

CareManagement

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Gary S. Wolfe

A New Tool for Case Managers: ArchiTools

Certified case managers are not the first, but among the many, who recognize that the United States health care system is broken. This is because the emphasis in the recent past was placed on volume of care rather than quality of care. Care is often not coordinated, which contributes to high costs and less-than-optimal patient outcomes. The Patient Protection and Affordable Care Act (ACA) addresses many of the specific problems in our health care system with the attempt to move us to value-based care. By incentivizing the achievement of better health outcomes, higher quality, and greater efficiency while also encouraging more patient-centered, coordinated care, overall cost of care will be reduced.

There is work to be done and a lot of that work will fall upon the certified case manager. The Academy of Certified Case Managers has partnered with Pfizer to bring you ArchiTools. ArchiTools is a centralized resource that will help you deliver value-driven health care and interactive training modules, downloadable tools, annotative and detailed articles, reprints, and more. ArchiTools provides you with the tools you will need to move ahead. There is a lot of information for the certified case manager to manage. ArchiTools helps

centralize this information so it is readily available in one place for you. Many of the tools are downloadable so you can print them out and use on a day-to-day basis. Others can be read on your monitor but are still available for reference. ArchiTools is comprehensive and will be updated regularly as information changes or as new information becomes available.

I commend to you an article, "The Role of Certified Case Managers in Case Coordination" by Gene Gosselin, RN, MA, CCM, LPC, in this issue. This article will explain more about ArchiTools.

This is a great partnership between Pfizer and the Academy of Certified Case Managers—two organizations working together to address the brokenness of the health care system can make a difference in solving problems to ensure better health care for more people.

Gary S. Wolfe, RN, CCM
Editor-in-Chief
GSWolfe@aol.com

**ACCM: Improving Case Management
Practice through Education**



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Gary S. Wolfe, RN, CCM

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Evolving Views on Disability Disclosure in the Workplace

CDMS recently asked Hannah Rudstam, PhD, senior extension associate, and Erin M. Sember-Chase, project coordinator, Northeast ADA Center, Cornell University, Ithaca, NY, how employers, service providers, and job seekers with disabilities view disability disclosure in the workplace today.

Rudstam believes that employers are confused about disclosure, particularly with the recent rule changes of Section 503 of the Rehabilitation Act (RA).

She explained that since 1990 under the ADA, employers cannot require applicants to disclose a disability and are limited in what they can ask an employee about disability. Further, employees or applicants who choose not to disclose a disability are not lying; they are exercising a legally protected choice. The only time employees need to disclose something is when they are requesting a reasonable accommodation, and, even then, laws dictate who within organizations can be told about disability.

Under RA Section 503, which was changed in March 2014, employers who are federal contractors are now required to invite applicants and employees to voluntarily and confidentially self-identify as a person with a disability. Many employers are now confused about what they can ask regarding a disability, believing that the new changes to RA Section 503 conflict with the ADA's that prohibits employers to ask about employees' disabilities.

"The important point that employers must understand is that this is not a contradiction," Rudstam said.

"Under the ADA, employers have always been allowed to ask applicants and employees to voluntarily self-identify as a person with a disability as long as certain guidelines were followed. This disclosure must be voluntary, employers

Employers cannot require applicants to disclose a disability and are limited in what they can ask an employee about disability. Further, employees or applicants who choose not to disclose a disability are not lying.

must maintain confidentiality of this disability data, and they must be able to show how this data will be used to improve disability inclusiveness in their organization." This type of disability inquiry was allowed under the ADA and is now required for employers covered under RA Section 503 changes.

However, in most situations, the ADA prohibits the employer from asking about disability in a non-confidential manner, such as during an in-person interview. Under both the ADA and RA Section 503 new changes, employers cannot require applicants or employees to disclose a disability.

Applicants for jobs with employers who are federal contractors (and hence covered under RA Section 503 law changes) should expect to receive

a form inviting them to disclose a disability when they apply for a job. "Supplying this information is voluntary, and the information should be kept confidential," Rudstam said.

Beyond legal issues, Rudstam stressed that disclosure is a human issue. "It is about trust," she said. Employees who need a reasonable accommodation to perform their job must tell their employer about the disability. Coming forward with this information involves trusting the employer. "If people with disabilities don't trust the employer enough to come forward with an accommodation need, then everyone loses. The employee will be frustrated in their job, and the employer will lose productivity."

To help build a climate of trust, employers need to ensure that applicants and employees who disclose a disability are treated respectfully and confidentially, and that necessary accommodations are put into place in a timely manner to allow them to be productive and remain in their jobs, she said.

Likewise, service providers need to understand their own legal obligations and conditions under which they disclose a disability to an employer on behalf of a service recipient.

"Service providers have to be very careful," Rudstam said. "It always makes sense to have service recipients decide themselves if, how, when, and where they make a disability disclosure."

She noted, however, that views on disability disclosure vary among people with disabilities. Some individuals with disabilities decide to open up about

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CARF Directors Elect Herb Zaretsky as New Board Chair



Herb Zaretsky

December 18, 2014, Tucson, Arizona—The CARF Board of Directors elected Herb Zaretsky, PhD, as Chair of the Board during its December 2014 meeting. His term begins January 1, 2015. He was also

voted to a new 3-year term as Board member. Dr. Zaretsky is currently a Clinical Professor at The Rusk Institute of Rehabilitation Medicine, New York University Langone Medical Center, and a longtime participant in CARF governance.

“I am thankful to my colleagues on the Board for their support and confidence,” said Zaretsky of the Board’s action. “I am looking forward to advancing CARF’s mission of providing quality services to persons served, and to supporting CARF’s international growth. We have the opportunity to help other countries advance quality services, and by so doing, make CARF’s exemplary standards even stronger.”

Dr. Zaretsky succeeds Kayda Johnson who was elected Chair of the CARF Board of Directors for three consecutive 1-year terms beginning in 2012. “I would also like to acknowledge Kayda Johnson for her outstanding leadership as Board Chair,” said Zaretsky. Johnson will remain on the Board as Past Chair through the end of her current 3-year term, which will be completed on December 31, 2016.

CARF President and CEO, Brian J. Boon, PhD, said, “CARF is very

fortunate to have had a supportive board over the past several years. I am looking forward to working with Dr. Zaretsky and the other board members as they continue to lead our efforts domestically and internationally as the accreditor of choice.”

Dr. Zaretsky has more than 2 decades of experience with CARF medical rehabilitation surveys stemming from his tenure at The Rusk Institute in New York. He previously served as Chair of what was then the CARF Board of Trustees in 2003 and has been involved in the governance of CARF since he joined the Board in 1998 as a sponsoring trustee. He served on the Board for 7 years as a representative for the American Psychological Association until his election to the first CARF Board of Directors in 2005. Possessing a sound governance and academic background in the medical community, Dr. Zaretsky also continues to serve on the Board of Directors of the Eastern Division (New York State and New Jersey) of the American Cancer Society, where he previously also served as Board President. Dr. Zaretsky is the author of over 100 publications, including several book chapters, and editor of four books on medical aspects of disability.

The CARF Board of Directors also elected to retain the seats of Susanne Bruyère and Karen Chastain for additional 3-year terms running January 1, 2015, through December 31, 2017. Serving in diverse health and human service fields, the 11 members of the CARF Board of Directors bring unique and valuable experience to their governance roles. The board roster for 2015 is:

- Herb Zaretsky, PhD, New York City, New York (Board Chair)
- Susanne M. Bruyère, PhD, CRC, Ithaca, New York
- Thomas J. Buckley, EdD, Hollywood, Florida
- Karen Chastain, Fort Lauderdale, Florida
- Richard Forkosh, Manchester, Missouri
- Kayda Johnson, Solana Beach, California
- Marvin Mashner, Maple Glen, Pennsylvania
- Paul Nathenson, RN, ND, Lincoln, Nebraska
- Sharon Osborne, Seattle, Washington
- Robert H. Short, Salt Lake City, Utah
- Sherry Wheelock, Clermont, Florida

About CARF International

Founded in 1966 as the Commission on Accreditation of Rehabilitation Facilities, CARF International is an independent, nonprofit accreditor of health and human service providers in the areas of aging services; behavioral health; child and youth services; durable medical equipment, prosthetics, orthotics, and supplies; employment and community services; medical rehabilitation; and opioid treatment programs. The CARF International group of companies accredits close to 50,000 programs on five continents. More than eight million persons of all ages are served annually by CARF-accredited providers.

For more information about the accreditation process, please visit the CARF International website at www.carf.org.

THE COMMISSION FOR CASE MANAGER CERTIFICATION

CCMC Unveils Toolkit to Train and Develop Tomorrow's Case Managers

The Commission for Case Manager Certification has released a new toolkit designed to help organizations prepare the case manager workforce.

The [Commission's Workforce Development Toolkit](#) includes 4 case manager-specific tools:

- [Case Management Body of Knowledge](#),[®] the online resource for professional and board-certified case managers that includes 25 post-tests and currently 57 continuing education credits, with more to come
- [CCM Certification Workshops](#), 2-day workshops that prepare case managers for the CCM exam
- [The CMLearning Network](#),[®] which features the latest intelligence from the top thought leaders in case management in free webinars, issue briefs, and online resources
- The Commission's [PACE™ directory](#), a free, searchable directory of pre-approved continuing education courses for case managers.

"The case manager's role as patient-centered guide and hub for the care team is more significant than ever," said Patrice Sminkey, the Commission's CEO. "The Commission recognizes the critical importance of workforce readiness for case managers to adapt and lead in this evolving landscape."

The Commission's Case Manager Role & Function Study ties the latest practice demands and knowledge requirements to the Certified Case Manager (CCM) credential. The Commission's focus on preparing and supporting the professional and board-certified case manager ensures the

insight health care leadership needs for competency and readiness for the challenges that lie ahead, Sminkey said.

"Every day, case managers are problem solvers, addressing myriad human questions and conflicts," she said. "The need for effective, efficient case management is why these tools are critical, now. We know people prefer online learning for some professional development, and some prefer face-to-face opportunities."

"Case management requires personal judgment, wisdom and knowledge of professional ethics and conduct. Any professional development resource must be considered in the context of a commitment to professional conduct," Sminkey said.

"The Commission wrote the book on case manager ethical guidelines and advocates for professionalism aligning with the Case Manager Code of Professional Conduct," she added.

Looking ahead, the more personal aspects of care improvement—such as care coordination and better transitions between settings—demand skilled, knowledgeable professionals. With the CCMC's new toolkit, organizations will be able to help prepare the case manager workforce for what tomorrow will bring. **CM**

The Commission for Case Manager Certification is the first and largest nationally accredited organization that certifies more than 35,000 professional case managers. The Commission is a nonprofit, volunteer organization that oversees the process of case manager certification with its CCM® credential. For more information, visit www.ccmcertification.org.

Protected Health Information: What Sharing Means

By Elizabeth Hogue

I recently witnessed an encounter in a doctor's office between a man whose wife has dementia and the members of the staff of the doctor's office. The man complained loudly about the fact that the staff refused to share information about his wife with him because they said that "HIPAA" prohibited them from doing so. I have encountered a number of other instances in which health care providers offered the same explanation.

HIPAA was never intended to and does not prohibit health care providers from sharing information with family members and others involved in patients' care. It's time to get it straight! The HIPAA Privacy Rule allows covered entities to disclose protected health information (PHI) to family members, other relatives, close personal friends, or other individuals identified by patients. Information may be shared that is directly relevant to such persons' involvement with patients' care or payment related to patients' care.

The Office for Civil Rights (OCR), the primary enforcer of HIPAA requirements, reaffirmed the appropriateness of such disclosures in a publication entitled *HIPAA and Same-sex Marriage: Understanding Spouse, Family Member, and Marriage in the Privacy Rule*, published in September, 2014. Specifically, OCR states as follows:

The HIPAA Privacy Rule contains several provisions that recognize the integral

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The Role of Certified Case Managers in Care Coordination

by Gene Gosselin, RN, MA, CCM, LPC

There is widespread agreement that the United States health care system is fragmented and volume-driven, and disproportionately focused on caring for the acutely ill rather than on keeping people healthy. Often, patients receive treatments and medicines from multiple providers and are transitioned across settings or levels of care with

little communication occurring between these providers. These patients, many of whom are diagnosed with multiple chronic conditions, are then frequently left to navigate a complex and confusing health care system with little support. Additionally, the current fee-for-service reimbursement structure, which compensates for each unit of service, fails to align those payments to

the quality or efficiency of the service delivered. Since providers are paid separately for each service, there is little incentive to coordinate care, or collaborate with other providers. This can result in unnecessary or duplicative tests, medication errors and preventable hospital admissions and readmissions.

Increasingly, the US health care

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Pfizer's ArchiTools

In an effort to help facilitate the shift from volume to value and address challenges in health care delivery, Pfizer has developed ArchiTools. ArchiTools is a comprehensive online platform that offers a wide range of tools and resources for use by case managers and other health care professionals who want to understand the changing health care landscape, lead the way in implementing new care coordination strategies, and improve the quality of care. Components of the ArchiTools platform include:

Training Rooms: There are two training rooms that provide fundamental education on Health Information Technology (HIT) and Payment Reform, two essential mechanisms driving the movement from volume to value. These virtual "rooms" are self-paced learning experiences that give an overview of HIT and payment reform.

Resource Centers: The resource centers provide access to actionable tools and materials that can help case managers enhance population health efforts, engage patients in better self-management, improve patient interaction skills, identify risk, address avoidable readmissions, and assist patients in finding ways to stay healthy.

- **Team-Based Practice Resource Center** contains materials that help enhance a holistic, team-based approach to health care delivery.
- **Care Transitions Resource Center** helps identify risks and address potentially avoidable admissions and readmissions through improved medication reconciliation and discharge planning.
- **Prevention & Wellness Resource Center** addresses the benefits of investing in prevention, and contains materials that encourage adults to participate more fully in their care and make choices that help them stay healthy.



- **Care Coordination Resource Center** offers materials focused on case management as a mechanism to improve adherence, patient engagement, and quality.

Common elements in the resource centers include:

Interactive Overviews: These self-paced learning modules are available on demand and provide in-depth information about the topic addressed in the resource center.

Articles Reprints: Annotated journal articles provide quick access to key information.

External Resources: These links to additional actionable tools and information further support innovations in care delivery.

Helpful Tools: These actionable resources, available on demand, are designed to help enhance capabilities, improve efficiencies, and deliver outcomes.

Related Resources: These Pfizer offerings that exist outside of ArchiTools can supplement quality improvement efforts.

To access ArchiTools and other important materials and resources available to ACCM members visit, www.academyccm.org/architools.php.

Employment Status Top Socioeconomic Factor in Readmissions

Employment status is the top socioeconomic factor affecting 30-day readmissions for heart failure, heart attacks or pneumonia, according to a new study from Truven Health Analytics.

As readmission penalties reach record highs, analyzing causes is more important than ever. Researchers, led by David Foster, PhD, collected 2011 and 2012 data from the Centers for Medicare & Medicaid Services and used a statistical test called the Variance Inflation Factor (VIF) for correlations among the nine factors in the Community Need Index (CNI): elderly poverty, single parent poverty, child poverty, uninsurance, minority, no high school, renting, unemployment and limited English. Their analysis found unemployment and lack of high school education were the only statisti-

cally significant factors in connection with readmissions, carrying a risk of 18.1% and 5.3%, respectively, according to the study.

In contrast, language limitations appeared to have a “protective effect” against readmissions, which researchers suggested may be due to non-English-speaking communities “taking care of their own” within the community rather than returning to the hospital for medical problems.

To prevent readmissions going forward, hospitals should consider factoring in CNI indicators to develop a profile of patient populations at higher risk for 30-day readmissions. “This will enable hospitals to develop new treatment solutions that may lead to reduced readmissions and improve the health of these populations,” they

write. Moreover, “specific community factors, such as a higher proportion of extended families, could potentially have some positive impact on readmission rates and is worth further exploration,” according to the authors.

Researchers continue to debate the importance of socioeconomic factors in readmissions. An April study published in Health Affairs found socioeconomic status may affect readmission rates significantly more than previously thought; combined with other community factors, such as physician mix and nursing home quality, it accounts for nearly half of the 60% of variations in readmission rates for myocardial infarction, heart failure and pneumonia. However, a May report indicated socioeconomic factors do not affect readmissions for congestive heart failure. ■

NEW SPANISH-LANGUAGE CARTOON AND CALCULATOR TO HELP CONSUMERS UNDERSTAND HEALTH INSURANCE

The Kaiser Family Foundation today released two new Spanish-language tools to help consumers better understand health insurance as they shop for plans during open enrollment for the Affordable Care Act’s marketplaces and in other venues.

[El seguro de salud, explicado: ¡los YouToons lo tienen cubierto!](#) is a Spanish version of the 5-minute cartoon video Health Insurance Explained—The YouToons Have It Covered, a light-hearted treatment of a difficult and important topic. It breaks down important health insurance concepts, such as premiums and provider networks, and explains how individuals pay for coverage and obtain medical care and prescription drugs when enrolled in various types of health

insurance, including HMOs and PPOs. Pamela Silva Conde, a six-time Emmy Award-winning journalist who co-anchors the Univision Network’s Primer Impacto, narrates the video, which is the third written and produced by the Foundation featuring the YouToons. All three videos are available in both English and Spanish.

Additionally, [la calculadora del Mercado de Seguros Médicos](#), the Spanish version of the Foundation’s Health Insurance Marketplace Calculator, now includes zip code-specific data on 2015 marketplace plans. It allows consumers to generate estimates of their health insurance premiums and government subsidies based on zip code, household income, family size and ages of family members. The [calculator](#) also

helps people determine whether they could be eligible for Medicaid.

The Foundation developed the video and calculator to aid Spanish-speaking consumers as they make decisions about health coverage for 2015—whether through the ACA marketplaces, job-based coverage, or Medicaid. Organizations and individuals are encouraged to embed both tools on their websites, as well as share them via social media. Detailed instructions are available for [embedding the calculator](#). The YouToons [video](#) can be embedded via YouTube’s share button.

The previous two Spanish-language videos, [La reforma de salud llega al público](#) and [Los YouToons se preparan para Obamacare](#), also are available. ■

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Health Share Oregon Coordinated Care Organization

By Sarah Klein, Douglas McCarthy, and Alexander Cohen

Impetus for ACO Formation and Development

In 2012, the Centers for Medicare & Medicaid Services (CMS) agreed to provide Oregon \$1.9 billion over 5 years to avert a budget shortfall in its Medicaid program, with the stipulation that the state reduce the rate of growth in per-capita Medicaid spending by 2% by the second year. To achieve this goal, Oregon implemented a Medicaid reform plan envisioned by its governor, John Kitzhaber, that required any health plan or provider participating in the Medicaid program to join or form a regional coordinated care organization (CCO) that would be responsible for meeting state-designated quality improvement and cost containment goals. Health Share of Oregon, the largest of 16 CCOs that formed across the state, was founded by four competing health plans, three county-run mental health agencies, and several health care provider organizations in the greater Portland area (Exhibit 1). The participating health plans and mental health agencies are designated risk-accepting entities (RAEs), which take financial

responsibility for providing defined benefits to Medicaid beneficiaries. The health plan CareOregon, the subject of a previous Commonwealth Fund case study, is one of these RAEs. The Portland area also is served by a competing CCO known as FamilyCare.

To meet the strict financial and quality targets set by the state, Health Share has instituted a wide range of initiatives to help member organizations improve the quality and coordination of care for high-need, high-cost patients. These efforts focus on improving care transitions, increasing care management, and addressing the socioeconomic barriers to health, including homelessness. This work is supported by a \$3.4 million state transformation grant to redesign care in accordance with local priorities and a \$17.3 million Health Commons grant from the Center for Medicare and Medicaid Innovation.

Building a System for Population Health Management

Care redesign. Because many of Health Share's provider organizations and payers had previously invested in the infrastructure needed to establish patient-centered medical homes (PCMHs), more than 90% of Health Share members are cared for in a state-certified PCMH. Health Share is now working to develop an advanced primary care model for patients with complex medical, behavioral, and social needs, using an approach similar to one

used by Legacy Medical Group, part of an urban health system that contracts with CareOregon. This approach relies on nurse case managers, pharmacists, and social workers to support primary care physicians in medical homes that care for a large number of high-needs patients. Early data from Legacy show that this intensification of care reduced use of the hospital: admissions declined from 6.5% to 5.7% percent of patients in 1 year, while emergency department (ED) visits declined from 12.6% to 11.6% of patients.

Because mental health problems are common among Health Share members, the CCO is also working to identify and spread best practices for addressing these needs. Part of this involves helping the three county-based mental health agencies integrate their efforts through collocation of services and improved care transitions between inpatient psychiatric units and community mental health programs. For the latter, Health Share established an intensive transition team, funded by the Health Commons grant, which provides short-term intensive case management and mental health services to individuals who have had a psychiatric hospital admission. The team deploys mobile crisis support specialists who can meet patients at the hospital and then follow them throughout their transition to outpatient care. Local mental health crisis programs in each county help connect these patients to community-based services and supports.

Sarah Klein is an independent journalist in Chicago.

Douglas McCarthy, MBA, directed this project as senior research adviser at the Institute for Healthcare Improvement from 2011 to 2013.

Alexander (Sandy) Cohen, MPH, MSW, is a research associate at the Institute for Healthcare Improvement.

EXHIBIT 1

At-A-Glance: Health Share of Oregon Coordinated Care Organization

Entity type	Nonprofit coordinated care organization that brings community partners together to improve health outcomes and reduce costs for a geographically defined population of Medicaid beneficiaries
Service area	Three counties (Clackamas, Multnomah, and Washington) encompassing greater Portland, the state’s largest metropolitan area
ACO program	Medicaid accountable care organization
ACO partners	Seven risk-accepting entities (RAEs) that take financial responsibility for providing defined medical or behavioral health services, nine dental health plans, and several community- based organizations and social service agencies. Four RAEs focus on physical health care; three of these—Kaiser Permanente, Providence Health and Services, and Tuality Healthcare— are integrated delivery systems with affiliated health plans. The fourth, CareOregon, is a network model health plan founded by safety-net providers, which include federally qualified health centers, urban hospital systems, and an academic medical center. Three RAEs are county mental health agencies that focus on behavioral health care.
Patients served	Approximately 227,000 Medicaid beneficiaries were enrolled in Health Share as of June 2014. For physical health care, approximately two-thirds are served by the CareOregon RAE, while the remaining third are served by the other three RAEs.
Providers	Health Share’s combined network includes 17,000 providers of all types, including nearly all hospitals in the tricity region (excluding the VA and Shriners Hospital for Children)
EHR systems	Health Share is promoting links between providers’ electronic health record (EHR) systems and has created a care coordination registry to aid those working with its members who have exceptional needs
Financial arrangement	Health Share receives a global per-capita budget from the Oregon Health Authority (the state’s Medicaid agency), which it apportions to its RAEs. These, in turn, pay contracted providers on a capitated or fee-for-service basis. The state withholds 2% of the CCO’s overall capitation budget, contingent on the CCO and its RAEs meeting cost and quality targets. Health Share retains 2% of its global budget to cover administrative expenses and reserves. Future increases in per-capita payments to the CCO (and its RAEs) will be reduced by 1% in the first year and a cumulative 2% the second year.
Governance	The CCO’s governing board includes representatives of the entities bearing financial risk, which have authority to make decisions about payment. By state mandate, the board also includes representatives of safety-net hospitals, dental clinics, and substance abuse treatment centers, as well as other stakeholders with expertise treating Medicaid beneficiaries.

The three county mental health agencies also are working to increase efficiency by standardizing administrative processes, which has the added benefit of improving Health Share’s ability to monitor performance across its network as all three providers define and measure services in the same way. The administrative simplification has led to a reduction in the number of ways that services are authorized from several

hundred to a few dozen, as well as agreement on standards for the length and intensity of services and the creation of a single contracting mechanism for residential treatment services. Discussions are under way to create and fund specialized high-cost substance abuse treatment services on a regional basis, which would be difficult for individual RAEs to sustain alone given the small numbers of patients who will benefit.

Care management of patients with complex, costly needs. Health Share is using funds from the Health Commons grant to wrap additional care management services around those already provided by its RAEs, with a focus on improving care transitions, increasing patient activation, and ensuring appropriate and cost-effective use of health care resources. One such program assigns “health resilience specialists” to

EXHIBIT 2

Health Share Interventions Supported by the Health Commons Grant

- 1. ED Guides:** A program that places nontraditional health care workers in emergency departments to help patients with nonacute needs find the most appropriate place to get care.
- 2. Standard Transitions:** A program focused on building standard discharge summaries into electronic health record systems of hospitals affiliated with the CCO and creating standardized workflows to ensure that the primary care and inpatient care teams know exactly who is responsible for each step in the care process.
- 3. C-Train:** A care transitions intervention that provides high-intensity support to high-use patients who are discharged from the hospital. This program helps patients transition from inpatient to outpatient care, provides pharmacist support to increase medication adherence, and links patients to resources to meet psychosocial needs.
- 4. Intensive Transitions Teams:** A program that provides transitions support for patients who have had a psychiatric hospital admission. It relies on mobile crisis support specialists to meet patients at the hospital and then follow them throughout their transition to outpatient care.
- 5. Interdisciplinary Community Care Teams (ICCTs):** Teams provide multidisciplinary support to high-use patients to help them build health literacy, address psychosocial needs, and overcome barriers to health. Within the ICCT program, there are four subprograms that have each hired outreach workers with specialized skill sets to meet the needs of the unique populations served.
 - a. Health Resilience Program:** A program run centrally by CareOregon that embeds 16 health resilience specialists in primary care clinics across the community. Two are embedded in specialty clinics that serve patients with complex pulmonary and liver conditions. One is paired with a physician assistant in a community setting.
 - b. Central City Concern Health Improvement Project:** This program employs five outreach workers, including a recovery specialist, a registered nurse, and a mental health professional who are embedded in a primary care clinic and serve patients experiencing homelessness.
 - c. New Directions:** This program employs three social workers embedded in a hospital emergency department (ED) who work with frequent ED utilizers with mental health challenges.
 - d. Tri-County 911 Service Coordination Program:** This program employs four social workers who work in the three counties with frequent 911 callers.

Source: Adapted from *Health Commons Grant Narrative Progress Report, June 30, 2014*, www.healthcommonsgrant.org/wp-content/uploads/Grant-Update.pdf.

engage and mentor patients who have had 6 or more ED visits or 1 nonobstetric hospital admission in a year. Home and community visits are common, allowing the health resilience specialists to observe firsthand the challenges

patients face, including lack of transportation, safe housing, and refrigeration to store medications.

The Health Commons grant also funds several other interventions aimed at improving care and reducing costs

for high-risk Medicaid beneficiaries (Exhibit 2). Evaluation is integral to the grant program, allowing rapid learning as findings reveal ways in which the interventions can be recalibrated to achieve aims. For example, an evaluation of the ED Guides program, which places nontraditional health care workers in emergency departments to help patients with nonacute needs find the most appropriate place to get care, found the intervention reduced costs only among a subgroup of newly enrolled individuals and those with four or more ED visits in the past year.⁶ This discovery led the project team to refine the target population to increase the program's effectiveness.⁷

Patient and family engagement and activation. Policy leaders in Oregon believe consumers play a critical role in improving health outcomes and redesigning the health care system around their needs. As such, the CCO program requires the establishment of a community advisory council, with consumers making up half of the membership. The council is tasked with performing a community health assessment and health improvement plan. In addition, one of Health Share's largest RAEs uses outreach workers to support patients in navigating the health care system, improving their health literacy, and advocating for their needs and treatment preferences.

Integrated data and analytics. Health Share is working to build an integrated data system that will enable hospitals—the majority of which use the same electronic health record (EHR) system—to share information with clinics and outreach workers serving the same population of patients. Health Share also plans to leverage the state's investment in health information exchange and quality reporting systems to identify patients in need of care management and enable better care coordination. The CCO also has created a performance dashboard to help providers track their individual and

joint progress in meeting performance targets set by the state to improve quality for Medicaid beneficiaries.⁸

Supportive payment models and financial incentives. The Oregon Health Authority—the state’s Medicaid agency—pays CCOs a fixed amount per Medicaid member. The state is reducing the rate of increase in these per-capita payments by 1 percentage point in the first year and a cumulative 2 percentage points the second year. Health Share apportions per-capita payments to its RAEs after retaining 2 percent to cover administrative expenses and reserves. RAEs have the flexibility to use per-capita payments for care redesign activities in partnership with their contracted providers, which are paid on a capitated or fee-for-service basis. The RAEs also have the opportunity to earn performance incentives worth up to 2 percent of their capitation payments, contingent on the CCO meeting performance targets on 17 metrics collected by the Oregon Health Authority.

The state’s payment model also provides flexibility for CCOs to use their funding to address nonmedical needs that impact health, like housing. For instance, funds could be used to buy an air conditioner for a homebound patient to help prevent exacerbations of chronic conditions leading to hospitalization. Health Share is working with community-based organizations and social services agencies to use these resources in an effective and prudent way, given the limited pool of funding.

Results

The Oregon Health Authority reported performance results for 2013, the first full year that CCOs were operating statewide. Health Share earned 100% of its performance incentive pool for meeting benchmark or improvement targets set by the state on 12 of 16 measures, such as an 18% reduction in ED visits, and for enrolling more than 80% of its members in primary care medical

homes. Through initiatives funded by its Health Commons grant, Health Share seeks to produce savings of \$32.5 million through a reduction in avoidable hospitalizations of 17% and ED use of 20% for the target high-use population of 19,000 patients in the first 3 years. These estimated savings were based partly on early results of pilot programs.

Lessons Learned

Enabling factors. Oregon is unique among US states in terms of the sophistication of its Medicaid agency and its willingness to experiment with managed care techniques that are fundamental to the design of CCOs.

Challenges and insights. While Health Share enjoys both state and federal support, its ultimate success depends on the willingness and capacity of its stakeholders to invest in new approaches to care. The Medicaid financial crisis that led to the creation of Health Share and other CCOs offered a powerful incentive for provider organizations to cooperate to avoid disrupting the flow of Medicaid payments that help cover their fixed costs. With a bailout from the federal government, that sense of urgency lessened, reducing the momentum for immediate change.

Like other CCOs in the state, Health Share faces the challenge of accommodating a large number of newly enrolled Medicaid beneficiaries who joined the program when the state expanded eligibility under the Affordable Care Act. The rapid influx of new members has strained the capacity of existing primary care sites, leading to a spike in ED visits in the Portland area and elsewhere in the state.

Although the three mental health RAEs have made progress in integrating behavioral health services across the three counties, there has not yet been meaningful integration among physical and mental health RAEs. A related challenge is the desire of staff in competing

physical health RAEs to retain autonomy in executing programs designed to achieve shared cost and quality goals. To help address this, Health Share established a chief medical officer workgroup to encourage collaboration and increase accountability for joint approaches to clinical transformation and has more recently created joint operating committees for its physical, behavioral health, and dental partners.

Health Share also must find a way to ensure that the administrative costs of its efforts to centralize processes and procedures yield benefits that are greater than its member organizations could realize from alternative use of the funds. Determining the best use of funds and the strategic focus for the organization has not been easy given the diversity of opinion regarding the strongest levers for achieving transformation, according to the organizations’ leaders. Some believe the greatest benefit will come from engaging hospital systems, which control the means of health care production, while others see opportunity in engaging community organizations and social service agencies that can influence the socioeconomic determinants of health.

Next steps. Health Share leaders say fostering greater transparency of quality and cost data will be one of the organization’s next steps. It also must find ways of sustaining care management programs now supported by grant funding, by demonstrating that the programs are worth direct investment by RAEs as a mechanism for reducing hospital use and costs.

Health Share also will continue to encourage provider organizations to assume risk as a means of accelerating practice transformation. This may mean some safety-net hospital systems that now contract with CareOregon will become separate risk-bearing entities—a shift that may be accelerated as commercial payers seek to enter risk-sharing agreements

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Redesigning Case Management to Integrate Into the Patient-Centered Medical Home

By Kathy Shelly, RN, BSN; Stephanie Porta, BS; and Susan Witmyer, RN, BSN, BC

How health care entities receive payment is changing, so how health care providers do business must change if they are going to survive. At Wellspan Health, we have changed the entire process of how we provide case management and want to share our successes and challenges with fellow case managers. We are continuing to make changes and evolve, keeping the long-term health of each patient as our focus.

When our leadership approached the department about redesigning our work flow, the entire department was disrupted: “Why do we have to make all these changes?” We were a well-oiled machine operating basically the same way for the last 20 years. We came to work ready to attend to immediate discharge needs and develop a new plan for the next person filling the bed on our unit. We didn’t understand the bigger picture, but we are fortunate in that our administration had vision and a desire for Case Management to pioneer new objectives of population health and the need to adapt to a changing reimbursement. We are to be a key element in improving the health of our community.

A brief background of Wellspan Health: We are a 4-hospital system with 700+ acute care beds, 660 primary care providers, a Level I Trauma Center, and

NCQA Level 3 patient-centered medical homes (PCMHs). At York Hospital, the largest hospital of the system, we have 550 beds, 26 case management nurses, and 20 social workers. Our mission statement at Wellspan is “working as one to improve health through exceptional care for all, lifelong wellness, and healthy communities.” It is important to know this statement as the changes we are making directly relate to our mission.

We understand health care reimbursement is moving from revenue based on volume to revenue based on value. Although our goal as case managers and social workers was always to provide the best possible care, now we are making sure that our goals include improving the overall health of the population while reducing costs and improving the patient experience. We are striving to meet these goals by improving communication, collaboration, access, and integration of all involved in our patients’ care.

What Does Moving to PCMHs Look Like to Case Managers?

The process change started at the primary care provider (PCP) offices with the formation of PCMHs. The goal of the PCMHs is to deliver comprehensive, whole-person care via a care team by coordinating care with other providers and resources in the community. Four years after the onset of the PCMHs, our hospital case management leadership team decided the next natural step was

to incorporate case management into the PCMHs. We don’t know about you, but our hospital social worker and case management registered nurse (RN) were not involved with the PCP office. We had no idea what merging them together was going to look like. We knew the change implemented had to improve patient care, improve patient experience, lower hospital utilization, improve outcomes, and reduce readmissions. To make that connection with the primary care office, it was decided to have the hospital case managers and social workers assigned to hospitalized patients based on a patient’s PCP.

The previous case management model included an RN case manager and a social worker paired together and assigned geographically by unit in the hospital. Every time patients came to the hospital, or transferred within the hospital, a different team would work with them. The new care design changes from geographic assignments to following patients by PCP. This design provides continuity of care: every time patients enter the hospital, they have the same care team working with them. There is also a team assigned to patients without a PCP or a PCP who is out of the area. As patients enter the hospital and are registered, they are assigned to a team. No patients are missed.

Developing the Teams

We were able to develop our teams by first establishing a complete list of all PCPs in the area. This was a difficult

The authors work in the Corporate Case Management Department at Wellspan Health in York, PA. Kathy and Susan are case management nurses, and Stephanie is a social worker.

We have to train ourselves to anticipate issues that may arise in order to ensure successful outcomes and avoid preventable hospital admissions.

and time-consuming task because no such list previously existed. There are many PCPs who are not part of Wellspan, and most of the PCPs in our area no longer follow their patients in the hospital but instead use hospitalists to care for their hospitalized patients. Once the list was compiled, it was then divided into what was estimated to be relatively equal caseloads and assigned to the teams of case management RN and social worker. Each team has at least one Wellspan PCMH practice and several non-WellSpan practices.

Now that we were following patients by their PCP, we next had to change our philosophy and how we carried out Case Management in the hospital. Rather than just focusing on discharge planning needs for this hospitalization, we needed to evaluate the possible issues that arise in the future. We have to look outside the hospital walls and include the continuum of health care. We have to train ourselves to anticipate issues that may arise in order to ensure successful outcomes and avoid preventable hospital admissions.

We have to be willing to develop a meaningful relationship with our patients and their families. Every time they come into the hospital, they are going to get the same team and this establishes a trust. The team introduces themselves as being affiliated with their PCP office. This creates an automatic bond because we are connecting ourselves with someone whom they already have a relationship. We let patients know that their care does not stop at the door of the hospital. In this new model, the team is there for them while they navigate the healthcare system. We are there “through the continuum of care.”

Challenges

This redesign came with challenges. Efficiency is a challenge because of the travel time spent walking to different floors and buildings. We no longer have an established workspace on the floor, so we carry our office with us including laptops, forms, reference guides, and educational information. The loss of efficiency was and continues to be a challenge. We have to establish new processes and continue to refine them to make them efficient. This is especially difficult for staff who have spent 20+ years refining a system to get the most amount of work done in a limited time. Now, our focus is more about the relationship with the patient not the amount of discharges performed in a given day. This definitely requires a mental shift.

Communication is one of the most challenging aspects of this new model. First, we had to establish a list that would identify which patients were assigned to our PCP practices, and second, develop a tool to communicate to the rest of the system which Case Management team was assigned to each patient. A daily census was created for each team that identifies the patients from the assigned practices that are currently inpatient, observation status, or in the emergency department (ED). A screen was created in the patient’s electronic medical record (EMR) that identifies the Case Management Nurse and Social Worker with phone number, the discharge plan that is being worked on, and the utilization management information. Each case management staff member is required to identify themselves on their assigned patient’s charts in the EMR by 9:00 am daily.

This enables anyone with access to the medical record to identify the case management team assigned.

Physicians, staff nurses, case managers, and ancillary departments involved in patient care all felt extreme discomfort at the loss of a dedicated case management team on the floor. Relationships that were built over time were gone, and now an effort will have to be made to establish new relationships, trust, and rapport. This takes time. Time will take care of itself, but as professionals we need to jump in and make the effort to promote our project, invest ourselves, and savor the positive outcomes.

The Bright Side

The positive outcomes are undeniable. In the acute care setting, patients will have the same case management team working with them, which builds stronger relationships with patients and families. We are able to develop plans of care that will follow through the health care continuum. It’s a long-term relationship—the feeling of knowing the person and not simply their diagnosis. We are more effective because of our established relationship with the patients and their families. We are building relationships with staff throughout the hospital and our PCMH practices and developing our skills beyond the silo of the floor we had previously been assigned.

Care Coordination Team

Once we identified the Case Management PCMH framework, now we needed to establish how the case management team was going to impact the patient throughout their continuum

Case managers obtain authorizations for both current hospitalization and post-hospitalization needs. The case manager assesses the patient's risk for readmission and makes sure issues that may cause readmission are addressed.

of care. We needed a bridge; a bridge to connect the inpatient and outpatient worlds. This bridge is the Care Coordination Team (CCT). The CCT is established for each PCMH and is the one constant in the patient's health management. Each CCT consists of a health coach, social worker, and case management RN.

The health coach is the hub and is located in the PCP practice. The health coach calls each patient within 24 hours of hospital or ED visit to ensure follow-up appointments are made, and to evaluate if there are any immediate issues that need to be addressed before the office visit. They review the medication list on that follow-up phone call. They provide ongoing support in navigating the health care system and community resources, help identify goals, teach disease self-management skills, create action plans, and keep patients motivated. They encourage patients to complete a shared care plan to share the patient's goals and aspirations. A shared care plan ensures that the patient is the focus of the care plan. The health coach identifies barriers and then shares them with the case management team. Their role is to connect the hospital team with the PCP.

The social worker is based in the hospital and visits the practice weekly. Their role is discharge planning, community referrals, and social and emotional support. The hospital is the first step in the development of a long-term relationship between the social worker and the patient. A trust and connection is developed, and patients are encouraged to reach out to the social worker from the community if a need arises.

The case manager role is to assess the quality and care gaps for hospitalized patients and to coordinate between the payer and care team. Case managers obtain authorizations for both current hospitalization and post-hospitalization needs. The case manager assesses the patient's risk for readmission and makes sure issues that may cause readmission are addressed. In addition, the case manager, as part of the team, assists in developing self-management goals.

Together the CCT works to identify barriers and ways to assist patients to become successful in dealing with their overall health care. The case manager RN brings the clinical perspective, the social worker brings the social/emotional/financial expertise, and the health coach provides ongoing coaching, instruction, and encouragement to reach goals. Each member of the CCT has important information to share about the patient; a daily huddle (conference call) was established to share that important information.

Primary Mechanisms for a Successful CCT

Each team member needs to establish a relationship and have purposeful communication. Monday through Friday, each CCT conducts a conference call to discuss patients that are currently in the hospital. We discuss patients who were admitted or are being discharged, and high-risk patients, and share medical and social information crucial to these patients' care. We discuss the continued needs of the patient in the community, the

current plan, and strategies to improve care and outcomes.

Each month all CCTs are brought together for a collaborative meeting. This is an opportunity to build relationships and evaluate our processes. We review metrics. Our teams are rated on the percentage of follow-up phone calls within 24, the number of PCP follow-up appointments within 7 days of hospital discharge, and the percentage of days that all CCT staff were present for their daily huddles. During the meeting, we also share "Bright Spots"—success stories of how the CCT has affected patient outcomes. The meeting is a time to provide skills development and process improvement planning.

Case management had to integrate into the primary care office and build relationships. We started by attending staff meetings and introducing ourselves to physicians and office staff. By talking with them, we determined their needs and expectations and educated them on our role and the resources available for their patients. We share with the staff how we can assist their patients by being a liaison between the hospital and the practice; we will assist with readmission to the hospital, identify social issues before they escalate and result in hospitalization, and facilitate higher levels of care. Staff are particularly amazed that we can place their patients into skilled nursing facilities, rehab centers, substance abuse facilities, and assisted livings from home. Before our integration into the office, their option was to send their patients into the ED. Being an active presence in the office is

the key to integrating case management into the PCMH.

Technology Changes

As part of this effort, we also needed to change our case management software to be able to support the process, computerized our referral system, and also started using an embedded version of Interqual criteria in the electronic record. Every aspect of staff work had to change for this redesign.

Lessons Learned

To ensure a successful transition of a new case management design, we wish to offer you things we learned:

1. Be patient and remember, **CHANGE IS HARD**. We still have staff asking when we are going back to the “old way.”

2. Good communication is essential. Educate the system about planned changes in detail before the changes are made. Keep communication positive and constructive when discussing the changes. Explain how this change will benefit the patient.
3. Be sensitive to the feeling of loss. The change affects the case management staff as much as the floor they left.
4. Continue to assess and evaluate the process.
5. Establish meaningful metrics to determine if you are meeting goals.

This program has been in effect with the entire team since March 2013, a very short time to see the effectiveness of such a change. That being said, the program is already showing promise. The readmission rate in 2012 was 30% (Figure 1), whereas the rate in fiscal

year 2013 was 13.7% (Figure 2). The system has more to accomplish with this program, but the stories of our patients have provided tangible facts to suggest that we are making a significant impact.

Although it is still early in development, the benefits of the new case management process can be seen. It has been a worthwhile endeavor, and our patients have benefited from our change.

We identify success stories each month—“Bright Spots.” “Bright spots” are examples of how we are “working as one” with our patients.

Here are a few of the ways this new model has impacted our patients.

- Prevented readmissions to the hospital by identifying medication errors
- Placed patients in physical and substance abuse rehabs from the office
- Intervened to prevent a suicide
- Prevented a crisis by performing a complete assessment of the home situation
- Obtained medication assistance for patients unable to afford medications at home
- Coordinated a family meeting for a very medically complex patient who wanted help talking to her family about her choice to stop certain treatments
- Obtained permanent housing for a transient patient
- Warded off caregiver burnout

Another Bright Spot example follows: We had a patient in the hospital that rehab staff felt should go to short-term rehab before returning home. This elderly gentleman wanted no parts of going to rehab. He wanted to go home and have his elderly frail wife help him. We made the best of a bad plan and sent him home with Home Health. When home therapy staff visited the day after discharge, they discovered that the patient had been out of his recliner only to go to the bathroom and was unsteady on his

continues on page 27

FIGURE 1

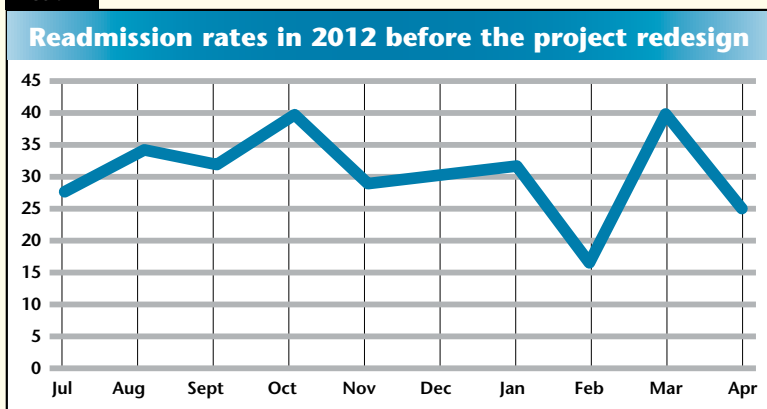
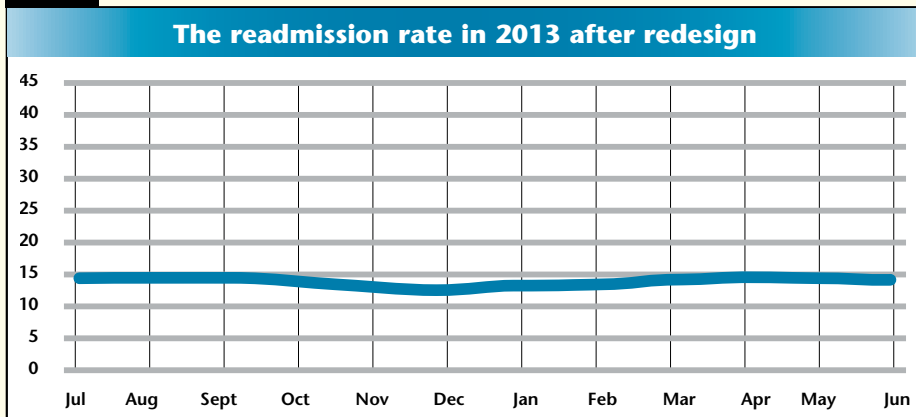


FIGURE 2



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Exam 1

Take this exam >

Health Share Oregon Coordinated Care Organization

- To meet the financial and quality targets, the authors of this article implemented a wide range of initiatives to improve quality and coordination of care for high-risk, high-cost patients.
 - True
 - False
- Efforts to improve quality and coordination of care included:
 - Improving care transition
 - Increasing care management
 - Addressing socioeconomic barriers to health
 - All of the above
- In building a new system for population health management, the following had to be included:
 - Care design
 - Case management
 - Integrated data and analytics
 - All of the above
- The patient-centered medical home model is an important component in the coordinated care organization.
 - True
 - False
- The Legacy Medical Clinic's advanced primary care model for complex patients reduced the admissions in 1 year to:
 - 4.8%
 - 5.7%
 - 6.9%
 - 7.5%
- Some of the interventions aimed at improving care and reducing cost for high-risk Medicaid beneficiaries include:
 - ED Guide
 - Intensive Transition Team
 - C-Train
 - All of the above
- If all providers and hospitals used the same electronic health record, it would be easier to integrate data.
 - True
 - False
- In the first full year of operation, the Oregon coordinating care organization reduced ER visits by:
 - 14%
 - 16%
 - 18%
 - 20%
- It is important that physical and mental health be well integrated.
 - True
 - False
- In moving ahead, these organizations must find ways to ensure that the administrative costs yield benefits that are greater than member organizations could realize from alternative use of the funds.
 - True
 - False

Exam 2

Take this exam >

Redesigning Case Management to Integrate Into the Patient-Centered Medical Home

- How health care entities receive payment is changing; thus, how health care providers do business if they are to survive must change too.
 - True
 - False
- There is no reason to redesign work flow if everything is working well.
 - True
 - False
- A desire for case management to pioneer new objectives of population health places case management in a key position to improve health care.
 - True
 - False
- In redesigning case management, a new mission statement must reflect the population that you are serving along with all the providers and levels of care.
 - True
 - False
- One important step in redesigning case management is to incorporate case management into the patient-centered medical home model.
 - True
 - False
- The new case management design does not change from geographic assignment to following patients by provider.
 - True
 - False
- Challenges in the redesign of case management include:
 - Efficiency
 - Communication
 - Team identity
 - All of the above
- Information technology has to change to support the case management process since many aspects of staff work have to change for redesign.
 - True
 - False
- In the successful transfer to a new case management design, the following things were learned:
 - Be patient
 - Be good communicators
 - Be sensitive to the feelings of loss
 - All of the above
- One of the benefits of this case management redesign was the lowering of readmission rates in 1 year to an average of:
 - 25%
 - 20%
 - 15%
 - 10%

Exam 1: Health Share Oregon Coordinated Care Organization

Objectives:

1. State four characteristics of a coordinated care organization.
2. Define three areas in which a coordinated care organization can improve quality and coordination of care for high-need, high-cost patients.
3. State four strategies in building a system for population health management.

Please indicate your answer to the exam questions on page 16 by filling in the letter:

1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8. _____ 9. _____ 10. _____

Exam 2: Redesigning Case Management to Integrate Into the Patient-Centered Medical Home

Objectives:

1. Define the process to integrate case management into the patient-centered medical home.
2. Define two challenges of integrating case management into the patient-centered medical home.
3. State four ways the integrated case management model with the patient-centered medical home can impact patients.

Please indicate your answer to the exam questions on page 16 by filling in the letter:

1. _____ 2. _____ 3. _____ 4. _____ 5. _____ 6. _____ 7. _____ 8. _____ 9. _____ 10. _____

Continuing Education Program Evaluation Please indicate your rating by circling the appropriate number using a scale of 1 (low) to 5 (high).

	Exam 1:	Exam 2:
1. The objectives were met.	1 2 3 4 5	1 2 3 4 5
2. The article was clear and well organized.	1 2 3 4 5	1 2 3 4 5
3. The topic was both relevant and interesting to me.	1 2 3 4 5	1 2 3 4 5
4. The amount and depth of the material was adequate.	1 2 3 4 5	1 2 3 4 5
5. The quality and amount of the graphics were effective.	1 2 3 4 5	1 2 3 4 5
6. I would recommend this article.	1 2 3 4 5	1 2 3 4 5
7. This has been an effective way to present continuing education.	1 2 3 4 5	1 2 3 4 5
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PharmaFacts for Case Managers



New Approvals

Opdivo (nivolumab)

Opdivo (nivolumab) is a human monoclonal antibody that blocks the interaction between PD-1 and its ligands, PD-L1 and PD-L2. Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells, inhibits T-cell proliferation and cytokine production.

Opdivo is specifically indicated for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab and, if BRAF V600 mutation positive, a BRAF inhibitor.

Opdivo is supplied as a solution for intravenous administration. The recommended dose of Opdivo is 3 mg/kg administered as an intravenous infusion over 60 minutes every two weeks until disease progression or unacceptable toxicity.

Clinical Results

FDA Approval

Opdivo was approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in the confirmatory trials. The FDA approval of Opdivo for melanoma was based on a multicenter, open-label trial that randomized patients with unresectable or metastatic melanoma to receive either Opdivo administered intravenously at 3 mg/kg every 2 weeks or investigator's choice of chemotherapy, either single-agent dacarbazine 1000 mg/m² every 3 weeks or the combination of carboplatin AUC 6 every 3 weeks plus paclitaxel 175 mg/m² every 3 weeks. Patients were required to have progression of disease on or following ipilimumab treatment and, if BRAF V600 mutation positive, a BRAF inhibitor. Tumor assessments were conducted 9 weeks after randomization then every 6 weeks for the first year, and every 12 weeks thereafter. Efficacy was evaluated in a single-arm, non-comparative, planned interim analysis of the first 120 patients who received Opdivo and in whom the minimum duration of follow up was 6 months. The major efficacy outcome measures in this population were confirmed objective response rate (ORR) as measured by blinded independent central review using Response Evaluation Criteria in Solid Tumors (RECIST 1.1) and duration of response. The ORR was 32%, consisting of 4 complete

responses and 34 partial responses in Opdivo-treated patients. Of 38 patients with responses, 33 (87%) had ongoing responses with durations ranging from 2.6+ to 10+ months, which included 13 patients with ongoing responses of 6 months or longer. There were objective responses in patients with and without BRAF V600 mutation positive melanoma.

Side Effects

The most common adverse reaction associated with the use of Opdivo was rash.

Mechanism of Action

Opdivo (nivolumab) is a human immunoglobulin G4 (IgG4) monoclonal antibody that binds to the PD-1 receptor and blocks its interaction with PD-L1 and PD-L2, releasing PD-1 pathway-mediated inhibition of the immune response, including the anti-tumor immune response. Binding of the PD-1 ligands, PD-L1 and PD-L2, to the PD-1 receptor found on T cells, inhibits T-cell proliferation and cytokine production. Upregulation of PD-1 ligands occurs in some tumors and signaling through this pathway can contribute to inhibition of active T-cell immune surveillance of tumors.

Signifor LAR (pasireotide)

Signifor LAR (pasireotide) is a somatostatin analog.

Signifor LAR is specifically indicated for the treatment of patients with acromegaly who have had an inadequate response to surgery and/or for whom surgery is not an option.

Signifor LAR is supplied as an injectable suspension for intramuscular injection. The recommended initial dose is 40 mg administered by intramuscular injection once every 4 weeks (every 28 days). For dose modifications please see drug label.

Clinical Results

FDA Approval

The FDA approval of Signifor LAR for acromegaly was based on two studies in two populations.

Treatment naive population:

A multicenter, randomized, double-blind study was conducted to assess the safety and efficacy of Signifor LAR in subjects with active acromegaly. A total of 358 subjects naive to drugs used to



treat acromegaly were randomized to Signifor LAR or another somatostatin analog active comparator. Randomization was stratified based on previous pituitary surgical status. The starting dose of Signifor LAR was 40 mg. Dose increase was allowed in both arms, at the discretion of investigators, after three and six months of treatment if mean GH was greater than or equal to 2.5 mcg/L and/or IGF-1 was greater than the ULN for age and sex. The maximum allowed dose for Signifor LAR was 60 mg. The maximum dose of the active comparator was not used in this trial because the trial was multi-national and the maximum dose approved in the US was not approved in all participating countries. The efficacy endpoint was the proportion of patients with a mean GH level less than 2.5mcg/L and a normal IGF-1 levels at month 12 (age and sex adjusted). The proportion of patients achieving this level of control was 31.3% and 19.2% for Signifor LAR and active comparator, respectively.

Population Inadequately Controlled on other Somatostatin Analog

A multicenter, randomized, 3-arm trial was conducted in subjects with acromegaly inadequately controlled on somatostatin analogs. Subjects were randomized to double-blind Signifor LAR 40 mg (n=65) or Signifor LAR 60 mg (n=65) or to continued open-label pre-trial somatostatin analog therapies at maximal or near maximal doses (n=68). A total of 181 subjects completed the 6 month trial. The efficacy endpoint was the proportion of subjects with a mean GH level less than 2.5 mcg/L and normal IGF-1 levels at week 24. The primary analysis compared Signifor LAR 60 mg and 40 mg to continued pretrial therapy (i.e., no change in treatment). The proportion of subjects achieving biochemical control was 15.4% and 20.0% for Signifor LAR 40 mg and 60 mg, respectively, at 6 months. Biochemical control was achieved by Month 3 in 15.4% and 18.5% of subjects in the Signifor LAR 40 mg and 60 mg arms, respectively.

Side Effects

Adverse effects associated with the use of Signifor LAR may include, but are not limited to diarrhea, cholelithiasis, hyperglycemia, and diabetes mellitus.

Mechanism of Action

Signifor LAR is an injectable cyclohexapeptide somatostatin analog. Pasireotide exerts its pharmacological activity via binding to somatostatin receptors (SSTR). There are five known human somatostatin receptor subtypes: SSTR 1, 2, 3, 4, and 5. These receptor subtypes are expressed in different tissues under normal physiological conditions. Somatostatin analogs bind to SSTRs with different potencies. Pasireotide binds with high affinity to four of the five SSTRs. Somatostatin receptors are expressed in many tissues including neuroendocrine tumors (e.g., growth hormone secreting pituitary adenomas). Pasireotide binds to SSTR2 and SSTR5 subtype receptors which may be relevant for

inhibition of GH secretion. In vivo studies show that Signifor LAR lowers GH and IGF-1 levels in patients with acromegaly.

Saxenda (liraglutide [rDNA origin] injection)

Saxenda (liraglutide [rDNA origin] injection) is a glucagon-like peptide-1 (GLP-1) receptor agonist. GLP-1 is a physiological regulator of appetite and calorie intake, and the GLP-1 receptor is present in several areas of the brain involved in appetite regulation.

Saxenda is specifically indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m² or greater (obese), or 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).

Saxenda is supplied as a solution for subcutaneous administration. The recommended dose of Saxenda is 3 mg daily. Administer at any time of day, without regard to the timing of meals. Dosing should be initiated at 0.6 mg per day for one week. Increase the dose in weekly intervals until a dose of 3 mg is reached. Saxenda should be injected subcutaneously in the abdomen, thigh or upper arm. The injection site and timing can be changed without dose adjustment.

Clinical Results

FDA Approval

The FDA approval of Saxenda for chronic weight management was based on three 56-week, randomized, double-blind, placebo-controlled trials. In all studies, Saxenda was titrated to 3 mg daily during a 4-week period. All patients received instruction for a reduced calorie diet (approximately 500 kcal/day deficit) and exercise counseling (recommended increase in physical activity of minimum 150 mins/week) that began with the first dose of study medication or placebo and continued throughout the trial. Study 1 was a 56-week trial that enrolled 3,731 patients with obesity (BMI greater than or equal to 30 kg/m²) or with overweight (BMI 27-29.9 kg/m²) and at least one weight-related comorbid condition such as treated or untreated dyslipidemia or hypertension; patients with type 2 diabetes mellitus were excluded. Study 2 was a 56-week trial that enrolled 635 patients with type 2 diabetes and with either overweight or obesity (as defined above). Patients were to have an HbA1c of 7-10% and be treated with metformin, a sulfonylurea, or a glitazone as single agent or in any combination, or with diet and exercise alone. Study 3 was a 56-week trial that enrolled 422 patients with obesity (BMI greater than or equal to 30 kg/m²) or with overweight (BMI 27-29.9 kg/m²) and at least one weight-related comorbid condition such as treated or untreated dyslipidemia or hypertension; patients with type 2 diabetes mellitus were excluded. All patients were first treated with a low-calorie diet (total energy intake 1200-1400 kcal/day) in a run-in period lasting up to 12 weeks. Patients who lost at least 5% of their screening body weight after 4 to 12 weeks dur-



ing the run-in were then randomized, with equal allocation, to receive either Saxenda or placebo for 56 weeks. The subjects in Studies 1 and 2 also received either Saxenda or placebo for 56 weeks. The proportions of patients who discontinued study drug in the 56-week trials were 27% for the Saxenda-treated group and 35% for the placebo-treated group. Approximately 10% of patients treated with Saxenda and 4% of patients treated with placebo discontinued treatment due to an adverse reaction.

Study Results:

For Study 1 and Study 2, the primary efficacy parameters were mean percent change in body weight and the percentages of patients achieving greater than or equal to 5% and 10% weight loss from baseline to week 56. For Study 3, the primary efficacy parameters were mean percent change in body weight from randomization to week 56, the percentage of patients not gaining more than 0.5% body weight from randomization to week 56, and the percentage of patients achieving greater than or equal to 5% weight loss from randomization to week 56. After 56 weeks, treatment with Saxenda resulted in a statistically significant reduction in weight compared with placebo. Statistically significantly greater proportions of patients treated with Saxenda achieved 5% and 10% weight loss than those treated with placebo. In Study 3, statistically significantly more patients randomized to Saxenda than placebo had not gained more than 0.5% of body weight from randomization to week 56.

Side Effects

Adverse effects associated with the use of Saxenda may include, but are not limited to nausea, hypoglycemia, diarrhea, constipation, vomiting, headache, decreased appetite, dyspepsia, fatigue, dizziness, abdominal pain, and increased lipase.

Liraglutide causes thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Saxenda causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined. Saxenda is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Mechanism of Action

Saxenda is an acylated human glucagon-like peptide-1 (GLP-1) receptor agonist. GLP-1 is a physiological regulator of appetite and calorie intake, and the GLP-1 receptor is present in several areas of the brain involved in appetite regulation. In animal studies, peripheral administration of liraglutide resulted in the presence of liraglutide in specific brain regions regulating appetite, including the hypothalamus. Although liraglutide activated neurons in brain regions known to regulate appetite, specific brain regions mediating the effects of liraglutide on appetite were not identified in rats.

Zerbaxa (ceftolozane + tazobactam)

Zerbaxa is a combination of ceftolozan, a novel cephalosporin, and tazobactam, a beta-lactamase inhibitor.

Zerbaxa is specifically indicated for the treatment of patients 18 years or older with the following infections caused by designated susceptible microorganisms:

- **Complicated intra-abdominal infections**

Zerbaxa used in combination with metronidazole is indicated for the treatment of complicated intra-abdominal infections caused by the following Gram-negative and Gram-positive microorganisms: *Enterobacter cloacae*, *Escherichia coli*, *Klebsiella oxytoca*, *Klebsiella pneumoniae*, *Proteus mirabilis*, *Pseudomonas aeruginosa*, *Bacteroides fragilis*, *Streptococcus anginosus*, *Streptococcus constellatus*, and *Streptococcus salivarius*.

- **Complicated Urinary Tract Infections, including Pyelonephritis**

Zerbaxa is indicated for the treatment of complicated urinary tract infections including pyelonephritis, caused by the following Gram-negative microorganisms: *Escherichiacoli*, *Klebsiella pneumoniae*, *Proteus mirabilis*, and *Pseudomonas aeruginosa*.

Zerbaxa is supplied as a solution for intravenous infusion. The recommended dosage regimen of Zerbaxa (ceftolozane/tazobactam) for Injection is 1.5 g (1 g/0.5 g) administered every 8 hours by intravenous infusion over 1 hour in patients 18 years or older and with normal renal function or mild renal impairment. The duration of therapy should be guided by the severity and site of infection and the patient's clinical and bacteriological progress.

Clinical Results

FDA Approval

The FDA approval of Zerbaxa was based on the following studies:

- **Complicated intra-abdominal infections:**

A multinational, double-blind enrolled 979 adults hospitalized with cIAI who were randomized to Zerbaxa (ceftolozane/tazobactam 1 g/0.5 g intravenously every 8 hours) plus metronidazole (500 mg intravenously every 8 hours) or meropenem (1 g intravenously every 8 hours) for 4 to 14 days of therapy. The primary efficacy endpoint was clinical response, defined as complete resolution or significant improvement in signs and symptoms of the index infection at the test-of-cure (TOC) visit which occurred 24 to 32 days after the first dose of study drug. The primary efficacy analysis population was the microbiological intent-to-treat (MITT) population, which included all patients who had at least 1 baseline intra-abdominal pathogen regardless of the susceptibility to study drug. The MITT population consisted of 806 patients. Zerbaxa plus metronidazole was non-inferior to meropenem with regard to clinical cure rates at the TOC visit in the MITT population; 83% and 87.3%, respectively.

- **Complicated urinary tract infections:**

A multinational, double-blind study enrolled 1,068 adults hospitalized with cUTI (including pyelonephritis) who were randomized to Zerbaxa (ceftolozane/tazobactam 1



g/0.5 g intravenously every 8 hours) or levofloxacin (750 mg intravenously once daily) for 7 days of therapy. The primary efficacy endpoint was defined as complete resolution or marked improvement of the clinical symptoms and microbiological eradication. The primary efficacy analysis population was the microbiologically modified intent-to-treat (mMITT) population, which included all patients who received study medication and had at least 1 baseline uropathogen. The mMITT population consisted of 800 patients with cUTI, including 656 (82%) with pyelonephritis. Zerbaxa demonstrated efficacy with regard to the composite endpoint of microbiological and clinical cure at the TOC visit in both the mMITT and ME populations. In the mMITT population, the composite cure rate in Zerbaxa-treated patients with concurrent bacteremia at baseline was 23/29 (79.3%). Although a statistically significant difference was observed in the Zerbaxa arm compared to the levofloxacin arm with respect to the primary endpoint, it was likely attributable to the 212/800 (26.5%) patients with baseline organisms non-susceptible to levofloxacin. Among patients infected with a levofloxacin-susceptible organism at baseline, the response rates were similar.

Side Effects

Adverse effects associated with the use of Zerbaxa may include, but are not limited to nausea, diarrhea, headache, and pyrexia.

Mechanism of Action

Zerbaxa is a combination of ceftolozane and tazobactam. Ceftolozane belongs to the cephalosporin class of antibacterial drugs. The bactericidal action of ceftolozane results from inhibition of cell wall biosynthesis, and is mediated through binding to penicillin-binding proteins (PBPs). Ceftolozane is an inhibitor of PBPs of *P. aeruginosa* (e.g. PBP1b, PBP1c, and PBP3) and *E. coli* (e.g., PBP3). Tazobactam sodium has little clinically relevant in vitro activity against bacteria due to its reduced affinity to penicillin-binding proteins. It is an irreversible inhibitor of some beta-lactamases (e.g., certain penicillinases and cephalosporinases), and can bind covalently to some chromosomal and plasmid-mediated bacterial beta-lactamases.

Lynparza (olaparib)

Lynparza (olaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor. It selectively binds to and inhibits PARP, inhibiting PARP-mediated repair of single strand DNA breaks; PARP inhibition enhances the cytotoxicity of DNA-damaging agents and reverses tumor cell chemoresistance and radioresistance.

Lynparza is specifically indicated as monotherapy in patients with deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA-approved test) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.

Lynparza is supplied as capsules for oral administration. The recommended dose is 400 mg taken twice daily. Continue treatment until disease progression or unacceptable toxicity.

Clinical Results

FDA Approval

Lynparza was approved for ovarian cancer under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials. The FDA approval of Lynparza was based on a single-arm study in patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced cancers. A total of 137 patients with measurable, gBRCAm associated ovarian cancer treated with three or more prior lines of chemotherapy were enrolled. All patients received Lynparza at a dose of 400 mg twice daily as monotherapy until disease progression or intolerable toxicity. Objective response rate (ORR) and duration of response (DOR) were assessed by the investigator according to RECIST v1.1. The percentage of patients with ORR was 34% and the median DOR was 7.9 months. The percentage with Complete Response was 2% and partial response was 32%.


Side Effects

Adverse effects associated with the use of Lynparza may include, but are not limited to anemia, nausea, fatigue (including asthenia), vomiting, diarrhea, dysgeusia, dyspepsia, headache, decreased appetite, nasopharyngitis/pharyngitis/URI, cough, arthralgia/musculoskeletal pain, myalgia, back pain, dermatitis/rash, and abdominal pain/discomfort.

Myelodysplastic syndrome/Acute Myeloid Leukemia: (MDS/AML) occurred in patients exposed to Lynparza, and some cases were fatal.

Monitor patients for hematological toxicity at baseline and monthly thereafter.

Mechanism of Action

Lynparza (olaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor. PARP enzymes are involved in normal cellular homeostasis, such as DNA transcription, cell cycle regulation, and DNA repair. Olaparib has been shown to inhibit growth of select tumor cell lines in vitro and decrease tumor growth in mouse xenograft models of human cancer both as monotherapy or following platinum-based chemotherapy. Increased cytotoxicity and anti-tumor activity following treatment with olaparib were noted in cell lines and mouse tumor models with deficiencies in BRCA. In vitro studies have shown that olaparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complex, resulting in disruption of cellular homeostasis and cell death. 

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

Eur J Neurol. 2015 Jan 2. doi: 10.1111/ene.12624.
[Epub ahead of print]

Time Course of Clinical and Neuroradiological Effects of Delayed-release Dimethyl Fumarate in Multiple Sclerosis.

Kappos L, Giovannoni G, Gold R, et al; the DEFINE and CONFIRM study investigators

BACKGROUND AND PURPOSE: Delayed-release dimethyl fumarate (DMF, also known as gastro-resistant DMF), demonstrated efficacy and safety in relapsing-remitting multiple sclerosis in the 2-year, randomized, placebo-controlled, phase 3 DEFINE and CONFIRM trials. A post hoc analysis of integrated data from DEFINE and CONFIRM was conducted to determine the temporal profile of the clinical and neuroradiological effects of DMF.

METHODS: Eligible patients were randomized to receive placebo, DMF 240 mg twice (BID) or three times (TID) daily or glatiramer acetate (GA; reference comparator; CONFIRM only) for up to 96 weeks. Patients in the GA group were excluded from this analysis.

RESULTS: A total of 2301 patients were randomized and received treatment with placebo (n = 771) or DMF BID (n = 769) or TID (n = 761). DMF significantly reduced the annualized relapse rate beginning in weeks 0-12 (BID, P = 0.0159; TID, P = 0.0314); the proportion of patients relapsed beginning at week 10 (BID, P = 0.0427) and week 12 (TID, P = 0.0451); and the proportion of patients with 12-week confirmed disability progression beginning at week 62 (BID, P = 0.0454) and week 72 (TID, P = 0.0399), compared with placebo. These effects were sustained throughout the 2-year study period. DMF significantly reduced the odds of having a higher number of gadolinium-enhancing lesions by 88% (BID) and 75% (TID) and the mean number of new or enlarging T2 lesions by 72% (BID) and 67% (TID), from the first post-baseline magnetic resonance imaging assessment at 24 weeks (all P < 0.0001 versus placebo). **CONCLUSIONS:** In phase 3 clinical trials, DMF demonstrated rapid and sustained clinical and neuroradiological efficacy in relapsing-remitting multiple sclerosis.

Aust N Z J Obstet Gynaecol. 2014 Dec 31. doi: 10.1111/ajo.12292. [Epub ahead of print]

Antenatal Care Provider's Advice Is the Key Determinant of Influenza Vaccination Uptake in Pregnant Women.

Mak DB, Regan AK, Joyce S, Gibbs R, Effler PV.

BACKGROUND: Although influenza vaccination is an important component of antenatal care and is recommended and funded by the Australian government, vaccination uptake has been low. **AIMS:** This study compared seasonal influenza vaccination uptake among pregnant Western Australian (WA) women and identified factors associated with vaccination uptake.

MATERIALS AND METHODS: Adult women who were pregnant during the 2012 and 2013 influenza vaccination seasons were selected at random and invited to complete a computer-assisted telephone interview survey about whether they received influenza vaccination during pregnancy. Data analyses were weighted to the age distribution of women of reproductive age in WA. Multivariate logistic regression was used to identify factors associated with vaccination uptake.

RESULTS: Between 2012 and 2013, the proportion of WA women whose antenatal care provider recommended influenza vaccination increased from 37.6 to 62.1% and vaccination uptake increased from 23.0% to 36.5%. The antenatal care provider's advice to have influenza vaccine was the single most important factor associated with vaccination (OR 11.1, 95% CI 7.9-15.5). Most women (63.7%) were vaccinated in general practice, 18.8% in a public hospital antenatal clinic and 11.0% at their workplace. Wanting to protect their infant from infection (91.2%) and having the vaccine recommended by their GP (60.0%) or obstetrician (51.0%) were commonly reported reasons for vaccination; worrying about side effects was a common reason for nonvaccination.

CONCLUSIONS: To optimise maternal and infant health outcomes, Australian antenatal care providers and services need to incorporate both the recommendation and delivery of influenza vaccination into routine antenatal care.

Am J Hematol. 2015 Jan 2. doi: 10.1002/ajh.23933. [Epub ahead of print]

[Effect of Cumulative Bortezomib Dose on Survival in Multiple Myeloma Patients Receiving Bortezomib-Melphalan-Prednisone in the Phase III VISTA Study.](#)

Mateos M, Richardson PG, Dimopoulos MA, et al.

This analysis, using data from the bortezomib-melphalan-prednisone (VMP) arm of the Phase III VISTA study, investigated whether increased cumulative bortezomib dose could improve overall survival (OS) in transplant-ineligible patients with previously untreated multiple myeloma. Median cumulative bortezomib dose received by the 340 patients was 39 mg/m²; this was selected as the cut-off for defining the dose groups to be compared for OS. Patient characteristics were well balanced between dose groups except for age. OS was significantly longer in the higher (≥ 39 mg/m²) versus lower (< 39 mg/m²) cumulative bortezomib dose group (median 66.3 vs. 46.2 months; hazard ratio [HR] 0.533, $P < 0.0001$; age-adjusted HR 0.561, $P = 0.0002$). To overcome confounding effects of early discontinuations/deaths, which were more common in the lower cumulative dose group (27% vs 4% of patients discontinued due to adverse events in the lower and higher cumulative dose groups, respectively), a landmark analysis was conducted at 180 days, eliminating patients who died or discontinued before this time from the analysis. OS from this landmark remained significantly longer in the higher dose group (median 60.4 vs. 50.3 months; HR 0.709, $P = 0.0372$). Thus, higher cumulative bortezomib dose, reflecting prolonged treatment duration and/or dose intensity, appears associated with improved OS. Approaches to achieve higher cumulative doses could include subcutaneous bortezomib administration, dose/schedule modifications, continuing therapy in responding patients, and proactive adverse event management.

Influenza Other Respir Viruses. 2015 Jan 4. doi: 10.1111/irv.12301. [Epub ahead of print]

[Zanamivir Versus Trivalent Split Virus Influenza Vaccine: A Pilot Randomized Trial.](#)

Coleman BL, Fadel SA, Drews SJ, Hatchette TF, McGeer AJ.

BACKGROUND: Healthcare workers may be exposed to people with respiratory viral infections more often than other working adults. Understanding the risk and the effectiveness of different

preventive measures is of great importance.

OBJECTIVES: To estimate adherence to prophylactic antiviral medication for a full influenza season, to compare efficacy of antiviral prophylaxis to that of the seasonal influenza vaccine and to identify exposures that increase risk of acute respiratory illnesses (ARI) in healthy adults.

METHODS: Participants were randomized 1:2 to receive the 2008-2009 influenza vaccine or daily prophylaxis with 10 mg of zanamivir during the season. Web-based questionnaires collected information on demographics, symptoms, exposures, medication use and side effects. **RESULTS:** Sixty-four healthy adults were recruited in November 2008. Three of 40 active participants discontinued zanamivir due to side effects; the remaining 37 took $> 85\%$ of scheduled doses for a median of 121 days. Symptomatic, laboratory-confirmed influenza was detected in one person randomized to zanamivir (2.5%) and 2/20 (10%) who received the vaccine ($P = 0.25$). Forty-seven participants reported 109 episodes of ARI. Factors associated with an ARI were exposure to a spouse (OR 7.2), child (OR 2.4) or patient (OR 2.0) with symptoms of an ARI in the previous 7 days.

CONCLUSIONS: Breakthrough influenza infection occurred in both vaccinated participants and those receiving antiviral prophylaxis. Most adults were willing and able to comply with season-long prophylaxis. Report of recent exposure to family members and patients with an ARI increased the risk of developing an ARI in healthy adults.

Support Care Cancer. 2015 Jan 6. [Epub ahead of print]

[Variation in Fatigue Among 6011 \(Long-term\) Cancer Survivors and a Normative Population: A Study From the Population-based PROFILES Registry.](#)

Husson O, Mols F, van de Poll-Franse L, de Vries J, Schep G, Thong MS.

PURPOSE: Cancer survivors commonly experience fatigue, related to disease and its treatment. This study aimed to compare fatigue severity among survivors of different cancer types with a normative population and also to identify variations in fatigue among cancer survivors according to clinical and demographic variables.

METHODS: We used cancer survivorship data from the population-based PROFILES registry. We included survivors of endometrial (EC, $n = 741$) or colorectal cancer (CRC, $n = 3878$) (1998-2007), thyroid cancer (TC, $n = 306$) (1990-2008), Hodgkin (HL, $n = 150$) or non-Hodgkin lymphoma (NHL, $n = 716$), or multiple myeloma (MM, $n = 120$) (1999-2008). A representative ►

Dutch normative population (n=2040) was also assessed. Participants completed the Fatigue Assessment Scale.

RESULTS: Cancer survivors were more often classified as fatigued (EC/CRC 39%, HL 40%, NHL 43%, MM 51%, TC 44%) compared with the normative population (21 %; $P < 0.001$). MM survivors were more often classified as fatigued than all other cancer groups, except NHL (overall $P = 0.02$). Shorter times since diagnosis (< 5 years, 41 versus 38%; $P < 0.05$), younger age (≤ 65 years, 42% versus 39%; $P < 0.01$), being female (43% versus 36%; $P < 0.01$), chemotherapy treatment (43% versus 39%; $P < 0.01$), comorbidity (no (27%) versus 1 (35%) versus ≥ 2 (52%); $P < 0.01$), educational level (low (44%) versus medium (41%) versus high (32%); $P < 0.01$), and absence of a partner (47% versus 38%; $P < 0.01$) were associated with fatigue.

CONCLUSIONS: Fatigue levels are substantial in (long-term) cancer survivors and vary depending on cancer type, time since diagnosis, age, gender, treatment with chemotherapy, number of comorbid conditions, educational level, and partnership. Since significantly more cancer survivors feel fatigued in comparison with the normative population, appropriate information, assessment, and interventions for fatigue are needed during or after oncologic treatment. Furthermore, focus on better control or management of comorbid conditions of cancer survivors is recommended.

World J Gastroenterol. 2014 Dec 21;20(47):17932-17940.
doi: 10.3748/wjg.v20.i47.17932.

[Lean-non-alcoholic Fatty Liver Disease Increases Risk for Metabolic Disorders in a Normal Weight Chinese population.](#)

Feng RN, Du SS, Wang C, et al.

AIM: To study the prevalence and clinical biochemical, blood cell and metabolic features of lean-non-alcoholic fatty liver disease (lean-NAFLD) and its association with other diseases.

METHODS: Demographic, biochemical and blood examinations were conducted in all the subjects in this study. We classified the subjects into four groups according to their weight and NAFLD status: lean-control, lean-NAFLD [body mass index (BMI) < 24 kg/m²], overweight-obese control and overweight-obese NAFLD. One-way analysis of variance (ANOVA) was used to compare the means of continuous variables (age, BMI, blood pressure, glucose, lipid, insulin, liver enzymes and blood cell counts) and the χ^2 test was used to compare the differences in frequency of categorical variables (sex, education, physical activity, smoking, alcohol consumption and prevalence of hypertension, hyperlipidemia, diabetes, metabolic syndrome central obesity

and obesity). Both univariate and multivariate logistic regression models were adopted to calculate odds ratios (ORs) and predict hyperlipidemia, hypertension, diabetes and metabolic syndrome when we respectively set all controls, lean-control and overweight-obese-control as references. In multivariate logistic regression models, we adjusted potential confounding factors, including age, sex, smoking, alcohol consumption and physical activity.

RESULTS: The prevalence of NAFLD was very high in China. NAFLD patients were older, had a higher BMI, waist circumference, blood pressure, fasting blood glucose, insulin, blood lipid, liver enzymes and uric acid than the controls. Although lean-NAFLD patients had lower BMI and waist circumference, they had significantly higher visceral adiposity index than overweight-obese controls. Lean-NAFLD patients had comparable triglyceride, cholesterol and low-density lipoprotein cholesterol to overweight-obese NAFLD patients. In blood cell examination, both lean and overweight-obese NAFLD was accompanied by higher white blood cell count, red blood cell count, hemoglobin and hematocrit value. All NAFLD patients were at risk of hyperlipidemia, hypertension, diabetes and metabolic syndrome (MetS). Lean-NAFLD was more strongly associated with diabetes (OR = 2.47, 95%CI: 1.14-5.35), hypertension (OR = 1.72, 95%CI: 1.00-2.96) and MetS (OR = 3.19, 95%CI: 1.17-4.05) than overweight-obese-NAFLD (only OR for MetS was meaningful: OR = 1.89, 95%CI: 1.29-2.77). NAFLD patients were more likely to have central obesity (OR = 1.97, 95%CI: 1.38-2.80), especially in lean groups (OR = 2.17, 95%CI: 1.17-4.05).

CONCLUSION: Lean-NAFLD has unique results in demographic, biochemical and blood examinations, and adds significant risk for diabetes, hypertension and MetS in lean individuals.

Transpl Int. 2015 Jan 3. doi: 10.1111/tri.12510. [Epub ahead of print]

[Early Kidney Transplantation Improves Neurocognitive Outcome in Patients With Severe Congenital Chronic Kidney Disease.](#)

Hartmann H, Hawellek N, Wedekin M, et al.

BACKGROUND: Renal replacement therapy has become available for the majority of patients suffering from severe congenital chronic kidney disease (CKD). Data on the long-term neurocognitive outcome and the impact of early kidney transplantation (KTx) in this setting is unclear.

METHODS: Neurocognitive outcomes in 15 patients (11 male) with isolated congenital CKD (stage 3-5) requiring KTx at a mean age of 2.8 ± 1.3 were assessed at a mean age of 8.3

±1.4 years. Patients underwent neurological examination and testing for neuromotor and neurocognitive function using three independent tests.

RESULTS: Pre-emptive KTx was performed in 6 patients and 9 patients were dialyzed prior to KTx for a mean period of 11.1 ± 8.6 months. Neuromotor function was abnormal in 8/15 patients. HAWIK III showed a global IQ of 93.5±11.4 (P = 0.05) due to a significantly reduced performance IQ of 89.1±11.3 (P < 0.01). In 3 patients the global IQ was clinically significantly reduced by > 1 SD to < 85. In patients with neuromotor dysfunction, performance IQ was lower than in patients with normal neuromotor function (83.8 ± 10.2 vs. 96.2 ± 9.0, P = 0.04). Time on dialysis was inversely correlated to verbal IQ (r = 0.78, P = 0.02). Pre-emptive KTx and duration of dialysis treatment less than 3 months was associated with superior neurocognitive outcome.

CONCLUSIONS: Early (pre-emptive) KTx results in superior long-term neurocognitive outcome in children with severe congenital CKD.

Catheter Cardiovasc Interv. 2015 Jan 2. doi: 10.1002/ccd.25807. [Epub ahead of print]

[Procedural Failure of Chronic Total Occlusion Percutaneous Coronary Intervention: Insights from a Multicenter US Registry.](#)

Sapontis J, Christopoulos G, Grantham JA, et al.

BACKGROUND: The hybrid approach to chronic total occlusion (CTO) percutaneous coronary intervention (PCI) has significantly increased procedural success rates, yet some cases still fail. We sought to evaluate the causes of failure in a contemporary CTO PCI registry.

METHODS: We examined 380 consecutive patients who underwent CTO-PCI at 4 high volume PCI centers in the United States using the 'hybrid' approach. Clinical, angiographic, complication, and efficiency outcomes were compared between successful and failed cases. Failed cases were individually reviewed by an independent reviewer to determine the cause of failure.

RESULTS: Procedural success was 91.3%. Compared with patients in whom CTO PCI was successful, those in whom CTO PCI failed had similar baseline clinical characteristics, but were more likely to have longer occlusion length, more tortuosity, more proximal cap ambiguity and blunt stump, and higher mean J-CTO scores (2.8±1.1 vs. 3.5±1.0, p<0.001), and less likely to have collaterals suitable for the retrograde approach (66% vs 45%, p=0.021). Failure was due to a complication in 10 cases (30%). In the remaining 23 cases (70%) failure was due to inability to wire

the lesion (n=21, 4 of which were CTOs due to in-stent restenosis), or poor antegrade flow after PCI (n=5).

CONCLUSIONS: Compared with successful cases, failed CTO-PCI cases are more likely to have higher J-CTO scores, longer occlusion length, ambiguous proximal cap and no appropriate collaterals for retrograde crossing. Development of novel CTO crossing techniques is needed to further increase CTO PCI success rates.

J Clin Endocrinol Metab. 2015 Jan 2;jc20142443. [Epub ahead of print]


Rev Esp Cardiol (Engl Ed). 2015 Jan;68(1):39-46. doi: 10.1016/j.rec.2014.02.021. Epub 2014 Jul 23.

[Economic Impact of Heart Failure According to the Effects of Kidney Failure.](#)

Sicras Mainar A, Navarro Artieda R, Ibáñez Nolla J.

INTRODUCTION AND OBJECTIVES: To evaluate the use of health care resources and their cost according to the effects of kidney failure in heart failure patients during 2-year follow-up in a population setting.

METHODS: Observational retrospective study based on a review of medical records. The study included patients ≥ 45 years treated for heart failure from 2008 to 2010. The patients were divided into 2 groups according to the presence/absence of KF. Main outcome variables were comorbidity, clinical status (functional class, etiology), metabolic syndrome, costs, and new cases of cardiovascular events and kidney failure. The cost model included direct and indirect health care costs. Statistical analysis included multiple regression models. **RESULTS:** The study recruited 1600 patients (prevalence, 4.0%; mean age 72.4 years; women, 59.7%). Of these patients, 70.1% had hypertension, 47.1% had dyslipidemia, and 36.2% had diabetes mellitus. We analyzed 433 patients (27.1%) with kidney failure and 1167 (72.9%) without kidney failure. Patients with kidney failure were associated with functional class III-IV (54.1% vs 40.8%) and metabolic syndrome (65.3% vs 51.9%, P < .01). The average unit cost was 10 711.40. The corrected cost in the presence of kidney failure was 14 868.20 vs 9364.50 (P = .001). During follow-up, 11.7% patients developed ischemic heart disease, 18.8% developed kidney failure, and 36.1% developed heart failure exacerbation.

CONCLUSIONS: Comorbidity associated with heart failure is high. The presence of kidney failure increases the use of health resources and leads to higher costs within the National Health System. 

Health Share Oregon Coordinated Care Organization

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with these providers. Although it will likely continue to serve as a RAE for safety-net clinics, CareOregon is supportive of this change in its network as part of its transition toward a company that offers management services for health system improvement. **CE**

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CMS Proposed Rule Would Require All Hospitals to Recognize gay marriage

As same-sex marriage rights expand around the country, it's time for medical facilities to follow suit when it comes to the rights of patients and their spouses, the Centers for Medicare & Medicaid Services (CMS) proposed.

The proposed revision to the CMS patient rights regulations would "ensure that same-sex spouses in legally valid marriages are recognized and afforded equal rights" in facilities throughout the country that accept Medicare, even in states in which gay marriage is not yet legal. The current regulations leave room for hospitals, nursing homes, hospice centers, mental health clinics and surgery centers to deny spousal rights to legally married gay couples if they visit a facility in a state that doesn't

recognize their union, Bloomberg reported.

The regulation changes mainly concern who can legally be recognized as a patient's representative—a person who can make life-and-death decisions to authorize or stop care if the patient is unable to make those decisions. Federal regulations already mandate that Medicare and Medicaid participating facilities cannot discriminate based on sexual orientation and gender identity in their patient visitation policies, according to CMS rule revisions made in 2011.

The impetus for the recently proposed rule change, according to the CMS proposal, is the Supreme Court decision in June 2013 that effectively gutted the 1996 Defense of Marriage Act, which

prohibited the federal government from recognizing same-sex marriages. As the gay-rights movement picks up steam, the healthcare industry is now a key player in the nationwide trend. The Human Rights Campaign, for example, ranks facilities via a "healthcare equality index" based on the four core values of patient non-discrimination, employee non-discrimination, equal visitation and training, according to its [website](#). The gay-rights advocacy group says 427 facilities meet these criteria, a 101% increase from those responding to its survey in 2013.

The CMS proposal comes amid an industry-wide trend in which healthcare facilities strive to provide more inclusive care for certain populations. ■

Redesigning Case Management to Integrate Into the Patient-Centered Medical Home *continued from page 15*

feet. The CCT Team had discussed the patient daily and was aware of pending issues. The second day after discharge, the patient was scheduled to see the PCP. The case management nurse went to the office for the visit and together, the physician, health coach, and case manager discussed the issues before the patient was seen. The patient and his wife arrived for the visit and the patient acknowledged he needed rehab. The case manager called the social worker, who was able to secure a rehab bed. The patient left the office and was admitted to rehab. This patient had a

great outcome and was able to return home. No falls, and no readmission to the hospital. How do we quantify results like this for our system or the patient and his family?

Redesigning case management to integrate with the PCMH has been challenging. However we are seeing the benefits to this new design. Change is hard, but it is easier when your personal and professional goals can also be met through these changes. We are getting to really know our patients, across the continuum of their lives, not just at hospitalization. They know we care. The care we provide is reflected in decreased readmission and admissions to the hospital. Even more important is that we will be affecting the wellness of

the population of our community. In our hearts we know we are doing the right thing. **CE**

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Evolving Views on Disability Disclosure in the Workplace

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their disability because they don't want to "live in the closet." However, others, who don't trust the employer, may choose not to disclose.

"There is not one right decision for everybody and every situation," Rudstam said. "People with disabilities need to reflect on their values, the situation, and the job. They need to think through how they feel about their disability, if they trust the particular employer, and whether they need an accommodation." Also, individuals with disabilities need to keep in mind that several laws restrict employers from broadly sharing a disability disclosure with others within their organization or work group.

Finally, Rudstam recommends that employees or applicants needing accommodations do their homework to prepare to discuss with the employer how the impairment is affecting their job and what type of accommodation

might be most effective.

Meanwhile, Sember-Chase discussed how attitudes toward disability disclosure are shifting as businesses and employers try to diversify the workforce and create more inclusive environments.

"Historically, those efforts have predominantly focused on creating more diverse workplaces in terms of race, gender, and sexual orientation... now we're starting to see more businesses including disability in their diversity efforts," Sember-Chase said. "There is more of a recognition and understanding that people with different disabilities also represent diversity in a good way."

To attract and recruit individuals with disabilities, employers are starting to be more mindful of disabilities, including those that are not easily noticed, such as learning disabilities.

"Businesses need to think more creatively about how to put the message out there that individuals with disabilities are welcome and wanted, because that's the only way an

individual is going to feel comfortable disclosing," Sember-Chase said. "If individuals with disabilities previously experienced any sort of negative outcomes or ramifications to sharing that part of their identity, they're going to be hesitant about doing it again."

To help job seekers and individuals feel more compelled to share a disability, businesses will need to reshape their message in "very simple, subtle ways," Sember-Chase noted. This may include welcoming people with disabilities in job announcements and postings, and including the term disability in Equal Opportunity statements.

Companies also should consider forming an affinity or employee resource group for employees with disabilities, just as they have for other underrepresented minority groups. "Creating a disability resource or affinity group in an organization sends a powerful message that this is something [a company] welcomes as part of its workforce," she said. **CM**

The Role of Certified Case Managers in Care Coordination

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system is shifting away from this volume-driven approach to one that is more driven by value. The Patient Protection and Affordable Care Act (ACA) contains numerous mechanisms designed to move the US health care system toward value-based care. Broadly, the ACA seeks to reduce the overall costs of care by incentivizing the achievement of better health outcomes, higher quality and greater efficiency, and encouraging more patient-centered, coordinated care. The result is an evolving system where providers stand to share in the savings that result from better disease management and improved care coordination.

Adding Value Through Care Coordination

Certified case managers (CCMs) are poised to play an increasingly important and vital role as hospitals, ambulatory care practices, and other health care organizations adopt new approaches to deliver patient-centered, coordinated care. CCMs have the demonstrated abilities and qualifications to be key members of the care coordination teams these organizations design to facilitate the achievement of positive patient health outcomes.

The Agency for Healthcare Research and Quality (AHRQ) broadly defines care coordination as, “the deliberate organization of patient care activities between two or more participants (including the patient) involved in a patient’s care to facilitate the appropriate delivery of health care services.”¹ In short, care coordination is a means to ensure that the right care is delivered in the right place, at the right time, by the right person.

The Certified Case Manager’s Role

Care coordination often falls within the domain of the certified case manager, who has the unique skills to assess, plan,

facilitate, evaluate, and advocate for options and services to meet an individual’s comprehensive health needs. Today’s evolving environment offers enormous opportunity for certified case managers, as organizations increasingly recognize and prioritize the role of the care coordinator. As part of a patient-centered care team, the care coordinator is responsible for engaging the patient and identifying his or her health goals and coordinating services, providers, and supports to meet those goals. The care coordinator must also possess the skills and expertise to navigate complex systems and have the ability to communicate with a range of people from physicians to patients and their families. They must be willing to learn about and understand the patient’s struggles, be able to identify their strengths, and have the skills to work with the patient to adjust the care plan based on changing issues, needs, and priorities. Ultimately, the care coordinator has the responsibility for ensuring that a comprehensive, flexible care plan is developed and executed in partnership with the person at the center of that plan—the patient. **CM**

Gene Gosselin, RN, MA, CCM, LPC, is Director, Customer Strategy & Solutions Group, Pfizer, in New York, NY.

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Protected Health Information: What Sharing Means

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role that family members, such as spouses, often play in a patient’s health care.

For example, the Privacy Rule allows covered entities to share information about the patient’s care with family members in various circumstances.

OCR also makes it clear in the above publication that the term “spouse” includes individuals who are in legally valid same-sex marriages sanctioned by a state, territory, or foreign jurisdiction as long as a US jurisdiction would also recognize the marriages. It goes on to state that the term “marriage” includes both same-sex and opposite-sex marriages and “family member” includes dependents of those marriages. These terms apply to individuals who are legally married, whether or not they live in or receive services in jurisdictions that recognize their marriages. OCR also makes it clear that legally married same-sex spouses, regardless of where they live, are family members for the purposes of sharing PHI.

The above requirements are applicable to both covered entities and business associates.

OCR plans to publish additional guidance in the future about same-sex spouses in the role of personal representatives.

As usual in health care, stay tuned for more! **CM**

Elizabeth E. Hogue, Esq., is an attorney who specializes in health care. She can be reached at ElizabethHogue@ElizabethHogue.net.

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Editor-in-Chief: Gary S. Wolfe, RN, CCM
831-443-6847;
email: gwolfe@academyccm.org

Executive Editor: Jennifer Maybin, MA, ELS
203-454-1333, ext. 3;
email: jmaybin@academyccm.org

Publisher/President: Howard Mason, RPH, MS
203-454-1333, ext. 1;
e-mail: hmason@academyccm.org

Art Director: Laura D. Campbell
203-256-1515
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Executive Vice President:
Gary S. Wolfe, RN, CCM
831-443-6847;
email: gwolfe@academyccm.org

Member Services:
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