CareManagement

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

Vol. 23, No. 5, October/November 2017

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CareManagement Is Now the Journal of the Commission for Case Manager Certification (CCMC), the Case Management Society of America (CMSA), and the Academy of Certified Case Managers (ACCM)

The Commission for Case Manager Certification (CCMC) and the Case Management Society of America (CMSA) have appointed *CareManagement*, the journal of the Academy of Certified Case Managers (ACCM), as the journal of the three organizations. This collaboration is designed to provide a central communications vehicle for the three organizations and to improve case management practice through education. All members of these organizations will receive *CareManagement* bimonthly.

CareManagement is published electronically six times a year and provides information on case management practice, disease management, trends in case management, pharmaceutical information, and information from the medical literature pertinent to case management practice. With this collaboration, *CareManagement* will have the largest circulation of any case management journal.

All three organizations have worked together since their inception, sharing a common goal of advocating quality case management and improving case management practice through education. The dynamic changes in health care delivery and disease management make staying informed about best practice and trends incumbent for the case manager. *CareManagement* serves that purpose.

"This ongoing collaboration provides certified case managers (CCM®s) with direct access to *CareManagement* journal," says MaryBeth Kurland, CAE, Chief Executive Officer, The Commission for Case Manager Certification. "The journal is an excellent source of relevant case management information and education, providing continuing education (CE) credits to assist CCMs in fulfilling their certification renewal requirements."

"CMSA provides a wealth of resources for our members, and when we identify a new tool to enhance education for professional case managers, we take advantage of the opportunity," states Kathleen Fraser, MSN, MHA, RN-BC, CCM, CRRN, Executive Director, Case Management Society of America. "We're looking forward to this collaboration with CCMC and ACCM as we continue to move in the same direction, together, to advance the practice of case management."

About the Commission for Case Manager Certification

The Commission for Case Manager Certification is the first and largest nationally accredited organization that certifies more than 42,000 professional case managers and over 2,500 disability management specialists. The Commission is a nonprofit, volunteer organization that oversees the process of case manager certification with its CCM® credential. The Commission also oversees the process of disability management specialist certification with its CDMS® credential. The Commission is positioned as the most active and prestigious certification organization supporting the practice of case management. For more information, visit www.ccmcertification.org, connect with the Commission on Facebook, or follow CCMC on Twitter @CCM_Cert.

About the Case Management Society of America

Established in 1990, the Case Management Society of America is the leading nonprofit case management membership association dedicated to the support and development of the profession of case management. CMSA serves more than 36,000 members, subscribers, and participants, and over 85 local and international chapters through educational forums, an on-line Educational Resource Library with nearly 160 educational sessions available 24/7, providing RN, SW, CCM and CDMS CEs. Our annual conference provides networking opportunities supporting our continued legislative advocacy, and established standards of practice to advance the profession. Visit www.cmsa.org or follow CMSA on Twitter #CMSANational.

About the Academy of Certified Case Managers

The Academy of Certified Case Managers is the first membership organization for certified case managers and publishes the journal *CareManagement*. The goal of the ACCM is to improve case management practice through education. Members of the Academy are eligible for continuing education (CE) self-study in each issue. For more information, visit www.academyccm.org.

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Gary S. Wolfe

CareManagement Is Now the Journal for Three Professional Case Management Organizations

CareManagement has been appointed the journal of the Commission for Case Manager Certification, the Case Management Society of America, and the Academy of Certified Case Managers.

All three organizations are all committed to professional case management. Their mission, vision, and values are as follows:

The Commission for Case Manager Certification (CCMC)

- To advocate for professional case management
- To promote excellence through certification and interrelated programs and services
- To promote, advance, and advocate for:
  - –Quality case management practice
  - –Ethical standards and behavior
  - –Scientific knowledge, development, and dissemination

The Case Management Society of America (CMSA)

- To advance case management practice in all respects by:
  - –Promoting opportunities through discussion, study, and publication
  - –Educating its members
  - –Developing and encouraging consistent professional standards of performance, competence, service, and conduct of professional case managers

The Academy of Certified Case Managers (ACCM)

- To improve professional case management practice through education

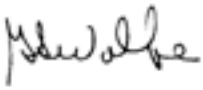
A common theme of all three organizations is to promote professional case management practice, which is why *CareManagement* is published.

CareManagement, which has a distinguished and proud history, has addressed the needs of professional case managers in all settings for over 20 years. The journal publishes articles on a variety of issues (eg, health care delivery, disease management, case management process, reimbursement, and ethics) to provide the professional case manager with information to improve the practice of case management.

The three organizations—CMSA, CCMC, ACCM—have a history of collaboration, and this relationship is now strengthened. This collaboration will provide a central means of communication for the three organizations. All members of these organizations will receive *CareManagement* bimonthly. With this collaboration, *CareManagement* will have the largest circulation of any case management journal.

This is an exciting time for professional case managers, who are leading the way in the delivery of accessible, compassionate, cost-effective, and outcome-driven health care. I welcome the opportunity to hear from all of our readers about issues and challenges in their case management practice.

The theme of National Case Management Week is "Together We Stand Strong," and thus our new collaboration is fitting. I salute my fellow professional case managers!



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ACCM: Improving Case Management Practice through Education

CareManagement

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

Vol. 23, No. 5, October/November 2017. *CareManagement* (ISSN #1531-037X) is published electronically six times a year, February, April, June, August, October, and December, and its contents are copyrighted by Academy of Certified Case Managers, 2740 SW Martin Downs Blvd. #330, Palm City, FL 34990; Tel: 203-454-1333; Fax: 203-547-7273.

Subscription rates: $120 per year for ACCM members; $150 for institutions.

CareManagement is indexed in the CINAHL® Database and Cumulative Index to Nursing & Allied Health Literature™ Print Index and in RNdex.™

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CCMC Symposium 2018: Future Dimensions of Case Management

By MaryBeth Kurland, CAE, CEO, *Commission for Case Manager Certification*

Case managers are a diverse group of professionals practicing across the health and human services spectrum, from acute and subacute care to patient-centered medical homes, and they have specializations such as workers' compensation and home health. Although job functions vary, they are all part of the practice of case management, which the Commission for Case Manager Certification (CCMC) defines as "a collaborative process that assesses, plans, implements, coordinates, monitors, and evaluates the options and services required to meet the client's health and human service needs."[1]

Given the diversity of the field, there are exciting opportunities for practitioners from various settings and specialties to interact with each other at an event such as CCMC's New World Symposium 2018—Future Dimensions of Case Management. The symposium will be held January 18–20, 2018, at the Gaylord Opryland Resort & Convention Center in Nashville, Tennessee. (For information see symposium.ccmcertification.org/why-attend.)

As in prior years, the symposium will feature an all-star lineup of case management subject matter experts, thought leaders, researchers, and other high-caliber speakers. The goal is to provide attendees with real-world takeaways they can apply to their own practice settings.

Increasingly, the symposium is being recognized as a premier event to foster thought leadership and promote professional excellence. The event puts case managers in the company of others who are driving change and implementing the highest standards of care across the continuum. In addition, attendees will be able to interact with vendors showcasing the latest products and services.

This year's symposium includes plenary and general sessions on topics such as innovation in case management, cultural and social determinants of health, telehealth, public policy, motivating patient behavior, the opioid crisis, and patient care data and analytics. (See symposium.ccmcertification.org/program/schedule-at-a-glance.) Attendees will have the ability to earn continuing education units (CEUs) toward maintaining CCM certification, with the added benefit of earning credits toward licenses and certifications from multiple allied health organizations in nursing, social work, and other related fields.

As the oldest and largest nationally accredited organization that certifies case managers, CCMC is proud to host such a unique event that fosters learning and the sharing of ideas. The symposium is organized to fulfill the following goals and objectives for each participant:

- Develop Me: Create awareness of the current and future landscape influencing the patient, family, and care provider(s) across the care continuum.
- Empower Me: Empower the case manager through education, advocacy, and ethical practice.
- Inspire Me: Establish a forum and provide resources, knowledge, and skill development for evidence-based practice across the healthcare continuum.
- Entertain Me: Participate in multisensory learning activities.

Through the pursuit of these goals and objectives, CCMC seeks to present the right information at the right time for board-certified case managers, professional case managers, and others who recognize the importance of quality case management practice in a range of settings.

We encourage all professionals in case management or those who are interested in case management to attend the 2018 New World Symposium. It promises to be a unique opportunity to engage with others around highly relevant topics related to "Future Dimensions of Case Management." CM

MaryBeth Kurland, CAE, *is the CEO of the Commission for Case Manager Certification (CCMC). For more information about the Commission and the Certified Case Manager (CCM) credential, please visit ccmcertification.org. More than 42,000 board-certified case managers are in practice today.*

Reference

1. Commission for Case Manager Certification (2017). Definition and Philosophy of Case Management. Retrieved from ccmcertification.org/about-ccmc/about-case-management/definition-and-philosophy-case-management

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Shoot the Fraud and Abuse Manager and Pay the Price

By Elizabeth Hogue, Esq.

Providers must take concerns of employees seriously regarding possible fraudulent and abusive practices. Most whistleblowers take their concerns to their employers first. It is only when employers ignore their concerns or, even worse, retaliate against employees for raising issues in the first place, that employees turn to outside enforcers for assistance in pursuing their concerns. Whether or not the allegations of employees are valid, providers must take them seriously. Thorough investigations are required in order to demonstrate to employees that there is no problem or that the problem has been corrected.

Private citizens may initiate so-called "whistleblower" or qui tam lawsuits to enforce prohibitions against fraud and abuse in the Medicare, Medicaid, and Medicaid Waiver Programs and other state and federal health care programs such as VA and TRICARE.

One of the federal statutes that allows for whistleblower actions is the False Claims Act. This Act generally prohibits providers from "knowingly" presenting or causing to be presented false or fraudulent claims for payment by the government. Whistleblowers continue to be a major source of information for government enforcers.

In order to bring a qui tam action under the False Claims Act, private parties must have direct and independent knowledge of fraud by providers against whom suits are filed.

Current or former employees who are familiar with providers' practices may often initiate whistleblower actions under the False Claims Act. As you can imagine, employees who are ignored or retaliated against when they bring possible violations to the attention of their employers by firing them, for example, are likely to initiate whistleblower suits.

Thus, current or former employees who are familiar with providers' practices may often initiate whistleblower actions under the False Claims Act. As you can imagine, employees who are ignored or retaliated against when they bring possible violations to the attention of their employers by firing them, for example, are likely to initiate whistleblower suits. An example follows.

In United States ex rel. Chorches v. American Medical Response, No. 15-3920 (2d Cir. July 27, 2017), Paul Fabula worked as an emergency medical technician (EMT) for American Medical Response. Fabula realized that his employer fraudulently sought reimbursement from the Medicare Program by falsely claiming that ambulance services were medically necessary when they weren't. Specifically, EMTs were asked to falsify electronic Patient Care Reports (PCRs) to make it appear that services were medically necessary. Supervisors printed copies of PCRs, revised them, and directed staff members to signed the revised forms.

In one instance Fabula provided services with another staff member who prepared the PCR. A supervisor directed the staff member to fraudulently revise the form. When the staff member refused, the supervisor directed Fabula to sign the revised form. When Fabula refused, he was fired.

And what did Fabula do? Why, of course, he filed a whistleblower suit! The message from this case and numerous others is clear: Don't shoot the proverbial messenger who brings information about possible fraud and abuse violations. There is a very heavy price to be paid. CM

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.*

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After the Hurricanes: Assessing the Impact on Employees

By Ed Quick, MA, MBA, CDMS, CRC

Hurricanes leave a wake of destruction in their path, but the damage goes beyond property losses. The lingering emotional and physical effects can be significant for people on the front lines of trauma along the Gulf Coast, especially in Texas and Florida, as well as parts of the Caribbean. The impact becomes even more widespread when considering families who serve as support systems outside the Gulf Coast; these families may still be dealing with feelings of fear, separation, and helplessness as their loved ones recover from these mega-storms.

In the midst of any trauma, from a natural disaster to an unexpected death, people are often able to "power through" whatever they are facing in the moment. Only after some level of safety or control is restored is the full impact of the event felt–physically, mentally, and emotionally. This leads to a protracted and more-complicated recovery period than one might expect. For example, the fallout from Hurricane Katrina in 2005 was devastating because some New Orleans–area residents were forced to abandon their homes for more than a year, creating problems for public health, education, and employment.

Now, weeks after Hurricanes Harvey and Irma, people may still be suffering physically and emotionally from the direct impact of the storms and having their lives disrupted. For those already dealing with mental and physical health issues, the storms and their aftermath may have triggered a setback. Symptoms may include exhaustion, lack of sleep, depression, becoming more vulnerable to illness and injury, and potentially abusing alcohol and prescription and nonprescription drugs.

Long after the hurricanes are "news," case managers and disability managers must be aware of the lingering impact on the health, wellness, and productivity of individuals, whether they were in the direct path, were indirectly affected, or were among the heroes who helped others.

Long after the hurricanes are "news," case managers and disability managers must be aware of the lingering impact on the health, wellness, and productivity of individuals, whether they were in the direct path, were indirectly affected, or were among the heroes who helped others.

Disability managers, such as those working onsite at an employer, may see an increase in absenteeism as people take off more days from work or there may be performance issues because of employees' mental and emotional burdens. Case managers who work in various clinical settings may encounter individuals whose chronic conditions are exacerbated. Asthma, hypertension, and other chronic conditions can become more difficult to manage, whether because of stress or environmental conditions such as elevated mold levels that affect a compromised immune system or because of the inability to access medication to maintain treatment adherence.

Both case managers and disability managers also need to be attuned during intake interviews to any mention of personal, family, and/or financial stresses that are linked to the hurricanes, even many months after these incidents. Responses during and immediately after a natural disaster also serve as a reminder to case managers and disability managers of the importance of making sure people know the extent of resources available to them, whether in the community or through their employer, such as an Employee Assistance Program (EAP).

In the aftermath of the hurricanes, there are other lessons to be learned, particularly the need to review policies

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Ed Quick, MA, MBA, CDMS, CRC, *is a Commissioner with the Commission for Case Manager Certification (CCMC), which manages and governs CDMS certification. He has more than 15 years of experience in disability and workforce management with Fortune 100 companies and currently works as a global senior benefits manager.*

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- *Certifications expiring in 2017: four (4) Ethics CEUs will be required for renewal.*
- *Certifications expiring 2018 and after: eight (8) Ethics CEUs will be required for renewal.*

Author's Interview with Catherine M. Mullahy, RN, BS, CRRN, CCM

CareManagement recently sat down with case management pioneer, Catherine M. Mullahy, RN, BS, CRRN, CCM, president of Mullahy & Associates, a leading provider of case management education and training programs and resources. Catherine is the author of The Case Manager's Handbook, *now in its sixth edition. She shared her thoughts about the motivation for writing this latest edition of what many believe is the definitive reference book for case managers. She noted how the* The Case Manager's Handbook *reflects the evolution of case management and discussed her journey from clinical nursing roles and case management industry leader to successful entrepreneur and educator/trainer.*

Q. What was your primary motivation for writing the sixth edition of *The Case Manager's Handbook*?

CM: As the health care environment continued to evolve, growing uncertainty regarding the Affordable Care Act and the creation of still more delivery and reimbursement models were evident. I felt that the case manager's role also was changing and not always for the better. It seemed that the professionals involved were moving farther and farther away from those that needed our intervention the most—the most vulnerable and complex patients. I have always believed that case managers can make a difference, one patient at a time. It seemed to me that professionals—both seasoned ones and those who are just entering the practice—needed to be reminded that the process of case management is guided by "Standards of Practice": essential activities and defined knowledge, as per the Commission for Case Manager Certification (CCMC) and its most recent "Role and Function Study in 2014."

I believe leaders in organizations that employ case managers need to advocate for the role of the case management professional rather than permit the assignment of duties and responsibilities outside the scope of their practice. Additionally, as a direct result of these non-case management functions being performed under titles such as care coordinator, patient navigator, and patient advocate, virtual "silos" of case management are being created rather than adhering to a defined and specific process that incorporates, for example, care coordination and patient advocacy. In short, these positions undermine the role of the case managers but they don't incorporate essential functions. The visibility, credibility, and power of the case management profession are clearly at risk. It was my intent to reframe and clearly demonstrate the process while also acknowledging that, even with these changes, case managers need to stand firm. Through this latest edition of *The Case Manager's Handbook*, I have addressed both the changes in health care and challenges that case managers have to understand and be prepared to address.

Q. What are some of the most significant additions to this latest edition of *The Case Manager's Handbook*?

CM: As I considered the additions to the sixth edition, I think that perhaps shining a bigger spotlight on the high-risk, high-cost patient was important. It is this group of individuals, after all, that really demands our attention. If we're not identifying and connecting with these folks, then what are we doing? Case management itself is an expensive resource, there aren't enough of us to manage these complex folks, and case management should only be utilized for those most at risk. Case management itself is a risk management tool. Therefore, acknowledging this should translate naturally to the management of these patients. One wonders then, how did we get involved in so many other activities like data collection and financial management?

Q. Does updating *The Case Manager's Handbook* get more difficult with each edition?

CM: Each new edition presents challenges. I carefully consider which issues are really important and need to be included and whether some of the draft content should be considered "nice to know" but nonessential. To make space in the print version for new material, we moved some of the content from previous editions to Navigate 2, an online resource to the book that is available on the publisher's website once the book is purchased. This way, readers have

Catherine M. Mullahy, RN, BS, CRRN, CCM *is President of Mullahy & Associates and author of* The Case Manager's Handbook, Sixth Edition

access to the material even though it doesn't appear in the print edition.

Q. Case managers today face many challenges that you may not have had when you were a practicing case manager. Can you discuss what you think are the primary differences in practicing case management today compared with how it was practiced in the past? What is the most important factor that hasn't changed at all?

CM: I only worked as a case manager employee for 5 years. I was frustrated with the way that case management services were provided and marketed, and that frustration led to the formation of my case management firm, Options Unlimited. During its operation from 1983 to 2003, I was fortunate enough to be able to create case management services the way I thought they should be provided. Fortunately, my instincts and experience were decent and our results were strong enough to convince our clients to use what we now call "Best in Class" case management services.

I have been fortunate to also have a wonderful partner in Jeannie Boling, who shares my commitment to these highest standards of case management. Jeannie and I, along with our team, have been able to create a platform for our key messages. To some extent, I am still very driven by the fact that case management across all settings can be improved dramatically with better and more consistent training and education of hands-on case managers as well as their department heads and other decision makers within their organizations.

One of the upsides of the earlier days of case management was that because we weren't so reliant on technology, we needed to use our personal intervention, knowledge, and expertise. We discuss technology and the challenges it poses for case managers in *The Case Manager's Handbook, Sixth Edition*. Today, there is so much emphasis on technology from electronic health records (EHRs) to telehealth services and the increasing number of metrics and data collection involved in today's environment almost to the exclusion of the patient's best interests. Case managers are still searching for the Rosetta Stone that will guarantee their success and communicate their outcomes. What they are failing to realize is that, unless they really spend the necessary time to identify and resolve the problems, their value will remain unknown or unrecognized at the level it should be. Metrics, data, and the micromanagement of "stuff" that doesn't matter is increasingly getting the attention. That problem, coupled with the fact that many leaders are simply not leading, is why case management remains a stepchild of the health care system when, today, more than ever before, it should be regarded as the child who will lead us out of the darkness that reflects much of our current health care system.

I agree that technology should be used to deliver greater benefit to the patient and facilitate better patient outcomes rather than impede the ability for case managers and other health care professionals to perform their roles, which certain legislation such as "The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009" seems to have done.

What hasn't changed and shouldn't change in case management is the process of case management. When allowed to function as intended and in accordance with our standards of practice and code of ethics, case management does improve outcomes, enhance patient satisfaction and, yes, save dollars too.

Q. What advice do you have for case managers today that is conveyed in *The Case Manager's Handbook, Sixth Edition?*

CM: My best advice to today's case managers is to obtain the skills and knowledge that is so necessary to be a competent, confident case manager; to pursue professional certification; and to recognize that they can and do make a difference, one patient at a time

Q. How important is it for Case Management department heads to rely on the content of *The Case Manager's Handbook, Sixth Edition* in the training and skill development of their staff?

CM: Well, obviously, but hardly objectively, I continue to believe that *The Case Manager's Handbook, Sixth Edition* is the "nuts and bolts" of case management and the "go-to" resource for so many aspects of the process. Since the first edition, *The Case Manager's Handbook* has been aligned with the Standards of Practice and the essential activities, core components, and knowledge domains as defined by the Commission for Case Manager Certification (CCMC). I believe case management training, education, and certification should be driven from the top of an organization, with department heads and supervisors encouraging their staff to pursue the highest level of skill development and certification. Having a resource like *The Case Manager's Handbook* available as a resource to their case managers would seem a good first step in this direction.

Q. *The Case Manager's Handbook* is widely recognized as the definitive reference book for case managers. It is used in graduate and undergraduate nursing and health management courses in the United States, Canada, and 18 other countries across the world. Why do you think it has gained *this stature among the many other* textbooks on case management?

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Managing Postacute Care Networks

By Laura Kukral, MBA, LNHA, Demi Paulus, MPH candidate, and Thomas W. Brewer, PhD, MJur

Various demonstration projects authorized by the Centers for Medicare & Medicaid Services (CMS) have incentivized the creation of network relationships along the continuum of care (physician, acute care, postacute care, and other community-based services). These networks create a variety of challenges for the professionals that lead, manage, and interact with them.

The relatively wide latitude permitted in the design of networks and the resulting diversity of structure complicates the process for administrators looking to choose a network model that will work best in their organization. A 2016 survey of 3,750 hospital members of Premier Inc. found that "while 85% of health system leaders are interested in creating or expanding partnerships with preferred and local postacute care providers, more than 9 of 10 report they experience challenges in creating these partnerships.[1]" The propensity of these networks to evolve over time places a premium on its leaders' abilities to anticipate problems as well as to recognize when issues require changes in network design, membership, or modification of operational procedures to optimize results. To be sure, these are valuable skills for any network leader or care management professional to develop, but they become even more critical when working within a network of outside providers.

Postacute Care Network Models

Network design is driven by the unique goals of its creators. Few networks are exactly alike. To simply say a network is in place in your market area doesn't tell us much about its purpose, functions, membership criteria, or potential patient experience issues. Research was conducted in Spring 2017 to get a picture of the types of models being used. A convenience sample of 12 health care leaders in a Midwestern state were surveyed about all aspects of the network in which they were a leader or in which they participated. What emerged from the interviews was a picture of 6 distinct network typologies that will be discussed in detail below. These network types include Quality Alliance Models, Member Models, Embedded Staff Models, Ownership Models, "SNFist" Models, and Independent Open Models.

All these models were identified as having common management challenges as well as some that are unique to specific models. The common challenges could be categorized as those related to network design or to network operation. The primary concern related to network design was reported as failure to select network members using objective, purposeful criteria within safe harbor guidelines. The most common challenges related to network operation were identified as failure to: 1) identify a singular, clear leader; 2) integrate the network with hospital service lines; 3) establish financial alignment among providers; 4) provide adequate guidance and resources to support data transfers, analysis, and reporting; and 5) failure to identify, engage, and communicate with all stakeholders who could help or hinder the initiative. This article will elaborate on the aforementioned challenges of network operation including both the common challenges and the challenges that are unique to specific models.

Common Challenges

Failing to identify a specific individual with responsibility for leadership of network design and administration was a concern. Health systems reported having more than 1 network in operation, with several different executives claiming authority over them. This created confusion among providers about which networks they should/did join, what the purpose was, and whose directions they should follow. Often, the perceived lack of a clear singular leader was connected to failure to integrate network operations with hospital service lines.

Since hospitals are typically organized around service lines such as "orthopedics and spine," "heart and vascular," "gastrointestinal, urinary and kidney," or similar condition-based services, it is imperative that postacute care networks collaborate with hospital service line leaders to ensure that clinicians (particularly physicians) understand the need for the network, lead the development of care pathways, and

***Laura Kukral, MBA, LNHA**, is currently Vice President of Strategic Consulting with Health Dimensions Group in Minneapolis, Minnesota. She has nearly 30 years' experience in health care operations and strategy, and she was a Strategy Partner at the Cleveland Clinic in her previous position. **Demi Paulus, MPH candidate,** is a graduate student at Kent State University with research and operations interest in postacute care delivery systems. **Thomas W. Brewer, PhD, MJur**, is Associate Professor of Health Policy and Management at the College of Public Health, Kent State University. Dr. Brewer teaches and conducts research in health law and health care compliance.*

A 2016 survey of 3,750 hospital members of Premier Inc. found that "while 85% of health system leaders are interested in creating or expanding partnerships with preferred and local postacute care providers, more than 9 of 10 report they experience challenges in creating these partnerships."

know when and how to refer patients to network providers to ensure smooth care transitions and patient outcomes. Priority service lines were identified as those impacted by bundled payments. If these service lines are unaware of an existing network initiative, they may develop their own. Subsequently, health systems may operate multiple postacute care networks that are not necessarily part of a coordinated strategy. Operating multiple postacute care networks seems to be more common when the health system is very large, with many institutes and service lines; when the health system serves disparate geographic areas; and/or when the health system has acquired or merged with other hospitals and provider organizations in recent years. This situation can create confusion among downstream providers as to what the purpose of the networks are, which network they belong to, what is expected of the members, and who is in charge.

In addition, one of the more common oversights in network implementation is integration of hospitalists into the process. Although hospitalist programs are not typically identified as a service line, these physicians can have more influence over patient decisions than primary care or service line clinicians because they are often the last physician to speak with a patient before discharge. Hospitalists who are unaware of or disengaged from the health system's effort to create a postacute care network may refer patients away from its preferred providers.

Equally challenging is that payer policies have not yet established financial alignment among all providers involved in an episode of care. Subsequently, the burden of creating this alignment is borne by whichever provider(s) entity carries accountability, attribution, and/or risk. Risk-based contracting should operate in compliance with the bundling or Accountable Care Organization (ACO) waivers and relationships must avoid any mechanism to increase referrals in return for services not paid at fair market value. Risk- and gain-sharing arrangements can facilitate financial alignment, but the long-term viability of these arrangements is a common concern. Without financial alignment, postacute care networks may not fully achieve their goals.

Concerns over electronic data transfer, integrity, and analysis were so pervasive in interviews that the topic warrants a full discussion. Respondents reported that postacute care providers often do not have the financial, human, and technological resources to fully support the data needs demanded by network designers.

The final common plea of network participants, along the entire continuum, was for more frequent and transparent communication with network leaders. Many of those interviewed noted that meetings were irregular, phone calls were not returned, and questions were left unanswered regarding network operation as well as specific patient care.

Network Typology

The following section lays out the basic structure and operation of the 6 basic typologies of network structures identified by the researchers and some of the specific challenges to operating them.

Quality Alliance Models: Networks based on quality alliances essentially create collaborations between physicians, hospitals, and postacute care providers that ensure that patients receive standardized protocol-driven care across the episode-of-care to achieve higher quality and lower costs. These networks are often loose affiliations of providers that focus on quality improvement processes and not on creating a financial or contractual link between the organizations. Collaborators from all sites of care and disciplines typically work together on a standardized treatment protocol for patients with a specific diagnosis such as heart failure.

One of the more common issues with this network model is failure to include professionals from across the continuum in collaborative discussions. For example, one health system worked hard over a 6-month period to create a care pathway for joint replacement patients and included nurses, physicians, and rehabilitation experts from the hospital's care management department, outpatient and long-term rehabilitation program, orthopedic service line, and home care team, yet they failed to include any representatives from the skilled nursing facilities selected as preferred providers. Without the input of all relevant and specialized knowledge, the results of the network fell short of its goals.

Member Models (health plan networks, ACOs, bundled payment): To drive value, health plans and other organizations that carry risk for covered lives are limiting the number of skilled providers they refer patients to in order to focus on a select few offering the best quality and costs. These networks operate similar to Quality Alliances but are formalized

The primary concern related to network design was reported as failure to select network members using objective, purposeful criteria within safe harbor guidelines.

through a business and/or operating agreement. The most frequently cited challenge in operating this type of network was the impact of changes in quality by the member providers and how to go about excluding or adding new members in response. Networks that do not have a regular, frequent process for evaluating and adjusting membership tended to drift into situations where declining performers were able to remain in the network and improvers found it impossible to join. Ultimately, network access to quality care can suffer if it is not actively managed through membership standards. Some of the respondents reported relying heavily on "scorecards" that help them rank member providers; these scorecards are addressed at weekly and monthly meetings to ensure standards of care are met.

Embedded Staff Models: Postacute care networks using an embedded staff model use hospital-employed physicians and advanced practice professionals to visit patients in preferred skilled nursing facilities (SNFs) at least 4-5 times per week. The objectives are to increase contact with physicians as a means to reduce readmissions among patients with the most complex illnesses, improve functional status, and lower 1-year mortality rates. The Cleveland Clinic implemented such a program with seven "Connected Care" facilities and reported reduced 30-day readmission rates at the network facilities compared with other SNFs it referred to between 2011 and 2014.[2]

The practical challenge of this model is related to the actual business model. It potentially increases costs more than it impacts quality and can tip the value equation in the wrong way. Physicians are embedded nearly full time at SNFs under the premise that a large enough number of high-cost, high-risk patients will be admitted to those SNFs each week to justify a dedicated physician. The model also presumes that the individual patients pose such a high risk for readmission that daily visits are warranted.

The selection of partner sites for the embedded model requires regular analysis of historical patient draw data from the hospital as well as the nature and costs of care. Superficial review of key performance indicators (like readmission rates) may not be enough to establish the business case or ensure that the right providers are in the network at any given time. It is easy for the situation to occur where intense physician care is provided to patients who did not need that level of service simply because they received care at a facility with an embedded physician.

Ownership Models: Some health systems own and operate nursing facilities under the belief that fragmentation in care causes high rates of readmission and poor outcomes. Numerous studies over the past 20 years have examined whether costs/outcomes were better or worse in hospital-based skilled facilities than those in the community. In a 2016 academic study, more than 800,000 Medicare beneficiaries discharged from roughly 3,000 hospitals and 14,000 SNFs were evaluated for outcomes and spending across a 180-day episode period.[3] The study found that hospital-based SNF patients had fewer days in the SNF and that Medicare spent almost $2,900 less per patient in the 30 days after the acute discharge. The investigators suggest that the results support vertical integration of hospitals and SNFs. However, the SNF environment is markedly different than acute care in terms of regulations and operations, and thus those who are responsible need deep experience in both hospital and postacute care delivery systems.

SNFist Models: A SNFist program, which is also known as a "posthospitalist" program in some areas, is a physician-driven model in which a primary physician, nurse practitioner, or physician assistant makes caring for nursing home patients their full-time business. These practitioners sometimes also function as hospitalists, rounding on acute inpatients, but do not see patients in an office-based practice like a community-based primary care physician. With no private practice distractions, SNFists often round daily and develop expertise in the types of medical situations common to patients who receive care in nursing homes for rehabilitation, chronic disease, and end-of-life care.

SNFist programs are positioned to improve value by handling a broader range of complex medical problems directly in the SNF. For example, rather than transfer a patient to the emergency department, a SNFist practitioner is engaged to first try to solve a patient's problem at the postacute care facility. This care may even incur additional costs at the SNF, such as intravenous medications. These additional costs would normally be far less expensive than a hospital readmission. Advocates for the model point out that this approach has distinct benefits for the patients by minimizing transfers between settings. For patients, transfers can disrupt other needed care (like rehabilitation services), increase physical and emotional stressors, and introduce potential for medical errors related to

The most common challenges related to network operation were identified as failure to: 1) identify a singular, clear leader; 2) integrate the network with hospital service lines; 3) establish financial alignment among providers; 4) provide adequate guidance and resources to support data transfers, analysis, and reporting; and 5) failure to identify, engage, and communicate with all stakeholders who could help or hinder the initiative

care coordination. Although the SNFist model of care offers potential advantages to SNF operators and patients, the simple act of hiring a SNFist does not mean the nursing home has "joined" a postacute care network as a preferred provider.

That said, some health systems have transformed their relationships with SNFists into bona fide postacute care networks and set quality criteria for nursing homes to participate. The SNFist-based network members work collaboratively to establish procedures to improve care transitions, deploy shared care pathways, and jointly monitor outcomes and pursue quality improvement programs.

Adapting the SNFist model of care into a postacute care network presents vulnerabilities for health systems and care managers. Most notably, there is the possible perception of "pay to play" among postacute care providers and payers. Contracts to provide physician coverage to postacute care providers can be lucrative, and if nursing homes are construed to receive preferred status only because of the financial arrangement between the SNFist and the facility, the payer's conditions of participation may be violated. As with all such arrangements, careful review by legal experts specializing in health care compliance is critical.

Managing expectations of outcomes for the SNFist program can also be difficult. SNFists face the same obstacles to improving care for postacute care patients as any other attending physician. Obtaining comprehensive medical records may be difficult and cause delays in care. Staffing shortages in the nursing home are not uncommon and can impact care delivery. And, patients are often unrealistic about their outcomes and/or returning to their previous functional status, which affects satisfaction with their care and experience. As pointed out by one of the executives who was interviewed, patient experience is more positive with physicians who have saved a patient's life (at the hospital) than with caregivers who are associated with the longer-term realities of a medical (and possibly a financial) crisis.

Independent Open Models: Exclusion from hospital- or payer-sponsored networks can significantly and negatively impact a postacute care provider's potential pool of patients. Upstream narrow network "owners" can not only slow the flow of new referrals to a postacute care provider, but they can also redirect the residential clients of a provider to their competitors. The forced relocation of these residents-turned-patients not only impacts the postacute care provider, but the patients themselves lose the continuum-of-care benefits they sought by living in a health care campus setting in the first place.

Some of these "full continuum" providers have responded to the exclusion problem by uniting to create their own independent networks and strategically pursue insurance contracts. These networks offer access to an entire group of high-performing facilities that otherwise would be inefficient to contract with individually.

One of the challenges of independent postacute care networks is the required expertise and costs associated with their formation. Without the sponsorship of a payer or health system, the uncertainty of a return-on-investment can be a limiting factor for its members. These networks are costly to join, and even if they are able to negotiate insurance contracts, they may or may not be successful in securing preferred network status or inclusion.

Conclusion

Although this article addresses the challenges of managing postacute care networks, respondents also reported successes. Whereas the preceding 6 examples provide insight into broad strategies for preferred provider networks, the actual variations are practically limitless within legal and ethical boundaries. There is a premium placed on organizational readiness to design and adapt models to fit the unique objectives of an organization, existing standard operating practices, and available partners.

The best tips came from project managers who say that a clear and empowered leader and a dedicated program manager are essential. A clear work plan is needed with allocated resources to implement it, well-defined agreements on roles and responsibilities, and a means to gather and report key performance indicators.

As value-based care increases and as more health care providers start joining the various "new" models such as SHFFT (surgical hip/femur fracture treatment excluding

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CE II

Care Management Plus: Strengthening Primary Care for Patients with Multiple Chronic Conditions

By Susan L. Hayes and Douglas McCarthy

Maria Viera, age 75, takes a dozen medications to treat her diabetes, high blood pressure, mild congestive heart failure, and arthritis. After she begins to have trouble remembering to take her pills, she and her husband visit her primary care physician to discuss this and a list of other worrisome developments, including hip and knee pain, dizziness, low blood sugar, and a recent fall. Maria's primary care doctor spends as much time with her as he dares, knowing that every extra minute will put him further behind schedule. Yet despite his efforts, there is not enough time to address her myriad ailments. She sees several specialists, but no one talks to all her providers about her care, which means she may now be dealing with conflicting recommendations for treatment or medications that could interact harmfully. As a result, Maria is at high risk for avoidable complications and potentially preventable emergency department visits and hospital stays.

Maria is a "persona" created by David A. Dorr, MD, to illustrate the type of patient who might benefit from Care Management Plus, a health care delivery model designed for older adults with multiple chronic conditions. Dorr and colleagues at Intermountain Healthcare, an integrated care delivery system serving patients in Utah and Idaho, created the program some 15 years ago not only to improve the quality and coordination of care but also to reduce health care costs and support primary care providers who treat these high-need high-cost patients. Care Management Plus is built on the pillars of the Chronic Care Model, which identifies 6 essential components for high-quality chronic disease care: the community, the health system, self-management support, delivery system design, decision support, and clinical information systems.[1]

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Care Management Plus itself has roots stretching to 1995, when Intermountain extended its hospital-based care-management program to 10 primary care clinics within its medical group, which employs primary care physicians and specialists to provide care to Intermountain patients in clinic settings. The clinics hired "continuum care managers," with an initial focus on improving diabetes management and thereby reducing avoidable hospitalizations, unnecessary primary care use, and costs. In 2001, the John A. Hartford Foundation's Geriatric Interdisciplinary Teams in Practice initiative provided support for Intermountain to expand the focus of this work by adding training and specially designed information technology tools. The continuum care managers helped develop these tools, aiming to better address the medical, mental health, and social needs of older patients with multiple chronic conditions.

Between 2002 and 2005, the program was tested in 7 primary care clinics within Intermountain, where physicians were given the option to refer chronically ill patients age 65 and older to an on-site nurse care manager. At the end of 2 years, patients enrolled in Care Management Plus, especially those with diabetes, had fewer hospitalizations and lower mortality compared with matched controls. The program had a positive effect on physicians as well. Doctors in the intervention clinics who were "high users" of the program—meaning they referred more than 2% of their patient population to a care manager—increased their productivity and were more satisfied.[2]

With the demonstration of these benefits, the Hartford Foundation in 2006 awarded Dorr and Cherie P. Brunker, MD, the chief of geriatrics at Intermountain, financial support to disseminate the program nationally. The model, branded Care Management Plus, or CM+, has now been implemented in 420 primary care clinics nationwide, covering 3 million patients. This profile describes the program's implementation at Intermountain and at Oregon Health & Science University (OHSU) in Portland, Oregon, where Dorr joined the faculty in 2005 and is now professor and vice chair of clinical informatics in the Department of Medical Informatics and Clinical Epidemiology.

Care Management Plus is a health care delivery model designed for older adults with multiple chronic conditions

Population Served

Embedded in primary care clinics, Care Management Plus targets Medicare patients (age 65 or older) and other populations with multiple chronic conditions. As a rule of thumb, about 5%–10% of patients in primary care practices using CM+ are invited to participate in the program.

Patients of all ages have been served by the program at Intermountain, which has made care management a standard feature of its "personalized primary care practices"—Intermountain's version of the patient-centered medical home model. At OHSU, CM+ is used in 5 large primary care clinics serving 2 populations: adults ages 40–65 with multiple chronic diseases that frequently include diabetes or cardiovascular illness, and are often coupled with behavioral health or substance abuse issues; and older adults who are growing frail or have multiple chronic conditions and who are at risk of functional decline and may become unable to live independently. Patients entering the program are often in need of a variety of social services like Supplemental Nutrition Assistance Program (SNAP) benefits.

Patients may be identified for CM+ using risk stratification, disease condition, and algorithms. But referral to the program within Intermountain and OHSU is intentionally flexible and inclusive, with discretion given to the patient's primary care team.

Care managers like Nancy Swanson, RN, who works in a large Intermountain internal medicine clinic in Salt Lake City, Utah, that currently serves about 6,500 adult patients, identify patients for care management in 2 ways. One way, introduced in the summer of 2016, is through a "high-risk" list generated quarterly by the Integrated Care Management division. The list alerts care managers in Intermountain's primary care clinics if any of their patients are among the health system's top 1% of highest-use, highest-cost patients—or at risk of becoming so. It is these individuals who could potentially benefit the most from care management. The list is created using an algorithm that takes into account numerous factors ranging from patients' recent use of health care services and costs to their diagnosed chronic conditions and predictive risk of adverse events. "A lot of the folks on the list recently had a major surgery, and I reach out to them to see if I can be of service," says Swanson, who earlier worked as a surgical nurse and in a gynecology oncology clinic. "Some are overjoyed to hear from me, while others will say, 'I've got it all in hand.'"

Patients are also identified via direct referral from providers. In the clinic where Swanson works, these patients range widely in age from their 30s to their 90s, but all tend to have comorbidities and chronic conditions—often uncontrolled diabetes or a mental illness, such as severe depression—that make it difficult for them to take care of their physical health. "A patient that needs some extra help may not be high acuity at the time," Swanson says, "but if they don't get an intervention they are going to be."

Leaders at both institutions strongly encourage care teams to use their clinical intuition and judgment to determine which patients to refer, so that patients who might benefit are not overlooked. "Even the best risk stratification and algorithms have not been able to identify at least 2% of people who appear to benefit from care management, and it may be because of an inability to capture psychosocial issues," says Teresa Garrett, RN, assistant professor at the University of Utah College of Nursing and formerly assistant vice president for Integrated Care Management at Intermountain.[3]

Key Features

Care Management Plus Training and Curriculum

Training for CM+ care managers, who are usually nurses or social workers, starts with an intensive 1-day, in-person workshop that lays a foundation of knowledge in the core competencies of care management. The workshop is followed by 8 weeks of online instruction, hosted by OHSU, including assignments, online discussions, and chats with experts. The training covers patient assessment, motivational interviewing, quality improvement, and the information technology elements of CM+; protocols and patient education for specific chronic diseases, including diabetes, hypertension, asthma, and chronic obstructive pulmonary disease; care for seniors

Patients may be identified for Care Management Plus using risk stratification, disease condition, and algorithms, but referral to the program within Intermountain and OHSU is intentionally flexible and inclusive, with discretion given to the patient's primary care team

and caregiver support; and ways to connect patients with community resources. Intermountain's Brunker directs the CM+ training, which, in addition to care managers, draws clinic managers, physician leaders, pharmacists, and other members of the care team. Participants can earn continuing education credits for the in-person and online portions.

Embedded Care Managers

Care managers are full-fledged members of the practice's care team, with office space located in the practice. They are hired by and report to practice managers. Within OHSU's general internal medicine clinic, a care manager is assigned to each of the 6 clinical teams, made up of 8–10 providers; each care manager works with about 200 patients. At Intermountain, each care manager is affiliated with a personalized primary care practice and is responsible for about 250 patients.

Care managers can take the additional time with patients that providers cannot. "A provider in our clinic would always say, 'Nancy has the gift of time,'" Swanson says. "And I do. I don't have to rush patients." Dorr sees the care managers at OHSU as being similarly "gifted" with time. "They are not fee-for-service, churning through 20-28 patients a day," he says.

During the initial visit, the care manager assesses the patient's needs. A key part of that first encounter is eliciting the patient's goals and priorities. Based on the information gleaned, the care manager, in partnership with the patient, develops a care plan tailored to that patient. Subsequent encounters may happen face to face or by telephone. The amount of contact varies depending on the patient. During the evaluation of CM+ at the 7 clinics within Intermountain, care managers had, on average, 4.3 encounters with a patient, and the average amount of time patients spent in the program was just under 4 months (112 days).[4]

Patient and Caregiver Engagement and Empowerment

Care managers establish a trusting relationship with patients and help them identify health care goals; any barriers that may be holding them back from achieving those goals, such as untreated depression or an exhausted caregiver; and ways to overcome the barriers. They educate patients about their conditions and medications so they can better understand their role in self-management. They also provide connections to community resources and support.

In the evaluation of CM+ at Intermountain, nearly half (47%) of encounters between care managers and patients involved establishing connections to community-based programs. Commonly needed services were those addressing caregiver fatigue, medication assistance, and financial concerns.[5] These are still common needs today, says Swanson, who adds that transportation to appointments is another problem area, especially for older patients who no longer drive. A local government agency, Salt Lake County Aging & Adult Services, offers a program in which volunteer drivers take older adults to doctors' appointments, but Swanson says many patients are not aware it exists. "As a care manager," she says, "you become an expert in what your community has to offer as far as no-cost or low-cost resources."

When possible, CM+ seeks to help patients and caregivers help themselves. "Care managers could spend an infinite amount of time with populations like these, so there has got to be a partnership with the patients," Dorr says. At OHSU, care managers try to draw on a patient's social support system, asking, "Is there someone in your life who can support you in these changes you are making and be an accountability partner?"

Use of a Specialized Clinical Information System

A suite of sophisticated health information technology tools for population management, developed at Intermountain and refined by Dorr and his team at OHSU, supports the work of care managers and the interdisciplinary care team. Known as the Integrated Care Coordination Information System (ICCIS), this web application "sits on top of" a patient's electronic health record (EHR) and is adaptable for use with several EHR systems.[6] ICCIS allows practices to:

- track patient encounters and record activities
- create "tickler," or reminder, lists
- perform assessments for depression and functional status (PHQ9 [Patient Health Questionnaire] and ADL/IADL [Activities of Daily Living/Instrumental Activities of Daily Living] questionnaires)
- generate clinic summary and quality performance reports.

Financing

In the primary care clinics at OHSU, the estimated salary and training cost for a care manager is $90,000 to $100,000 per year, based on the assumption that the care manager is a senior-level nurse and the practice has 8–10 providers. A specialized population-management information system to track patients, organize data, and generate performance reports for the primary care clinical team would be an additional cost for clinics that do not already have such a system in place, but most practices at OHSU have this system now. Smaller clinics with just 3 or 4 providers have made the model work less expensively by using a medical assistant as the care manager. "Very small clinics often have a more focused, constantly-in-touch team," Dorr says, "so the experience of the providers can be more easily shared with the medical assistant."

Primary care clinics may now be able to leverage alternative payment models, such as capitation, per-member, per-month fees and chronic-care management codes, to help offset the program's cost. A cost analysis of the program's implementation at Intermountain in the early 2000s, however, suggested that the program paid for itself through enhanced provider productivity. In the 7 primary care clinics at Intermountain where the program was tested, providers who referred patients to a care manager were 8%–12% more productive, as measured by relative value units, than providers at 14 control clinics that did not use the program.[7] The additional annual revenue generated as a result was estimated to be $99,986 per 7-physician clinic—almost $8,000 above the cost of the salary, training, and other expenses associated with employing a care manager ($92,077).[8] Home visits conducted by nurse care managers also can be a source of additional revenue for clinics that adopt CM+. Reimbursements for such visits can bring in an additional $10,000 per year in a 7-physician clinic.[8]

Since 2001, the Hartford Foundation has provided more than $5 million to develop and disseminate CM+. In November 2011, the Gordon and Betty Moore Foundation awarded OHSU a multiyear, $1.6 million grant to undertake a randomized controlled trial in 4 diverse health care settings within Oregon to determine whether an enhanced version of CM+ tailored for the patient-centered medical home environment would lead to improved patient outcomes and lower costs of care. The Agency for Healthcare Research and Quality (AHRQ) and the National Library of Medicine (NLM) also have provided funding for the program.

Results

The controlled clinical trial at Intermountain in the early 2000s found that patients enrolled in CM+ had slightly more emergency department visits but lower annual mortality rates than those in the control group. Patients with diabetes especially benefited: in addition to lower mortality, they had significantly fewer hospitalizations than diabetic patients in the control group (see chart below). The potential savings to Medicare from decreased hospitalizations were estimated at $70,349 per clinic per year for diabetic patients enrolled in the program.[9]

Next Steps

Leaders are examining how the principles of the CM+ model can be applied to serve persistently high-use high-cost patients who may benefit from more intensive care management than can be provided in a primary care clinic setting. Garrett, of the University of Utah College of Nursing,[10] says that in a new world of value-based purchasing and alternative payment models, "a sweet spot moving forward is to understand how a comprehensive care-management approach can help patients who have truly complex disease management, social determinants of health, and behavioral health issues be healthier." **CE II**

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PharmaFacts for Case Managers

MVASI (bevacizumab-awwb) Solution for intravenous infusion

MVASI is a vascular endothelial growth factor-specific angiogenesis inhibitor.

INDICATIONS AND USAGE

Metastatic Colorectal Cancer (mCRC)

MVASI is indicated for the first-or second-line treatment of patients with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil (5-FU)–based chemotherapy.

MVASI, in combination with fluoropyrimidine-irinotecan– or fluoropyrimidine-oxaliplatin–based chemotherapy, is indicated for the second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab product-containing regimen.

Limitation of Use: MVASI is not indicated for adjuvant treatment of colon cancer..

Non-Squamous Non–Small Cell Lung Cancer (NSCLC)

MVASI is indicated for the first-line treatment of unresectable, locally advanced, recurrent or metastatic non–squamous non–small cell lung cancer in combination with carboplatin and paclitaxel.

Glioblastoma

MVASI is indicated for the treatment of glioblastoma with progressive disease in adult patients following prior therapy as a single agent.

The effectiveness of bevacizumab products in glioblastoma is based on an improvement in objective response rate. There are no data demonstrating an improvement in disease-related symptoms or increased survival with bevacizumab products.

Metastatic Renal Cell Carcinoma (mRCC)

MVASI is indicated for the treatment of metastatic renal cell carcinoma in combination with interferon alfa.

Persistent, Recurrent, or Metastatic Carcinoma of the Cervix

MVASI in combination with paclitaxel and cisplatin or paclitaxel and topotecan is indicated for the treatment of persistent, recurrent, or metastatic carcinoma of the cervix.

DOSAGE AND ADMINISTRATION

Administration

Administer only as an intravenous (IV) infusion. Do not administer as an intravenous push or bolus.

- Do not initiate MVASI until at least 28 days following major surgery. Administer MVASI after the surgical incision has fully healed.
- First infusion: Administer infusion over 90 minutes.
- Subsequent infusions: Administer second infusion over 60 minutes if first infusion is tolerated; administer all subsequent infusions over 30 minutes if infusion over 60 minutes is tolerated.

Recommended Doses and Schedules

Patients should continue treatment until disease progression or unacceptable toxicity.

Metastatic Colorectal Cancer (mCRC)

The recommended doses are 5 mg/kg or 10 mg/kg every 2 weeks when used in combination with intravenous 5-FU-based chemotherapy.

- Administer 5 mg/kg every 2 weeks when used in combination with bolus-IFL.
- Administer 10 mg/kg every 2 weeks when used in combination with FOLFOX4.
- Administer 5 mg/kg every 2 weeks or 7.5 mg/kg every 3 weeks when used in combination with a fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin–based chemotherapy regimen in patients who have progressed on a first-line bevacizumab product-containing regimen.

Non-Squamous Non-Small Cell Lung Cancer (NSCLC)

The recommended dose is 15 mg/kg every 3 weeks in combination with carboplatin and paclitaxel.

Glioblastoma

The recommended dose is 10 mg/kg every 2 weeks.

Metastatic Renal Cell Carcinoma (mRCC)

The recommended dose is 10 mg/kg every 2 weeks in combination with interferon alfa.

Cervical Cancer

The recommended dose of MVASI is 15 mg/kg every 3 weeks as an intravenous infusion administered in combination with one of the following chemotherapy regimens: paclitaxel and cisplatin or paclitaxel and topotecan.

Preparation for Administration

Use appropriate aseptic technique. Parenteral drug products should be inspected visually for particulate matter and discoloration before administration. MVASI is a colorless-to-pale yellow solution. Do not use vial if solution is cloudy, discolored, or contains particulate matter.

Withdraw necessary amount of MVASI and dilute in a total volume of 100 mL of 0.9% Sodium Chloride Injection, USP. Discard any unused portion left in a vial, as the product contains no preservatives.

Diluted MVASI solutions may be stored at 2-8°C (36-46°F) for up to 8 hours.

DO NOT ADMINISTER OR MIX WITH DEXTROSE SOLUTION.

Dose Modifications

There are no recommended dose reductions.

Discontinue MVASI for:

- Gastrointestinal perforations (gastrointestinal perforations, fistula formation in the gastrointestinal tract, intra-abdominal abscess), fistula formation involving an internal organ
- Wound dehiscence and wound healing complications requiring medical intervention
- Serious hemorrhage (ie, requiring medical intervention)
- Severe arterial thromboembolic events
- Life-threatening (Grade 4) venous thromboembolic events, including pulmonary embolism
- Hypertensive crisis or hypertensive encephalopathy
- Posterior Reversible Encephalopathy Syndrome
- Nephrotic syndrome

Temporarily suspend MVASI for:

- At least 4 weeks before elective surgery
- Severe hypertension not controlled with medical management
- Moderate-to-severe proteinuria
- Severe infusion reactions

DOSAGE FORMS AND STRENGTHS

- Injection: 100 mg/4 mL (25 mg/mL) colorless-to-pale yellow, preservative-free, single-dose vial.
- Injection: 400 mg/16 mL (25 mg/mL colorless-to-pale yellow, preservative-free, single-dose vial.

WARNINGS

See Box 1.

WARNINGS AND PRECAUTIONS

Gastrointestinal Perforations and Fistulae

Serious and sometimes fatal gastrointestinal perforation occurs at a higher incidence in bevacizumab-treated patients compared with controls. The incidence of gastrointestinal perforation ranged from 0.3 to 3.2% across clinical studies. From a clinical trial in patients with persistent, recurrent, or metastatic cervical cancer, gastrointestinal perforations were reported in 3.2% of bevacizumab–treated patients, all of whom had a history of prior pelvic radiation. Fatal outcome was reported in <1% of bevacizumab-treated patients.

The typical presentation may include abdominal pain, nausea, emesis, constipation, and fever. Perforation can be complicated by intra-abdominal abscess, fistula formation, and the need for diverting ostomies. Most cases occurred within the first 50 days of initiation of bevacizumab. Permanently discontinue MVASI in patients with gastrointestinal perforation.

In bevacizumab clinical trials, gastrointestinal fistulae have been reported with an incidence of up to 2% in patients with metastatic colorectal cancer. In a cervical cancer trial, the incidence of gastrointestinal-vaginal fistulae was 8.3% in bevacizumab-treated patients and 0.9% in control patients, all of whom had a history of prior pelvic radiation. Patients who develop gastrointestinal vaginal fistulas may also have bowel obstructions and require surgical intervention as well as diverting ostomies.

BOX 1

WARNING: GASTROINTESTINAL PERFORATIONS, SURGERY AND WOUND HEALING COMPLICATIONS, and HEMORRHAGE

Gastrointestinal Perforations

The incidence of gastrointestinal perforation, some fatal, in bevacizumab product-treated patients ranges from 0.3 to 3.2%. Discontinue MVASI in patients with gastrointestinal perforation.

Surgery and Wound Healing Complications

The incidence of wound healing and surgical complications, including serious and fatal complications, is increased in bevacizumab product-treated patients. Discontinue MVASI in patients with wound dehiscence. The appropriate interval between termination of bevacizumab products and subsequent elective surgery required to reduce the risks of impaired wound healing/wound dehiscence has not been determined. Discontinue at least 28 days before elective surgery. Do not initiate MVASI for at least 28 days after surgery and until the surgical wound is fully healed.

Hemorrhage

Severe or fatal hemorrhage, including hemoptysis, gastrointestinal bleeding, central nervous systems (CNS) hemorrhage, epistaxis, and vaginal bleeding occur up to five-fold more frequently in patients receiving bevacizumab products. Do not administer MVASI to patients with serious hemorrhage or recent hemoptysis.

Nongastrointestinal Fistulae
Serious and sometimes fatal fistula formation involving tracheo-esophageal, bronchopleural, biliary, vaginal, and renal and bladder sites occurs at a higher incidence in bevacizumab-treated patients compared with controls. Uncommon (<1%) reports of fistulae that involve areas of the body other than the gastrointestinal tract were observed in clinical trials across various indications and have also been reported in postmarketing experience. Most events occurred within the first 6 months of bevacizumab therapy.

From a clinical trial in patients with persistent, recurrent, or metastatic cervical cancer, 1.8% of bevacizumab-treated patients and 1.4% of control patients were reported to have had non-gastrointestinal vaginal, vesical, or female genital tract fistulae.

Permanently discontinue MVASI in patients with tracheo-esophageal fistula or any Grade 4 fistula. Discontinue MVASI in patients with fistula formation involving an internal organ .

Surgery and Wound Healing Complications
Bevacizumab products impair wound healing in animal models. In clinical trials, administration of bevacizumab was not allowed until at least 28 days after surgery. In a controlled clinical trial, the incidence of wound healing complications, including serious and fatal complications, in patients with mCRC who underwent surgery during the course of bevacizumab treatment was 15% and in patients who did not receive bevacizumab, was 4%.

MVASI should not be initiated for at least 28 days following surgery and until the surgical wound is fully healed. Discontinue MVASI in patients with wound healing complications requiring medical intervention.

The appropriate interval between the last dose of a bevacizumab product and elective surgery is unknown; however, the half-life of bevacizumab products is approximately 20 days. Suspend MVASI for at least 28 days before elective surgery. Do not administer MVASI until the wound is fully healed.

Necrotizing fasciitis including fatal cases, has been reported in patients treated with bevacizumab products; usually secondary to wound healing complications, gastrointestinal perforation or fistula formation. Discontinue MVASI therapy in patients who develop necrotizing fasciitis.

Hemorrhage
Bevacizumab products can result in two distinct patterns of bleeding: minor hemorrhage, most commonly Grade 1 epistaxis; and serious, and in some cases fatal, hemorrhagic events. Severe or fatal hemorrhage, including hemoptysis, gastrointestinal bleeding, hematemesis, CNS hemorrhage, epistaxis, and vaginal bleeding occurred up to five-fold more frequently in patients receiving bevacizumab compared with patients receiving only chemotherapy. Across indications, the incidence of Grade ≥ 3 hemorrhagic events among patients receiving bevacizumab ranged from 0.4 to 6.9%

Serious or fatal pulmonary hemorrhage occurred in four of 13 (31%) patients with squamous cell histology and two of 53 (4%) patients with non-squamous non–small cell lung cancer receiving bevacizumab and chemotherapy compared with none of the 32 (0%) patients receiving chemotherapy alone.

In clinical studies in non–small cell lung cancer where patients with CNS metastases who completed radiation and surgery more than 4 weeks before the start of bevacizumab were evaluated with serial CNS imaging, symptomatic Grade 2 CNS hemorrhage was documented in one of 83 bevacizumab-treated patients (rate 1.2%, 95% CI: 0.06%-5.93%).

Intracranial hemorrhage occurred in 8 of 163 patients with previously treated glioblastoma; 2 patients had Grade 3-4 hemorrhage.

Do not administer MVASI to patients with recent history of hemoptysis of ≥1/2 teaspoon of red blood. Discontinue MVASI in patients with hemorrhage

Arterial Thromboembolic Events
Serious, sometimes fatal, arterial thromboembolic events (ATEs) including cerebral infarction, transient ischemic attacks, myocardial infarction, angina, and a variety of other ATEs occurred at a higher incidence in patients receiving bevacizumab compared with those in the control arm. Across indications, the incidence of Grade ≥3 ATEs in the bevacizumab-containing arms was 2.6% compared with 0.8% in the control arms. Among patients receiving bevacizumab in combination with chemotherapy, the risk of developing ATEs during therapy was increased in patients with a history of arterial thromboembolism, diabetes, or age >65 years.

The safety of resumption of bevacizumab products therapy after resolution of an ATE has not been studied. Discontinue MVASI in patients who experience a severe ATE.

Venous Thromboembolic Events
Patients treated for persistent, recurrent, or metastatic cervical cancer with bevacizumab products may be at increased risk of venous thromboembolic events (VTEs).

From a clinical trial in patients with persistent, recurrent, or metastatic cervical cancer, Grade ≥3 VTEs were reported in 10.6% of patients treated with chemotherapy and bevacizumab compared with 5.4% in patients receiving chemotherapy alone. Permanently discontinue MVASI in patients with life-threatening (Grade 4) VTEs, including pulmonary embolism

Hypertension
The incidence of severe hypertension is increased in patients receiving bevacizumab products compared with controls. Across clinical studies. the incidence of Grade 3 or 4 hypertension ranged from 5% to 18%.

Monitor blood pressure every 2–3 weeks during treatment with MVASI. Treat with appropriate antihypertensive therapy

and monitor blood pressure regularly. Continue to monitor blood pressure at regular intervals in patients with MVASI-induced or-exacerbated hypertension after discontinuation of MVASI.

Temporarily suspend MVASI in patients with severe hypertension that is not controlled with medical management. Discontinue MVASI in patients with hypertensive crisis or hypertensive encephalopathy.

Posterior Reversible Encephalopathy Syndrome (PRES)
PRES has been reported with an incidence of <0.5% in clinical studies. The onset of symptoms occurred from 16 hours to 1 year after initiation of bevacizumab. PRES is a neurological disorder that can present with headache, seizure, lethargy, confusion, blindness, and other visual and neurologic disturbances. Mild to severe hypertension may be present. Magnetic resonance imaging (MRI) is necessary to confirm the diagnosis of PRES.

Discontinue MVASI in patients developing PRES. Symptoms usually resolve or improve within days, although some patients have experienced ongoing neurologic sequelae. The safety of reinitiating bevacizumab product therapy in patients previously experiencing PRES is not known.

Proteinuria
The incidence and severity of proteinuria is increased in patients receiving bevacizumab products compared with controls. Nephrotic syndrome occurred in <1% of patients receiving bevacizumab in clinical trials, in some instances with fatal outcome. In a published case series, kidney biopsy of 6 patients with proteinuria showed findings consistent with thrombotic microangiopathy.

Monitor proteinuria by dipstick urine analysis for the development or worsening of proteinuria with serial urinalyses during MVASI therapy. Patients with a 2+ or greater urine dipstick reading should undergo further assessment with a 24-hour urine collection.

Suspend MVASI administration for ≥2 g of proteinuria/24 hours and resume when proteinuria is <2 g/24 hours. Discontinue MVASI in patients with nephrotic syndrome. Data from a postmarketing safety study showed poor correlation between UPCR (urine protein/creatinine ratio) and 24-hour urine protein (Pearson correlation, 0.39 [95% CI 0.17, 0.57]).

Infusion Reactions
Infusion reactions reported in the clinical trials and postmarketing experience include hypertension, hypertensive crises associated with neurologic signs and symptoms, wheezing, oxygen desaturation, Grade 3 hypersensitivity, chest pain, headaches, rigors, and diaphoresis. In clinical studies, infusion reactions with the first dose of bevacizumab were uncommon (<3%) and severe reactions occurred in 0.2% of patients.

Stop infusion if a severe infusion reaction occurs and administer appropriate medical therapy.

Embryo-Fetal Toxicity
Bevacizumab products may cause fetal harm based on the drug's mechanism of action and findings from animal studies. Congenital malformations were observed with the administration of bevacizumab to pregnant rabbits during organogenesis every 3 days at a dose as low as a clinical dose of 10 mg/kg. Furthermore, animal models link angiogenesis and VEGF and VEGF receptor 2 (VEGFR2) to critical aspects of female reproduction, embryo-fetal development, and postnatal development.

Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with and for 6 months after the last dose of MVASI.

Ovarian Failure
The incidence of ovarian failure was higher (34% vs. 2%) in premenopausal women receiving bevacizumab in combination with mFOLFOX chemotherapy compared with those receiving mFOLFOX chemotherapy alone for adjuvant treatment for colorectal cancer, a use for which bevacizumab products are not approved. Inform females of reproductive potential of the risk of ovarian failure before starting treatment with MVASI.

ADVERSE REACTIONS

The most common adverse reactions observed in bevacizumab patients at a rate >10% and at least twice the control arm rate are epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, rectal hemorrhage, lacrimation disorder, back pain, and exfoliative dermatitis. Some of the adverse reactions are commonly seen with chemotherapy; however, bevacizumab products may exacerbate these reactions when combined with chemotherapeutic agents. Examples include palmar-plantar erythrodysesthesia syndrome with capecitabine, peripheral sensory neuropathy with paclitaxel or oxaliplatin, and nail disorders or alopecia with paclitaxel.

Across all studies, bevacizumab was discontinued in 8.4% to 21% of patients because of adverse reactions.

HOW SUPPLIED/STORAGE AND HANDLING

MVASI (bevacizumab-awwb) injection is supplied as a sterile, colorless-to-pale yellow, preservative-free solution containing 25 mg/mL bevacizumab-awwb in a single-dose vial. The vial stopper contains dry natural rubber.

MVASI is provided as one vial per carton. Each single dose vial contains:

- 100 mg of bevacizumab-awwb in 4 mL (25 mg/mL)
- 400 mg of bevacizumab-awwb in 16 mL (25 mg/mL)

Store at 2-8°C (36-46°F) in the original carton until time of use. MVASI vials should be protected from light. Do not freeze or shake. Discard any unused portion remaining in the vial.

MVASI is manufactured by Amgen, Inc.

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AIDS. 2017 Sep 18. doi: 10.1097/QAD.0000000000001650. [Epub ahead of print]

Elevated ischemic stroke risk among women living with HIV infection.

Chow FC, Regan S, Zanni MV, et al.

OBJECTIVE: To determine if the greater risk of ischemic stroke observed in women living with HIV infection (WLWH) compared with HIV-uninfected women persists after accounting for both traditional and sex-specific stroke risk factors. METHODS: We performed an observational cohort study of WLWH (n=1,214) and demographics-matched HIV-uninfected women (n=12,041) seen between 1996 and 2011 at two tertiary care hospitals in Boston. We used Cox proportional hazards regression analyses to model time to ischemic stroke, adjusting first for demographics and traditional stroke risk factors and then for sex-specific stroke risk factors, including menopause and estrogen use. We also constructed demographics-adjusted Cox models to identify HIV-related risk factors associated with ischemic stroke among WLWH. RESULTS: The incidence of ischemic stroke was higher among WLWH compared with HIV-uninfected women (incidence rate ratio 2.39, 95% CI 1.62-3.43). After adjusting for demographics and traditional stroke risk factors, HIV infection was associated with almost twice the risk of ischemic stroke (hazard ratio (HR) 1.93, 95% CI 1.31-2.85). The association of HIV with ischemic stroke persisted after inclusion of sex-specific stroke risk factors in the model (HR 1.89, 95% CI 1.28-2.81). Among WLWH, longer duration of antiretroviral therapy was associated with lower ischemic stroke risk (HR 0.86 per year, 95% CI 0.76-0.96). CONCLUSION: The increased risk of ischemic stroke among WLWH compared with HIV-uninfected women persisted after adjusting for both traditional and sex-specific stroke risk factors. Further investigation into the mechanisms of elevated stroke risk among WLWH, including immunologic factors, will be key for developing targeted preventive strategies for this at-risk population.

Antivir Ther. 2017 Sep 21. doi: 10.3851/IMP3195. [Epub ahead of print]

Longitudinal study of falls among HIV-infected and uninfected women: the role of cognition.

Sharma A, Hoover DR, Shi Q, et al.

BACKGROUND: Although fracture rates are higher in HIV+ than HIV- women, whether HIV infection increases risk of falls is unclear. We determined the longitudinal occurrence and risk factors for falls in the Women's Interagency HIV Study (WIHS), and explored associations with cognitive complaints. METHODS: Recent (prior 6 months) self-reported falls were collected in 1816 (1250 HIV+; 566 HIV-) women over 24 months. Generalized estimating equation models using stepwise selection determined odds of any fall (vs. none). RESULTS: HIV+ women were older than HIV- women (median 49 vs. 47yrs, p=0.0004), more likely to report neuropathy (20% vs. 16%, p=0.023), and had greater central nervous system (CNS) medication use. At least one fall was reported in 41% HIV+ vs. 42% HIV- women, including ≥2 falls in 25% HIV+ and 24% HIV- (overall p =0.30). Cognitive complaints were associated with falls among HIV+ [odds ratio (OR) 2.38; 95% CI: 1.83-3.09] and HIV- women (OR 3.43; 95% CI: 2.37-4.97); in adjusted models, cognitive complaints remained significant only in HIV- women [adjusted (aOR) 2.26; 95%CI: 1.46, 3.48)]. Factors associated with any fall in adjusted analyses included: depressive symptoms and neuropathy (both HIV+ and HIV-); age, marijuana use, multiple CNS medications, and hepatitis C virus infection (HIV+ only); and cognitive complaints, quality of life, hypertension, and obesity (HIV- only). CONCLUSIONS: Middle-aged HIV+ and HIV- women had similar fall rates. Among HIV+ women, factors affecting cognition such as age, depressive symptoms, marijuana use, and multiple CNS medications were important predictors of falls, however cognitive complaints were not.

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Dig Dis Sci. 2017 Sep 14. doi: 10.1007/s10620-017-4754-0. [Epub ahead of print]

Risk factor analysis between newly screened and established hepatitis C in GI and hepatology clinics.

Hossain N, Puchakayala B, Kanwar P, et al.

BACKGROUND: Several studies show inconsistencies in the rate of hepatitis C virus (HCV) detection among baby boomers (born 1945-1965). We conducted a cross-sectional HCV screening followed by a case-controlled comparison of the newly screened population with established HCV subjects. METHOD: Enrollment was offered to subjects aged 40-75 at our gastroenterology and hepatology clinics. Demographic data and potential risk factors were obtained, and HCV antibody test was offered to those who had never been screened and compared with a group with established HCV. Logistic regression analysis and Fisher's exact test were performed. RESULTS: Six hundred and seventy-five patients were offered participation, of whom 128 declined while 50 consented to participate but did not perform the HCV antibody test. Of 497 enrolled subjects, 252 patients had HCV, while 245 subjects (188 patients among "baby boomer") underwent screening for HCV. There were more females (62.4 vs. 41.7%) and immigrants (34.7 vs. 22.2%) among the newly screened group. Among the screened population, five patients had HCV antibody (2.04%), and two of them had positive viral load (0.82%) of whom only one fell in the baby boomer category (0.53%). Compared to HCV group, screened group had significantly lower-risk factors, such as IV drug use (1.22 vs. 43.3%), intranasal cocaine use (14.3 vs. 49.6%), and blood transfusion (18.8 vs. 32.5%). CONCLUSION: We found a slightly lower but similar prevalence of HCV antibody when screening based on birth cohort as compared to larger baby boomer studies. Future studies evaluating addition of other screening strategies or possibly universal screening may be needed.

ASAIO J. 2017 Sep 12. doi: 10.1097/MAT.0000000000000599. [Epub ahead of print]

Utilization and outcomes of temporary mechanical circulatory support for graft dysfunction after heart transplantation.

Phan K, Luc JGY, Xu J, et al.

Graft dysfunction is the main cause of early mortality after heart transplantation. In cases of severe graft dysfunction, temporary mechanical circulatory support (TMCS) may be necessary. The aim of this systematic review was to examine the utilization and outcomes of TMCS in patients with graft dysfunction after heart transplantation. Electronic search was performed to identify all studies in the English literature assessing the use of TMCS for graft dysfunction. All identified articles were systematically assessed for inclusion and exclusion criteria. Of the 5,462 studies identified, 41 studies were included. Among the 11,555 patients undergoing heart transplantation, 695 (6.0%) required TMCS with patients most often supported using venoarterial extracorporeal membrane oxygenation (79.4%) followed by right ventricular assist devices (11.1%), biventricular assist devices (BiVADs) (7.5%), and left ventricular assist devices (LVADs) (2.0%). Patients supported by LVADs were more likely to be supported longer ($p = 0.003$), have a higher death by cardiac event ($p = 0.013$) and retransplantation rate ($p = 0.015$). In contrast, patients supported with BiVAD and LVAD were more likely to be weaned off support ($p = 0.020$). Overall, no significant difference was found in pooled 30 day survival ($p = 0.31$), survival to discharge ($p = 0.19$), and overall survival ($p = 0.51$) between the subgroups. Temporary mechanical circulatory support is an effective modality to support patients with graft dysfunction after heart transplantation. Further studies are needed to establish the optimal threshold and strategy for TMCS and to augment cardiac recovery and long-term survival.

Am J Med. 2017 Sep;130(9):1011-1014. doi: 10.1016/j.amjmed.2017.04.040. Epub 2017 May 22.

The history of the Salt Wars.

DiNicolantonio JJ, O'Keefe JH.

The "Salt-Blood Pressure Hypothesis" states that an increase in the intake of salt leads to an increased in blood pressure and subsequently increases the risk for cardiovascular events, which has been a point of contention for decades. This article covers the history and some of the key players pertaining to "The Salt Wars" during the first half of the 1900s, both in Europe and in the United States. Early studies finding benefits with salt restriction in those with hypertension were based on uncontrolled case reports. The overall evidence in the first half of the 1900s suggests that a low-salt diet was not a reasonable strategy for treating hypertension.

Circulation. 2017 Aug 29;136(9):798-812. doi: 10.1161/CIRCULATIONAHA.117.027362. Epub 2017 Jun 20.

Incident cardiovascular disease among adults with blood pressure <140/90 mm Hg.

Tajeu GS, Booth JN III, Colantonio LD, et al.

BACKGROUND: Data from before the 2000s indicate that the majority of incident cardiovascular disease (CVD) events occur among US adults with systolic and diastolic blood pressure (SBP/DBP) ≥140/90 mm Hg. Over the past several decades, BP has declined and hypertension control has improved. METHODS: We estimated the percentage of incident CVD events that occur at SBP/DBP <140/90 mm Hg in a pooled analysis of 3 contemporary US cohorts: the REGARDS study (Reasons for Geographic and Racial Differences in Stroke), the MESA (Multi-Ethnic Study of Atherosclerosis), and the JHS (Jackson Heart Study) (n=31 856; REGARDS=21 208; MESA=6779; JHS=3869). Baseline study visits were conducted in 2003 to 2007 for REGARDS, 2000 to 2002 for MESA, and 2000 to 2004 for JHS. BP was measured by trained staff using standardized methods. Antihypertensive medication use was self-reported. The primary outcome was incident CVD, defined by the first occurrence of fatal or nonfatal stroke, nonfatal myocardial infarction, fatal coronary heart disease, or heart failure. Events were adjudicated in each study. RESULTS: Over a mean follow-up of 7.7 years, 2584 participants had incident CVD events. Overall, 63.0% (95% confidence interval [CI], 54.9-71.1) of events occurred in participants with SBP/DBP <140/90 mm Hg; 58.4% (95% CI, 47.7-69.2) and 68.1% (95% CI, 60.1-76.0) among those taking and not taking antihypertensive medication, respectively. The majority of events occurred in participants with SBP/DBP <140/90 mm Hg among those <65 years of age (66.7%; 95% CI, 60.5-73.0) and ≥65 years of age (60.3%; 95% CI, 51.0-69.5), women (61.4%; 95% CI, 49.9-72.9) and men (63.8%; 95% CI, 58.4-69.1), and for whites (68.7%; 95% CI, 66.1-71.3), blacks (59.0%; 95% CI, 49.5-68.6), Hispanics (52.7%; 95% CI, 45.1-60.4), and Chinese-Americans (58.5%; 95% CI, 45.2-71.8). Among participants taking antihypertensive medication with SBP/DBP <140/90 mm Hg, 76.6% (95% CI, 75.8-77.5) were eligible for statin treatment, but only 33.2% (95% CI, 32.1-34.3) were taking one, and 19.5% (95% CI, 18.5-20.5) met the SPRINT (Systolic Blood Pressure Intervention Trial) eligibility criteria and may benefit from a SBP target goal of 120 mm Hg. CONCLUSIONS: Although higher BP levels are associated with increased CVD risk, in the modern era, the majority of incident CVD events occur in US adults with SBP/DBP <140/90 mm Hg. While absolute risk and cost-effectiveness should be considered, additional CVD risk-reduction measures for adults with SBP/DBP <140/90 mm Hg at high risk for CVD may be warranted.

Acad Emerg Med. 2017 Sep 16. doi: 10.1111/acem.13311. [Epub ahead of print]

Implementation and preliminary clinical outcomes of a pharmacist-managed venous thromboembolism clinic for patients treated with rivaroxaban post emergency department discharge.

DiRenzo BM, Beam DM, Kline JA, et al.

OBJECTIVE: To describe the implementation, work flow, and differences in outcomes between a pharmacist-managed clinic for the outpatient treatment of venous thromboembolism (VTE) using rivaroxaban versus care by a primary care provider. INTERVENTIONS: Patients in the studied health system that are diagnosed with low-risk VTE in the emergency department are often discharged without hospital admission. These patients are treated with rivaroxban and follow up either in a pharmacist-managed VTE clinic or with their primary care provider. Pharmacists in the VTE clinic work independently under a collaborative practice agreement. An evaluation of thirty-four patients, seventeen in each treatment arm, was conducted to compare the differences in treatment-related outcomes of rivaroxaban when managed by a pharmacist versus a primary care provider. RESULTS: The primary endpoint was a six month composite of anticoagulation treatment-related complications that included a diagnosis of major bleeding, recurrent thromboembolism, or fatality due to either major bleeding or recurrent thromboembolism. Secondary endpoints included number of hospitalizations, adverse events, and medication adherence. There was no difference in the primary endpoint between groups with one occurrence of the composite endpoint in each treatment arm (p=1.000), both of which were recurrent thromboembolic events. Medication adherence assessment was formally performed in 8 patients in the pharmacist group versus 0 patients in the control group. No differences were seen amongst other secondary endpoints. CONCLUSIONS: The pharmacist-managed clinic is a novel expansion of clinical pharmacy services that treats patients with low-risk VTEs with rivaroxaban in the outpatient setting. The evaluation of outcomes provides support

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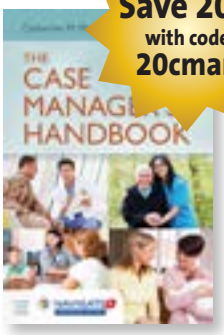

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that pharmacist-managed care utilizing standardized protocols under a collaborative practice agreement may be as safe as care by a primary care provider.

J Natl Cancer Inst. 2018 Jan 1;110(1). doi: 10.1093/jnci/djx119.

Circulating folate, vitamin B6, and methionine in relation to lung cancer risk in the Lung Cancer Cohort Consortium (LC3).

Fanidi A, Muller DC, Yuan JM, et al.

BACKGROUND: Circulating concentrations of B vitamins and factors related to one-carbon metabolism have been found to be strongly inversely associated with lung cancer risk in the European Prospective Investigation into Cancer and Nutrition (EPIC) study. The extent to which these associations are present in other study populations is unknown. METHODS: Within 20 prospective cohorts from the National Cancer Institute Cohort Consortium, a nested case-control study was designed including 5364 incident lung cancer case patients and 5364 control subjects who were individually matched to case patients by age, sex, cohort, and smoking status. Centralized biochemical analyses were performed to measure circulating concentrations of vitamin B6, folate, and methionine, as well as cotinine as an indicator of recent tobacco exposure. The association between these biomarkers and lung cancer risk was evaluated using conditional logistic regression models. RESULTS: Participants with higher circulating concentrations of vitamin B6 and folate had a modestly decreased risk of lung cancer risk overall, the odds ratios when comparing the top and bottom fourths (OR 4vs1) being 0.88 (95% confidence interval [CI] = 0.78 to 1.00) and 0.86 (95% CI = 0.74 to 0.99), respectively. We found stronger associations among men (vitamin B6: OR 4vs1 = 0.74, 95% CI = 0.62 to 0.89; folate: OR 4vs1 = 0.75, 95% CI = 0.61 to 0.93) and ever smokers (vitamin B6: OR 4vs1 = 0.78, 95% CI = 0.67 to 0.91; folate: OR 4vs1 = 0.87, 95% CI = 0.73 to 1.03). We further noted that the association of folate was restricted to Europe/Australia and Asia, whereas no clear association was observed for the United States. Circulating concentrations of methionine were not associated with lung cancer risk overall or in important subgroups. CONCLUSIONS: Although confounding by tobacco exposure or reverse causation cannot be ruled out, these study results are compatible with a small decrease in lung cancer risk in ever smokers who avoid low concentrations of circulating folate and vitamin B6.

Hepatology. 2017 Aug;66(2):564-574. doi: 10.1002/hep.29219. Epub 2017 Jun 28.

Development of a novel frailty index to predict mortality in patients with end-stage liver disease.

Lai JC, Covinsky KE, Dodge JL, et al.

Cirrhosis is characterized by muscle wasting, malnutrition, and functional decline that confer excess mortality not well quantified by the Model for End-Stage Liver Disease (MELD) Sodium (MELDNa) score. We aimed to develop a frailty index to capture these extrahepatic complications of cirrhosis and enhance mortality prediction in patients with cirrhosis. Consecutive outpatients listed for liver transplantation at a single transplant center without MELD exceptions were assessed with candidate frailty measures. Best subset selection analyses with Cox regression identified subsets of frailty measures that predicted waitlist mortality (=death or delisting because of sickness). We selected the frailty index by balancing statistical accuracy with clinical utility. The net reclassification index (NRI) evaluated the percentage of patients correctly reclassified by adding the frailty index to MELDNa. Included were 536 patients with cirrhosis with median MELDNa of 18. One hundred seven (20%) died/were delisted. The final frailty index consisted of: grip strength, chair stands, and balance. The ability of MELDNa and the frailty index to correctly rank patients according to their 3-month waitlist mortality risk (i.e., concordance-statistic) was 0.80 and 0.76, respectively, but 0.82 for MELDNa+frailty index together. Compared with MELDNa alone, MELDNa+frailty index correctly reclassified 16% of deaths/delistings (P = 0.005) and 3% of nondeaths/delistings (P = 0.17) with a total NRI of 19% (P < 0.001). Compared to those with robust frailty index scores (<20th percentile), cirrhotics with poor frailty index scores (>80th percentile) were more impaired by gait speed, difficulty with Instrumental Activities of Daily Living, exhaustion, and low physical activity (P < 0.001 for each). CONCLUSION: Our frailty index for patients with cirrhosis, comprised of three performance-based metrics, has construct validity for the concept of frailty and improves risk prediction of waitlist mortality over MELDNa alone.

Gynecol Oncol. 2017 Sep;146(3):457-464. doi: 10.1016/j.ygyno.2017.06.012. Epub 2017 Jun 20.

Insurance coverage among women diagnosed with a gynecologic malignancy before and after implementation of the Affordable Care Act.

Moss HA, Havrilesky LH, Chino J.

OBJECTIVE: The Patient Protection and Affordable Care Act (ACA) included provisions to expand insurance coverage by expanding Medicaid eligibility, providing subsidies of private coverage and enforcing an individual mandate. The objective of this study is to examine the impact of the ACA on insurance rates among women diagnosed with a gynecologic malignancy. METHODS: Using Surveillance, Epidemiology, and End Results 18 registries database, women newly diagnosed with cervical, uterine or ovarian cancer between 2008 and 2014 were identified. Insurance rates were examined before and after the passage of the ACA (2011) as well as before (January 2011-December 2013) versus after (January 2014-December 2014) Medicaid expansion to examine the impact of specific provisions. Rates of insurance were then compared between states that elected for expansion of Medicaid in 2014 vs. those states that had not. RESULTS: Among 181,866 diagnosed with cervical, uterine or ovarian cancer, there was a significant increase in patients enrolled in Medicaid after 2011. Between 2011 and 2014, there was a significant decrease in the rates of uninsured for all cancer types ($p=0.001$). Uninsured rates decreased by 50% for those diagnosed with uterine and ovarian cancer (6% to 3% and 8% to 4% respectively, $p\leq0.001$), and by 25% in cervical cancer (8.9% to 6.7%, $p=0.001$) after January 2014. Decreases in the rate of the uninsured and associated increases in insurance coverage were only observed in states which expanded Medicaid coverage ($p\leq0.001$). CONCLUSIONS: The Affordable Care Act resulted in expanded insurance coverage for women diagnosed with a gynecologic cancer, however, the impact was significantly increased in states which increased their Medicaid eligibility in 2014.

Am J Med. 2017 Sep;130(9):1015-1023. doi: 10.1016/j.amjmed.2017.04.015. Epub 2017 May 11.

Renal function considerations for stroke prevention in atrial fibrillation.

Fanikos J, Burnett AE, Mahan CE, Dobesh PP.

Renal impairment increases risk of stroke and systemic embolic events and bleeding in patients with atrial fibrillation. Direct oral anticoagulants (DOACs) have varied dependence on renal elimination, magnifying the importance of appropriate patient selection, dosing, and periodic kidney function monitoring. In randomized controlled trials of nonvalvular atrial fibrillation, DOACs were at least as effective and associated with less bleeding compared with warfarin. Each direct oral anticoagulant was associated with reduced risk of stroke and systemic embolic events and major bleeding compared with warfarin in nonvalvular atrial fibrillation patients with mild or moderate renal impairment. Renal function decrease appears less impacted by DOACs, which are associated with a better risk-benefit profile than warfarin in patients with decreasing renal function over time. Limited data address the risk-benefit profile of DOACs in patients with severe impairment or on dialysis.

Diabetes Care. 2017 Sep 20. pii: dc171118. doi: 10.2337/dc17-1118. [Epub ahead of print]

Cumulative kidney complication risk by 50 years of type 1 diabetes: the effects of sex, age, and calendar year at onset.

Costacou T, Orchard TJ.

OBJECTIVE: A common belief is that only a minority of patients with type 1 diabetes (T1D) develop advanced kidney disease and that incidence is higher among men and lower in those diagnosed at a younger age. However, because few patients with T1D survived to older ages until recently, long-term risks have been unclear. RESEARCH DESIGN AND METHODS: We examined the 50-year cumulative kidney complication risk in a childhood-onset T1D cohort diagnosed during 1950-80 (n = 932; mean baseline age 29 years, duration 19 years). Participants were 144 who died before baseline, 130 followed with periodic surveys, and 658 followed with biennial surveys and a maximum of nine examinations for 25 years. Micro- and macroalbuminuria were defined as an albumin excretion rate of 20-199 and ≥200 µg/min, respectively, and end-stage renal disease (ESRD) as dialysis or kidney transplantation. Cumulative incidence was estimated at 10-year intervals between 20 and 50 years duration and compared by calendar year of diabetes onset. RESULTS: By 50 years of T1D duration, ESRD affected 60% of the cohort; macroalbuminuria, 72%; and microalbuminuria, 88%. Little evidence existed for declines in cumulative incidence in recent cohorts, except for ESRD (microalbuminuria 3% increase, macroalbuminuria no change; ESRD 45% decrease by 40 years of T1D duration). Onset before age 6 years was associated with the lowest risk; incidence generally did not differ by sex. CONCLUSIONS: Some degree of kidney disease in T1D is virtually universal at long durations and not declining, which has major implications for health care and research strategies. ESRD has declined, but continues to affect >25% of the population by 40 years duration.

News From the HIMSS Pop Health Forum

Population health trends and information technology (IT) were the focus of the October HIMSS Pop Health Forum in Chicago. Change has come slowly to the health care industry as providers and payers adapt to value-based care. What happens in Washington, DC, doesn't really affect this trend. It's where health care is moving.

According to presenters, there is a movement toward a more holistic approach to data aggregation and integration, with payers working to ensure that they and providers are seeing information—not just clinical and financial, but increasingly sociodemographic and geographic data—"through a single pane of glass."

Addressing social determinants is a key part of any successful population health program. Henry Ford Health System in Detroit is working with a company that's helping it identify a broader array of socioeconomic factors for patients—not just their ethnicity and the language they speak at home but also information about how stable their housing is and their access to reliable transportation.

By assessing those social factors as well as the patient's motivation to change unhealthy habits (smoking cessation, for example), the health system can often then connect them to a community resource for help.

At Henry Ford, experts have also been looking at medical variation—building protocols into the electronic health record (EHR) that alert clinicians when to seek consultations from specialists or order certain tests—and also at post-acute care, which has enabled reductions in lengths of stay in its skilled nursing facilities.

The sandbox is bigger than ever. Health care facilities are playing outside their four walls. ■

The World Is Running Out of Antibiotics, WHO Report Confirms

A report, *Antibacterial Agents in Clinical Development—An Analysis of the Antibacterial Clinical Development Pipeline, Including Tuberculosis*, by the World Health Organization (WHO) shows a serious lack of new antibiotics under development to combat the growing threat of antimicrobial resistance.

Most of the drugs currently in the clinical pipeline are modifications of existing classes of antibiotics and are only short-term solutions. The report found very few potential treatment options for antibiotic-resistant infections identified by WHO as posing the greatest threat to health, including drug-resistant tuberculosis which kills around 250,000 people each year.

"Antimicrobial resistance is a global health emergency that will seriously jeopardize progress in modern medicine," says Dr. Tedros Adhanom Ghebreyesus, Director-General of WHO. "There is an urgent need for more investment in research and development for antibiotic-resistant infections including TB, otherwise we will be forced back to a time when people feared common infections and risked their lives from minor surgery."

In addition to multidrug-resistant tuberculosis, WHO has identified 12 classes of priority pathogens—some of them causing common infections such as pneumonia or urinary tract infections—that are increasingly resistant to existing antibiotics and urgently in need of new treatments.

The report identifies 51 new antibiotics and biologicals in clinical development to treat priority antibiotic-resistant pathogens as well as tuberculosis and the sometimes deadly diarrheal infection *Clostridium difficile*.

Among all these candidate medicines, however, only 8 are classed by WHO as innovative treatments that will add value to the current antibiotic treatment arsenal. ■

Pump May Beat Shots in Type 1 Diabetes

According to new German research, young people with type 1 diabetes may get better blood sugar control and have fewer complications with insulin pump therapy than with daily insulin injections. The complete study was published in *JAMA*. ■

HIV TREATMENT ELIMINATES TRANSMISSION RISK, SAYS CDC

The Centers for Disease Control and Prevention plans to update its guidelines on HIV transmission. The CDC has stated that HIV-positive individuals who are taking effective antiretroviral medication to suppress the virus cannot pass it on through sex. ■

Breast Cancer Awareness Month

In honor of Breast Cancer Awareness Month, *CareManagement* would like to share some resources that case managers may find helpful for their patients. Breast Cancer: Beyond the Shock is an app for IOS devices created by the National Breast Cancer Foundation. The American Cancer Society reminds everyone to participate in walks for breast cancer: fundraise and participate in one of more than 250 Making Strides events or participate virtually at makingstrideswalk.org. The Susan G. Komen Foundation offers support to survivors with a blog and other resources. For the newly diagnosed, the Foundation offers interactive educational tools and translated resources for patients who do not speak English. Patients who need financial assistance can find resources at the Susan G. Komen Foundation. For patients needing additional support, you might suggest Lump to Laughter.

Our sister organization, Commission for Case Manager Certification (CCMC), also offers the Novartis-sponsored Advanced Breast Cancer Case Manager Toolkit. A subscription to CCMC Case Manager Body of Knowledge is required. The Case Management Society of America (CMSA) provides a downloadable disease management guide on breast cancer.

News in the field of breast cancer research includes a study showing that the recently approved breast cancer drug neratinib can block the function of *Ras* as well as several other oncogenes through an unexpected process. Read more at ScienceDaily. Scientists at Yale University report solving the mystery of the *BRCA1* gene. Findings were published in *Nature*. ■

Resources for Care Managers Who Serve Patients With Alzheimer's Disease

The following is a list of resources provided to *CareManagement* by one of our readers:

- Preparing Your Home for a Loved One with Alzheimer's: A Caregiver's Guide
- Alzheimer's and Keeping Active/Involved
- The Benefits of Cooking with Alzheimer's
- Keep Your Pets Close: How Animals Help Dementia
- Helping Alzheimer's Sufferers Cope with the Loss of a Loved One—A Guide for Caregivers
- Dementia and Hygiene: How to Solve Hygiene Problems Common to People with Dementia
- Budget-Friendly Smart Home Accommodations for Seniors and Individuals with Special Needs
- Alzheimer's, Dementia and Money Management
- Overdose Response Guide: Awareness, Prevention, and Preparedness for Caregivers of Addicts
- 6 Signs of Elder Abuse in Seniors with Dementia ■

Smarter Drugs?

The rise of antibiotic-resistant diseases has prompted the development of more powerful drugs. More powerful drugs come with the potential for more powerful side effects or risks—as do current antibiotics.

The antibiotics we use today don't specifically target the harmful bacteria plaguing our bodies when we're ill. Instead, they attack both the good and bad bacteria. Because this mechanism is uncontrolled, it has contributed to the increased development of infectious diseases that are immune to the treatments we have at present. Those drug-resistant infections and their sequelae are expected to kill over 10 million people by 2050 if left unchecked.

A French startup company called Eligo Bioscience aims to introduce a new kind of drug, Eligobiotics, that can attack bacteria in a more focused way. The company announced in September 2017 that it had received $20 million in funding from Khosla Ventures and Seventure Partners, which includes a $2 million award from the Worldwide Innovation Challenge. Eligobiotics would be designed to carry out specific rather than broad attacks: these could range from killing the harmful bacteria to turning it into a drug producer.

Possibly the most attractive thing about Eligobiotics is how it uses CRISPR—the new method of gene editing—to scan the bacteria and deliver precise cuts to its genetic code to wipe it out completely. In the past, CRISPR has been used to create crops and to edit embryos to better understand human development; CRISPR may one day cure sickle-cell disease. ■

After the Hurricanes: Assessing the Impact on Employees
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and procedures that address major natural catastrophes. During the hurricanes, for example, disability managers may have experienced incidents that were not covered by workforce management policies and procedures. Let's say an employee in Houston had been on leave due to a work-related injury but was released by his physician to return to work on August 28th, while the Houston area was still being buffeted by Hurricane Harvey. Without power at home and unable to go into the office, the employee could not report to work, making his pay and work status unclear. Was he back to work or still considered off work? How does this uncertain status impact pay and job protection? Although disability managers can act in the moment to address such incidents, the experience should lead to a review of policies and procedures to address the contingencies so that employees who are off work or returning to work have the same rights and protections as those who are actively working.

Finally, companies whose employees were affected by the hurricanes should consider bringing together cross-functional teams to analyze the organization's response and determine what could have been done better not only for those impacted but for those who also wanted to help. These solutions could involve multiple departments such as human resources, health and wellness, environmental health and safety, and risk management. By including the expertise of case managers and disability managers, cross-functional teams become more aware of what is needed to help employees deal with catastrophic life events in the moment and well after the fact. CM

Author's Interview with Catherine M. Mullahy, RN, BS, CRRN, CCM
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CM: I think that the book demonstrates my passionate belief and determined persistence in the value of case management that has underscored the importance of case management and the need for the comprehensive preparation of professionals for this role. The story of case management, the personalization of the issues facing patients and their families, and the professionals who are trying to provide care and services to them is communicated throughout the book. Detailed and practical information on how case managers and the process can be used to address the challenges in our changing health care system and marketplace are all prominent throughout the book. I think this combination of passion with the practical guidance, tips, data, statistics, graphs, charts, and forms make *The Case Manager's Handbook* a comprehensive, accessible, and inspiring resource for case managers. That was my goal in writing this latest edition.

Q. What has been the response to *The Case Manager's Handbook, Sixth Edition*, from the field?

CM: The response has been phenomenal. When we are exhibiting at conferences, the folks we are meeting show me the Post-it notes, the dog-eared pages, and the underlined sections, which indicate to me that they are really using and relying on our content.

Q. You and your partner, Jeanne Boling, have both held many leadership roles in case management over the years and are now providing educational and training programs and products to drive "Best in Class" case management services. You even have an award-winning seminar called "Best in Class." How satisfying do you find the role of teacher and mentor compared with being directly on the line providing patient care?

CM: While we both, I believe, will always have fond memories of the cases we successfully managed, and those that, for a variety of reasons, were less than successful, I believe that our greatest contribution has been to teach the process of case management in such a way that others can envision themselves being a case manager and really making a difference. It is our hope that we can continue to provide mentoring, to communicate our passion and, hopefully, to motivate and inspire others to be the change agents within their organizations. In addition to our "live" programs, we have created other ways to connect with folks to empower them to help those individuals who need their help. Our long-distance learning course, along with some of our other educational programs, is one way we are remotely training case managers when they are unable to attend a live program or when they don't have the flexibility in their schedules to attend one of our seminars.

Q. Any last words of encouragement for today's case managers?

CM: I would say that, regardless of your practice setting, always try to make a difference, one patient at a time. We can't change the world, and we must contend with the challenges our health care system and nation's changing demographics present, but we can, with a caring heart, connect with the patients and their families who are truly in need of our assistance, expertise, and commitment.

More information about *The Case Manager's Handbook*, Sixth Edition
In addition to containing updated

Author's Interview with Catherine M. Mullahy, RN, BS, CRRN, CCM

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information, the 850-page long Sixth Edition also includes 6 new chapters: Pediatric Case Management, Workers' Compensation Case Management, New Characteristics of Today's Healthcare Systems and How They Affect Case Managers, The Case Manager's Role in the Era of Value-Based Healthcare, New Case Management and Healthcare Provider Approaches for Managing the High-Risk, High-Cost Patient, and Transformative Healthcare Approaches for the Millennial Generation.

Each new print copy of the Sixth Edition includes Navigate 2 Advantage Access, which unlocks a comprehensive and interactive eBook, midterm, and final examination (available to professors), instructor's manual, and learning analytics reporting tools. In addition, new printed versions of *The Case Manager's Handbook, Sixth Edition,* allow readers to access an online Student Study Guide that provides additional resources to help read and master the material in the text. These resources include chapter objectives, multiple choice questions, bonus appendices, and cases in profile, which are real-life situations involving case management. CM

The Case Manager's Handbook, Sixth Edition, ISBN: 978-1-284-10240-6 is published by Jones & Bartlett Learning, ©2017. It is available for $99.95 and is available at: mullahyassociates.com/products/the-case-managers-handbook-sixth-edition.html as well as at Jones & Bartlett Learning and on Amazon, Barnes & Noble, and other ecommerce sites. Copies personally inscribed by the author are available only through the mullahyassociates.com website. To order your copy or for more information, visit: mullahyassociates.com/products/the-case-managers-handbook-sixth-edition.html

CE I Managing Postacute Care Networks

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lower extremity joint replacement), CABG (coronary artery bypass graft), and AMI (acute myocardial infarction), providers will need to figure out how to best run their network. Keep in mind that the value equation is mathematical, not conceptual. To improve value, benefits need to increase while costs decrease. If costs increase or benefits decrease, value does not improve. Networks and its member providers are accountable to all aspects of value. CE I

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CE II Care Management Plus: Strengthening Primary Care for Patients With Multiple Chronic Conditions

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Notes

1. The model was developed by Edward Wagner, MD, and colleagues at the Group Health Research Institute's MacColl Center for Health Care Innovation in Seattle, Washington. For more information, see http://www.improvingchroniccare.org/index.php?p=The_Chronic_CareModel&s=2

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9. Dorr DA, Wilcox AB, Brunker CP, et al. The effect of technology-supported, multidisease care management on the mortality and hospitalization of seniors. *J Am Geriatr Soc.* 2008;56(12):2195-2202.

10. The University of Utah College of Nursing is also home to the Gerontology Interdisciplinary Program, which offers a Master of Science degree and certificates in gerontology, and to the Hartford Center of Geriatric Nursing Excellence.

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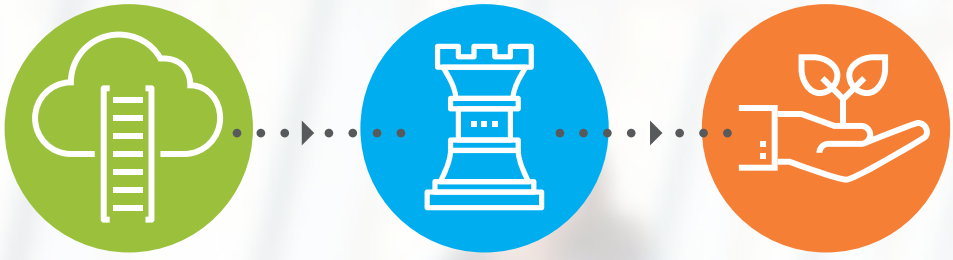

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