were intubated, died, or discharged within 24 hours after presentation to the emergency department (study baseline). The primary end point was a composite of intubation or death in a time-to-event analysis. We compared outcomes in patients who received hydroxychloroquine with those in patients who did not, using a multivariable Cox model with inverse probability weighting according to the propensity score.

**RESULTS:** Of 1446 consecutive patients, 70 patients were intubated, died, or discharged within 24 hours after presentation and were excluded from the analysis. Of the remaining 1376 patients, during a median follow-up of 22.5 days, 811 (58.9%) received hydroxychloroquine (600 mg twice on day 1, then 400 mg daily for a median of 5 days); 45.8% of the patients were treated within 24 hours after presentation to the emergency department, and 85.9% within 48 hours. Hydroxychloroquine-treated patients were more severely ill at baseline than those who did not receive hydroxychloroquine (median ratio of partial pressure of arterial oxygen to the fraction of inspired oxygen, 223 vs. 360). Overall, 346 patients (25.1%) had a primary end-point event (180 patients were intubated, of whom 66 subsequently died, and 166 died without

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intubation). In the main analysis, there was no significant association between hydroxychloroquine use and intubation or death (hazard ratio, 1.04, 95% confidence interval, 0.82 to 1.32). Results were similar in multiple sensitivity analyses.

**CONCLUSIONS:** In this observational study involving patients with Covid-19 who had been admitted to the hospital, hydroxychloroquine administration was not associated with either a greatly lowered or an increased risk of the composite end point of intubation or death. Randomized, controlled trials of hydroxychloroquine in patients with Covid-19 are needed. (Funded by the National Institutes of Health.).

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*N Engl J Med.* 2020 May 1. doi: 10.1056/NEJMoa2007621.  
[Epub ahead of print]

### [Cardiovascular disease, drug therapy, and mortality in Covid-19.](#)

Mehra MR, Desai SS, Kuy S, et al.

**BACKGROUND:** Coronavirus disease 2019 (Covid-19) may disproportionately affect people with cardiovascular disease. Concern has been aroused regarding a potential harmful effect of angiotensin-converting-enzyme (ACE) inhibitors and angiotensin-receptor blockers (ARBs) in this clinical context.

**METHODS:** Using an observational database from 169 hospitals in Asia, Europe, and North America, we evaluated the relationship of cardiovascular disease and drug therapy with in-hospital death among hospitalized patients with Covid-19 who were admitted between December 20, 2019, and March 15, 2020, and were recorded in the Surgical Outcomes Collaborative registry as having either died in the hospital or survived to discharge as of March 28, 2020.

**RESULTS:** Of the 8910 patients with Covid-19 for whom discharge status was available at the time of the analysis, a total of 515 died in the hospital (5.8%) and 8395 survived to discharge. The factors we found to be independently associated with an increased risk of in-hospital death were an age greater than 65 years (mortality of 10.0%, vs. 4.9% among those  $\leq 65$  years of age; odds ratio, 1.93; 95% confidence interval [CI], 1.60 to 2.41), coronary artery disease (10.2%, vs. 5.2% among those without disease; odds ratio, 2.70; 95% CI, 2.08 to 3.51), heart failure (15.3%, vs. 5.6% among those without heart failure; odds ratio, 2.48; 95% CI, 1.62 to 3.79), cardiac arrhythmia (11.5%, vs. 5.6% among those without arrhythmia; odds ratio, 1.95; 95% CI, 1.33 to 2.86), chronic obstructive pulmonary disease (14.2%, vs. 5.6% among those without disease; odds ratio, 2.96; 95% CI, 2.00 to 4.40), and current smoking (9.4%, vs. 5.6% among former smokers or

nonsmokers; odds ratio, 1.79; 95% CI, 1.29 to 2.47). No increased risk of in-hospital death was found to be associated with the use of ACE inhibitors (2.1% vs. 6.1%; odds ratio, 0.33; 95% CI, 0.20 to 0.54) or the use of ARBs (6.8% vs. 5.7%; odds ratio, 1.23; 95% CI, 0.87 to 1.74).

**CONCLUSIONS:** Our study confirmed previous observations suggesting that underlying cardiovascular disease is associated with an increased risk of in-hospital death among patients hospitalized with Covid-19. Our results did not confirm previous concerns regarding a potential harmful association of ACE inhibitors or ARBs with in-hospital death in this clinical context. (Funded by the William Harvey Distinguished Chair in Advanced Cardiovascular Medicine at Brigham and Women's Hospital.).

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*Clin Infect Dis.* 2020 Apr 27. pii: ciaa490. doi: 10.1093/cid/ciaa490. [Epub ahead of print]

### [Early risk factors for the duration of SARS-CoV-2 viral positivity in COVID-19 patients.](#)

Lin A, He ZB, Zhang S, et al.

**BACKGROUND:** Pneumonia COVID-19 has become a pandemic. However, information on early risk factors for the duration of SARS-CoV-2 viral positivity is unavailable yet.

**METHODS:** In this prospective study, a cohort of 137 patients with confirmed SARS-CoV-2 infection were enrolled. Clinical information and laboratory data were retrieved from electronic medical records. Viral positivity duration was calculated by an interval from the day SARS-CoV-2 positive confirmed to the day SARS-CoV-2 returned to negative in these 137 COVID-19 patients. Early risk factors for the duration of SARS-CoV-2 viral positivity were evaluated.

**FINDINGS:** The median SARS-CoV-2 viral positivity duration is 12 days (range: 4 days - 45 days) for this cohort. Cox regression results showed a significantly shorter viral positivity duration was related to younger [hazard ratio (HR) = 0.658,  $p = 0.017$ ], not severe patient (HR = 0.653,  $p = 0.076$ ), higher count of lymphocytes (HR = 1.464,  $p = 0.033$ ), eosinophils (HR = 1.514,  $p = 0.020$ ) and CD8+ T cells (HR=1.745,  $p=0.033$ ), and lower IL-6 (HR = 0.664,  $p = 0.036$ ) and IL-10 (HR = 0.631,  $p = 0.021$ ). Multivariate analysis with covariables adjusted results showed that the count of CD8+ T cells (HR=2.376,  $p=0.114$ ) was a predominant risk factor for the SARS-CoV-2 viral positivity duration.

**INTERPRETATION:** Our findings firstly provided early laboratory parameters such as count of CD8+ T cells, as risk factors for the duration of SARS-CoV-2 viral positivity, which have significance in control and prevention of the disease. ■

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## Latest CDMS Role and Function Study Underway *continued from page 7*

function study is undertaken regularly to identify the essential activities performed by disability managers as well as the important knowledge statements of what is needed to effectively perform this role. Specific questions in the survey seek insights into several areas, from demographics among practitioners to specialization. For example, questions in the current survey explore:

- Employer organization—for example, for-profit company, government agency, health insurer, consulting agency, and third-party administrator
- Areas of responsibility—including accommodations/

ADA compliance, disability case management, disability program management, benefits, leave and absence management, return to work, program development/management/evaluation, safety, vocational rehabilitation, workers' compensation

- Other credentials held
- Preferred method of learning

In addition, the current survey seeks feedback from participants on whether they feel the term “disability management” accurately encompasses current practice and the scope of work required in the industry. If not, participants are asked to suggest terms that, in their view, would best reflect the current practice and scope of work.

The results of the survey will, no doubt, paint a compelling picture of

disability management practice at a time when both the composition of the workforce and the needs of the workplace continue to evolve. The Commission is excited to be able to share insights from the current survey, which will inform the CDMS examination in 2021. **CM**

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*MaryBeth Kurland, CAE, is CEO of the Commission for Case Manager Certification, the first and largest nationally accredited organization that certifies over 48,000 professional case managers and nearly 2,300 disability management specialists. The Commission is a nonprofit volunteer organization that oversees the process of case manager certification with its CCM credential and the process of disability management specialist certification with its CDMS credential.*

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## CE I Chronic Pain, Opioids, And Disability:

### A Frank Conversation *continued from page 16*

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## Case Managers on the Front Lines of COVID-19 *continued from page 6*

to basic resources as well as several webinars. Of particular interest is the section “Telephone Triage and COVID-19.”

Last, but certainly not least, the Commission has made some changes in its certification examination schedule. Because the Prometric test centers

are closed, we had to cancel the April 2020 CCM examination. However, those who were scheduled to take the April 2020 examination are eligible to take their test between August 1, 2020, and September 19, 2020, as part of an extended testing window.

In addition, the Commission has delayed the release of the new examination blueprint until the December 2020 administration to ensure that

candidates who have already invested in preparatory materials will not be adversely affected.

As we get through these unprecedented times, case managers are rising to the challenge. They continue to move forward with resilience and commitment. In their professionalism, case managers continue to showcase what it means to be an advocate for others. **CM**

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## Case Managers in the COVID-19 Environment: Resist, Recharge, Regroup *continued from page 8*

at-risk employees in the workplace and prevent lost duty time or long-term illnesses. Case managers can **regroup** and become experts in home monitoring technology as the telehealth market using artificial intelligence continues to evolve. Post COVID-19 America will necessitate greater engagements with the mental health community. The need for sustained contact tracing will produce new roles for case managers interested in working within the public health arena.

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### It is critically important for case managers to pause and devote deliberate time to resist, recharge, and regroup.

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One can sometimes find a silver lining in the most difficult of times, but one must have the strength and courage to **resist** operating from a place of fear. Being stuck on the same page prevents one from turning to the next chapter, and case managers are perfectly positioned to write new stories. Invest time to **recharge** and find your center. Recharging provides the space to think clearly and **regroup**

as a practice and profession.

In closing, leverage your member association in this changed environment. The Case Management Society of America is not just an organization, but rather a collection of nurses, social workers, and other health care professionals who share a common goal of helping people achieve their best selves or a new normal of health. The COVID-19 environment should inspire a new, innovative normal for case management practice in the myriad of care, community, hospital, school, and industrial settings that will be operating differently in the months and potentially years to come. Let's lead the way! **CM**

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## Care Transitions: Understanding Challenges/Identifying Solutions *continued from page 12*

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- Quality management program
- 340B
- Increasing access to infusion care and reducing costs for patients with Medicare Part D coverage.
- Partnerships with manufacturers of limited distribution drugs for cost-effective solutions. **CM**

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*This Satellite Symposium was sponsored by Option Care Health.*

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**CE II Marijuana and Opiates** *continued from page 20*

the high prices as the barrier. Another major barrier is the proximity to an open dispensary. As previously stated, Ohio is running at 20% capacity of the program. Despite the delays, the results pertaining to medication cessation and quality of life were also consistent with other findings. Lotus Health LLC patients reported a 57% successful treatment rate before there was a close dispensary and a 76% success rate once a local dispensary was open. As of March 2020, the successful treatment rate had increased to 94.1% (**Figure 1**) and 62% of patients were able to stop or decrease at least 1 prescribed medication (**Figure 2**), with 23% of those medications being opiates/opioids and 18% including benzodiazepines. When asked about overall quality of life, 95% of patients reported an increase in quality of life overall (**Figure 3**).

I was curious about the response of other providers of cannabis medicine. Seventy-eight percent of clients were able to communicate medical cannabis use to at least some of their other health care providers. Clients reported that 42% of the providers referred them to Lotus Health LLC for cannabis integration to begin with. Only 3% of clients reported being “fired” by other health care providers for choosing to use cannabis as medicine. The previous survey in 2019 indicated a much less accepting health care provider community. Education is key in order to continue the trend. Through continued education and destigmatization, I plan to not only continue to offer cannabis as a viable option for treating opiate use disorder and chronic pain but also to stay abreast of the research worldwide. **CE II**

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