

CareManagement

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INSIDE THIS ISSUE

CONTINUING EDUCATION ARTICLES:

12 Successful Communication in Care Coordination for More-Effective Outcomes **CE**

Dawn Elledge, RN, CCM, CGCM

Basic communication skills for certified case managers must be considered in daily practices. This article includes tips for being a good listener, ways to help speak to a client, and a list of personal reminders for more-effective communication.

16 Hospital Case Management: CMSA's White Paper **CE**

Stefani Daniels, MSNA, RN, ACM, CMAC

The White Paper on Hospital Case Management Practice from the Case Management Society of America is a rare expression of the current state of hospital case management practice. The 8 transformative priorities that every hospital leader should consider when planning for the next generation of hospital case management programs are discussed.

CE Exam **CE**

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Nonmembers:

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SPECIAL SECTIONS:

20 **PharmaFacts for Case Managers**

Approvals, warnings and the latest information on clinical trials—timely drug information case managers can use.

24 **LitScan for Case Managers**

The latest in medical literature and report abstracts for case managers.

DEPARTMENTS:

2 **From the Editor-in-Chief**

Connect With Us on Facebook!

4 **From the Executive Editor**

Education at a Crossroad

6 **News from CCMC**

CCMC Offers Remote Proctoring for Certification Examinations; Executive Committee Terms Extended During COVID-19

7 **Case Manager Insights**

COVID-19 and the Hidden Enemy

8 **News from CMSA**

A Letter From the Incoming President of the Case Management Society of America

9 **CDMS Spotlight**

Addressing COVID-19-Related Mental Health in the Workplace

10 **Legal Update I**

Access to Residents of Assisted Living Facilities

11 **Legal Update II**

Will Home Care Come Full Circle?

34 **How to Contact Us**

34 **FAQs**

35 **Membership Application**

join/renew
ACCM online at
academyCCM.org
or use the application
on page 35



Gary S. Wolfe

Connect With Us on Facebook!

Facebook is the largest of all the social platforms, with approximately 1.7 billion active users worldwide. In the current era, people are looking for ways to communicate information, ask questions, seek direction, and get answers quickly. Social networking has become the tool to reach out to people for a quick response.

Some interesting thoughts about social networking and Facebook:

- Facebook is a never-ending virtual social gathering.
- Facebook is an acceptable means of communication.
- By being on Facebook, you belong to a community.
- Facebook provides strong connections.
- Facebook engagement results in a virtual presence.
- Facebook fulfills our need for self-presentation.
- Facebook satisfies our need to belong.

CareManagement and the Academy of Certified Case Managers has a Facebook page. Click on the banner at right to like and follow.

I invite you to have a Facebook presence in your case management practice. Our Facebook page is a great example of sharing best practice approaches to difficult challenges. It is an excellent platform to seek answers to questions you might have in your practice, it allows case managers to contribute to the case management body of knowledge, and it is quick, easy, and informative. Please take advantage of this opportunity and work to improve case management practice.

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Catherine M. Mullahy

Education at a Crossroad

The summer of 2020 continues to be one like no other. Case managers who have been on the front line during such uncertainty continue to demonstrate their expertise, creativity, and ability to adhere to evidence-based guidelines while being part of strategic teams forging new ones as directed by the Centers for Disease Control and Prevention (CDC) and other agencies. The need to provide foundational preparation for professionals new to this role, to assist others in their pursuit of Certified Case Manager (CCM) certification, and to provide continuing educational opportunities for all of us is a never-ending challenge but an important one if case managers are to remain an integral component within our health care systems. *CareManagement* continues to explore opportunities to provide educational support to our readers and to the organizations that are a vital part of our existence. Because live seminars, workshops, and other in-person educational meetings have been curtailed for a variety of reasons (including COVID-19), *CareManagement* has become increasingly popular as a source of educational and informational resources. We are grateful for your continuing support and welcome ideas and recommendations that will prepare you for your increasingly complex role now and in the future.

Our country is fighting the pandemic and civil unrest in far too many of our cities, and many of us

are wondering just how education for our children and grandchildren will continue. There are so many competing interests, and yet education continues to be front and center in our personal and professional lives. In just the past few months, we have witnessed the cancellation of most, if not all, local, regional, and national case management conferences, and yet education continued. The Case Management Society of America (CMSA), whose members receive *CareManagement* as a member benefit, made the transition from what should have been their 30th anniversary live conference in Boston to a virtual one in an incredibly short period. From the many comments heard and posted, it was a successful and enjoyable conference. Admittedly, I was a skeptic, old school if you will. I have thoroughly enjoyed all our case management conferences where I was able to meet colleagues, see friends, and discuss our shared experiences over the years, and I wondered what a virtual experience might be like. Surprisingly, at least to me, the format was user friendly, engaging, and allowed for a real-time open exchange of comments, questions, and responses. Engaging attendees across the country for educational purposes is challenging enough, but successfully involving them in the celebration of case management during a virtual “party” spoke loudly to the creative and undaunted spirit of case management. We recognize that even in the best case management plans, when Plan A becomes problematic,

one needs to have a Plan B, C, and perhaps even D. That is precisely what we need to keep in mind as we create new case management educational programs and content in publications. *CareManagement* will be addressing those opportunities as well. If traditional training and educational formats are Plan A, then what is your Plan B, and yes, D? As a case manager, do you have educational preferences and ways that you want to be engaged? For those of you in leadership positions, what are your plans to educate and motivate your staff? In the Case Management Institute’s 2020 Case Management Salary and Trends Survey, of more than 1000 case managers, almost 25% of those surveyed did not believe the training they received was adequate and 26% did not believe their organization offered professional case managers a career ladder. This same survey also noted that turnover was incredibly high—upwards of 79%! The challenges to do better are right in front of us. How can we work together to meet these needs?

We can make a difference, one patient at a time!

Catherine M. Mullahy

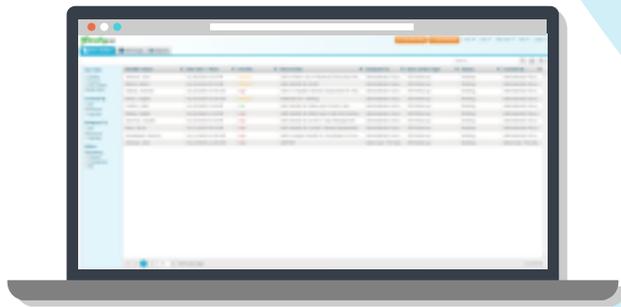
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CCMC Offers Remote Proctoring for Certification Examinations; Executive Committee Terms Extended During COVID-19

MaryBeth Kurland, CAE

Since the outbreak of the COVID-19 pandemic, the Commission for Case Manager Certification (CCMC) has taken positive steps on behalf of our community of professional case managers, especially with regard to remote access.

Our latest action, approved by our Board in June 2020, is to offer the option of remote proctoring for those registered and preapproved to take the Certified Case Manager®

(CCM) certification examination in August 2020 and the Certified Disability Management Specialist® (CDMS) certification examination in September 2020.

For the upcoming examinations, candidates will have the choice of taking the CCM and CDMS certification examinations either in person at

a testing facility or at home with live proctoring provided remotely through ProProctor,™ our test administration partner. To use the ProProctor online app, candidates must have a computer with a camera, microphone, and internet connection and must also be able

For the upcoming examinations, candidates will have the choice of taking the CCM and CDMS certification examinations either in person at a testing facility or at home with live proctoring provided remotely through ProProctor,™ our test administration partner.

to install the app before the text event. (Please see remote proctoring [details here](#).) Individuals who want to schedule or change how and where they will take the certification examination may select their [scheduling option here](#) (see left-hand column).

The dual delivery method for the certification examinations is a significant step forward. It is being allowed, at least on a temporary basis during the pandemic, by the National Commission for Certifying Agencies (NCCA). Previously, before the pandemic, NCCA had been beta-testing remote proctoring. Now, the experience of remote proctoring during this time will provide more input for NCCA to make a decision about dual examination delivery on a more permanent basis.

CCMC Executive Committee Terms Extended

Separately, CCMC also made other decisions with regard to governance to provide consistency and eliminate the disruption due to transitions during this time. To that end, the Executive

Committee positions and terms have been extended for another year (until June 30, 2021). Continuing in these leadership roles are Michelle Baker, Chair; Jared Young, Chair-Elect; Sheila Nelson, Secretary;

Chikita Mann, Treasurer; and Jeannie LeDoux, Immediate Past Chair.

In addition, all existing commissioners will remain on the board and no new commissioners were added for this year. CCMC believes these actions will promote continuity as other COVID-19-related actions are contemplated. Furthermore, having a mature board provides calmness and clarity in a time of great change and disruption. [CM](#)

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.

Readers

Have an idea for an article?
Send your suggestions for editorial topics to:
cmullahy@academyccm.org.

COVID-19 and the Hidden Enemy

Sue Bowers, RN-BC, BSN, CCM

There is evidence that links loneliness and social isolation to depression. *JAMA (Journal of the American Medical Association)* reports that “The worldwide COVID-19 pandemic, and efforts to contain it, represent a unique threat, and we must recognize the pandemic that will quickly follow it—that of mental and behavioral illness—and implement the steps needed to mitigate it.”

I am not an expert on COVID-19, the elderly, or mental health. I am an expert on what COVID-19 has done to my mom. As a daughter and nurse case manager, my role is as an advocate to keep my mom safe and healthy. The purpose of this article is to

provide a personal perspective in caring for an aging parent and the impact on mental health during a pandemic.

As the coronavirus made its way to the United States in March 2020, my 87-year-old mother was a vibrant, healthy, and independent woman. She

cooked, cleaned, shopped, attended church, drove, ran errands, had her hair and nails done, and indulged in other freedoms. She was in control.

On March 16, 2020, a Shelter-in-Place order was mandated in [continues on page 31](#)



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A Letter From the Incoming President of the Case Management Society of America

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

The year 2020 will be recorded as a year of “firsts” for many events and momentous occasions. “Virtual” may be the largest word in any 2020 Word Cloud that will be used by people around the world. I join this group as I celebrated the virtual gavel exchange between Jose Alejandro, PhD, RN-BC, CCM, FACHE, FAAN, and myself as I accepted the position and responsibilities of CMSA President. I am honored, humbled, and excited about this opportunity! I am also grateful to Jose Alejandro, Fraser Imagineers, and many others who supported past administrations and this transition to the 2020-2022 CMSA Board of Directors. I am ready to forge new paths with bold determination, innovation, and leading-edge programs to position CMSA as a power player within the profession of case management and the health care industry at large. The realization of this statement will require a community effort... the proverbial “it takes a village!”

Melanie A. Prince, MSS, MSN, BSN, RN, NE-BC, CCM, is the incoming President of the Case Management Society of America (CMSA). She recently retired as an Active Duty Military Colonel assigned to Headquarters Air Force, where she was responsible for developing strategies to eliminate interpersonal violence in the military. Melanie is now the Chief Executive Officer, Care Associates Consulting.

Community is more important than ever. A rallying cry of unity and the declaration of “stronger together” were resounding themes during the CMSA 2020 Conference, Virtual Edition. These sentiments around community and unity are silver linings in today’s

that I humbly and excitedly take the reins of the CMSA presidency with equal determination and boldness to drive innovation, to provide new strategies to enhance member value, and to renew our focus on public policy.

CMSA can be even stronger if we develop symbiotic and complementary strategies to not only advance the value of CMSA but also support the success of partners who are members of the total professional team employed in professional case management

complex challenges. The “silver lining” metaphor is apt because the setbacks and harm some of us are experiencing also may lead to a good outcome. Unity and the prospect of joining together in a more intentional way are the basis for hope, comfort, and positivity in the midst of health challenges, financial insecurity, the passing of family members and friends, job loss or career change, social discord, feelings of fear or isolation, and a general sense of uncertainty about the future.

I strive to see the positivity in any situation, and I am inspired by the general temperament of case managers everywhere! Professional case managers coordinate care and assist families under the most challenging of circumstances. Therefore, it is no surprise that the tone and attitude of our professional community is determined and resolute, rising not only to the occasion but indeed above the occasion. It is with this backdrop

As president, I look forward to energizing coalitions of community at every level. Building on the concept of unity and “stronger together,” a connected community will propel CMSA forward into an expectedly new,

but hopeful, normal. One of my strategic goals is to engage member talent (whole talents) and connect complementary talents in ways that will transform CMSA. Imagine a “Smart Connection” where a coalition community focuses on use of technology in case management practice and throughout CMSA. Or a “Change Connection” where a coalition community connects to affect change in policy, standards, and CMSA member value. Consider a “Virtual Connection” where a coalition of talented members sustain the merits of online meetings, presentations, educational offerings, networking, and socialization experienced during the 2020 CMSA Conference, Virtual Edition. These are only three examples of how I plan to use the “whole” of our organization to develop a transformative future for us and by us.

While the goals are to transform our

[*continues on page 30*](#)

Addressing COVID-19–Related Mental Health in the Workplace

Ed Quick, MA, MBA, CDMS

A new [national survey](#), conducted by CVS Health and Morning Consult, has revealed what many of us have observed in our professional practices: adults in the United States are experiencing more stress today than a year ago. The increase is especially pronounced among health care workers, with increased stress reported by 75%

family life, including homeschooling their children. Economic losses because of layoffs and furloughs have compounded the health crisis. As [two psychiatrists](#), writing in *Scientific American*, observed: “With widespread social isolation, increasing unemployment, and unprecedented levels of stress, we are witnessing an impending mental health crisis.”

Accessing Available Resources

All too often, people are not aware of the resources available to them. The CVS Health/Morning Consult survey, for example, found a lack of familiarity with employee assistance programs (EAPs), which offer telephonic counseling and other services to support mental health and wellness. Only 8% of respondents had used an EAP, while

No matter where they practice, Certified Disability Management Specialists and Certified Case Managers should be aware of the impact of stress, anxiety, and other mental health issues on the lives of the people for whom they advocate. A simple mental health screening can help identify needs and direct people to the resources they require.

of health care workers on the front line of the pandemic.

COVID-19 has caused widespread disruption. A sudden shift to remote working has caused many people to feel isolated and/or burdened by the often-conflicting demands of work and

Ed Quick, MA, MBA, CDMS, is a Commissioner with the Commission for Case Manager Certification and has more than 15 years of experience in disability and workforce management with Fortune 100 companies. He currently works as a global senior benefits manager. CCMC is the first and largest nationally accredited organization that certifies more than 48,000 professional case managers and nearly 2,300 disability management specialists. The Commission oversees the process of case manager certification with its CCM® credential and the process of disability management specialist certification with its CDMS® credential.

The adverse effects of COVID-19 have been felt disproportionately in minority communities because of inadequate access to health resources, socioeconomic opportunities, and insurance coverage. As a result, during recent antiracism protests, there has been a continuous outcry against the impact of COVID-19 on people of color.

Brought together, these stresses and calls for systemic change escalate the need for greater mental health resources. No matter where they practice, Certified Disability Management Specialists (CDMSs) and Certified Case Managers (CCMs) should be aware of the impact of stress, anxiety, and other mental health issues on the lives of the people for whom they advocate. A simple mental health screening can help identify needs and direct people to the resources they require.

nearly 40% had never heard of an EAP.

These survey findings speak directly to the role of CCMs and CDMSs to provide access to resources that can support their clients' health and wellness—both physical and mental. One of the first things that CCMs and CDMSs should ascertain is whether the individuals for whom they advocate are working for employers that offer EAPs or similar resources. Even if they have never accessed these resources before, employees may be more aware of EAPs today, given the increase in communication around these offerings, particularly by larger employers. As a [behavioral health expert](#), writing in *Crain's New York Business*, observed recently, “Employers should feel comfortable taking the lead to ensure their employees are aware of the mental health resources available

[continues on page 30](#)

Access to Residents of Assisted Living Facilities

Elizabeth Hogue, Esq.

Ancedotally, at this time home health providers are often denied access to their patients who reside in assisted living facilities (ALFs). The rationale of ALFs is that denial of access is necessary in order to

agencies who wear all recommended PPE may assist ALFs to regularly check on residents' health. In addition, ill residents may be able to remain at ALFs if they can remain isolated in their apartments and if home health agency personnel can provide the level

Likewise, ALFs may be targeted by patients and their families alleging negligence or perhaps even wrongful death because home health personnel could not provide needed care. Legal counsel for patients and their families may rely on guidance from the CDC

Receipt of needed skilled care by residents of assisted living facilities is serious business, especially during the pandemic. The efforts of assisted living facilities to protect residents by denying access to home health agencies are surely misplaced.

void exposure to COVID-19. The experience of skilled nursing facilities (SNFs) with multiple infections and deaths from the virus may increase ALFs commitment to denial of access.

The Centers for Disease Control and Prevention (CDC) has issued guidelines for ALFs entitled "Considerations When Preparing for COVID-19 in Assisted Living Facilities." These guidelines are clearly based, in part, on the CDC's expectation that patients who need skilled services from home health agencies will continue to receive them. First, the CDC points out that:

Because staff at many of these facilities are generally not trained to provide medical care, their access to and training to use recommended personal protective equipment (PPE) and their ability to care for residents with COVID-19 is limited...

The CDC, therefore, goes on to say out that personnel from home health

of care needed with access to PPE. The guidance further states that if home health agencies cannot provide care to residents who have the virus, then these residents should, of course, be transferred to hospitals or other appropriate care sites.

It is certainly clear that ALFs should limit or deny visitors' access to their facilities, but, according to the CDC, "visitors" do not include clinical personnel from home health agencies. Guidance from the CDC makes it clear that home health agencies should be active participants in the ongoing care of residents, including residents who are ill with COVID-19.

The failure of ALFs to follow CDC guidance in this regard may have significant adverse consequences for ALFs. The denial of needed skilled services provided by home health agencies to residents may result in enforcement action against ALFs by state licensure boards, especially if patients' conditions worsen or go untreated altogether.

to show that national standards of care do not support denial of access to residents by home health agencies.

By the same token, home health agencies cannot maintain residents on census if they cannot visit them over an extended period of time. Home health agencies must work directly with ALF administrators to gain access and document their efforts to do so. In the meantime, to the extent that virtual visits are appropriate, they should be used to the maximum extent possible.

Receipt of needed skilled care by ALF residents is serious business, especially during the pandemic. The efforts of ALFs to protect residents by denying access to home health agencies are surely misplaced. **CM**

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Will Home Care Come Full Circle?

Elizabeth Hogue, Esq.

“My view, you know, is that the ultimate destination of all nursing is the nursing of the sick in their own homes...I look to the abolition of all hospitals...

But no use to talk about the year 2000.”

—Florence Nightingale; June, 1867

The roots of healthcare in the United States are clearly in the care of patients at home. Perhaps the definitive book on home care nursing in this country is *No Place Like Home: A History of Nursing and Home Care in the United States* authored by Karin Buhler-Wilkerson in 2001. As Ms. Buhler-Wilkerson points out in her book, care for the sick was part of domestic life in early 19th century America. Physicians and nurses delivered care in patients’ homes, most often with the help of female family members, neighbors, and perhaps servants. For those who had no one to care for them, the options for care were scarce.

Enter The Ladies Benevolent Society (LBS) of Charleston, South Carolina! The LBS was founded in 1813 during the British blockade of Charleston harbor to address the needs of patients for whom there were few other options. The Society was founded by 125 women who were the wives, sisters, and daughters of Charleston’s wealthiest families. The Society was a philanthropic organization only. Members raised needed funds for care of the sick and distributed them, including hiring nurses to care for

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.

patients in their homes. A visiting committee conducted the daily work of the Society.

Patient load varied with the seasons and the occurrence of epidemics. In the early years, the Society cared for an average of 290 patients annually. Ms. Buhler-Wilkerson says in her book, “Most important, the LBS supplied the

Home care has once again become the “fashion.” An increasing number of treatments are provided at home.

sick poor with nurses, for “of what avail are medicines or proper nourishment, unless there be some kind hand to administer them in due season?”

Home care has once again become the “fashion.” An increasing number of treatments are provided at home. An article by Shantanu Nundy and Kavita K. Patel entitled “Hospital-at-Home to Support COVID-19 Surge-Time to Bring Down the Walls” that appeared on the JAMA Health Form, JAMA Network on May 2, 2020, makes the point that both COVID-19 patients and patients with other diagnoses should be cared for at home. The authors state that “the concept of a hospital stay in the home has been tested and proven to be effective in a wide variety of

settings and clinical conditions...”

The article goes on to say that:

A 2016 Cochrane review evaluating the effectiveness and cost of hospital care at home found no difference in 6-month mortality..., no difference in being transferred or readmitted to a hospital..., and lower costs...

It is clear, contrary to Florence Nightingale’s prediction above, that hospitals will always have a role to play in the delivery of healthcare. It is also clear, however, that home care of all types provides an important answer to many dilemmas currently encountered in the healthcare industry and must, therefore, be ascendant! Will healthcare now come full circle to its roots of caring for patients in their homes? [CM](#)

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CE I

Successful Communication in Care Coordination for More-Effective Outcomes

Dawn Elledge, RN, CCM, CGCM

Have you heard the old saying that “An ounce of prevention is worth more than a pound of cure?” This is certainly relevant to the art of communication desired for mediation services in the scope of case management practice. Whether in relation to clients, care recipients, medical, legal, financial, or other professional providers in the everchanging health care industry, the art of mediation, which has its origin in the ability to communicate openly and prioritize issues appropriately, is key for more-effective outcomes. Basic communication skills for certified case and/or care managers must be considered in daily practices. Focusing on how we approach mediation is foundational to communicating with families while articulating perfectly across the board in any given case management scenario. How proficiently case managers may impact others depends highly on improved communication skills to either create ideal case scenarios or to be a causative factor in failed attempts to build foundational client relations. Discerning a client-focused and outcome-driven approach in addition to using the skill of transparency is also key in most desired results. Exactly how does communication and case mediation work harmoniously in care coordination? This is a good question and worth the time to take a look at, or better yet, assess your ability as a case or care manager to best communicate in the collaborative process of case management practice standards.

This article, which focuses on the more generalized art of case management, will help remind licensed health care professionals that no matter how the landscape or the layout of the health care delivery system may change or seem altogether complex, one thing remains constant: change. Change is a constant in our society. And while rules or trends change, basic human needs in our clients do not. Every client we get “assigned to” is a person who has a fundamental right to be heard, cared for, and respected. Meeting others’ needs as well as our own can oftentimes be overwhelming in our call of duty. Every case manager can attest to the fact that no matter how hard we all try, we can’t always please everyone. There are cases we can all share where we had to learn a hard lesson or two about how we can better communicate with either the care recipient, our clients, or the providers we work with on each case. Especially since all too often case managers find themselves in the center point of a case, or what I have more commonly referred to as the “middle.” With a conscious effort, and a sincere perception, a more professional approach occurs when we see ourselves in a service role that allows direct communication among the case manager, the client, the payer, the primary care provider, and other service delivery professionals. The case manager is able to enhance these services by maintaining the client’s privacy, confidentiality, health, and safety through advocacy and adherence

to ethical, legal, accreditation, certification, and regulatory standards or guidelines.” Case managers offer available resources in a holistic manner so as to develop a multidisciplinary team in a case where applicable. A seamless and collaborative effort that partners the care recipient with the right providers at the right time with the right resources is the aim in the process by which case managers can lean towards best outcomes. How can case managers learn to prioritize the issues in the most difficult cases and put this seamless approach to work repeatedly in a fail-proof fashion? What is a systematic approach that uses the cyclical process of care planning and care coordination that clients can relate to? What areas of basic communication skills can be added in to such a process?

Leadership ability is learned and respect is earned, which is applicable to the care planning process built on case manager and client relationships. Some case managers are natural born leaders while others may not be so bold. Some of us are more

Dawn Elledge, RN, CCM, CGCM, was a former Vanderbilt University hospital physical rehabilitation nurse in Nashville, Tennessee, before becoming an RN case manager and board-certified RN geriatric care manager. Dawn was also a former RN Investigator for the TN Long Term Care Facility Ombudsman. Dawn is a staunch elder care advocate and speaks to community groups and peers about elder care issues, while offering eldercare caregiving insights.

A seamless and collaborative effort that partners the care recipient with the right providers at the right time with the right resources is the aim in the process by which case managers can lean towards best outcomes.

task oriented than people oriented, and some of us need to know how to communicate better. In many instances, there may be more than 1 client in a case; in this circumstance, for example, communication style will enhance the outcomes for care planning with multiple family members who are present in an initial care planning meeting. Case managers may be too quick to proceed in the plan of care process before actually listening to each family member present. Also, there are many instances in which 2 or more family members may not agree on specific assessments, plans, implementations, or provider referrals. Are case managers being trained to provide a seamless approach to a client-centered process? Until a broad perspective of how well we effectively listen and communicate to both our clients and our peers is examined, we may continue to learn through growth trends in the industry or other feedback systems anticipated in the future as we progress to partner more with health care payers. On the more practical side, how well we retain our clients is usually a best indicator of how well we are communicating to our clients. Basic communication takes place between a speaker and a listener. To be both an effective speaker as well as an effective listener takes skill sets requiring various levels of responsibility and intention. Being intentional happens with motive or desire. If case managers tend to be more outcome driven while being more client focused, this will show in

any style of communication. It really does not matter whether you are a brilliant communicator or whether you tend to be quiet and/or shy. The client is looking to see if you are truly listening. Are you listening to the words in this article? Can you relay any of the key points brought up in the last few sentences here? While reading and listening may not exactly be the same thing, when our clients are answering our questions or describing their issues, are we really listening to them? Good communication begins with being a good listener!

What does being a good listener entail?

When in person or conducting an on-site interview:

1. What is your body language conveying when you are listening? Are you facing the person speaking? Does your facial expression and eye contact convey a high, medium, or low interest?
2. What does your posture say as you listen? Body language is crucial in communicating with our clients.
3. Are you more focused on the questionnaire or clipboard in your hand or have you put all paperwork aside for even a moment to relay a more humanistic approach?

When conducting telephonic interviews or when on calls:

4. Do you ever restate what was said to be sure you understood correctly?
5. Do you ask open-ended questions to

gather more of a personal perspective on the issues in a given case or do you stick to the script?

6. Have you ever asked a client to offer their perception of the case issues?
7. Do you affirm or clarify what is being said?
8. Are you listening for deeper issues such as anticipatory grief or worry or guilt?
9. Have you set a positive mood for interaction for formal initial consult?
10. Is assurance offered as well as an attentive ear?

With every initial client consult the life of the case will depend highly upon how well you as a professional case manager empowered the patient to participate in his/her own personal care. People (and peers, too) seem to know if you as a professional are caring and confident or otherwise. If allowed, call or meeting schedules should be agreed upon by both you and your clients, and it is most important to always explain the “next steps,” in as much clarity as possible, and ask for feedback. Try to think in terms of the services you expect from your own health care professionals when you’re on the “other side!”

Another saying comes to mind here, stated by President Theodore Roosevelt:

“Nobody cares how much you know, until they know how much you care.” Your patients will know how much you care by how much actual care you put into communication, care

WAYS TO HELP SPEAK TO A CLIENT MAY INCLUDE:

1. Get the person's attention; "(YOU) Tell me about..."
2. State your message clearly.
3. Ask simple, answerable questions.
4. Ask open-ended questions to get your client to speak freely.
5. Ask for feedback often to keep your client engaged.
6. Explain in simple terms what your role is and ask for feedback.
7. Keep all topics relative and to the point.
8. Be mindful of facial expressions with caring attitude and tone of voice.
9. Engage your client as much as possible.
10. Stay focused on client-centered approach.
11. Keep issues relative to care of the care recipient as much as possible, with clarity.
12. Share ideas relative to the care planning process and explain what the process looks like.
13. Allow client to explore options and give feedback to key issues.
14. Gently help client to identify and prioritize each issue moving into care-planning process.
15. Ensure most important questions or concerns have been at least discussed.

planning, and care coordination. For every individualized issue identified, no matter how complex, there must be a plan to follow. Communicating a plan of care will require you as a case manager to have listened well and written or made a note of any barriers to that plan. For example, does the client understand your availability or who to call if you are not available? Following up with good initial assessments should begin and end well, and ensuring that the client is well equipped and well informed is a part of listening and acting in action! Does the client understand the basic process for his/her art in his/her case? Perhaps we assume all too often that our client understands our key role and how the case management process works to solve or address any issues. Think again. Most clients who I talk to actually do not fully comprehend

the complexities of the case/care management (planning) process, and for this very reason alone, we review and revise the plan of care as needed, marking the questionable options or difficult parts for continued review. This has made a huge difference in the successful outcomes noted. We cannot be too quick to judge, assume, or proceed unless we are 100% sure our clients have a better understanding with all the "moving parts" in an active or complex case.

Our clients need to realize that in the midst of continual decisions, case and care managers are equipped to handle the problem-solving approach that case detail work or care planning entails along with any and all professional referrals. Does your client trust that you will follow through or have you given every possible indication in your ongoing

communication with your patient or the client that you are capable of handling all of the issues in a case? One of the most challenging issues our clients will ever face is having someone else "call the shots" or "take over." It is extremely important to convey otherwise. When we have established a trusting case/care manager and client relationship using client-centered communication per professional standards, the effective outcome will develop into creating a lasting bond with our client. That's what you as a case/care manager should strive for and what is sure to be what your organization or company desires most.

Following up becomes easier when we get to know our patients and clients better with each call—or at least it should be. Follow up calls are absolutely priceless! This is most often when clarity comes for the client when discussing the initial meeting or the next steps. Calling our clients regularly also emphasizes how much we want them to be aware of the next steps in the case as well as outline additional concerns or issues that they may have omitted in the initial meeting. Interestingly, there is no "cookie cutter" approach to scheduling client follow-up calls since every case is different. One client may need daily calls, while other clients prefer not to be called more than on a weekly basis or prefer to be called on an "as needed" basis. Nonetheless, follow-up calls should be made on a routine basis that both the case manager and the client have agreed upon. For the needier client, it is a good idea to allow them to vent as much as possible and to be informed about the case-specific active local support groups in the area. For example, if your patient has ongoing ostomy issues despite good medical and case/care management, inform your patient about the local area "Ostomates" organization or other associated durable medical equipment

HERE IS A LIST OF SOME PERSONAL REMINDERS FOR MORE-EFFECTIVE COMMUNICATION:

1. Do not assume others heard what is said or they know what is meant.
2. Always get feedback and confirm comprehension.
3. Follow up with client on regular basis as anticipated.
4. Schedule adequate uninterrupted time for each and every meeting and/or call.
5. Don't act hurried or noncaring. Think how you prefer to be treated.
6. Research which mode of communication works best with each individual client.
7. When engaging a client in person, always maintain good eye contact.
8. Don't be too bossy or a know-it-all.
9. Try to listen for or hear your own tone of voice.
10. **AIM** high for in-person contacts:
 - A**ctive listening
 - I**nitiate eye contact!
 - M**aintain positive body language!

companies that offer similar or better ostomy products. Letting your client know how much you care along the care continuum is priceless. Allowing someone to vent also takes practice and know-how through ongoing training in effective listening skills.

Perhaps one of the most important issues that relates to the work of case and care management mediation and communication skills is that of being in the middle. As stated, being in the middle is not easy since it is almost impossible to please everyone. Case and care managers will find themselves in the role of mediation having to also facilitate, educate, and collaborate with other members of the health care team. Case management services are best offered in a climate that allows direct communication between the case manager, the client, and appropriate service personnel to optimize the outcome for all concerned. Our profession is currently caught up in the epicenter of a global

pandemic that is forever changing everyone's lives. Whether we work from home or we are still able to commute to an office or other work space, our skill sets will be more valuable than any of us could have ever imagined. Now is the time to embrace your work as a case or care manager and to improve your communication techniques so that your voice echoes that of someone who can be entrusted to optimize outcomes. We are in this together, and we are smack dab in the middle of it. We will leave our mark on the telecommunication highways for years to come. We are pioneers and we must learn today how to effectively communicate for a better tomorrow in our ever-growing and ever-changing health care industry.

The 2019 pandemic that has extended into 2020 has been challenging for case management service delivery methodology, while telehealth has become a new normal for the health care industry.

Successful telehealth communication requires being able to relate to others. Being relatable or relevant is only a part of this challenge because the process of transitioning to electronic devices is not going to happen as rapidly as the need for expediting the process of personal health care during COVID-19. Case managers are currently helping patients to learn more about health information technology and its counterparts (eg, electronic health records and personal health records) as well as educating patients about personal online health care communities and/or mobile applications during routine assessments. Being able to communicate clearly and effectively will be vital in assisting patients telephonically while trailblazing new practice standards related to telehealth for future case managers. In addition to considering what professional etiquette is required for timely, effective, and satisfactory communication skills with telehealth, the case manager must adhere to strict HIPAA (Health Insurance Portability and Accountability Act) compliance as usual and customary in practice standards, no matter what type of communication is taking place.

First, it is a good idea to understand that, more than likely, telehealth is not only a new normal but is highly likely to sustain itself in the long haul. Case managers must be able to keep in step with the current health care delivery system, bringing highly complex communication skill sets along the way, while being knowledgeable and respectful of patient's privacy rights. The Health Resources and Services Administration of the U.S. Department of Health and Human Services defines telehealth as the use of electronic information and telecommunications technologies to support and promote long-distance clinical health care,

[continues on page 32](#)

CE II Hospital Case Management: CMSA's White Paper

Stefani Daniels, MSNA, RN, ACM, CMAC

The hospital industry has been forced to accept the change from volume to value. Nearly every article, every speech, and every conference targeted at hospital executives begins by acknowledging the new expectations. However, little has been said about operational changes that need to take place in hospitals to thrive in the new value-based environment. And almost nothing has been said about its impact on hospital case management, which is why the White Paper on Hospital Case Management Practice recently released by the Case Management Society of America¹ is a significant milestone. Not only does it serve to reinforce the conceptual framework of the 2016 Standards of Practice by applying them directly to the practice of case management in hospitals, but it also lays down fundamental challenges to the prevailing models found in many hospitals.

While many professional organizations exist to increase the level and scope of knowledge concerning professional practice, they rarely take a position about the underlying values that frame the components of a practice model as has the Case Management Society of America (CMSA). Through its standards of practice model graphic (Figure 1), CMSA broadcast to the industry that the iterative process of case management applies to the primary domains of care coordination considerations including health needs, social needs, financial issues, and ethical/legal matters that are enabled through advocacy across the care continuum.

As the White Paper states, "Although this framework represents the vast majority of case management settings today, the question raised by the task force is whether this conceptual framework reflects the predominant practice of case management in the hospital. The consensus among the task force members is that it does not."¹ Recognizing that hospitals vary in size, culture, community, and leadership, the White Paper avoids prescriptive mandates and instead calls

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readers' attention to the unsustainable health care economy and the need for close cooperation with and continuous collaboration among professional staff to coordinate care for the patients. Through the integration of a value component into this model, hospital case management practice becomes a value-added strategy for hospital leaders to adopt.



From Standards of Practice for Case Management, CMSA, 2016, Little Rock, AR

Hospitals are notoriously dysfunctional. Care and service personnel operate in siloes and cross-boundary pollination is rare. Systemness is a foreign word, and teamwork is a delusionary goal and rarely achieved. Despite the call for more patient-centric care, where patients are expected to be involved in decisions about their care, measurement of

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outcomes that matter to them remains limited. The electronic medical record, touted as being the best tool for coordinating care, is a mess of key strokes in search of an interoperable audience. And professional staff who are educated, trained, and committed to provide quality patient care are compelled to take on clerical and administrative duties as financial officers in search of the best metrics to appease corporate puppet masters and reduce full-time employees. Is there any wonder why burn out among doctors, nurses, and hospital case managers is the subject of numerous articles and e-commerce opportunists?

Which brings me back to the subject of the White Paper on Hospital Case Management Practice. While the paper avoids prescriptive recommendations, it is a rare expression of the current state of hospital case management practice with all of its blemishes and scars. It acknowledges the confusion brought about by multiple practice models and mourns the lost opportunities that accompanied the original intent when it was introduced in hospitals in the early 1980s as a strategy to adapt to the new prospective payment system.

The White Paper provides a comprehensive overview of the evolution of hospital case management practice, a history lesson every hospital executive in general, and every hospital case management leader specifically, should read with interest. Not only does it trace the evolutionary trajectory of practice design, it is a reflection of the mounting pressures of the hospital industry as it adapts to ongoing marketplace challenges. From the nursing care delivery model that introduced case management concepts to the hospital environment through the publication of the landmark paper “To Err is Human” in 1999 (which made newspaper headlines by declaring that avoidable errors in hospitals is the 8th leading cause of death in the United States) to the introduction of value-based payments in health care, hospital case management practice in many hospitals changed its practice focus to accommodate new expectations. But not all, by any means.

The biggest change occurred in the 1990s when the full effect of the prospective payment system hit the hospital industry with a wallop, causing bankruptcies, closings, and acquisitions. Hospital executives who were trying to hold on called in the management engineers, who were charged with quickly reducing expenses. Having read of the success at New

England Medical Center, where hospital case management originated, the management engineers downsized, consolidated, and eliminated departments and full-time employees and in the process created case management departments charged with performing tasks similar to those departments and personnel who were downsized. The prevalent model created during this era made discharge planning and utilization review central to the role of the hospital case manager and, as the White Paper states, “we’ve been living with variations of this model ever since.”¹

Having made its point about how we got to where we are today, the task force, which prepared the White Paper and included subject matter experts from around the country, spent almost 2 years reviewing studies and articles and interviewing patients, payers, and hospital personnel to gain a broad and fair perspective on the future practice of hospital case management. From everything that was considered during this investigative project, a single theme emerged: Care coordination is the missing feature of many hospital case management programs and is the essential component for tomorrow’s success.

There are many definitions and explanations of what care coordination means in practical hospital-based terms, and the White Paper includes a description that summarizes many of the definitions found in the literature: Care coordination is a “*deliberate and longitudinal organization of safe, efficient and appropriate care and services for selected patients with multiple needs as they move through the care continuum from acute care to community settings.*” There’s really nothing earth-shattering about this portrayal, but its implications are numerous. The most significant of these is that care coordination is not a synonym for discharge planning, a finding that refutes many assumptions expressed by practicing hospital case managers during the interview process. Rather, care coordination is universally cited as the key initiative to achieve the Triple Aim and close the gaps in communication, care, and services that plague our current system. Although many different participants should be involved in coordinating care, a case manager designated to coordinate care is essential to effectively use resources within our system as patients and families encounter multiple providers across multiple settings.^{2,3}

The cited description also sets the stage regarding role

The White Paper provides a comprehensive overview of the evolution of hospital case management practice, a history lesson every hospital executive in general, and every hospital case management leader specifically, should read with interest.

responsibilities and performance expectations of the hospital case manager although it is vague about how to organize for future practice. For example, what competencies must be demonstrated to influence “safe, efficient and appropriate care?” How are “selected patients” selected? To what extent is the care continuum the responsibility of a single hospital case manager? The White Paper is silent about these and other questions that are bound to be raised after reading the document. It’s up to executive and department leaders at each organization to interpret the “desired state” of hospital case management practice to reflect their own culture, experiences, and mission.

Noting the broad experience in hospital case management evidenced by the backgrounds of the task force members, the caveat to rally the expressed consensus of the executive team before attempting a change in a case management practice model is a sound one. Without it, trying to achieve the “desired state” of case management practice will be a significant challenge. It is the responsibility of executive leadership to set the tone for a new practice model by broadcasting a clearly articulated vision for the future and then supporting the alignment of the various aspects of planning and tactical problem solving with the vision. As cited in the paper, “there are many steps that can be taken independently within the hospital’s case management department, but they offer limited opportunities to affect the quality, safety, and outcomes needed to manage the expectations of an enterprisewide care coordination program.” A lack of clarity, mixed messages from different executives, or constantly shifting priorities spell the death of many a transformation project.

Once a vision is articulated, the White Paper cites 8 transformation priorities that every hospital leader should consider when planning for the next generation of hospital case management programs.

1. Redesign scope of services—In a traditional fee-for-service, hospital case management is generally thought of as a compilation of hospital services. Historically, the services often found under case management arrived there because they were thought to be closely aligned with the legacy expectation of discharge planning and utilization review. In the new marketplace, however, discharge planning and utilization review is replaced with coordination of the total care

for selected patients in collaboration with other members of the patient’s care team. There is no one best way to redefine the scope of services. Hospitals are continuously experimenting: Utilization review and its related activities including access management and appeals/denial processing may become a separate component of the case management program or, as in many organizations, realigned under finance/revenue cycle. Clinical documentation improvement may find its way to medical records/coding though role expertise may be merged with utilization review in the emergency department as part of access management where coaching physician documentation matters most.

2. Establish clear roles and responsibilities—“Case management practice extends beyond the basic training of any single discipline within the healthcare field.”¹ Eligible candidates may come from many professional clinical disciplines including medicine, social work, pharmacy, and nursing. The Paper makes clear that these professions serve as the “clinical underpinning for adoption of the standards governing the practice of case management. Although each discipline brings unique perspective and skill set to case management practice, case management standards of practice is the common denominator.”¹
3. Develop an entrepreneurial structure to support care coordination goals. There are no statutes, no regulations, and no standards that dictate the structure of a hospital case management program. It’s all a product of “That’s the way we’ve always done it.”

The White Paper suggests 5 infrastructure considerations:

- a. The program structure must be congruent with the intent and goals of care coordination and leaders must clarify expectations to ensure both effective deployment of resources as well as principled investment in new roles. The Paper notes that investing in transformation to care coordination does not require executives to hire new staff members. “Instead, leaders will reallocate existing FTEs and provide additional training and education so professional staff can practice at the top of their license” and will introduce support staff to manage logistics, clerical, and data operations.¹

Recognizing that hospitals vary in size, culture, community, and leadership, the White Paper avoids prescriptive mandates and instead calls readers' attention to the unsustainable health care economy and the need for close cooperation with and continuous collaboration among professional staff to coordinate care for the patients.

- b. Psychosocial counseling is often a distinct component of the case management program although there are a few indications that as social determinants escalate as real variables in managing progression of care, the frequency of clinic and emergency department visits, and avoidable readmissions, counseling resources (master's prepared social workers and licensed professional counselors) may warrant a place of their own with other ancillary programs to simplify access within an integrated delivery system.
 - c. Utilization review is a subset of utilization management and involves documented confirmation that hospital level of care is medically necessary. Because utilization review is often a "missing component" of the revenue cycle, organizations may want to consider shifting utilization activities to the hospital's revenue cycle program.
 - d. Building an efficient care coordination infrastructure requires coordinating care coordination roles across system care settings. Perform an audit of all personnel who provide care coordination services across the campus. Once completed, consider consolidating existing coordinator resources to establish a single point of reference for the entire enterprise. Evidence exists that patients complain of receiving multiple postdischarge phone calls and don't know who is the right person to contact if there is a problem/question.
 - e. The White Paper reports that "Staffing ratios, one of the most frequent questions addressed to CMSA, become moot as care coordination outcomes and patient reported outcome measures (PROM) for high-risk patients become the primary metrics of ROI success."
4. Position case management with a transformative executive sponsor, the one best positioned to provide new information to the case management team. There are many new senior leadership positions being created to manage population health, accountable care organizations, and other integrated care delivery initiatives. These new positions typically focus on developing new channels for patient engagement and delivering care in a manner that eliminates overuse, underuse, and misuse of resources while increasing professional satisfaction and building trust relationships and financial stability for both physicians and hospitals. If your organization has one of these new roles, give consideration to a change in executive sponsorship.
 5. Realign the role of the hospital case manager for greater effectiveness. Peripheral activities accumulated over the years will have to be jettisoned to provide the full benefit of targeted care coordination, which is the centerpiece of a new hospital case management model. In addition to accrediting agencies' and regulatory bodies' expectation of effective care coordination, hospital systems require coordination strength and cohesiveness within the walls of the facility and also within the community infrastructure through preferred provider alliances.
 6. Fine tune case manager workflow through the adoption of CMSA's Standards of Professional Case Management Practice. Section VIII of the Standards provides a generic overview of the workflow process that can be modified based on each hospital's characteristics. Note, however, as cited in the White Paper, that "to be successful at coordinating care for the most vulnerable hospitalized patients selected through the analytical process, case managers must be freed from hospital-wide discharge planning responsibilities."¹ This will cause quite a stir in hospital nursing circles but it is really not a "new" feature of professional nursing practice, which has historically been responsible for planning a patient's discharge. What has changed over the years is the burdensome clerical tasks necessary to implement the professionally designed discharge plan. As you will see in Priority #7, the task force considered this issue to be a major stumbling block unless addressed.
 7. Any hospital-based service provider (eg, nursing, respiratory therapy, physician) can tell you that the clerical chores required to organize the transition of a patient from acute care to almost any postacute service provider can be a logistical nightmare as commercial for-profit payers increase their contractual presence in hospitals. This is why the task force strongly recommends the creation of a support team to work their logistical magic. Support teams come in different varieties, but they typically work best
- [continued on page 33](#)*

PharmaFacts for Case Managers



Rukobia (fostemsavir) extended-release tablets, for oral use

INDICATIONS AND USAGE

Rukobia, in combination with other antiretroviral(s), is indicated for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in heavily treatment-experienced adults with multi-drug-resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations.

DOSAGE AND ADMINISTRATION

The recommended dosage of Rukobia is one 600-mg tablet taken orally twice daily with or without food. Swallow tablets whole. Do not chew, crush, or split tablets.

DOSAGE FORMS AND STRENGTH

Each Rukobia extended-release tablet contains 600 mg of fostemsavir (equivalent to 725 mg of fostemsavir tromethamine). The tablets are beige, oval, film-coated, biconvex tablets, debossed with "SV IV7" on one side.

CONTRAINDICATIONS

Rukobia is contraindicated in patients:

- with previous hypersensitivity to fostemsavir or any of the components of Rukobia.
- coadministered strong cytochrome P450 (CYP)3A inducers, as significant decreases in temsavir (the active moiety of fostemsavir) plasma concentrations may occur which may result in loss of virologic response. These drugs include, but are not limited to:
 - Androgen receptor inhibitor: Enzalutamide
 - Anticonvulsants: Carbamazepine, phenytoin
 - Antimycobacterial: Rifampin
 - Antineoplastic: Mitotane
 - Herbal product: St John's wort (*Hypericum perforatum*)

WARNINGS AND PRECAUTIONS

Immune Reconstitution Syndrome

Immune reconstitution syndrome has been reported in patients treated with combination antiretroviral therapy, including Rukobia. During the initial phase of combination antiretroviral treatment, patients whose immune systems respond may develop an inflammatory response to indolent or residual opportunistic infections (such as *Mycobacterium avium* infection,

cytomegalovirus, *Pneumocystis jirovecii* pneumonia [PCP], or tuberculosis), which may necessitate further evaluation and treatment. Autoimmune disorders (such as Graves' disease, polymyositis, Guillain-Barré syndrome, and autoimmune hepatitis) have also been reported to occur in the setting of immune reconstitution; however, the time to onset is more variable and can occur many months after initiation of treatment.

QTc Prolongation with Higher than Recommended Dosages

Rukobia at 2,400 mg twice daily, 4 times the recommended daily dose, has been shown to significantly prolong the QTc interval of the electrocardiogram. Rukobia should be used with caution in patients with a history of QTc interval prolongation, when coadministered with a drug with a known risk of Torsade de Pointes, or in patients with relevant pre-existing cardiac disease. Elderly patients may be more susceptible to drug-induced QT interval prolongation.

Elevations in Hepatic Transaminases in Patients with Hepatitis B or C Virus Coinfection

Monitoring of liver chemistries is recommended in patients with hepatitis B and/or C coinfection. Elevations in hepatic transaminases were observed in a greater proportion of subjects with HBV and/or HCV co-infection compared with those with HIV mono-infection. Some of these elevations in transaminases were consistent with hepatitis B reactivation, particularly in the setting where anti-hepatitis therapy was withdrawn. Particular diligence should be applied in initiating or maintaining effective hepatitis B therapy (referring to treatment guidelines) when starting Rukobia in patients co-infected with hepatitis B.

Risk of Adverse Reactions or Loss of Virologic Response Due to Drug Interactions

The concomitant use of Rukobia and certain other drugs may result in known or potentially significant drug interactions, some of which may lead to:

- Loss of therapeutic effect of Rukobia and possible development of resistance due to reduced exposure of temsavir.
- Possible prolongation of QTc interval from increased exposure to temsavir. Consider the potential for drug interactions prior to and during therapy with Rukobia, review concomitant medications during therapy with Rukobia, and monitor for the adverse reactions associated with the concomitant drugs.



ADVERSE REACTIONS

The following adverse reactions are noted:
Immune reconstitution syndrome.

- QTc prolongation.
- Elevations in hepatic transaminases in patients with hepatitis B or C virus co-infection.

USE IN SPECIFIC POPULATIONS

Pregnancy

Pregnancy Exposure Registry

There is a pregnancy exposure registry that monitors pregnancy outcomes in individuals exposed to Rukobia during pregnancy. Healthcare providers are encouraged to register patients by calling the Antiretroviral Pregnancy Registry (APR) at 1-800-258-4263.

Risk Summary

There are insufficient human data on the use of Rukobia during pregnancy to adequately assess a drug-associated risk of birth defects and miscarriage. In animal reproduction studies, oral administration of fostemsavir to pregnant rats and rabbits during organogenesis resulted in no adverse developmental effects at clinically relevant temsavir exposures. The background risk for major birth defects and miscarriage for the indicated population is unknown. The background rate for major birth defects in a U.S. reference population of the Metropolitan Atlanta Congenital Defects Program (MACDP) is 2.7%. The estimated background rate of miscarriage in clinically recognized pregnancies in the U.S. general population is 15% to 20%.

Lactation

Risk Summary

The Centers for Disease Control and Prevention recommends that HIV-1-infected mothers in the United States not breastfeed their infants to avoid risking postnatal transmission of HIV-1 infection. It is not known whether Rukobia is present in human breast milk, affects human milk production, or has effects on the breastfed infant. When administered to lactating rats, fostemsavir-related drug was present in rat milk. Because of the potential for (1) HIV-1 transmission (in HIV-negative infants), (2) developing viral resistance (in HIV-positive infants), and (3) adverse reactions in a breastfed infant similar to those seen in adults, instruct mothers not to breastfeed if they are receiving Rukobia.

Pediatric Use

The safety and effectiveness of Rukobia have not been established in pediatric patients.

Geriatric Use

Clinical trials of Rukobia did not include sufficient numbers of subjects aged 65 and older to determine whether they respond differently from younger subjects. In general, caution should be exercised in administration of Rukobia in elderly patients

reflecting greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Elderly patients may be more susceptible to drug-induced QT interval prolongation.

CLINICAL STUDIES

The efficacy of Rukobia in heavily treatment-experienced adult subjects with HIV-1 infection is based on 96-week data from a Phase 3, partially-randomized, international, double-blind, placebo-controlled trial (BRIGHTE [NCT02362503]). The BRIGHTE trial was conducted in 371 heavily treatment-experienced subjects with multiclass HIV-1 resistance. All subjects were required to have a viral load ≥ 400 copies/mL and classes of antiretroviral medications remaining at baseline due to resistance, intolerability, contraindication, or other safety concerns. Subjects were enrolled in either a randomized or nonrandomized cohort defined as follows:

Within the randomized cohort (n = 272), subjects had 1, but no more than 2, fully active and available antiretroviral agent(s) at screening which could be combined as part of an efficacious background regimen. Randomized subjects received either blinded Rukobia 600 mg twice daily (n = 203) or placebo (n = 69) in addition to their current failing regimen for 8 days of functional monotherapy. Beyond Day 8, randomized subjects received open-label Rukobia 600 mg twice daily plus an investigator-selected OBT. This cohort provides primary evidence of efficacy of Rukobia.

Within the nonrandomized cohort (n = 99), subjects had no fully active and approved antiretroviral agent(s) available at screening. Nonrandomized subjects were treated with open-label Rukobia 600 mg twice daily plus OBT from Day 1 onward. The use of an investigational drug(s) as a component of the OBT was permitted in the nonrandomized cohort.

Overall, the majority of subjects were male (78%), white (70%), and the median age was 49 years (range: 17 to 73 years). At baseline, the median HIV-1 RNA was 4.6 log₁₀ copies/mL and the median CD4+ cell count was 80 cells/mm³ (100 and 41 cells/mm³ for randomized and nonrandomized subjects, respectively). Seventy-five percent (75%) of all treated subjects had a CD4+ cell count 15 years; 85% had been exposed to 5 different HIV treatment regimens upon entry into the trial. Fifty-two percent (52%) of subjects in the randomized cohort had 1 fully active agent within their initial failing background regimen, 42% had 2, and 6% had no fully active agent. Within the nonrandomized cohort, 81% of subjects had no fully active agent(s) in their original regimen and 19% had 1 fully active agent, including 15% (n = 15) who received ibalizumab, which was an investigational agent at the time of the BRIGHTE trial start-up.



Randomized Cohort

The primary efficacy endpoint was the adjusted mean decline in HIV-1 RNA from Day 1 to Day 8 with Rukobia versus placebo in the randomized cohort. The results of the primary endpoint analysis demonstrated superiority of Rukobia compared with placebo.

At Day 8, 65% (131/203) and 46% (93/203) of subjects who received Rukobia had a reduction in viral load from baseline >0.5 \log_{10} copies/mL and >1 \log_{10} copies/mL, respectively, compared with 19% (13/69) and 10% (7/69) of subjects, respectively, in the placebo group. By subgroup analysis, randomized subjects who received Rukobia with baseline HIV-1 RNA $>1,000$ copies/mL achieved a mean decline in viral load of 0.86 \log_{10} copies/mL at Day 8 compared with 0.20 \log_{10} copies/mL in subjects treated with blinded placebo. Subjects with baseline HIV-1 RNA 1,000 copies/mL achieved a mean decline in viral load of 0.22 \log_{10} copies/mL at Day 8 compared with a mean increase of 0.10 \log_{10} copies/mL in subjects treated with blinded placebo. Virologic outcomes by ITT-E Snapshot Analysis at Weeks 24 and 96 in the BRIGHT-E trial are shown in Table 12 and Table 13 for the randomized cohort. There was considerable variability in the number of antiretrovirals (fully active and otherwise) included in OBT regimens. The majority of subjects (84%) received dolutegravir as a component of OBT, of which approximately half (51% overall) also received darunavir with ritonavir or cobicistat. Virologic outcomes by ITT-E Snapshot Analysis at Week 48 were consistent with those observed at Week 24.

In the randomized cohort, HIV-1 RNA <200 to copies/mL was achieved in 68% and 64% of subjects at Weeks 24 and 96, respectively (ITT-E, Snapshot algorithm). Mean changes in CD4+ cell count from baseline increased over time: 90 cells/mm³ at Week 24 and 205 cells/mm³ at Week 96. Based on a sub-analysis in the randomized cohort, subjects with the lowest baseline CD4+ cell counts (>200 to <500 cells/mm³).

HOW SUPPLIED/STORAGE AND HANDLING

Rukobia extended-release tablets, 600 mg, are beige, oval, film-coated, biconvex tablets debossed with “SV IV7” on one side. Bottle of 60 tablets with child-resistant closure. NDC 49702-250-18. Store at 20°C to 25°C (68°F to 77°F); excursions permitted between 15°C and 30°C (59°F and 86°F) Rukobia extended-release tablets may have a slight vinegar-like odor.

Please see Product Insert for full prescribing information.

Rukobia is manufactured by ViiV Healthcare.

Lyumjev (insulin lispro-aabc) injection, for subcutaneous or intravenous use

INDICATIONS AND USAGE

Lyumjev™ is indicated to improve glycemic control in adults with diabetes mellitus.

DOSAGE AND ADMINISTRATION

Important Administration Instructions

- Always check insulin labels before administration.
- Inspect Lyumjev visually before use. It should appear clear and colorless. Do not use Lyumjev if particulate matter and discoloration is seen.
- Do not perform dose conversion when using any Lyumjev U-100 or U-200 prefilled pens. The dose window of Lyumjev prefilled pens shows the number of units of Lyumjev to be injected.
- Do not transfer Lyumjev U-200 from the prefilled pen to a syringe for administration.
- Use Lyumjev prefilled pens with caution in patients with visual impairment that may rely on audible clicks to dial their dose.
- Do not mix Lyumjev with any other insulin products.

Route of Administration

Instructions for Subcutaneous Injection

- Administer Lyumjev at the start of a meal or within 20 minutes after starting a meal subcutaneously into the abdomen, upper arm, thigh, or buttocks.
- Rotate injection sites within the same region from one injection to the next to reduce the risk of lipodystrophy and localized cutaneous amyloidosis. Do not inject into areas of lipodystrophy or localized cutaneous amyloidosis
- Lyumjev given by subcutaneous injection should generally be used in regimens with intermediate or long-acting insulin.
- The Lyumjev U-100 KwikPen, Lyumjev U-100 Tempo Pen, and Lyumjev U-200 KwikPen each dial in 1 unit increments and deliver a maximum dose of 60 units per injection.
- The Lyumjev U-100 Junior KwikPen dials in 0.5 unit increments and delivers a maximum dose of 30 units per injection.

Intravenous Administration for Lyumjev U-100 Only

- Do not administer Lyumjev U-200 intravenously.
- Administer Lyumjev U-100 intravenously only under medical supervision with close monitoring of glucose and potassium levels to avoid hypoglycemia and hypokalemia.
- Dilute Lyumjev U-100 to a concentration of 1 unit/mL using 0.9% Sodium Chloride Injection, USP or 5% Dextrose Injection, USP infusion solutions. Dilutions to concentrations below 1 unit/mL are not recommended.
- Diluted Lyumjev may be stored for up to 4 days when refrigerated at 36°F to 46°F (2°C to 8°C) until time of use. The same solution may be stored for up to 12 hours at room temperature at 68°F to 77°F (20°C to 25°C).

General Dosage Instructions

- Individualize and adjust the dosage of Lyumjev based on the patient's metabolic needs, glucose monitoring results, and glycemic control goal.



- If converting from another mealtime insulin to Lyumjev, the change can be done on a unit-to-unit basis.
- Dosage adjustments may be needed when switching from another insulin, with changes in physical activity, changes in concomitant medications, changes in meal patterns (i.e., macronutrient content or timing of food intake), changes in renal or hepatic function or during acute illness to minimize the risk of hypoglycemia or hyperglycemia
- During changes to a patient's insulin regimen, increase the frequency of glucose monitoring
- Instruct patients who forget a mealtime dose to monitor their glucose level to decide if an insulin dose is needed, and to resume their usual dosing schedule at the next meal.

DOSAGE FORMS AND STRENGTHS

Injection: 100 units per mL (U-100) clear and colorless solution available as:

- 10 mL multiple-dose vial
- 3 mL single-patient-use Lyumjev KwikPen
- 3 mL single-patient-use Lyumjev Junior KwikPen
- 3 mL single-patient-use Lyumjev Tempo Pen
- 3 mL single-patient-use cartridges
- Injection: 200 units per mL (U-200) clear and colorless solution available as:
- 3 mL single-patient-use Lyumjev KwikPen

CONTRAINDICATIONS

Lyumjev is contraindicated:

- during episodes of hypoglycemia.
- in patients with hypersensitivity to insulin lispro-aabc or one of the excipients in Lyumjev.

WARNINGS AND PRECAUTIONS

Never Share a Lyumjev Prefilled Pen, Cartridge, or Syringe Between Patients

Lyumjev prefilled pens or cartridges should never be shared between patients, even if the needle is changed. Patients using Lyumjev vials must never share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens.

Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen

Changes in an insulin regimen (e.g., insulin, insulin strength, manufacturer, type, injection site or method of administration) may affect glycemic control and predispose to hypoglycemia or hyperglycemia. Repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis have been reported to result in hyperglycemia; and a sudden change in the injection site (to an unaffected area) has been reported to result in hypoglycemia. Make any changes to a patient's insulin regimen under close medical supervision with increased

frequency of blood glucose monitoring. Advise patients who have repeatedly injected into areas of lipodystrophy or localized cutaneous amyloidosis to change the injection site to unaffected areas and closely monitor for hypoglycemia. For patients with type 2 diabetes, dosage adjustments of concomitant anti-diabetic products may be needed.

Hypoglycemia

Hypoglycemia is the most common adverse reaction associated with insulins, including Lyumjev. Severe hypoglycemia can cause seizures, may lead to unconsciousness, may be life-threatening, or cause death. Hypoglycemia can impair concentration ability and reaction time; this may place an individual and others at risk in situations where these abilities are important (e.g., driving or operating other machinery). Lyumjev, or any insulin, should not be used during episodes of hypoglycemia. Hypoglycemia can happen suddenly and symptoms may differ in each individual and change over time in the same individual. Symptomatic awareness of hypoglycemia may be less pronounced in patients with longstanding diabetes, in patients with diabetic nerve disease, in patients using medications that block the sympathetic nervous system (e.g., beta blockers), or in patients who experience recurrent hypoglycemia.

Risk Factors for Hypoglycemia

The risk of hypoglycemia after an injection is related to the duration of action of the insulin and, in general, is highest when the glucose lowering effect of the insulin is maximal. The timing of hypoglycemia usually reflects the time-action profile of the administered insulin formulation. As with all insulin preparations, the glucose lowering effect time course of Lyumjev may vary in different individuals or at different times in the same individual and depends on many conditions, including the area of injection as well as the injection site blood supply and temperature. Other factors which may increase the risk of hypoglycemia include changes in meal pattern (e.g., macronutrient content or timing of meals), changes in level of physical activity, or changes to co-administered medication. Patients with renal or hepatic impairment may be at higher risk of hypoglycemia.

Risk Mitigation Strategies for Hypoglycemia

Patients and caregivers must be educated to recognize and manage hypoglycemia. Self-monitoring of glucose plays an essential role in the prevention and management of hypoglycemia. In patients at higher risk for hypoglycemia and patients who have reduced symptomatic awareness of hypoglycemia, increased frequency of glucose monitoring is recommended.

Hypoglycemia Due to Medication Errors

Accidental mix-ups between basal insulin products and other insulins, particularly rapid-acting insulins, have been reported.

[*continued on page 31*](#)



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.

AIDS. 2020 Jun 25. doi: 10.1097/QAD.0000000000002607. Online ahead of print.

[Disproportionate burden of COVID-19 among racial minorities and those in congregate settings among a large cohort of people with HIV](#)

Meyerowitz EA, Kim AY, Ard KL, et al.

BACKGROUND: Many people living with HIV (PLWH) have comorbidities which are risk factors for severe COVID-19 or have exposures that may lead to acquisition of SARS-CoV-2. There are few studies, however, on the demographics, comorbidities, clinical presentation or outcomes of COVID-19 in people with HIV.

OBJECTIVE: To evaluate risk factors, clinical manifestations and outcomes in a large cohort of PLWH with COVID-19.

METHODS: We systematically identified all PLWH who were diagnosed with COVID-19 at a large hospital from March 3 to April 26, 2020 during an outbreak in Massachusetts. We analyzed each of the cases to extract information including demographics, medical comorbidities, clinical presentation, and illness course after COVID-19 diagnosis.

RESULTS: We describe a cohort of 36 PLWH with confirmed COVID-19 and another 11 patients with probable COVID-19. Almost 85% of PLWH with confirmed COVID-19 had a comorbidity associated with severe disease, including obesity, cardiovascular disease, or hypertension. Approximately 77% of PLWH with COVID-19 were non-Hispanic Black or Latinx whereas only 40% of the PLWH in our clinic were Black or Latinx. Nearly half of PLWH with COVID-19 had exposure to congregate settings. In addition to people with confirmed COVID-19, we identified another 11 individuals with probable COVID-19, almost all of whom had negative PCR testing.

CONCLUSION: In the largest cohort to date of PLWH and confirmed COVID-19, almost all had a comorbidity associated with severe disease, highlighting the importance of non-HIV risk factors in this population. The racial disparities and frequent link to congregate settings in PLWH and COVID-19 need to be explored urgently.

J Acquir Immune Defic Syndr 2020 Aug 1;84(4):387-395. doi: 10.1097/QAI.0000000000002351.

[Trajectories of viral suppression in people living with HIV receiving coordinated care: differences by comorbidities](#)

Li MJ, Su E, Garland WH, et al.

BACKGROUND: In March of 2013, the Los Angeles County (LAC) Division of HIV and STD Programs implemented a clinic-based Medical Care Coordination (MCC) Program to increase viral suppression (VS) (<200 c/mL) among people living with HIV (PLWH) at high risk for poor health outcomes.

OBJECTIVE: This study aimed to estimate trajectories of VS and to assess whether these trajectories differed by stimulant use, housing instability, and depressive symptom severity as reported by PLWH participating in MCC.

METHODS: Data represent 6408 PLWH in LAC receiving services from the MCC Program and were obtained from LAC HIV surveillance data matched to behavioral assessments obtained across 35 Ryan White Program clinics participating in MCC. Piecewise mixed-effects logistic regression with a random intercept estimated probabilities of VS from 12 months before MCC enrollment through 36 months after enrollment, accounting for time by covariate interactions for 3 comorbid conditions: housing instability, stimulant use, and depressive symptoms.

RESULTS: The overall probability of VS increased from 0.35 to 0.77 within the first 6 months in the MCC Program, and this probability was maintained up to 36 months after enrollment. Those who reported housing instability, stimulant use, or multiple comorbid conditions did not achieve the same probability of VS by 36 months as those with none of those comorbidities.

CONCLUSIONS: Findings suggest that MCC improved the probability of VS for all patient groups regardless of the presence of comorbidities. However, those with comorbid conditions will still require increased support from patient-centered programs to address disparities in VS.

J Acad Emerg Med 2020 Jun 29. doi: 10.1111/acem.14067. Online ahead of print.

[Guidance and patient instructions for proning and repositioning of awake, non-intubated COVID-19 patients](#)

Bentley SK, Iavicoli L, Cherkas D, et al.

Prior studies on proning awake, non-intubated patients with hypoxemic acute respiratory failure, as well as evolving study of similar COVID-19 patients, coupled with experience and dramatic anecdotal evidence from the COVID-19 pandemic, suggest the importance of proning all such patients with COVID-19 to improve oxygenation and reduce respiratory effort. Literature and experience from healthcare teams in the midst of the pandemic suggest that any COVID-19 patients with respiratory compromise severe enough to warrant admission should be considered for proning. We additionally suggest these patients should be considered for proning as well as ongoing patient re-positioning (e.g. right lateral decubitus, seated, and left lateral decubitus positions). Figure 1 represents the proning and positioning instructions developed at New York City Health + Hospitals/Elmhurst, a large, inner-city, tertiary public hospital in the epicenter of the COVID-19 pandemic in New York City, and later adapted and utilized at facilities across the United States.

Clin Infect Dis 2020 Jun 29;ciaa886. doi: 10.1093/cid/ciaa886. Online ahead of print.

[Distribution of transmission potential during non-severe COVID-19 illness](#)

Shrestha NK, Marco Canosa F, Nowacki AS, et al.

BACKGROUND: Patients recovering from coronavirus disease 2019 (COVID-19) often continue to test positive for the causative virus by PCR even after clinical recovery, thereby complicating return-to-work plans. The purpose of this study was to evaluate transmission potential of COVID-19 by examining viral load with respect to time.

METHODS: Health care personnel (HCP) at Cleveland Clinic diagnosed with COVID-19, who recovered without needing hospitalization, were identified. Threshold cycle (Ct) for positive PCR tests were obtained and viral loads calculated. Association of viral load with days since symptom onset was examined in a multivariable regression model, which was reduced by stepwise backward selection to only keep variables significant at a level of 0.05. Viral loads by day since symptom onset were predicted using the model and transmission potential evaluated by examination of a viral load-time curve.

RESULTS: Over six weeks, 230 HCP had 528 tests performed.

Viral loads declined by orders of magnitude within a few days of symptom onset. The only variable significantly associated with viral load was time since onset of symptoms. Of the area under the curve (AUC) spanning symptom onset to 30 days, 96.9% lay within the first 7 days, and 99.7% within 10 days. Findings were very similar when validated using split-sample and 10-fold cross-validation.

CONCLUSIONS: Among patients with non-severe COVID-19, viral loads in upper respiratory specimens peak by two or three days from symptom onset and decrease rapidly thereafter. The vast majority of the viral load-time AUC lies within 10 days of symptom onset.

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J Viral Hepat 2020 Jul 2. doi: 10.1111/jvh.13359. Online ahead of print.

[Age and risk-factor based serologic screening for hepatitis C virus among an urban, high-risk population](#)

Dimova RB, Rude E, Tala AH.

ABSTRACT: Hepatitis C virus (HCV) screening among individuals born between 1945 and 1965 (i.e. birth cohort) may augment risk-factor based screening. We assessed HCV seropositivity among injection drug users (IDUs) and birth cohort members from New York City. We assessed HCV risk factors and seropositivity in 7722 participants from community health, HIV prevention, syringe exchange, and drug treatment programs. A total of 26.6% were HCV seropositive, 55.8% were born between 1945-1965, and 82.2% had ever injected drugs. Among all participants, HCV seropositivity was higher among IDUs compared to non-IDUs (60.5% versus 7.7%, odds ratio (OR)=18.5, 95% confidence interval (CI) [16.2, 21.1], $p<0.0001$) and among birth cohort (BC) members compared to non-BC members (31.3% versus 22.3%, OR=1.6, 95%CI [1.4, 1.8], $p<0.0001$). Within the birth cohort, HCV seroprevalence among IDUs was 68.5% versus 11.8%, OR=16.2, 95%CI [13.7, 19.3]. After adjustment, HCV seroprevalence was higher in IDUs, previously incarcerated, whites (<42 years) and "other races" (versus blacks), HIV-infected, those who snorted heroin, those with liver disease history, and those who had sex with an HCV-seropositive partner. HCV seroprevalence among IDU, birth cohort members was considerably higher than among the general population. In this high-risk, urban population, the association between IDU and HCV seropositivity was approximately ten times that between birth cohort membership and HCV seropositivity.

Am J Cardiol 2020 Mar 1;125(5):673-677. doi: 10.1016/j.amjcard.2019.12.009. Epub 2019 Dec 13.

[Changing trends in the landscape of patients hospitalized with acute myocardial infarction \(2001 to 2011\) \(from the Worcester heart attack study\)](#)

Mercado-Lubo R, Yarzebski J, Lessard D, et al.

During the past several decades, new diagnostic tools, interventional approaches, and population-wide changes in the major coronary risk factors have taken place. However, few studies have examined relatively recent trends in the demographic characteristics, clinical profile, and the short-term outcomes of patients hospitalized for acute myocardial infarction (AMI) from the more generalizable perspective of a population-based investigation. We examined decade long trends (2001 to 2011) in patient's demographic and clinical characteristics, treatment practices, and hospital outcomes among residents of the Worcester metropolitan area hospitalized with an initial AMI (n = 3,730) at all 11 greater Worcester medical centers during 2001, 2003, 2005, 2007, 2009, and 2011. The average age of the study population was 68.5 years and 56.9% were men. Patients hospitalized with a first AMI during the most recent study years were significantly younger (mean age = 69.9 years in 2001/2003; 65.2 years in 2009/2011), had lower serum troponin levels, and experienced a shorter hospital stay compared with patients hospitalized during the earliest study years. Hospitalized patients were more likely to have received evidence-based medical management practices over the decade long period under study. Multivariable-adjusted regression models showed a considerable decline over time in the hospital death rate and a significant reduction in the proportion of patients who developed atrial fibrillation, heart failure, and ventricular fibrillation during their acute hospitalization. These results highlight the changing nature of patients hospitalized with an incident AMI, and reinforce the need for surveillance of AMI at the community level.

Am J Cardiol 2020 Mar 1;125(5):812-819. doi: 10.1016/j.amjcard.2019.12.001. Epub 2019 Dec 9.

[Assessing pregnancy, gestational complications, and co-morbidities in women with congenital heart defects \(Data from ICD-9-CM codes in 3 US surveillance sites\)](#)

Raskind-Hood C, Saraf A, Riehle-Colarusso T, et al.

Improved treatment of congenital heart defects (CHDs) has resulted in women with CHDs living to childbearing age. However, no US population-based systems exist to estimate pregnancy frequency or

complications among women with CHDs. Cases were identified in multiple data sources from 3 surveillance sites: Emory University (EU) whose catchment area included 5 metropolitan Atlanta counties; Massachusetts Department of Public Health (MA) whose catchment area was statewide; and New York State Department of Health (NY) whose catchment area included 11 counties. Cases were categorized into one of 5 mutually exclusive CHD severity groups collapsed to severe versus not severe; specific ICD-9-CM codes were used to capture pregnancy, gestational complications, and nongestational co-morbidities in women, age 11 to 50 years, with a CHD-related ICD-9-CM code. Pregnancy, CHD severity, demographics, gestational complications, co-morbidities, and insurance status were evaluated. ICD-9-CM codes identified 26,655 women with CHDs, of whom 5,672 (21.3%, range: 12.8% in NY to 22.5% in MA) had codes indicating a pregnancy. Over 3 years, age-adjusted proportion pregnancy rates among women with severe CHDs ranged from 10.0% to 24.6%, and 14.2% to 21.7% for women with nonsevere CHDs. Pregnant women with CHDs of any severity, compared with nonpregnant women with CHDs, reported more noncardiovascular co-morbidities. Insurance type varied by site and pregnancy status. These US population-based, multisite estimates of pregnancy among women with CHD indicate a substantial number of women with CHDs may be experiencing pregnancy and complications. In conclusion, given the growing adult population with CHDs, reproductive health of women with CHD is an important public health issue.

Am J Hypertens 2020 Jul 2;hpaa102. doi: 10.1093/ajh/hpaa102. Online ahead of print.

[Artificial intelligence and hypertension: recent advances and future outlook](#)

Chaikijurajai T, Laffin LJ, Wilson Tang WH.

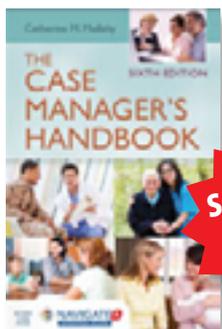
Prevention and treatment of hypertension (HTN) is a challenging public health problem. Recent evidence suggests that artificial intelligence (AI) has potential to be a promising tool for reducing the global burden of HTN, and furthering precision medicine related to cardiovascular (CV) diseases including HTN. Since AI can stimulate human thought processes and learning with complex algorithms and advanced computational power, AI can be applied to multimodal and big data, including genetics, epigenetics, proteomics, metabolomics, CV imaging, socioeconomic, behavioral and environmental factors. AI demonstrates the ability to identify risk factors and phenotypes of HTN, predict the risk of incident HTN, diagnose HTN, estimate blood pressure (BP), develop novel cuffless methods for BP measurement, and comprehensively identify factors associated with treatment adherence and success. Moreover, AI has



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also been used to analyze data from major randomized controlled trials exploring different BP targets to uncover previously undescribed factors associated with cardiovascular outcomes. Therefore, AI-integrated HTN care has the potential to transform clinical practice by incorporating personalized prevention and treatment approaches, such as determining optimal and patient specific BP goals, identifying the most effective antihypertensive medication regimen for an individual, and developing interventions targeting modifiable risk factors. Although the role of AI in HTN has been increasingly recognized over the past decade, it remains in its infancy, and future studies with big data analysis and N-of-1 study design are needed to further demonstrate the applicability of AI in HTN prevention and treatment.

Ann Thorac Surg 2020 Jun 29;S0003-4975(20)31015-8. doi: 10.1016/j.athoracsur.2020.05.051. Online ahead of print.

[The academic facility type is associated with improved overall survival for early stage lung cancer](#)

Merritt RE, Abdel-Rasoul M, Fitzgerald M, et al.

BACKGROUND: Early stage Non-small cell lung cancer (NSCLC) is potentially curable with surgical resection. The overall survival rate for early stage NSCLC may be determined by the healthcare facility type where patients receive their lung cancer treatment.

METHODS: A total of 103,748 cases with the American Joint Committee on Cancer (AJCC) clinical stage I and II NSCLC that were reported to the National Cancer Database at over 1,150 facilities were analyzed in this study. Healthcare facilities were dichotomized into the community and academic facility types. Marginal multivariable Cox proportional hazard models were used to evaluate differences in overall survival. Propensity score methodology with inverse probability of treatment weighting was used to adjust for facility volume and patient related baseline differences between facility types.

RESULTS: Patients with early stage NSCLC who were treated at academic facility types had a significantly better median overall survival (63.2 months) compared to patients who received care at community healthcare facilities (54.2 months) [HR= 0.86 (95% CI: 0.82-0.91) (p<0.0001)]. The surgical quality outcomes for NSCLC surgery, including 30-day mortality, 90-day mortality, and the median number of lymph nodes removed were significantly better for patients treated at the academic facility types.

CONCLUSIONS: Patients with early stage NSCLC who were treated at academic facility types had a significantly higher overall median survival compared to community facility types. The short-term surgical quality outcomes were significantly better for patients who underwent surgery for early stage NSCLC at academic facility types.

Semin Dial 2020 Jul;33(4):330-337. doi: 10.1111/sdi.12889. Epub 2020 Jun 24.

[Preventive care for patients with end-stage kidney disease: crossroads between nephrology and primary care](#)

Phen SS, Kazory A, Bozorgmehr S, et al.

Patients with end-stage kidney disease (ESKD) undergoing maintenance hemodialysis (HD) might expect their nephrologists to coordinate all their healthcare needs. We performed a survey among adult patients with ESKD undergoing HD in two outpatient dialysis centers at the University of Florida to identify differences in characteristics between patients with and without primary care providers (PCP) and to explore the association of PCP utilization with adherence to preventive health measures. Of the 132 participants, 89.4% reported having a PCP. This group was more likely to be female, older, and with higher education level. Having a PCP was associated with influenza, pneumococcal, and tetanus/Tdap vaccinations as well as screening for tuberculosis, depression, hypertension, and dyslipidemia. The PCP group had statistically significant higher rates of influenza immunization (89.8% vs 71.4%, P = .04) as well as screening for hypertension (93.2% vs 64.3%, P = .04) and depression (78.8% vs 42.9%, P = .004), compared to the group without PCP, in the multivariable analysis. Having a PCP is associated with higher rates of influenza vaccination and screening for depression and hypertension. These findings could have important implications as far as identifying patients with ESKD at risk for fragmented care and potential gaps in optimal preventive care.

Cancer. 2020 Jan 15;126(2):281-292.doi: 10.1002/cncr.32529. Epub 2019 Oct 22.

[Facilities that service economically advantaged neighborhoods perform surgical metastasectomy more often for patients with colorectal liver metastases](#)

Uppal A, Smieliauskas F, Sharma MR, et al.

BACKGROUND: Metastasectomy of isolated colorectal liver metastases (CRLM) requires significant clinical expertise and may not be readily available or offered. The authors hypothesized that hospitals that treat a greater percentage of patients from higher income catchment areas are more likely to perform metastasectomies regardless of patient or tumor characteristics.

METHODS: Using the National Cancer Data Base, the authors classified facilities into facility income quartiles (FIQs) based on

[continued on page 32](#)

Addressing COVID-19–Related Mental Health in the Workplace

continued from page 9

through their company’s employee assistance program, and direct workers to the right telehealth and digital services for mental health counseling.”

In addition, many companies, particularly large employers, are expanding their support services for employees. A survey from consulting firm [Willis Towers Watson](#), for example, found that nearly half (47%) of companies responding are enhancing their health care, well-being, and leave programs. The breakdown of employers expanding or enhancing offerings included: 47% for health care benefits, 45% for well-being programs, and 33% for paid time off or vacation. Even when companies are reducing costs, such as through furloughs, pay cuts, and/or reductions in 401(k) plan contributions, many reported that they are preserving well-being plans to help employees who face significant challenges.

Federal and state governments have also expanded mental health

resources. For example, several states have received federal grants to increase access to mental health support during COVID-19. The Families First Coronavirus Response Act has provided economic protections for employees but was limited to small employers (500 employees or less). Before and after this federal legislation, several states also enacted their own emergency laws to ensure employees were financially protected to some degree when impacted by COVID-19. For example, two important pieces of legislation were enacted in California in response to the pandemic to support workers in the state. First, California’s COVID-19 Supplemental Paid Sick Leave Order provides employees with 80 hours of special sick time strictly related to COVID-19, in addition to existing state sick leave regulations requiring mandatory sick time for employees.

Second, on May 6, 2020, under an [executive order](#) issued by California Governor Newsom, any employee who reported to his or her employer’s worksite between March 19, 2020, and July 5, 2020, and who tested positive

or who was diagnosed with a COVID-19–related illness may be eligible for workers’ compensation benefits. This is significant because the governor’s order changes the presumptive rules of workers’ compensation in California, making it possible for employees in California with COVID-19 to be covered.

Know the Impact—and the Resources

As we have seen already during the pandemic, change has been rampant in how and where people work and in the actions taken to reduce contagion. Even now, as economies reopen, COVID-19 has a significant impact on people and their mental and physical health. To advocate for these individuals—whether in the context of acute care, workers’ compensation, disability management, or other practice settings—CCMs and CDMSs need to be aware that the impact of the pandemic is not just physical and financial. Mental health issues such as stress, anxiety, and depression must also be addressed to support the health and wellness of the whole person. **CM**

A Letter From the Incoming President of the Case Management Society of America *continued from page 8*

association, we should also embrace a connectedness to other entities with similar interests in coordinating care and elevating patients to the best version of themselves throughout their health journey. Case managers orchestrate sometimes impossible care strategies that require alliances with other health care professionals, agencies, and industry partners. CMSA can be even stronger if we develop symbiotic and complementary strategies to not only advance the value of CMSA but also support the success

of partners who are members of the total professional team employed in professional case management. These ideas will require a different mindset, a unique manner of using time and space, and an embracement of diversity in thought, professional discipline, and demography to elevate CMSA to the pinnacle position of association excellence. I hope you will join me, and I say again, “Let’s do this!” **CM**

Sincerely,
Melanie Prince, MSS, MSN, BSN,
NE-BC, CCM
President, CMSA

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COVID-19 and the Hidden Enemy

continued from page 7

California. Life, as we knew it, stopped. My mom was consumed with fear of getting COVID-19. I shopped for her groceries and ran errands for her in the first few weeks of the Shelter-in-Place order, but my mom was terrified of leaving her home or having any in-person contact.

The first month of the Shelter-in-Place order was spent “social distancing” where drive-by events replaced gatherings. Church services were streamed online; in-person bible study and lunch dates were cancelled. No more gatherings, and no more errands. Fear prevented my mom from getting together with her friends. The “hidden enemy” was at work. My mom’s hair became longer and whiter, and my mom let me know that she was “looking old.” Her nails grew, and her clothes became baggy. The “hidden enemy” lurked, ready to invade her life in last 2 weeks of March and all of April.

May arrived. The Shelter-in-Place order was still in effect. “Phased reopening” offered hope. Quietly, the “hidden enemy” had found my mom. A vibrant 131-lb independent and active woman had become a frail and tiny 110-lb inactive woman who now looked 87 years old and had become more dependent on her family. She became forgetful and struggled with words. She stopped driving. I hear the following from my mom: “I think I am depressed,” “I am so tired,” and “I’m lonely.” Technology and the inability to manage it made her frustrated. Her cell phone caused anxiety and fear. The “hidden enemy”—social isolation—invaded my mom.

I believe using the words “social distancing” instead of physical distancing set up our elderly up for the perfect storm that is ravaging the mind, body, and spirit. Social distancing and the Shelter-in-Place order led to social

isolation, which has been associated with a myriad of psychological and physical complications. For the elderly, this is a recipe for a mental health disaster. I witnessed mental health issues in my mom that I have never seen or had to worry about. She has signs and symptoms of depression and symptoms of social isolation, and there are millions of elderly who are in the same situation.

There is evidence that links loneliness and social isolation to depression.¹ *JAMA (Journal of the American Medical Association)* reports that “The worldwide COVID-19 pandemic, and efforts to contain it, represent a unique threat, and we must recognize the pandemic that will quickly follow it—that of mental and behavioral illness—and implement the steps needed to mitigate it.”² The NCBI (National Center for Biotechnology Information) reports that “The current distancing guidelines are the first time mental health has been a concern. There are many studies that confirm the impact of social distancing on mental health, particularly if it results in social isolation.”³ According to these studies, the possibility of a mental health crisis clearly exists.

Do we have a mental health disaster? Could it be possible that we may be on the brink of a posttraumatic stress disorder (PTSD), anxiety, or depression pandemic? Are we ready? Do we know how to step in and help those who during this time are experiencing COVID-19 isolation, PTSD, anxiety, and depression? Now is the time!

My job is to keep my mom safe and healthy, so I making sure that I am paying attention to the tips to help elderly who are socially isolated. No, we have not directly experienced COVID-19 but are directly experiencing the impacts of the “hidden enemy.” If we implement steps now to identify needed resources to assist our elderly, we can expose the “hidden enemy”

SOME HELPFUL TIPS TO HELP OUR ELDERLY WHO ARE SOCIALLY ISOLATED:

- Create a list of people to who can check in by phone, FaceTime, or by driving by
- Assess frequently for changes in physical and emotional status
- Help arrange and attend medical visits
- Send notes/texts/prayers
- If overwhelmed with financial responsibility, set up automatic payments or direct billing
- Grocery shop/run errands
- Send a dinner via DoorDash
- Find things to laugh about
- As things reopen, take them out

and possibly avoid other potential comorbidity disasters.

Our elderly should maintain physical distancing but should not be socially isolated. Let them know they are not “isolated” or alone. Tell them they matter. Together, we can make a difference and change the social isolation that has impacted our elderly during this pandemic. **CM**

Sue Bowers, RN-BC, BSN, CCM, is the President at Choices Case Management, Inc., in Brentwood, California.

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PharmaFacts for Case Managers

continued from page 23

To avoid medication errors between Lyumjev and other insulins, instruct patients to always check the insulin label before each injection. Do not transfer Lyumjev U-200 from the Lyumjev KwikPen to a syringe. The markings on the insulin syringe will not measure the dose correctly and can result in overdosage and severe hypoglycemia

Hypokalemia

All insulin products, including Lyumjev, cause a shift in potassium from the extracellular to intracellular space, possibly leading to hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia if indicated (e.g., patients using potassium-lowering medications, patients taking medications sensitive to serum potassium concentrations).

Hypersensitivity and Allergic Reactions

Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulin products, including Lyumjev. If hypersensitivity reactions occur, discontinue Lyumjev; treat per standard of care and monitor until symptoms and signs resolve. Lyumjev is contraindicated in patients who have had hypersensitivity reactions to insulin lispro-aabc or any of its excipients

Fluid Retention and Heart Failure with Concomitant Use of PPAR-Gamma Agonists

Thiazolidinediones (TZDs), which are peroxisome proliferator-activated receptor (PPAR)-gamma agonists, can cause dose-related fluid retention, particularly when used in combination with insulin. Fluid retention may lead to or exacerbate heart failure. Patients treated with insulin, including Lyumjev, and a PPAR-gamma agonist should be observed for signs and symptoms of heart failure. If heart failure develops, it should be managed according to current standards of care, and discontinuation or dose reduction of the PPAR-gamma agonist must be considered.

ADVERSE REACTIONS

The following are adverse reactions:

- Hypoglycemia
- Hypokalemia
- Hypersensitivity and Allergic Reactions

CLINICAL STUDIES

Overview of Clinical Studies

The safety and efficacy of Lyumjev was evaluated in 2 randomized, active controlled trials of 26 weeks in adult patients with type 1 diabetes (N=780) or type 2 diabetes (N=336).

Type 1 Diabetes – Adults

PRONTO-T1D (NCT03214367) was a 26 week, randomized

(4:4:3), active controlled, treat-to-target, multinational trial that evaluated the efficacy of Lyumjev in 1222 patients with type 1 diabetes. Patients were randomized to either blinded mealtime Lyumjev (N=451), blinded mealtime HUMALOG (N=442), or open-label postmeal Lyumjev (N=329), all in combination with either insulin glargine or insulin degludec. Mealtime Lyumjev or HUMALOG was injected 0 to 2 minutes before the meal and postmeal Lyumjev was injected 20 minutes after the start of the meal. Patients had a mean age of 44 years; mean duration of diabetes of 19 years; 56% were male; race: 77% White, 19% Asian, and 2% Black or African American. Eight percent of the randomized patients were Hispanic. The mean BMI was 26.6 kg/m². At week 26, treatment with mealtime Lyumjev provided a mean reduction in HbA1c that met the pre-specified noninferiority margin (0.4%). In addition, postmeal Lyumjev met the prespecified non-inferiority margin (0.4%) compared to mealtime HUMALOG. Insulin doses were similar in all treatment groups at baseline and at 26 weeks.

Type 2 Diabetes – Adults

PRONTO-T2D (NCT03214380) was a 26-week, randomized (1:1), active controlled, treat-to-target, multinational trial that evaluated the efficacy of Lyumjev in 673 patients with type 2 diabetes who at study entry were on up to three oral antidiabetic medications (OAMs), basal insulin and at least one prandial insulin injection or premixed insulin with at least two injections daily. Patients were allowed to continue on metformin and/or a SGLT2 inhibitor and were randomized to either mealtime Lyumjev (N=336) or to mealtime HUMALOG (N=337), both in combination with insulin glargine or insulin degludec in a basal-bolus regimen. Mealtime Lyumjev or mealtime HUMALOG was injected 0-2 minutes before the meal. Patients had a mean age of 61 years; mean duration of diabetes of 17 years; 53% were male; race: 69% White, 24% Asian, and 5% Black or African American. Twenty-three percent of the randomized patients were Hispanic. The mean BMI was 32.3 kg/m². At week 26, treatment with mealtime Lyumjev provided a mean reduction of HbA1c from baseline that met the prespecified non-inferiority margin (0.4%) compared to mealtime HUMALOG. Insulin doses were similar in both treatment groups at baseline and at 26 weeks.

Storage and Handling

- Dispense in the original sealed carton with the Instructions for Use.
- Refrigerate unopened Lyumjev vials, pens, and cartridges between 36°F to 46°F (2°C to 8°C) until time of use and keep in the original carton to protect from light. Do not freeze or use Lyumjev if it has been frozen. Do not expose to direct heat. Discard opened or unopened Lyumjev vials, pens, and cartridges stored at room temperature below 86°F (30°C) after 28 days

For full prescribing information please see Product Insert.

Lyumjev is manufactured by Eli Lilly and company. 

Case management services are best offered in a climate that allows direct communication between the case manager, the client, and appropriate personnel to optimize the outcome for all concerned.

continued from page 15

patient and professional health-related education, and public health and health administration. Technologies include videoconferencing, the internet, store-and-forward imaging, streaming media, and landline and wireless communications.

Telehealth services may be provided, for example, through audio, text messaging, or video communication technology, including videoconferencing software. It is strongly recommended that case managers periodically review the latest rulings and information related to the 1996 HIPAA laws to maintain compliance and reduce any improprieties accordingly. That's what being client centered is all about. During this transition to technological aspects of the health care delivery system, the need for precise communication skills cannot be overstated.

Whether the case manager is using FaceTime, telephonic, or other internet or wireless technology, sending concise and clear messaging will be a determining factor in the patient response that ultimately connects the patient to better overall treatment or patient education compliance. Furthermore, case managers will need to become more self-aware of voice tone and quality with the rise of telephonic case management programs being incorporated across the health care spectrum. With the use of teleconferencing comes new meeting protocols and changing variables for production. Being able to listen well and communicate clearly with peers is as important as being able to do the same with patients for better outcomes. It helps to consider the other person on the phone is just that, a person. What if that person were you?

CE I

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continued from page 28

the percentage of patients from the wealthiest neighborhoods (by zip code). Quartile 1 included facilities with <2.1% of the patients residing within the highest income zip codes, quartile 2 included facilities with 2.2% to 15.6% of patients residing within the highest income zip codes, quartile 3 included facilities with 15.7% to 40.2% of patients residing within the highest income zip codes, and quartile 4 included facilities with 40.3% to 90.5% of patients residing within the highest income ZIP codes. Patient, tumor, and facility characteristics were analyzed using a multivariate logistic regression to identify associations between metastasectomy and FIQ.

RESULTS: Patients with CRLM were more likely to undergo metastasectomy at facilities in the highest FIQ compared with the lowest FIQ (18% vs 11% in FIQ4; $P = .001$). This trend was not

observed in the resection of primary tumors for nonmetastatic CRLM (rates of 95% vs 93%; $P = .94$). After adjusting for individual insurance status, distance traveled, zip code-level individual income, tumor, and host, patients who were treated at the highest FIQ facilities were found to be more likely to undergo metastasectomy (odds ratio, 1.29; 95% CI, 1.02-1.72 [$P = .03$]).

CONCLUSIONS: Metastasectomy for CRLM is more likely to occur at facilities that serve a greater percentage of patients from high-income catchment areas, regardless of individual patient characteristics. This disparity uniquely affects those patients with advanced cancers for which specialized expertise for therapy is necessary. ■

CE II Hospital Case Management: CMSA's White Paper*continued from page 19*

when they are centralized and easily accessed by any case manager, hospitalist, nurse, or other care team member.

8. The final priority included in CMSA's White Paper on Hospital Case Management Practice states that opposing views of hospital case management practice must be resolved to forge ahead with transformation. It may be challenging when one stakeholder has a different viewpoint. The key is to understand their perspective but keep the focus on the vision and the best interests of the transformation project.

Are all these considerations worth the effort to transition a legacy discharge planning/utilization review model to a care coordination model?

According to the Centers for Medicare & Medicaid Services (CMS), coordinated care aims to ensure that patients get the right care at the right time, while avoiding unnecessary duplication of services and preventing medical errors. The goal of care coordination is to facilitate the appropriate and efficient delivery of healthcare services both within and across systems of care. The Department of Health and Human Services is focused on transforming the healthcare system from one that pays for procedures and sickness to one that pays for outcomes and health....It's also an opportunity to think of all we do for patients from a "systemness" perspective—how do we break down traditional siloes to create a collaborative system dedicated to coordinating care for our most vulnerable patients.⁴

Changing the culture of care will take time, and it will be challenging for everyone to adjust to new roles and expectations. But when the dust settles and all the

behind-the-scenes preparations are completed, the result will be a patient-centered conceptual framework synthesizing professional practice standards, multistakeholder interests, and new care delivery strategies to deliver targeted, effective care coordination interventions across the continuum to selected patients. Yes, it's worth it! **CE II**

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