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Gary S. Wolfe

Digital Health and Case Management: The Future is Now

Digital health is a driving force in how healthcare is administered, customized, and reimagined. It is breeding revolutionary approaches, unprecedented partnerships, and groundbreaking solutions. We have witnessed a proliferation of digital technologies in our lifetime. Just think about the smartphone and all of its uses and applications. If you have a smartphone, you have a computer in your hand, purse, or pocket at all times.

Some of the interventions using digital health include:

- Tracking chronic diseases
- Identifying risk factors and care gaps
- Technology-enabled provider house calls
- Artificial intelligence–powered voice-enabled digital assistant that helps providers focus on taking care of patients
- Smart watches measuring patient vital signs
- Total transformation of remote and home health care with cutting-edge technology

Digital technologies promote access, control costs, and improve outcomes.

Technology is putting healthcare directly in the hands of consumers. From remote monitoring to wearable diagnostic solutions, new tools and technologies are increasing patient engagement. Revolutionary technologies have the potential to cure disease, drive efficiency, and bring down barriers between providers and patients. We must reduce bureaucracy and regulations to safely and expeditiously embrace the benefits for patient care.

Innovation will come from forward-thinking companies. As health insurance costs continue to increase, many employers are on the lookout for new ways to cut costs. Employers are using technology solutions to improve healthcare quality and reduce costs.

Digital health is changing the entry point to the health system (see article in this issue titled "Top Trends in Digital Health in 2019"). In the past, people who were sick visited their physician, but today technology is helping consumers to make more of their own healthcare decisions. The entry point to the healthcare system has multiple avenues: telehealth vendors, retailers, pharmacies, employers, and primary care physicians.

The Physician Fee Schedule in 2019 has created Healthcare Common Procedure Coding System (HCPCS) codes for digital health including:

- Virtual check-in
- Remote evaluation of prerecorded patient information
- Interprofessional internet consultation
- Remote patient monitoring

Technology is addressing some of our most pressing health problems such as the opioid epidemic. Research has found that virtual reality may help manage pain and distress. Studies have shown that virtual reality can reduce chronic pain by as much as 25% and that the effect can last for hours. In the future, a provider may prescribe virtual reality for patients with chronic pain rather than opioids.

Patient safety and privacy is a major concern in digital health. Patient data and interactions must be protected and

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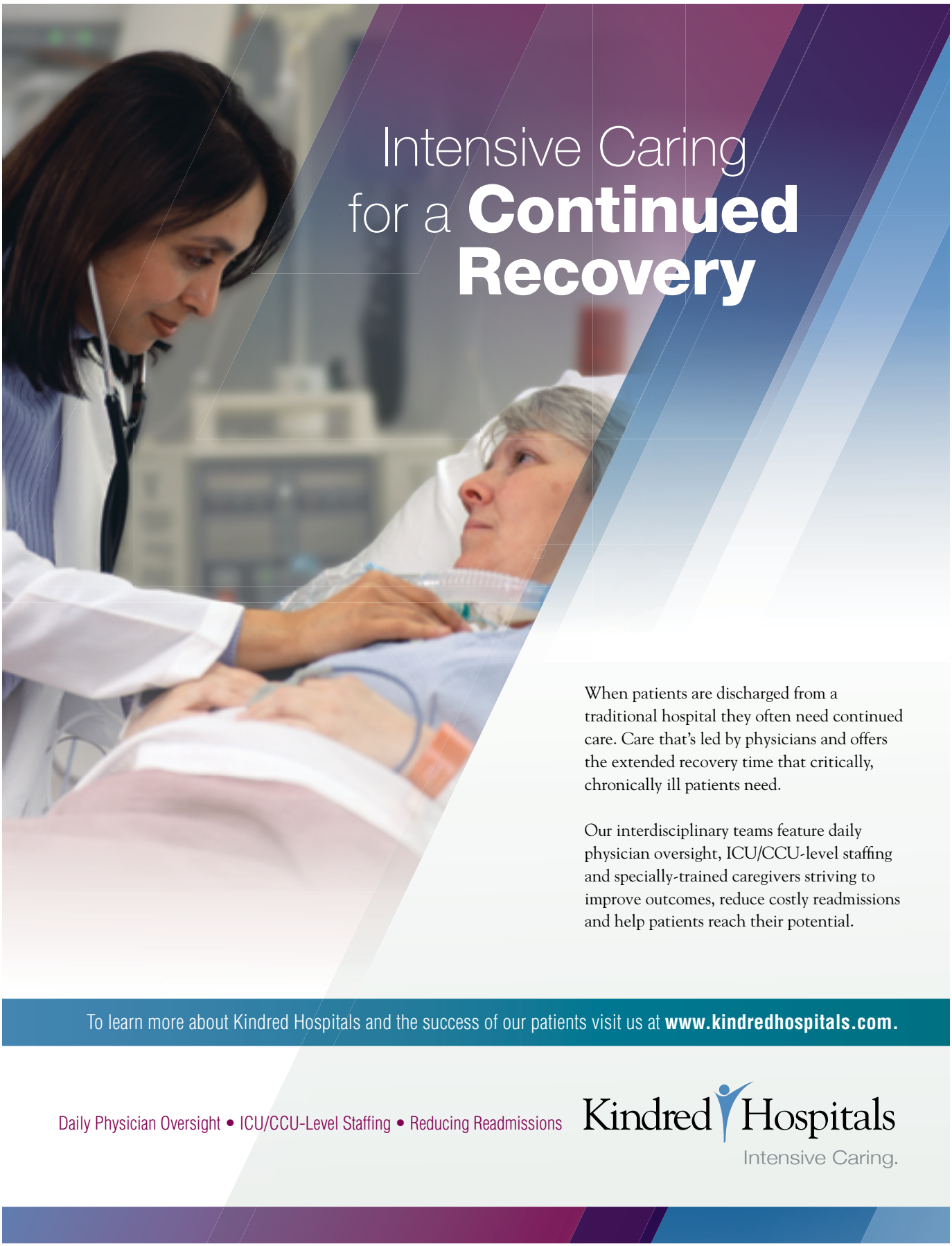

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"Wish List" 2019: Developing Others, Promoting Interprofessional Cooperation

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

As the new year begins, two goals top The Commission for Case Manager Certification's (CCMC) "wish list" for the field of case management. The first is developing others, part of a broader strategic plan to promote certification among current and next-generation case managers. The second is to promote greater collaboration among organizations committed to excellence in practice across a variety of disciplines and professional backgrounds.

Together, these new year "wishes" showcase the potential for professional case managers to play an integral role on interdisciplinary teams to better serve individuals across the continuum of care.

As the new year begins, two goals top The Commission for Case Manager Certification's (CCMC) "wish list" for the field of case management. The first is developing others, part of a broader strategic plan to promote certification among current and next-generation case managers. The second is to promote greater collaboration among organizations committed to excellence in practice across a variety of disciplines and professional backgrounds.

Developing Others

To further our first goal, CCMC recently launched the "Develop Others" toolkit. It offers a range of resources (most free or at low cost) to assist supervisors and experienced case managers in nurturing the professional growth of younger and less experienced colleagues, including their potential certification.

This is part of CCMC's broad, 3-part plan for professionals in the field: to get certified, stay certified, and develop others. This third pillar —Develop Others—looks to the future, with the knowledge that, according to a 2018 Commission survey, more than half (60%) of board-certified case managers have been in the role for more than a decade. As more experienced and highly valued case managers head toward retirement, other professionals must be prepared to take their place.

Among the nearly three-quarters (73%) of surveyed case managers who are supervisors, mentoring is one way their organization develops case managers. The Develop Others toolkit (accessed on the Commission's site under "Mentoring") is one way employers and others organizations can equip themselves to prepare a ready workforce of experienced case managers who are well qualified to meet the challenges of a complex care system.

As CCMC research has shown, the bulk of case manager professional development occurs on the job. There are few undergraduate programs in case management, and many newly licensed nurses and social workers enter their respective fields without knowing much about case management.

As their careers progress, however, many nurses and social workers may find they are engaged in many if not all aspects of professional case management. This positions them to pursue certification as part of advanced practice within their respective disciplines.

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***MaryBeth Kurland, CAE,** is CEO of the Commission for Case Manager Certification, the first and largest nationally accredited organization that certifies more than 45,000 professional case managers and over 2,600 disability management specialists. The Commission is a nonprofit volunteer organization that oversees the process of case manager certification with its CCM® credential and the process of disability management specialist certification with its CDMS® credential.*

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Improving Disability Data

Ed Quick, MA, MBA, CDMS, *Commission for Case Manager Certification*

An employee is off work due to a nonoccupational illness or injury—for example, a broken femur that requires surgery followed by a period of rehabilitation. The employer offers a return-to-work program that would allow the employee to go back to work with modified duties while recovery continues. The individual, however, remains off work for reasons unrelated to the primary diagnosis of a broken femur; rather, the individual has a secondary diagnosis of depression.

Although the claim is appropriately managed and the individual receives the care he/she needs, the disability claims data are not complete. Only the primary diagnosis is included in the disability record and not the secondary diagnosis.

Similar incompleteness can occur with a mental health claim. For example, the diagnosis may be "stress and anxiety at work." Only after the claim is examined does it become apparent that the real cause is bipolar disorder or clinical depression, but the diagnosis has not been updated. With all claims, after the initial diagnosis is recorded through employee self-report or perhaps the initial medical assessment, the case manager should confirm, throughout the life of the claim, that the correct primary diagnosis is reflected in the claim and that any secondary or ancillary diagnoses are captured as well. Otherwise, the disability data are incomplete or, even worse, inaccurate.

From a "population health" perspective across all employees, incomplete or incorrectly categorized disability data will lose predictive value for examining and projecting causes, duration, and frequency of claims among specific employee groups. The problem of incomplete or inaccurate data is surprisingly widespread. According to Ian Bridgman of The Claim Lab, there is a lack of "quality data," particularly around secondary diagnoses, updates on individuals' health conditions, and policy information.

Importantly, the problem is not a lack of information—there's plenty of it. But data quality varies by carrier and third-party administrator, and the variation is further magnified by size and sophistication of the employer. Sizeable companies may be sophisticated in tracking and managing "non-occ" absences (not work-related and therefore not covered by workers' compensation) with controls and quality measures for the data utilization. But smaller and less- sophisticated employers may have gaps in the quality of their claims data and rely only on their carrier or third-party administrator.

With incomplete or inaccurate data, it becomes difficult to understand the "whole person" view of an employee's absence history, including underlying causes, accurate durations, and frequency of claims. While it is possible to look at each employee absence manually by going into the record of each claim, it can become an exhaustive undertaking and, at times, an unrealistic expectation. An individual employee with a complex medical history may have more than 20 to 30 claims over the course of his/her employment and that employee

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

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How Accreditation Supports Child Welfare's Shift to Prevention

Brad Contento, CARF Corporate Communications

One night long ago, someone tried (and failed) to break into my car. Luckily, the would-be burglar succeeded only in punching out the lock on my driver's-side door. Nothing was taken, but the damage left me unable to enter the car from the driver's side.

Over the next year, I accessed my car through the passenger door, sliding over the center console to the driver's seat. This routine got to be so normal that I stopped thinking about it. I accepted it. The car functioned after all. Only after changing cars did I remember there was another way to get in.

Funny how the options we are given affect how we approach a situation. I used only the door available to me even though I would have benefited from having a new one.

This memory popped into my head as I spoke to Leslie Ellis-Lang, CARF's managing director of Child and Youth Services, discussing the Family First Prevention Services Act (FFPSA). I realized the new legislation is a lot like having access to a new car door. Whether you believe it replaces something broken or provides an alternative, it will change how we fund child welfare and provide services to children and families.

***Brad Contento** is the Corporate Communications Manager at CARF International, Tucson, Arizona.*

In the case of FFPSA, the new door is prevention.

Prevention Services

One of the biggest drivers of service options is the availability of funding. When a piece of federal legislation redefines how public funds can be used, it changes the array of available services.

FFPSA's primary focus is prevention services. Simply put, states will be able to use Title IV-E foster care funds for services for children at risk of entering foster care. Previously, these funds could be used only for foster care itself and for adoption assistance.

The primary focus of the Family First Prevention Services Act is prevention services. Simply put, states will be able to use Title IV-E foster care funds for services for children at risk of entering foster care. Previously, these funds could be used only for foster care itself and for adoption assistance.

In addition to prevention services, FFPSA also redefines congregate care–type settings for children who are removed from their homes and are unable to live within a family-like placement. These settings will have to meet specific criteria and will be called Qualified Residential Treatment Programs (QRTPs).

Leslie Ellis-Lang is encouraged by the changes she sees within the child welfare system that address concerns expressed over many years. "FFPSA may represent the opening of a door for providers to focus on issues that occur within families and negatively affect child well-being," she says. "This could allow the family to remain intact."

Leslie acknowledges it is too early to predict what effects the FFPSA legislation will have, but she supports the direction of change. "The intent of FFPSA is to redirect funding to maintain the stability of a family rather than removing children from families when safety is not actually an imminent concern. Though the current goal is not to disrupt families, the new law will provide additional means for families to receive services prior to removal. Then, should the child need to be removed, there is a stronger focus on kinship and community settings. In instances when a QRTP is in the best interest of the child, the setting must now meet specific requirements, such as standards of quality, limited duration, and aftercare services."

"Kids being able to remain with their families, or in a family setting, and being protected and safe align with CARF's values," adds Leslie. "When CARF talks about prevention or intervention, we are talking about services that are proactive, striving to reduce

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Ten Things Nurses Wish They Had Known When They Started Practicing

Elizabeth E. Hogue, Esq.

Nursing is surely at the heart of health care! Without intelligent, experienced, caring nurses in a variety of roles and practice settings, healthcare would suffer significant adverse impact.

What do nurses regard as essential to their jobs? Nurse.org recently asked nurses nationwide to share the most important lesson they learned during their first year on the job. Here is what nurses said:

1. **Accept that you won't know everything and it's OK.**
2. **You are likely to be required to work independently a lot of the time.**
3. **Slow down and take your time despite the pressures of the job.**
4. **Gratitude goes a long way in the workplace.**
5. **Always do what's best for patients.**
6. **Nursing is likely to change every aspect of your life.**
7. **Take care of yourself; it's a necessity.**
8. **When things are tough and stressful, it doesn't mean you're a bad nurse.**
9. **There is no such thing as a stupid question.**
10. **Take time to listen to your patients.**

It's important to add to the above that nurses must engage both their brains and their hearts in the practice of nursing. Patients will be short-changed if both of these are not wholeheartedly put to the task of caring for patients. CM

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

CMS Delays Finalizing New Rules on Discharge Planning

By Elizabeth Hogue, Esq.

On November 3, 2015, the Centers for Medicare & Medicaid Services (CMS) published proposed regulations governing discharge planning by hospitals. If finalized as proposed, these regulations will require hospitals to devote considerably more time and resources to discharge planning activities. Generally speaking, proposed rules must be finalized within 3 years of their publication. CMS announced on November 2, 2018, however, that finalization of the new rule on discharge planning has been delayed because of the "complexity of the rule and scope of public comments."

The proposed rule implements provisions of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act). As proposed, the new rules on discharge planning will apply to all types of hospitals, including acute care, long term acute care hospitals, inpatient rehabilitation facilities, and home health agencies. Proposed changes in Conditions of Participation for hospitals generally require:

- Development and implementation of an effective discharge planning process that focuses on patients' goals and preferences and prepares patients and their caregiver(s)/support person(s) to be active partners in postdischarge care
- Planning for care that is consistent with patients' goals for care and treatment preferences
- Effective transition of patients from hospitals to postdischarge care
- Reduction of factors leading to preventable hospital readmissions

Specifically, policies and procedures of hospitals governing discharge planning activities must be:

- Developed with input from hospitals' medical staff, nursing leadership, and other relevant departments
- Reviewed and approved by governing bodies of hospitals
- Specified in writing

The proposed regulations require the discharge planning process to be applied to:

- All inpatients
- Outpatients receiving observation services
- Outpatients undergoing surgery or other same day procedures for which anesthesia or moderate sedation is used
- Emergency department patients identified in accordance with hospitals' discharge planning policies and procedures by emergency department practitioners responsible for the care of patients who need a discharge plan
- Any other category of outpatients as recommended by the medical staff and specified in hospitals' discharge planning policies and procedures approved by hospitals' governing bodies

If finalized, these changes in discharge planning activities are significant in terms of the resources and skills that will be needed to meet new requirements! Stay tuned for publication of the final rule. CM

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Case Managers Are a Catalyst for Patient Activation

by Mary McLaughlin Davis, DNP, ACNS-BC, NEA-BC, CCM

Hospitals, health care systems, and health care plans are rapidly moving from a symmetrical health care model to an asymmetrical health care continuum. Community, ambulatory, and hospital health care providers have put their collective ideas and projects into practice. They share a common aim of engaging patients and their partners to improve health and treat chronic disease. It is through the dissemination of their research and evaluative projects that like-minded caregivers begin to discuss their work. They share their ideas on how to prevent unnecessary hospital admissions and improve the patient experience.

There is a heightened awareness among case managers that once the patient identifies a goal and the case manager identifies health-related action steps to reach the goal, the work has just begun. Health care systems recognize the need to enhance and assist their patients' transition from hospital to home, both while in the hospital and after discharge. Patients do not respond to uniform teaching styles and require disease education tailored to their specific needs.

Patient Activation is a term used to describe the knowledge, skills, confidence, and resources patients have to manage their disease state in an active and informed manner. This patient-centered approach meets patients at their personal level of readiness to learn and accomplish health-related goals. Patients with the highest level of activation display interest and involvement and actively decide their best course of action. A high patient activation level is associated with decreased health care costs.[1,2]

Case managers have long understood the value of patient-centered care. It is central to the Case Management Society of America (CMSA) Standards of Practice for Case Management. However, as with all initiatives, case managers need the education and the tools to engage the patient as a partner to prevent further health deterioration and to improve their well-being. The case manager will benefit from learning about the patient activation concepts and about the tools needed for implementation.

The relationship-based care model informs case managers that a relationship occurs every time a case manager makes a connection with the patient. Case managers, through the intentional presence with their patients, create an atmosphere of mindfulness and a human-to-human connection.[3] The case manager meets the patient at his or her level, aware of the importance of patient activation. Using this strategy to prepare patients for an active role in their care demonstrates that meaningful relationships are at the heart of the case manager's purpose. This approach enables the patient and the case manager to perform important work together to achieve shared goals. The case manager's willingness to individualize each patient's care plan validates his commitment to that particular patient.

Patient-centered care must also be patient-directed care for patients to be fully engaged. This is more than a subtle difference in direction and focus. Patients benefit from an education plan tailored to their current level of understanding and their acceptance of their medical condition. Judith Hibbard states, "Activated patients have important roles to play in self-managing care, collaborating with providers and maintaining their health."[2] Case managers achieve this process by embracing the patient relationship and viewing both the patient-centered plan and patient education from the patient's perspective.

It is the case manager who can coach and lead patients toward a higher level of learning and subsequent confidence in their ability to self-manage disease. To achieve success in this endeavor, the case manager, working across the continuum of care, requires the tools to plan, intervene, and evaluate their work with individuals as well as populations.

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***Dr. Davis** is a Senior Director of care management for the Cleveland Clinic Health System and contributes as a guest lecturer at Ursuline College. Dr. Davis serves as national immediate past president for the Case Management Society of America and is an active member of their Public Policy Committee. She is the cochair of the Cleveland Clinic Nursing Health Policy and Legislation Committee.*

Patient Activation is a term used to describe the knowledge, skills, confidence, and resources patients have to manage their disease state in an active and informed manner. This patient-centered approach meets patients at their personal level of readiness to learn and accomplish health-related goals. Patients with the highest level of activation display interest and involvement and actively decide their best course of action.

CMSA recognized this need and developed the ICM-CAG, a tool for case managers to identify intrinsic risks as well as strengths of vulnerable patients. Inherent in the CMSA Integrated Case Management (ICM) Program is the necessity of patient engagement in their own plan of care. ICM-CAG examines the four domains of health: Physical, Psychological, Social, and Health System. The risks and strengths of individual patients are identified within each domain and further detailed as to history, status, and future risk of vulnerability and peril.[4] The case manager who is well versed in the ICM model is able to tap into the patient's own abilities and strengths to achieve their goals.

The Patient Activation Assessment and the Patient Activation Measurement are 2 tools developed by Eric Coleman and Judith Hibbard, respectively, to allow case managers to measure their patients' activation levels and provide guidance on effective interventions to improve the patient activation level.

Dr. Coleman's Four Pillars provide the framework for The Patient Activation Assessment (PAA). They include medication self-management, dynamic patient-centered record, follow-up appointment, and red flags. The case manager can imbed the fundamentals for any chronic condition in the 4 pillars. Patients score points based on their ability to meet the criteria of each level of the pillar.[5] The PAA provides case managers with a method for tracking patients' progress in patient activation and it provides quantitative data on the value of the patient teaching intervention.

The patient's Personal Health Record is a patient tool that provides a log or diary of data such as blood pressure, blood sugar, or weight measurements.[5] The patient can also record medical, therapy, or any other health-related appointments.

The Patient Activation Measure (PAM) is a licensed quantitative tool. It is a 13-question instrument developed to measure a patient's knowledge, skill, and confidence for self-management. PAM measures each patient's developmental progress in these areas. The instrument provides a baseline activation level and may be used while the case manager is coaching the patient to determine the patient's progress in taking an active part in the management of his or her disease.[2] The case manager may measure patient activation before a coaching experience and after the coaching experience.

The case manager with the interprofessional team continues to learn from pioneer patient advocates such as Ernest Avery Codman and Avedis Donabedian that clear communication by practitioners creates the learning link to patients and improves the efficacy of the health care organization.[6,7] The benefit is an increased patient or caregiver confidence level in managing their condition, understanding their medication regime, and in communicating with the health care team.[8-10]

The literature is rich with evidence for providing patients' education, guidance, and coaching at their level of patient activation to achieve an optimal transition across the continuum of care. Case managers work across this continuum, and the degree to which patient activation tools are implemented will vary. The case manager may not determine a patient's activation level in a particular setting. However, knowledge of the activation level and a patient's response to a teaching intervention is important. The case manager with the interprofessional team can decide which intervention provides the most impact for their patient population in the most effective manner. CM

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The Value of Fracture Liaison Services as Experienced by People with Osteoporosis: An Exploratory Focus Group Study

Sharon Chow, DNP, RN, ANP-BC, PNP-BC, GNP, PHN, CCD

Osteoporosis is a major public health concern and threat for an estimated 54 million Americans.[1] The prevalence of osteoporosis and the mortality rate due to osteoporotic fracture increase with the aging population. Every year osteoporosis is responsible for 2 million broken bones in the United States.[2] Approximately 20% of patients who sustain an initial fracture will experience a repeat fracture within 5 years. Annually, 24% of the patients who suffer a hip fracture are placed in nursing homes, 50% never resume their prior functional ability, and 25% die within the first 12 months postfracture.[3-5] The annual healthcare cost would be $18 billion if 1.5 million Americans had a fragility fracture secondary to osteoporosis.[6] Fractures related to osteoporosis involved approximately 432,000 hospital admissions, 180,000 nursing home admissions, and 2.5 million office visits in the United States. Only 5% of patients with osteoporosis or multiple risk factors were properly diagnosed and treated.[3, 7] There were 5.2 million fragility fracture occurrences during 2010 in 12 industrialized countries.[6] The financial burden of osteoporosis is estimated to be at least $25 billion by 2025.[6]

The International Osteoporosis Foundation campaigns worldwide to advocate collaborative Fracture Liaison Services (FLS) as best practice to reduce subsequent fracture risk.[8, 9] Kaiser Permanente (KP) Healthy Bones Program (HBP) is globally recognized as an exemplar for patient-centered FLS.[10-12] The HBP avoids fragmented care through interprofessional collaboration with different departments and specialties as well as health education.[12,13] By incorporating advanced health information technology, the HBP successfully closes care gaps; reduces fracture rates and healthcare costs; improves treatment compliance, self-care knowledge, and care experience; and optimizes bone health.[14-16] Exploring patients' care experience and their perceived value of the HBP will help promote collaborative FLS to serve vulnerable osteoporosis population at the local, national, and global levels.[17]

Purpose of the Study/Objectives

Most osteoporosis research studies focus on patient knowledge of the disease process, treatment modality, and adherence to calcium and vitamin D supplements and exercise. Few studies have described patients' perceived value and care experiences of FLS and the HBP. This qualitative focus group study explored KP patients' perceived HBP value and care experiences as well as how they wanted to be involved throughout the care continuum.

Research Questions

The research questions were formulated to explore participants' perceived HBP value and care experiences as well as their involvement in osteoporosis care management.

1. What do participants know about the HBP?
2. What do participants know about the osteoporosis care coordination provided by the HBP?
3. What are participants' care experiences with the HBP?
4. What do participants know about self-care management of osteoporosis?

Research Methodology and Design

The researchers chose to examine the participants' perceived value of the HBP and their care experiences and osteoporosis self-care management as variables of interest for this study. The focus group study helped explore the participants' feedback and care experiences in greater detail. Both the primary investigator and coinvestigator had been nurse practitioner care managers for the HBP for 4 years. Two focus group interviews were conducted in English via semistructured open-ended questions on 2 separate days. The interviews were 60 minutes long and consisted of 4 questions, with 2–3 probes per questions. The interview questions and informed consent were approved by the KP Institutional Review Board (IRB). The interviews were recorded simultaneously with 2 digital voice

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recorders. The recorded interviews were professionally transcribed verbatim. Qualitative content analysis and interpretive processes were used to facilitate a better understanding of participants' responses and care experiences. NVivo software was used for data analysis.

Sampling Strategies

The burden of osteoporosis care in adults aged 65 and older has been identified as a global health issue. Participants in the study were aged 65 years and older and had osteoporosis or were at risk for fracture. Purposive sampling was used to recruit participants who had participated in the HBP and attended Osteoporosis and Your Health classes. Participants reported a bone density test and/or a fracture in past 12 months. Participants were able to read and speak English. Children, adolescents, and men and women aged 64 and younger were excluded from the study.

Procedures

The HBP registered nurse care manager/educator allowed the primary investigator to show up at the end of 3 Osteoporosis and Your Health classes. The participant recruitment letters were distributed to the KP patients. The researcher disclosed herself as one of the Healthy Bones nurse practitioner care managers. The study purpose and participation process were explained to patients using the IRB-approved recruitment script. Participants were fully informed that the study was voluntary and confidential. The participants chose whether to participate in the study and were informed that the care that they received at KP would not be affected. The participants could call the researcher for more study details. Upon completion of the interview, participants were compensated with a $10 Target gift card. Most of the participants signed up on site. Some participants called the researcher to sign up via a designated phone number.

The researcher registered the participants by reviewing the study inclusion criteria using the IRB-approved telephonic script. The participants filled out informed consent forms and demographic questionnaires that were designed by the primary investigator before the focus group interviews. They were fully informed that the interviewers (the primary investigator and coinvestigator) were Healthy Bones nurse practitioner care managers. To protect privacy, the participants were asked to use only a fake name for identification purposes. The participants were free to discontinue participation at any time.

Focus Group Interview Guide

The researchers used the interview guide flexibly with a list of semistructured open-ended questions to explore participants' views and opinions at 2 interview meetings. The primary investigator conducted the interviews while the coinvestigator took notes and added prompting questions to generate more discussion. The focus group interview questions were designed as follows:

Question 1: Evaluating participants' knowledge about the HBP services

What do you know about the HBP?

(probe 1): Who has been taking care of your osteoporosis/bone health at KP?

(probe 2): What has any healthcare personnel done for your osteoporosis/bone health at KP?

Question 2: Evaluating participants' knowledge about the osteoporosis care coordination provided by the HBP

What are your feelings about how different professionals from the HBP have served you?

(probe 1): How well do the healthcare professionals plan for your osteoporosis care?

(probe 2): How well do the healthcare professionals take care of your bone health needs?

(probe 3): How well do the healthcare professionals communicate among themselves about your bone health?

Question 3: Evaluating participants' care experiences with the HBP

Share your care experiences with the HBP.

(probe 1): What do you like the most about the care you have received from the HBP?

(probe 2): If you know someone who has the same needs, would you recommend the HBP? If you would not recommend the HBP, share why not.

Fracture liaison services function as care managers and patient advocates; they enhance patient care experiences, reduce healthcare costs, promote bone health, and prevent osteoporosis.

Question 4: Evaluating participants' knowledge about osteoporosis self-care management

1. What kinds of diet changes have you made to improve your bone health?
   (probe 1): Describe your daily calcium intake.
   (probe 2): Describe your daily vitamin D intake.
2. What kind of exercises are you doing for your bone health?
   (probe 1): Describe your exercise routine.
   (probe 2): What types of exercises do you do?
   (probe 3): What do you know about weight-bearing exercises?

Qualitative Data Analysis

All recorded interviews were professionally transcribed verbatim via a contracted transcription vendor. A coding book was developed based on the primary investigator's and coinvestigator's notes taken about the observations, responses, and issues discussed during the interviews. The responses were sorted into categories and subcategories, and it was hoped that themes would ultimately develop from the initial responses. The researchers carefully reviewed the interview transcriptions together for completeness and accuracy and revised them if necessary. The emerging themes from the transcripts were coded and recoded by the researchers. Verbatim quotes were finally extracted to support and illustrate the codes. Qualitative content analysis and interpretive processes were used to better understand participants' care experiences.[18, 19]

The NVivo software was used to assist in coding, sorting, and retrieval of the transcribed interviews and demographic questionnaire data and to generate reports of coded text for analysis. Through the coding process, observations were recorded and transferred from raw data into categories and classifications, which then became the subject of data analysis. The software was used to identify themes and make inferences about the overall meaning of the collected data and to encourage deeper thinking about the data. Memorable quotes were then used to support the findings and to expand on deeper meanings embedded in the data. A word cloud was derived to enhance a visual representation of the key themes emerging from the interviews.[20, 21]

Results

The participants were enthusiastic about sharing their perceived value and care experiences with the HBP. Laughter was audible throughout the 2 focus group interviews. The participants' positive care experiences reflected their eagerness to learn about bone health and general health maintenance for living healthier and longer lives. The meaningful and insightful data demonstrated that the sample size was sufficient to meet the goal of saturation of information for qualitative research.[19, 22, 23]

Participant Demographics

A total of 12 individuals participated in the study (3 males [25%] and 9 females [75%]). The participants ranged in age from 68 to 88 years (median age, 78 years). The age range difference between the first and second focus group was about 10 years (75–88 years old vs 68–75 years old). Most of the participants (n = 7; 58.3%) were Caucasian. The remaining participants were American Indian/Native American (n = 2; 16.7%), Hispanic/Latino (n = 2; 16.7%), and Black/African American (n = 1; 8.3%). Nine (75%) of the participants were college graduates or had some college/trade/technical or vocational training, and 3 (25%) of the participants were high school graduates. The first focus group included 2 married couples, and the second focus group included 1 married couple (Table 1).

Personal Health Status

Special attention was paid to personal health status that could impact participants' perception of health maintenance and osteoporosis care involvement. Personal health status could also affect participants' abilities to take care of their general health and bone health (Table 2).

Discussion

This study provided an initial picture of how patients wanted to be involved in their osteoporosis care. The participants recognized the HBP and bone health education as effective interventions for osteoporosis screening, prevention, and treatment.[24-26] They were empowered to practice healthy bones living so that they could lead healthier and longer lives. They advocated for bone health education and osteoporosis self-care management. They stated that the bone health education and osteoporosis prevention should be started at an earlier age (around

TABLE 1 **Participants' demographics**

		Focus Group 1	Focus Group 2	Combined
Gender	Male	2	1	3
	Female	4	5	9
Age range (y)		75–88	68–75	68–88
Highest level of education	Some high school			
	High school graduate		3	3
	Some college	3	1	4
	Trade/technical/vocational training	3	1	4
	College graduate		1	1
	Some postgraduate work			
	Postgraduate degree			
Ethnicity	American Indian/Native American	1	1	2
	Asian			
	Black/African American	1		1
	Hispanic/Latino		2	2
	White/Caucasian	4	3	7
	Pacific Islander			

TABLE 2 **Participants' personal health status**

FG1	Participant	Name	Personal Health Status
	FG1P1	Roscoe	Cancer and vitamin D deficiency
	FG1P2	Laura	Not mentioned
	FG1P3	Mary	Legally blind, anemia, arthritic back, history of brain tumor, seizure disorder, drug-induced osteoporosis, pelvic fracture related to fall, poor balance, using walker and cane for fall prevention
	FG1P4	Papa	Vitamin D deficiency
	FG1P5	Marie	Rheumatoid arthritis, osteopenia, and frequent falls
	FG1P6	Fannie	At risk of fracture
FG2	**Participant**	**Name**	**Personal Health Status**
	FG2P1	Jenny	History of breast cancer with lumpectomy, radiation treatment, osteoarthritis, osteopenia, and hyperlipidemia
	FG2P2	Lucy	Hyperlipidemia
	FG2P3	Brenda	Osteoporosis
	FG2P4	Nancy	History of osteoporosis
	FG2P5	Frank	Not mentioned
	FG2P6	Daisy	Osteoporosis and hyperlipidemia

Abbreviations: FG= Focus Group; P =Participant

30–40 years). The evidence-based FLS effectively improved patient care experiences, health outcomes, and health behaviors.[27] The results were confirmed with published literature about the FLS model of care promoting proactive osteoporosis care coordination. The participants' positive care experience and health outcomes help promote collaborative HBP/FLS. The laughter throughout the focus group interviews reflected genuine enjoyment and an active learning experience. The participants purposefully shared their learning experiences of osteoporosis self-care management.[28]

Data Significance and Implications

The study findings can trigger necessary osteoporosis care improvement. Healthcare leaders and professionals should actively address the implementation and sustainability of FLS for bone health education and osteoporosis care coordination.[29, 30]

Study Strengths and Limitations

The trustworthiness of data analyses showed that the sample size was adequate to produce a clear response to the research questions. Focus group study is a valuable qualitative research technique to explore research areas that are sensitive or difficult to observe.[23] The participants might have different levels of engagement, health literacy, and cultural preferences and/or sensitivity with their care experiences.[19] This study could not be generalized to the entire osteoporosis population. The researchers are Healthy Bones nurse practitioner care managers who might have influenced an interviewee because of subconscious bias.

Recommendations for Further Research

In today's ever-changing complex healthcare systems, patients' care experience is purposefully built into

Fracture liaison services function as care managers and patient advocates; they enhance patient care experiences, reduce healthcare costs, promote bone health, and prevent osteoporosis.

an organization's collaborative efforts to shape positive health outcome.[28] Additional research with a larger number of focus group interviews is needed to further evaluate the effectiveness of FLS practice. Future research can address the impact of healthy bones living education and osteoporosis screening as preventive intervention for younger populations and/or premenopausal women. Research can be conducted to contextualize a better understanding of the implementation of chronic disease management for diabetes, heart failure, depression, and asthma populations.[1, 31]

Conclusions

The participants' positive care experiences confirmed the value of patient-centered HBP and bone health education. People with osteoporosis were motivated to be actively involved in healthy bones living and osteoporosis self-care management. The participants learned to self-advocate for their own health, a healthy body, healthy aging, and better quality of life. They appreciated bone health education as a means to encourage osteoporosis self-care management and general health maintenance. The meaningful use of innovative advanced health information technology is transforming osteoporosis care coordination. Fracture liaison services function as care managers and patient advocates; they enhance patient care experiences, reduce healthcare costs, promote bone health, and prevent osteoporosis. The healthcare leaders and care managers should share a collaborative practice commitment to prevent as many osteoporotic fractures as possible. This study result helps promote collaborative FLS for osteoporosis care coordination worldwide. **CE 1**

continues on page 33

CE II Top Trends in Digital Health in 2019

Anish Sebastian

2018 was the year of the consumer, and there's no sign of a change any time soon. The smartphone has paved the way for direct-to-consumer marketing, driving refinements in marketing tools and redefining consumer expectations. Consumers increasingly value experience over product and have come to expect personalized, targeted experiences, which has radically shifted the focus of the business marketplace.

The healthcare landscape is no exception to this shift: it is increasingly driven by the needs and desires of patients. Thanks to the rise of high-deductible health plans and premiums, patients are shouldering a greater portion of healthcare costs than ever before. This increase has positioned patients as consumers at the center of operational changes across the healthcare marketplace.

But innovations in digital health look different than those in direct-to-consumer technology. First of all, health tools are not about "cutting out the middle man"—instead they are about reinforcing and improving the relationship between patient and provider that is fundamental to care. And they come with a unique set of challenges. At the risk of stating the obvious, the stakes are much higher when consumer health is the product: patient safety is an imperative. The variance in technology adoption and demographic diversity of the population also poses notable challenges in the implementation of any tech tool. Additionally, the wealth of data that is required for the success of many digital innovations raises serious concerns about data security and patient privacy, and the rapid growth of tech innovation is quickly outpacing and complicating regulation.

As technology becomes more sophisticated, however, these concerns are being mitigated. And as consumer demand continues to dominate the marketplace, the healthcare industry—supported by the policy makers—is increasingly on board with tech innovation.

Care managers have a particularly high stake in these digital innovations because an increasing number of their patients are supported by digital devices at home. Among other things, digital healthcare enables care managers to stratify risk, maintain increased touchpoints with patients, and empower patients to engage with their providers and take an active role in their health and wellness.

Here are some innovations to look out for in the coming year:

Patient engagement

"Patient engagement" has been a coveted label for apps and digital health companies from the get-go, and in the age of the consumer it is only increasing in importance, with rumors swirling that Amazon will leverage information it has learned from its 100 million+ users to roll out Prime Health. A recent survey conducted by SERMO, a social network for physicians, found that three quarters of physician participants linked improved patient engagement with digital patient engagement tools and 95% of participants had some form of digital education tool in their offices on the strength of this belief. For doctors, a group that is traditionally reluctant to adopt innovations, that is a staggering number. However, the label of "patient engagement" has been problematic: it has been ambiguously defined and unregulated and thus is impossible to quantify.

Patient engagement isn't going away, but we are learning how to determine its limits and place a value on it. Engagement cannot be measured by the initial reaction to an app—ultimately, if engagement is to be effective, it has to be sustained and sustainable. These metrics rely largely on clinical concerns—automation, workflow integration, and provision of actionable data—and ultimately are tied outcomes.

Patient engagement is already making a significant impact in the field of care and case management, with services such as Wellframe improving their patient engagement through mobile-enabled care. The increased,

Anish Sebastian *founded Babyscripts and successfully raised over 3.5 million dollars in initial capital and growth. He led product development and engineering efforts, including the creation of unique patent pending data algorithms. Anish scaled the product's initial pilot phase to multiple customers and millions of dollars in revenue. He was invited to present at several conferences including BioIT Showcase, Burrill Digital Health, Healthdatapalooza, NPR, mHealth Summit, Drexel University School of Medicine, and GW School of Public Health, and he was nominated by President Obama as a White House champion of change for the precision medicine initiative.*

Among other things, digital healthcare enables care managers to stratify risk, maintain increased touchpoints with patients, and empower patients to engage with their providers and take an active role in their health and wellness.

continuous touchpoints of mobile-enabled care make it the ideal solution to bridge the gaps that occur with telephonic and in-person delivery such as missed appointments, lost telephone numbers, and failure to answer phone calls. Sustained mobile messaging, reminders, educational content, and other interactions deliver care management that is personalized and convenient, an imperative for retaining patients in the consumer-centric marketplace. Migration to mobile creates efficiencies for providers and improves care for patients.

Mobile is old news, artificiaI intelligence is the new kid on the block

Mobile health devices have bridged the chasm between early adopters and the early majority to firmly entrench themselves in the healthcare marketplace. They have quickly pervaded both clinical and operational spaces, catalyzed by recent breakthroughs in the government's acceptance of mHealth and telehealth technology like three new current procedural terminology (CPT) codes for reimbursement of remote patient monitoring in the 2019 Physician Fee Schedule and Quality Payment program. Mobile is old news. The innovation to watch for is artificial intelligence (AI).

Artificial intelligence is pervasive across industries, and whether we realize it or not is deeply embedded in our daily interactions. Ever deposited a check with your phone? The app is using computer vision, a branch of AI that "sees" objects in a way similar to human sight: not simply capturing a photo, computer vision actually filters it for significant information. It's the same technology that allows rabbit ears to hover over and follow a face in a Snapchat filter or figure out the product information for a piece of clothing captured in a photo. Predictive algorithms driven by machine learning are another aspect of AI that we encounter more often than we realize: suggested watchlists on Netflix, product recommendations on Amazon, curated playlists from Spotify—all of these are compiled by machines that use historical data to identify key trends and anticipate patterns in behavior. And then there is image recognition—every time you open your phone with your face, AI is at work.

While the healthcare industry has provided a fertile proving ground for all aspects of AI innovation, it also stands to be its biggest hurdle. In a field that is intimately concerned with privacy and security, facial recognition technology is being leveraged to drastically simplify the security requirements that make multifactor authentication a time-consuming process for healthcare professionals. On the patient end, this same technology has the ability to detect emotional states of patients and anticipate needs based upon this. The massive amount of data collected by monitoring systems using AI has major potential for developing predictive algorithms to improve clinical interventions and mediate hospital readmissions, while U.S. Food and Drug Administration (FDA)-approved innovations from Microsoft and other companies claim that computer vision can assist radiologists in identifying tumors and abnormalities in the heart. But can algorithms predict risk of sepsis better than trained clinicians in intensive care unit? Can computer replace the work of the radiologist and pathologist? And even if that is to be the case, will consumers have difficulty buying into the power and promise of AI? The answers seem to rest in the industry working with stakeholders and policy makers to develop the right frameworks for monitoring and regulating the use of AI.

Care managers stand to benefit greatly from innovations in machine learning. As the number of patients using digital devices to monitor their health increases, there is an accompanying spike in the stream of data being communicated back to health systems. This data has incredible potential for early detection of problems and maintaining population health; however, the time and manpower needed to monitor and regulate such a massive stream of data is prohibitively costly if not impossible to obtain.

Gains in care management will center largely around intelligent data systems that can use this wealth of data to identify and potentially predict problems through deep learning algorithms, predictive analytics, and AI.

The list of AI's inroads in the healthcare sphere goes on, but the innovation that is picking up a lot of attention, and is poised to dominate the conversation in 2019, is the conversational user interface.

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Conversational User Interface

Conversational user interface (UI) has been in the marketplace for a minute, but its increasingly refined natural language processing (NLP) abilities that can identify a speaker's intention are positioning it for widespread adoption. Without NLP, conversational UI simply deciphers the literal words of the speaker and can be a nightmare. Because it relies on speech recognition, it requires a certain precision— particular terms, word order, pronunciation — that can complicate its benefits, particularly in the healthcare sphere where patients are often seeking information that they can't articulate.

With NLP, robots can learn, anticipating needs based on certain vocal or verbal cues. Hands-free, voice-activated interfaces such as the smart assistant Notable can reduce time spent searching through documents, making a phone call, or inputting information into a mobile app; with NLP, these interfaces can potentially be taught to anticipate needs of a doctor or patient, offering them the resources they need before it is even asked for. A conversation with a chatbot can replace the tedious and time-consuming preliminaries of a doctor's visit, and virtual visits for certain conditions could potentially eliminate the need for seeing a doctor altogether. Chatbots such as Buoy and Babylon offer real-time medical advice, facilitate booking appointments, and guide users toward the proper steps for care. Their learning capabilities position conversational UI to be a major player in the care continuum, particularly in the field of mental health, where virtual cognitive behavioral therapy that preserves anonymity (eg, like that provided by Woebot) has already been successful in addressing anxiety and neutralizing risk.

Conversational UIs particularly stand to benefit the case management workforce because so much of what they do hinges on the bedrock of human connection: the conversation. While machines today can't replace the human conversation, even if they can be used to augment the current workflow they stand to make a huge impact. At a recent keynote address, Google unveiled its duplex technology, where AI is having near-humanlike conversation. Even if a small fraction of this can be transported to case management in a thoughtful manner, we stand to make massive gains.

Application Programming Interfaces: the API Economy

Last year, Forbes touted 2017 as the "year of the API economy," and healthcare is getting on board. API (application programming interface) is a software intermediary that allows machines to communicate with each other: the part of a server that receives requests and sends responses. Every time you use an application on your phone, you are using an API. For example, when you open the weather app on your phone, the application connects to the Internet and sends data to a server. The server retrieves the data, interprets it, and sends it back to your phone. The application interprets that data and presents it to you, the user, in a readable way. This back-and-forth communication between your phone and the server is all taking place through the API.

As the modern web becomes more and more application driven, the need for these applications to speak with each other is paramount. Many of us have direct experience of this type of integration through social media: every time we post a picture to Instagram, we have the option to connect all of our social media platforms and share that post simultaneously to Twitter, Facebook, and Tumblr. Services like IFTTT and Zapier are simplifying this type of integration across the consumer marketplace. With their services, consumers have the ability to personalize integrations for themselves in areas above and beyond social media. These services integrate applications to automate workflow and decrease the amount of time spent transferring information between applications.

Interoperability is a major player in health technology innovation: patients will always receive care across multiple venues, and secure data exchange is key to providing continuity of care. Standardized APIs can provide the technological foundations for data sharing, extending the functionality of electronic health records and other technologies that support connected care. With interoperability, data can be aggregated across multiple providers. Complete access to electronic health records for patients and providers is an essential step in the push toward value-based care, providing a holistic picture of the patient's health profile to themselves and any provider and thus

Conversational user interfaces particularly stand to benefit the case management workforce because so much of what they do hinges on the bedrock of human connection: the conversation.

enabling targeted health outcomes. Platforms like Validic Inform leverage APIs to share patient-generated data from personal health devices to providers while giving them the ability to configure data streams to identify actionable data and automate triggers. With major players Apple and Google making their health kits available to developers, we are going to see major strides toward these goals in the upcoming year.

Internet of Things

The benefits of remote patient monitoring have been widely accepted across the healthcare sphere: the ability to monitor vital signs and assess reactions to treatments without the necessity of being in the same physical space as the patient is essential for delivering care to populations that lack immediate access to a provider. Remote patient monitoring should also enable real-time analysis and intervention without time-consuming office visits. Internet of Things devices have extended their capabilities by leaps and bounds in the previous few years. The first FDA-regulated "smart pill" was introduced to the market in November 2017. Ingested like a regular pill and releasing active medication, smart pills are also equipped with monitoring technology that relays information back to a sensor worn on the body, helping to regulate dosage and monitoring internal reactions. We are also going to see an emergence in wearable remote patient monitoring devices that provide a noninvasive alternative to managing care (eg, the connected contact lens conceived by Google and Novartis that monitors a diabetic patient's glucose level by analyzing their tears, relaying the levels back to an insulin pump and alerting the patients). These innovations hold a lot of promise but have met with mixed reactions from the healthcare community; for example, the electrocardiogram feature on the Apple Watch, though supported by the president of the American Heart Association, ignores recommendations of the US Preventative Task Force, and its roll out prompts many questions about the benefits of a user's increased insight into their own health.

The first inning: Blockchain

Blockchain is still a largely unknown entity across all industries. The idea of the block was introduced by Satoshi Nakamoto, the pseudonymous author of "Bitcoin: A Peer to Peer Electronic Cash System." His vision was to create a secure method of electronic transactions that does not require a third-party mediator: a tracking and validation system for 1-to-1 transactions. Simply put, blockchain is a decentralized public ledger, distributed globally to thousands of computers connected to a network. Together, these computers communally agree to validate a transaction. Once the transaction is validated, it is added to the ledger, and this linking of one transaction to the previous transaction creates the blockchain. It is a system nearly impossible to hack, requiring a breach into thousands of computers across the world and simultaneous manipulation of the same record on each of those computers. For this reason, blockchain lends itself well to currency (ie, "cryptocurrency" or "coin," of which the most famous is bitcoin); as an incorruptible and transparent means of conducting transactions, it is poised to revolutionize the way we buy and sell goods, pass laws, make contracts, and exchange information.

Despite being in an experimental stage, visionaries are already anticipating the potential of blockchain in the healthcare marketplace. As a tamper-proof public ledger, blockchain could provide the perfect solution to issues of data integrity, accessible medical records, and consent management. With an incentive-centered design, blockchain could also be used to facilitate patient engagement, supporting the patient's active participation in their health and wellness through a reward system and allowing providers to modify and expand incentives. However, healthcare is likely still years away from any true breakthrough in the use of

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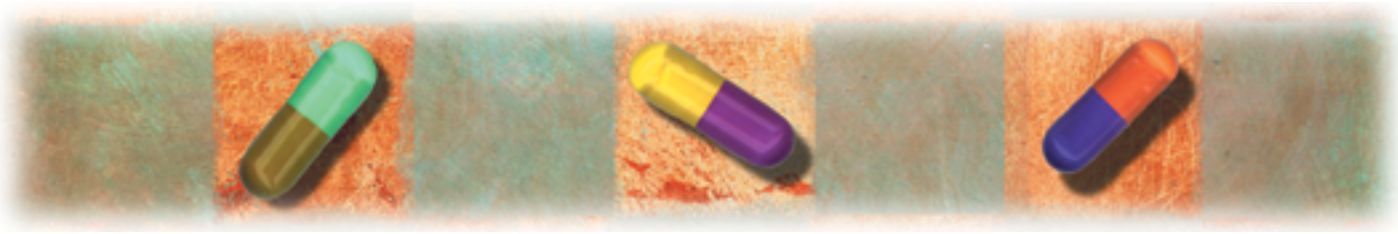
PharmaFacts for Case Managers



Ontruzant (trastuzumab-dttb) for injection, for intravenous use

INDICATIONS AND USAGE

Ontruzant is a HER2/neu receptor antagonist indicated for

- The treatment of HER2-overexpressing breast cancer.
- The treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.
- Select patients for therapy based on an FDA-approved companion diagnostic for a trastuzumab product.

DOSAGE AND ADMINISTRATION

Patient Selection

Select patients based on HER2 protein overexpression or HER2 gene amplification in tumor specimens. HER2 protein overexpression and HER2 gene amplification should be assessed using FDA-approved tests specific for breast or gastric cancers by laboratories with demonstrated proficiency. Information on the FDA-approved tests for the detection of HER2 protein overexpression and HER2 gene amplification is available at: http://www.fda.gov/CompanionDiagnostics.

HER2 protein overexpression and HER2 gene amplification in metastatic gastric cancer should be assessed using FDA-approved tests specifically for gastric cancers due to differences in gastric vs. breast histopathology, including incomplete membrane staining and more frequent heterogeneous expression of HER2 seen in gastric cancers.

Improper assay performance, including use of suboptimally fixed tissue, failure to utilize specified reagents, deviation from specific assay instructions, and failure to include appropriate controls for assay validation can lead to unreliable results.

Recommended Doses and Schedules

- Do not administer as an intravenous push or bolus. Do not mix Ontruzant with other drugs.
- Do not substitute Ontruzant (trastuzumab-dttb) for or with ado-trastuzumab emtansine.

Adjuvant Treatment, Breast Cancer

Administer according to one of the following doses and schedules for a total of 52 weeks of Ontruzant therapy:

During and following paclitaxel, docetaxel, or docetaxel and carboplatin:

- Initial dose of 4 mg/kg as an intravenous infusion over 90 minutes then at 2 mg/kg as an intravenous infusion over 30 minutes weekly during chemotherapy for the first 12 weeks (paclitaxel or docetaxel) or 18 weeks (docetaxel and carboplatin).
- One week following the last weekly dose of Ontruzant, administer Ontruzant at 6 mg/kg as an intravenous infusion over 30 to 90 minutes every three weeks.

As a single agent within three weeks following completion of multimodality, anthracycline-based chemotherapy regimens:

- Initial dose at 8 mg/kg as an intravenous infusion over 90 minutes.
- Subsequent doses at 6 mg/kg as an intravenous infusion over 30 to 90 minutes every three weeks.
- Extending adjuvant treatment beyond one year is not recommended.

Metastatic Treatment, Breast Cancer:

- Administer Ontruzant, alone or in combination with paclitaxel, at an initial dose of 4 mg/kg as a 90-minute intravenous infusion followed by subsequent once weekly doses of 2 mg/kg as 30-minute intravenous infusions until disease progression.

Metastatic Gastric Cancer:

- Administer Ontruzant at an initial dose of 8 mg/kg as a 90-minute intravenous infusion followed by subsequent doses of 6 mg/kg as an intravenous infusion over 30 to 90 minutes every three weeks until disease progression

Important Dosing Considerations

If the patient has missed a dose of Ontruzant by one week or less, then the usual maintenance dose (weekly schedule: 2 mg/kg; three-weekly schedule: 6 mg/kg) should be administered as soon as possible. Do not wait until the next planned cycle. Subsequent Ontruzant maintenance doses should be administered 7 days or 21 days later according to the weekly or three-weekly schedules, respectively.

If the patient has missed a dose of Ontruzant by more than one week, a re-loading dose of Ontruzant should be administered over approximately 90 minutes (weekly schedule: 4 mg/kg; three-weekly

schedule: 8 mg/kg) as soon as possible. Subsequent Ontruzant maintenance doses (weekly schedule: 2 mg/kg; three-weekly schedule 6 mg/kg) should be administered 7 days or 21 days later according to the weekly or three-weekly schedules, respectively.

Preparation for Administration

To prevent medication errors, it is important to check the vial labels to ensure that the drug being prepared and administered is Ontruzant (trastuzumab-dttb) and not ado-trastuzumab emtansine. Follow the package inset directions for reconstitution of medication.

DOSAGE FORMS AND STRENGTHS

For injection: 150 mg of Ontruzant as a white to pale yellow, preservative-free lyophilized powder in a single-dose vial.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

WARNING: CARDIOMYOPATHY, INFUSION REACTIONS, EMBRYO-FETAL TOXICITY, and PULMONARY TOXICITY

Cardiomyopathy: Administration of trastuzumab products can result in subclinical and clinical cardiac failure. The incidence and severity was highest in patients receiving trastuzumab with anthracycline-containing chemotherapy regimens. Evaluate left ventricular function in all patients prior to and during treatment with Ontruzant. Discontinue Ontruzant treatment in patients receiving adjuvant therapy and withhold Ontruzant in patients with metastatic disease for clinically significant decrease in left ventricular function.

Infusion Reactions; Pulmonary Toxicity: Administration of trastuzumab products can result in serious and fatal infusion reactions and pulmonary toxicity. Symptoms usually occur during or within 24 hours of administration. Interrupt Ontruzant infusion for dyspnea or clinically significant hypotension. Monitor patients until symptoms completely resolve. Discontinue Ontruzant for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome.

Embryo-Fetal Toxicity: Exposure to trastuzumab products during pregnancy can result in oligohydramnios and oligohydramnios sequence manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Advise patients of these risks and the need for effective contraception.

ADVERSE REACTIONS

- Cardiomyopathy
- Infusion reactions
- Embryo-fetal toxicity
- Pulmonary toxicity
- Exacerbation of chemotherapy-induced neutropenia

The most common adverse reactions in patients receiving trastuzumab products in the adjuvant and metastatic breast cancer setting are fever, nausea, vomiting, infusion reactions, diarrhea, infections, increased cough, headache, fatigue, dyspnea, rash, neutropenia, anemia, and myalgia. Adverse reactions requiring interruption or discontinuation of trastuzumab product treatment include CHF, significant decline in left ventricular cardiac function, severe infusion reactions, and pulmonary toxicity.

In the metastatic gastric cancer setting, the most common adverse reactions (≥ 10%) that were increased (≥ 5% difference) in the patients receiving trastuzumab compared with patients receiving chemotherapy alone were neutropenia, diarrhea, fatigue, anemia, stomatitis, weight loss, upper respiratory tract infections, fever, thrombocytopenia, mucosal inflammation, nasopharyngitis, and dysgeusia. The most common adverse reactions which resulted in discontinuation of trastuzumab treatment in the absence of disease progression were infection, diarrhea, and febrile neutropenia.

DRUG INTERACTIONS

Patients who receive anthracycline after stopping trastuzumab products may be at increased risk of cardiac dysfunction because of trastuzumab's long washout period based on population PK analysis. If possible, physicians should avoid anthracycline-based therapy for up to 7 months after stopping trastuzumab products. If anthracyclines are used, the patient's cardiac function should be monitored carefully.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Trastuzumab products can cause fetal harm when administered to a pregnant woman. In postmarketing reports, use of trastuzumab during pregnancy resulted in cases of oligohydramnios and of oligohydramnios sequence, manifesting as pulmonary hypoplasia, skeletal abnormalities, and neonatal death. Apprise the patient of the potential risks to a fetus. There are clinical considerations if a trastuzumab product is used in a pregnant woman or if a patient becomes pregnant within 7 months following the last dose of a trastuzumab product. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

Females and Males of Reproductive Potential
Pregnancy Testing
Verify the pregnancy status of females of reproductive potential before initiating Ontruzant.

Geriatric Use
Trastuzumab has been administered to 386 patients who were ≥65 years of age. The risk of cardiac dysfunction was increased in geriatric patients compared with younger patients in both those receiving treatment for metastatic disease in Studies 5 and 6, or adjuvant therapy in Studies 1 and 2. Limitations in data collection and differences in study design of the 4 studies of trastuzumab in adjuvant treatment of breast cancer preclude a determination of whether the toxicity profile of trastuzumab in older patients is different from younger patients. The reported clinical experience is not adequate to determine whether the efficacy improvements of trastuzumab treatment in older patients is different from that observed in patients <65 years of age for metastatic disease and adjuvant treatment.

In Study 7 (metastatic gastric cancer), of the 294 patients treated with trastuzumab, 108 (37%) were ≥65 years of age, while 13 (4.4%) were 75 and over. No overall differences in safety or effectiveness were observed.

CLINICAL STUDIES
Adjuvant Breast Cancer
The safety and efficacy of trastuzumab in women receiving adjuvant chemotherapy for HER2 overexpressing breast cancer were evaluated in an integrated analysis of two randomized, open label, clinical trials (Studies 1 and 2) with a total of 4063 women at the protocol-specified final overall survival analysis, a third randomized, open-label, clinical trial (Study 3) with a total of 3386 women at definitive Disease-Free Survival analysis for one-year trastuzumab treatment versus observation, and a fourth randomized, open-label clinical trial with a total of 3222 patients (Study 4).

Metastatic Breast Cancer
The safety and efficacy of trastuzumab in treatment of women with metastatic breast cancer were studied in a randomized, controlled clinical trial in combination with chemotherapy and an open-label single agent clinical trial. Both trials studied patients with metastatic breast cancer whose tumors overexpress the HER2 protein. Patients were eligible if they had 2 or 3 levels of overexpression (based on a 0 to 3 scale) by immunohistochemical assessment of tumor tissue performed by a central testing laboratory.

Metastatic Gastric Cancer
The safety and efficacy of trastuzumab in combination with cisplatin and a fluoropyrimidine (capecitabine or 5-fluorouracil) were studied in patients previously untreated for metastatic gastric or gastroesophageal junction adenocarcinoma (Study 7).

HOW SUPPLIED/STORAGE AND HANDLING
How Supplied
Ontruzant (trastuzumab-dttb) for injection 150 mg/vial is supplied in a single-dose vial as a white to pale yellow lyophilized sterile powder, under vacuum. Each carton contains one single-dose vial of Ontruzant.

Storage
Store Ontruzant vials in the refrigerator at 2° to 8°C (36° to 46°F) until time of reconstitution.

Ontruzant [trastuzumab-dttb]:

Manufactured by: Samsung Bioepis Co., Ltd., 107, Cheomdan-daero, Yeonsu-gu, Incheon, 21987, Republic of Korea U.S. License No. 2046

Manufactured for: Merck Sharp & Dohme Corp., a subsidiary of Merck & Co., Inc., Whitehouse Station, NJ 08889.

Inbrija™ (levodopa inhalation powder), for oral inhalation use

INDICATIONS AND USAGE
Inbrija is indicated for the intermittent treatment of OFF episodes in patients with Parkinson's disease treated with carbidopa/levodopa. OFF periods refer to times during the day in which a person with PD experiences a return of his/her PD symptoms.

DOSAGE AND ADMINISTRATION
Inbrija capsules are for oral inhalation only and should be used only with the Inbrija inhaler.

Important Administration Instructions
Inbrija capsules are for oral inhalation only and should be used only with the Inbrija inhaler. Inbrija capsules must not be swallowed as the intended effect will not be obtained. Inbrija capsules should be stored in their blister package and only removed immediately before use.

Recommended Dosage
Inbrija should be taken when symptoms of an OFF period start to return.

The recommended dosage of Inbrija is oral inhalation of the contents of two 42 mg capsules (84 mg) as needed, up to 5 times a day. The maximum dose per OFF period is 84 mg, and the maximum daily dosage is 420 mg. Inbrija has been shown to be effective only in combination with carbidopa/levodopa.

DOSAGE FORMS AND STRENGTHS
Inbrija (levodopa inhalation powder) consists of Inbrija capsules and the Inbrija inhaler. Inbrija capsules contain 42 mg dry powder formulation of levodopa in a white capsule with two black color bands and "A42" printed on one side.

CONTRAINDICATIONS

Inbrija is contraindicated in patients currently taking a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine and tranylcypromine) or who have recently (within 2 weeks) taken a nonselective MAO inhibitor. Hypertension can occur if these drugs are used concurrently.

WARNINGS AND PRECAUTIONS

Falling Asleep During Activities of Daily Living and Somnolence

Patients treated with levodopa, the active ingredient in Inbrija, have reported falling asleep while engaged in activities of daily living, including the operation of motor vehicles, which sometimes resulted in accidents. Although many of these patients reported somnolence, some reported no warning signs (sleep attack) and believed that they were alert immediately before the event. Some of these events have been reported more than 1 year after the initiation of treatment. Prescribers should reassess patients for drowsiness or sleepiness. Prescribers should also be aware that patients may not acknowledge drowsiness or sleepiness until directly questioned about drowsiness or sleepiness during specific activities. Before initiating treatment with Inbrija, advise patients about the potential to develop drowsiness and ask about factors that may increase the risk for somnolence with Inbrija such as the concomitant use of sedating medications and the presence of sleep disorders. Consider discontinuing Inbrija in patients who report significant daytime sleepiness or episodes of falling asleep during activities that require active participation (e.g., conversations, eating). If treatment with Inbrija continues, patients should be advised not to drive and to avoid other activities that might result in harm if the patients become somnolent. There is insufficient information to establish that dose reduction will eliminate episodes of falling asleep while engaged in activities of daily living.

Withdrawal-Emergent Hyperpyrexia and Confusion

A symptom complex that resembles neuroleptic malignant syndrome (characterized by elevated temperature, muscular rigidity, altered consciousness, and autonomic instability), with no other obvious etiology, has been reported in association with rapid dose reduction, withdrawal of, or changes in dopaminergic therapy.

Hallucinations/Psychosis

In placebo-controlled trials, hallucinations were reported in less than 2% of patients treated with Inbrija. Hallucinations may be responsive to reducing levodopa therapy. Hallucinations may be accompanied by confusion, insomnia, and excessive dreaming. Abnormal thinking and behavior may present with one or more symptoms, including paranoid ideation, delusions, hallucinations, confusion, psychotic-like behavior, disorientation, aggressive behavior, agitation, and delirium. Because of the risk of exacerbating psychosis, patients with a major psychotic disorder should ordinarily not be treated with Inbrija. In addition, medications that antagonize the effects of dopamine used to treat psychosis may exacerbate the symptoms of Parkinson's disease and may decrease the effectiveness of Inbrija.

Impulse Control/Compulsive Behaviors

Patients treated with Inbrija can experience intense urges to gamble, increased sexual urges, intense urges to spend money, binge eating, and/or other intense urges, and the inability to control these urges while taking one or more of the medications that increase central dopaminergic tone. In some cases, although not all, these urges were reported to have stopped when the dose was reduced or the medication was discontinued. Because patients may not recognize these behaviors as abnormal, it is important for prescribers to specifically ask patients or their caregivers about the development of new or increased gambling urges, sexual urges, uncontrolled spending or other urges while being treated with Inbrija. Consider stopping the medication if a patient develops such urges while taking Inbrija.

Dyskinesia

Inbrija may cause or exacerbate dyskinesias. If troublesome dyskinesias occur, prescribers may need to consider stopping treatment with Inbrija and/or adjusting the patient's daily medications for the treatment of Parkinson's disease.

Bronchospasm

In patients with lung disease because of the risk of bronchospasm, use of Inbrija in patients with asthma, COPD, or other chronic underlying lung disease is not recommended.

Glaucoma

Inbrija may cause increased intraocular pressure in patients with glaucoma. Monitor patients for increased intraocular pressure during therapy with Inbrija.

Laboratory Test Abnormalities

Abnormalities in laboratory tests may include elevations of liver function tests such as alkaline phosphatase, AST, ALT, lactic dehydrogenase (LDH), and bilirubin. Abnormalities in blood urea nitrogen (BUN), hemolytic anemia, and positive direct antibody test have also been reported. Patients taking levodopa or carbidopa-levodopa may have increased levels of catecholamines and their metabolites in plasma and urine giving false-positive results suggesting the diagnosis of pheochromocytoma in patients on levodopa and carbidopa-levodopa.

ADVERSE REACTIONS

- Falling asleep during activities of daily living and somnolence
- Withdrawal-emergent hyperpyrexia and confusion
- Hallucinations/psychosis
- Impulse control/compulsive behaviors

continues on page 34

LITSCAN FOR CASE MANAGERS

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.

Hepatology. 2019 Jan 11. doi: 10.1002/hep.30501

The HCV care continuum: linkage to HCV care and treatment among patients at an urban health network, Philadelphia, PA.

Coyle C, Moorman AC, Bartholomew T, et al.

BACKGROUND/AIMS: Improving care and treatment for persons infected with hepatitis C virus (HCV) can reduce HCV-related morbidity and mortality. Our primary objective was to examine the HCV care continuum among patients receiving care at five Federally Qualified Health Centers (FQHCs) in Philadelphia, PA where a testing and linkage to care program had been established. METHODS: Among the five FQHCs, one served a homeless population, two served public housing residents, one served a majority Hispanic population, and the last, a "test and treat" site, also provided HCV treatment to patients. We analyzed data from electronic health records of patients tested for HCV antibody from 2012-2016 and calculated the percentage of patients across nine steps of the HCV care continuum ranging from diagnosis to cure. We further explored factors associated with successful patient navigation through two steps of the continuum using multivariable logistic regression. RESULTS: Of 885 chronically infected patients, 92.2% received their RNA positive result, 82.7% were referred to an HCV provider, 69.4% were medically evaluated by the provider, 55.3% underwent liver disease staging, 15.0% initiated treatment, 12.0% completed treatment, 8.7% were assessed for sustained virologic response (SVR), and 8.0% achieved SVR. Regression results revealed that test and treat site patients were significantly more likely to be medically evaluated (aOR=2.76; 95% CI=1.82, 4.17) and undergo liver disease staging (aOR=1.92, 95% CI=1.02, 2.86) than patients at the other FQHCs combined. CONCLUSIONS: In this U.S. urban setting, over two-thirds of HCV-infected patients were linked to care. Although treatment uptake was low overall, it was highest at the test and treat site. Scaling up treatment services in HCV testing settings will be vital to improve the HCV care continuum.

Am Heart J. 2018 Dec 5;209:9-19. doi: 10.1016/j.ahj.2018.11.010.

Significant mortality, morbidity and resource utilization associated with advanced heart failure in congenital heart disease in children and young adults.

Burstein DS, Shamszad P, Dai D, et al.

BACKGROUND: Children with congenital heart disease (CHD) are at risk for advanced heart failure (AHF). We sought to define the mortality and resource utilization in CHD-related AHF in children and young adults. METHODS: All hospitalizations in the Pediatric Health Information System database involving patients ≤21 years old with a CHD diagnosis and heart failure requiring at least 7 days of continuous inotropic support between 2004 and 2015 were included. Hospitalizations including CHD surgery were excluded. RESULTS: Of 465,482 CHD hospitalizations, AHF was present in 2,712 (0.6%) [58% infant, 55% male, 30% single ventricle]. AHF therapies frequently used included extracorporeal membrane oxygenation (ECMO) (15%) and cardiac transplant (16%). Ventricular assist device (VAD) support was rare (3%), although VAD use significantly increased from 2004 to 2015 (P < .0010). Hospital mortality in CHD with AHF was 26%, with higher mortality associated with single ventricle heart disease (OR 1.64, 95% CI 1.23-2.19; P = .0009), infancy (OR 1.71, 95% CI 1.17-2.5; P = .0057), non-white race (OR 1.28, 95% CI 1.04-1.59; p=0.0234), and chronic complex comorbidities (OR 1.76, 95% CI 1.34-2.30; P < .0001). Over the 11-year study period, despite the significant increase in CHD-related AHF hospitalizations (P < .0001), hospital mortality improved (P = .0011). Median hospital costs were $252,000, a 6-fold increase above those without AHF, and was primarily driven by hospital length of stay (P < .0001). CONCLUSION: AHF in children with CHD in uncommon but increasing and is associated with significant morbidity, mortality and resource utilization. Approximately 1 in 5 children do not survive to hospital discharge. Many risk factors for mortality may not be modifiable, and further study is needed to identify modifiable risk factors and improve care for this complex population.

AIDS. 2019 Jan 14. doi: 10.1097/QAD.0000000000002154.

Cardiorespiratory fitness is associated with inflammation and physical activity in HIV+ adults.

Webel AR, Jenkins T, Vest M, et al.

OBJECTIVE: Our objective was to examine the effect of a lifestyle diet and exercise intervention on CRF and to examine predictors of change in CRF. DESIGN: People living with HIV (PLHIV) are at increased risk for cardiovascular disease (CVD). Cardiorespiratory fitness (CRF) is a better predictor of CVD-related mortality than established risk factors yet very little is known about CRF in PLHIV. METHODS: One-hundred and seven virally suppressed PLHIV were randomized to a group-based intervention to improve lifestyle behaviors or a control condition. All PLHIV maximal cardiorespiratory stress test to determine VO2 peak, VO2 at anaerobic threshold, and VE/VCO2, at baseline and six months later. Participants wore an accelerometer to measure physical activity, completed waist-hip circumference measures, and had a fasting lipid profile, interleukin-6, and hsCRP analyzed. Generalized estimating equations were used to examine the effect of the intervention on CRF and predictors of change in CRF. RESULTS: Participants were approximately 53 years old, 65% male (n=70), and 86% African American (n=93). There was no effect of the intervention on markers of CRF over time (p>0.05). After controlling for age, gender, waist-hip-ratio, the inflammatory biomarker IL-6 was inversely associated with a decline in both VO2 peak (p=0.03) and VO2 at anaerobic threshold (p=0.03). Additionally, participants who walked an additional 10,000 steps per day had a 2.69ml/kg/min higher VO2 peak (p=0.02). CONCLUSIONS: Despite HIV viral suppression, PLHIV had remarkably poor CRF and inflammation was associated with a clinically adverse CRF profile. However, increased physical activity was associated with improved CRF.

PLoS One. 2019 Jan 10;14(1):e0210179. doi: 10.1371/journal.pone.0210179. eCollection 2019.

Early treatment of acute hepatitis C infection is cost-effective in HIV-infected men-who-have-sex-with-men.

Popping S, Hullegie SJ, Boerekamps A, et al.

BACKGROUND: Treatment of hepatitis C virus infections (HCV) with direct acting antivirals (DAA) can prevent new infections since cured individuals cannot transmit HCV. However, as DAAs are expensive, many countries defer treatment to advances stages of fibrosis, which results in ongoing transmission. We assessed the epidemiological impact and cost-effectiveness of treatment initiation in different stages of infection in the Netherlands where the epidemic is mainly concentrated among HIV-infected MSMs. METHODS: We calibrated a deterministic mathematical model to the Dutch HCV epidemic among HIV-infected MSM to compare three different DAA treatment scenarios: 1) immediate treatment, 2) treatment delayed to chronic infection allowing spontaneous clearance to occur, 3) treatment delayed until F2 fibrosis stage. All scenarios are simulated from 2015 onwards. Total costs, quality adjusted life years (QALY), incremental cost-effectiveness ratios (ICERs), and epidemiological impact were calculated from a providers perspective over a lifetime horizon. We used a DAA price of €35,000 and 3% discounting rates for cost and QALYs. RESULTS: Immediate DAA treatment lowers the incidence from 1.2/100 person-years to 0.2/100 person-years (interquartile range 0.1-0.2) and the prevalence from 5.0/100 person-years to 0.5/100 person-years (0.4-0.6) after 20 years. Delayed treatment awaiting spontaneous clearance will result in a similar reduction. However, further delayed treatment to F2 will increases the incidence and prevalence. Earlier treatment will cost society €68.3 and €75.1 million over a lifetime for immediate and awaiting until the chronic stage, respectively. The cost will increase if treatment is further delayed until F2 to €98.4 million. Immediate treatment will prevent 7070 new infections and gains 3419 (3019-3854) QALYs compared to F2 treatment resulting in a cost saving ICER. Treatment in the chronic stage is however dominated. CONCLUSIONS: Early DAA treatment for HIV-infected MSM is an excellent and sustainable tool to meet the WHO goal of eliminating HCV in 2030.

J Am Acad Dermatol. 2019 Jan 9. pii: S0190-9622(19)30058-1. doi: 10.1016/j.jaad.2018.12.052

Incidence of pneumocystosis among patients exposed to immunosuppression.

Rekhtman S, Strunk A, Garg A.

BACKGROUND: The decision to administer prophylaxis to patients receiving immunosuppression against pneumocystosis remains a dilemma. OBJECTIVE: To determine overall and age-specific 5-year pneumocystosis incidence within a population exposed to immunosuppressants. METHODS: Retrospective cohort analysis identifying incident pneumocystosis cases among adults without HIV/AIDS or cancer exposed to immunosup-

pressant and/or corticosteroid therapy. RESULTS: We identified 406 new cases among patients prescribed an immunosuppressant, corticosteroid, or both. Overall incidence of pneumocystosis was 0.012% (406/3,366,086). Incidence was highest in those exposed to immunosuppresssant and corticosteroid medications (0.199%), followed by groups exposed to immunosuppresssant alone (0.012%), corticosteroid alone (0.008%), and neither medication (0.001%) (p<0.001). Greatest risk differences were noted between groups exposed to immunosuppresssant and corticosteroid compared with neither [0.198% (95% CI 0.166% - 0.230%)] and with immunosuppresssant alone [0.188% (95% CI 0.155% - 0.221%)]. Greatest relative risks were noted among those receiving immunosuppresssant and corticosteroid compared with those exposed to neither [RR 122.5 (95% CI 100.9-148.8)] or to immunosuppresssant alone [RR 16.5 (95% CI 7.3-37.4)]. LIMITATIONS: We could not confirm dose and duration of exposures. CONCLUSIONS: Incidence of pneumocystosis among patients exposed to immunosuppressants is very low. Prophylaxis for patients receiving combination immunosuppresssant and corticosteroid therapy, the group at highest risk, may be warranted.

Circ Heart Fail. 2019 Jan;12(1):e005171. doi: 10.1161/CIRCHEARTFAILURE.118.005171.

Characteristics of acute heart failure hospitalizations based on presenting severity.

Parikh KS, Sheng S, Hammill BG, et al.

BACKGROUND: Hospitalizations for acute heart failure (HF) are significant events with downstream implications for patients, as well as healthcare systems and payers. However, from anecdotal experience, both hospitalization and postdischarge courses vary significantly based on severity of presenting decompensation. METHODS AND RESULTS: We compared patient and hospitalization characteristics, resource utilization, and associated outcomes, among modern era acute HF patients enrolled in the GWTG-HF (Get With the Guidelines-Heart Failure) registry between 2011 and 2016, by varying severity of their acute HF. Among over 165 000 hospitalizations included in our analysis, 2% were considered high-risk and 32% intermediate-risk for in-hospital mortality, similar to findings from 15 years prior. Further, the 1-year mortality rate was 40% among Medicare beneficiaries in GWTG-HF who survived to hospital discharge. CONCLUSIONS: The long-term outcomes among acute HF survivors remain poor and, in the context of an increasing HF burden, warrant further study of postdischarge management strategies including inpatient-to-clinic transitions and ambulatory HF systems-based care.

Eur J Cardiothorac Surg. 2019 Jan 10. doi: 10.1093/ejcts/ezy443.

Reoperative sternotomy is associated with increased early mortality after cardiac transplantation.

Astell AL, Fiedler AG, Lewis G, et al.

OBJECTIVES: Outcomes of cardiac transplantation in patients undergoing reoperative sternotomy are often worse than primary transplants. However, the risks imposed by a prior sternotomy, left ventricular assist device (LVAD) or retransplantation have not been independently analyzed. METHODS: Using the United Network for Organ Sharing (UNOS) database, a retrospective propensity-matched cohort analysis was performed on 14 730 patients who received a heart transplant between 2005 and 2017. Of 7365 patients who underwent a reoperative sternotomy, 4526 (61%) patients had previous cardiac surgery, 2364 (32%) patients had an LVAD and 475 (6%) patients had a previous transplant. Baseline characteristics were compared, and survival was analyzed using a Cox model. RESULTS: Compared to patients who underwent a primary transplant, patients with a prior sternotomy had a worse long-term survival (P < 0.001). There was no significant difference in survival between patients who had an LVAD and those who had a previous cardiac operation. However, all subgroups had better survival compared to patients who underwent a retransplant (P < 0.05). On the multivariable analysis, prior sternotomy and radiation demonstrated an increased risk of death compared to primary transplants [prior cardiac surgery: hazard ratio (HR) 1.13, 95% confidence interval (CI) 1.05-1.22; P = 0.001; LVAD: HR 1.19, 95% CI 1.08-1.32; P = 0.001; retransplant: HR 1.68, 95% CI 1.42-1.99; P < 0.001; radiation: HR 1.82, 95% CI 1.00-3.30; P = 0.04]. When excluding patients who died in the first year, there were no significant differences in survival between the primary transplant, prior cardiac surgery, LVAD and retransplant groups. CONCLUSIONS: Prior sternotomy is a risk factor for worse survival after cardiac transplantation, mainly due to increased early postoperative mortality. A history of prior transplant confers the greatest risk compared to those who received an LVAD or had prior cardiac surgery.

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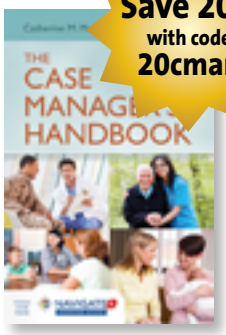

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LITSCAN FOR CASE MANAGERS

J Hypertens. 2019 Jan 11. doi: 10.1097/HJH.0000000000002037.

Diet behaviors and hypertension in US adults: the National Health and Nutrition Examination Survey 2013-2014.

Zhou L, Feng Y, Yang Y, et al.

OBJECTIVE: The present study aims to explore the association between ideal diet behaviors recommended by the American Heart Association (AHA) and hypertension in the United States (US) adults using data from the National Health and Nutrition Examination Survey (NHANES) 2013-2014. METHODS: Whole grains, fruits and vegetables, fish, sodium and sugar-sweetened beverages at an ideal level were defined as the AHA's recommendation. Associations between number of ideal diet behaviors and hypertension were assessed through multivariate logistic regression models. RESULTS: A total of 4462 US adult participants (2110 men and 2352 women) were included in the analysis, of whom 1516 (34.0%) were diagnosed with hypertension. The multivariate adjusted odds ratios and 95% confidence intervals (95% CIs) for hypertension in the groups with one, two and at least three ideal diet behaviors were 0.88 (0.71-1.10), 0.89 (0.70-1.12) and 0.67 (0.49-0.91), when the group with 0 ideal diet behavior was used as the reference. Results also showed that women with three or more ideal diet behaviors had 43% (95% CI: 10-64%) lower odds of hypertension. CONCLUSION: The number of diet behaviors at the ideal level recommended by the AHA was inversely associated with hypertension in US adults.

BMC Cancer. 2018 Jul 28;18(1):769. doi: 10.1186/s12885-018-4679-9.

Pancreatic adenocarcinoma: insights into patterns of recurrence and disease behavior.

Sahin IH, Elias H, Chou JF, et al.

BACKGROUND: Pancreatic ductal adenocarcinoma (PDAC) is one of the most aggressive cancers with high metastatic potential. Clinical observations suggest that there is disease heterogeneity among patients with different sites of distant metastases, yielding distinct clinical outcomes. Herein, we investigate the impact of clinical and pathological parameters on recurrence patterns and compare survival outcomes for patients with a first site of recurrence in the liver versus lung from PDAC following original curative surgical resection. METHODS: Using the Memorial Sloan Kettering Cancer Center ICD billing codes and tumor registry database over a 10-year period (January 2004-December 2014), we identified PDAC patients who underwent resection and subsequently presented with either liver or lung recurrence. Time from relapse to death (TRD) was calculated from date of recurrence to date of death. Using the Kaplan-Meier method, TRD was estimated and compared by recurrence site using log-rank test. RESULTS: The median overall follow-up was 37.3 months among survivors in the entire cohort. Median TRD in this cohort was 10.7 months (95% CI: 8.9-14.6 months). Patients with first site of lung recurrence had a more favorable outcome compared to patients who recurred with liver metastasis as the first site of recurrence (median TRD of 15 versus 9 months respectively, P = 0.02). Moderate to poorly or poor differentiation was associated more often with liver than lung recurrence (40% vs 21% respectively, P = 0.047). A trend to increased lymph node metastasis in the lung recurrence cohort was observed. CONCLUSION: PDAC patients who recur with a first site of lung metastasis have an improved clinical outcome compared to patients with first site of liver recurrence. Our data suggests there may be epidemiologic and pathologic determinants related to patterns of recurrence in PDAC.

Improving Disability Data *continued from page 6*

may not have had a long tenure. Gaps and inaccuracies in data will make it difficult to identify strategies to assist the employee or address the effect on his/her productivity. For large employers, this can have significant impact on program development and management.

This problem is getting more attention in the disability management community, including among certified disability management specialists (CDMSs) who advocate for ill and/or injured employees and who work closely with employers to manage the cost and productivity impact of unscheduled employee absences. CDMSs and disability case managers, in particular, are well positioned to help address this problem by alerting insurers, administrators, and employers to the importance of updating the disability absence record to reflect the true medical picture of the employee and claim and to ensure its completeness.

CDMSs and disability case managers can encourage and influence the recording of up-to-date diagnoses in the disability data and the use of correct ICD-10 (International Statistical Classification of Disease and Related Health Problems, 10th revision) diagnostic coding. With the appropriate coding, more complete and accurate data are captured. CM

Schizophrenia: Defining and Managing Functional Recovery

Functional recovery is not well defined in schizophrenia. A group of 53 psychiatrists from Spanish hospitals developed recommendations for how to define functional recovery in patients with schizophrenia as well as factors associated with it. The experts ranked items on a 75-item questionnaire, which had been drawn from a literature search. Responses were then examined for consensus. Quality of life, cognition, and clinical remission should be considered elements of functional recovery. No matter what tool is used to assess functional recovery, information should be gathered from patients, relatives and/or caregivers, and the health care team. The patient's sociocultural background should be accounted for in the assessment of functional recovery. The effects of stressful life events, substance abuse, socioeconomic conditions, and family relationships should be considered when assessing functional recovery. Negative symptoms are important, but symptom remission should not be the only factor in considering functional recovery. Functional recovery requires psychosocial interventions, which can mean a combination of therapies, including social skills training, family therapy, cognitive rehabilitation, social cognitive training, and occupational programs. Efforts to achieve functional recovery should be made with input from all stakeholders, including patients, relatives, and clinicians. ■

Upcoming Meetings of Interest to Case Managers

2019 Population Health Management Summit for Payers & Providers
Miami, FL
February 21–22, 2019

2019 CCMC New World Symposium
National Harbor, MD
February 28–March 2, 2019

2019 Case Managers Cruise
Departing Orlando, FL
March 16–23, 2019

2019 ACMA National Case Management and Transitions of Care Conference
Seattle, WA
April 14–17, 2019

2019 CMSA Navigating the Full Spectrum of Case Management
Las Vegas, NV
June 10–14, 2019

No Cash, No Heart. Transplant Centers Require Proof of Payment

"It happens every day," said Arthur Caplan, a bioethicist at the New York University Langone Medical Center. "You get what I call a 'wallet biopsy.'" Caplan's comments were reported by *Kaiser Health News*.

Virtually all of the nation's more than 250 transplant centers, which refer patients to a single national registry, require patients to verify how they will cover bills that can total $400,000 for a kidney transplant or $1.3 million for a heart, plus monthly costs that average $2,500 for antirejection drugs that must be taken for life, Caplan said. Coverage for the drugs is more scattershot than for the operation itself, even though transplanted organs will not last without the medicine.

In a statement, officials there defended their position, saying that financial resources, along with physical health and social well-being, are among crucial factors to consider.

"The ability to pay for post-transplant care and life-long immunosuppression medications is essential to increase the likelihood of a successful transplant and longevity of the transplant recipient," officials wrote.

In the most pragmatic light, that makes sense. More than 114,000 people are waiting for organs in the United States and fewer than 35,000 organs were transplanted last year, according to the United Network for Organ Sharing, or UNOS. Transplant centers want to make sure donated organs aren't wasted.

Nearly half of the patients waiting for organs in the United States have private health insurance, UNOS data show. The rest are largely covered by the government, including Medicaid, the federal program for the disabled and poor, and Medicare.

Medicare also covers kidney transplants for all patients with end-stage renal disease. But, there's a catch. While the cost of a kidney transplant is covered for people younger than 65, the program halts payment for antirejection drugs after 36 months. That leaves many patients facing sudden bills, said Tonya Saffer, vice president of health policy for the National Kidney Foundation.

GoFundMe efforts have become a popular way for sick people to raise money. About a third of the campaigns on the site target medical needs, the company said.

continues

continued from page 31

But when patients need to raise money, they should use fundraising organizations specifically aimed at those costs, transplant experts say, including HelpHopeLive, the National Foundation for Transplants, and the American Transplant Foundation.

Every transplant center in the United States has a team of social workers and financial coordinators who help patients negotiate the gaps in their care. Lara Tushla, a licensed clinical social worker with the Rush University transplant program in Chicago, monitors about 2,000 transplant patients. She urges potential patients to think realistically about the costs they'll face.

"The pharmacy will not hand over a bag full of pills without a bag full of money," she said. "They will not bill you. They want the copays before they give you the medication." ■

Family First Prevention Services Act

Attention Children and Youth Programs: CARF is a recognized, U.S. Department of Health and Human Services (HHS) approved, accrediting body for "Qualified Residential Treatment Programs" per a mandate included in the Family First Prevention Services Act (FFPSA).

On February 9, 2018, Congress passed FFPSA, also known as the Bipartisan Budget Act of 2018. Under the new law, after the first 2 weeks of child placement, only "specified settings" outside of foster-family homes are eligible for reimbursement through Title IV-E foster care funds. Specified settings includes the creation of a new category of residential intervention called a Qualified Residential Treatment Program (QRTP).

FFPSA specifies that to be considered a QRTP, the program must be licensed and accredited by an HHS-approved accreditor by October 1, 2019, unless a state requests a delay for up to 2 years. ■

The Washington Post: Apple Now Says Its Smartwatch Tech to Detect Atrial Fibrillation Is Not for Those with Atrial Fibrillation

The fine print on Apple's latest foray into health care carries a seemingly strange caveat: its new Apple Watch technology to detect atrial fibrillation is not intended for people who have atrial fibrillation. The contradiction sums up the deeper questions raised by the introduction of a mass-market monitoring tool for the heart. Apple's products are designed to inspire, with clean designs and seamless operation. But health care is messy and unpredictable. ■

"Wish List" 2019: Developing Others, Promoting Interprofessional Cooperation

continued from page 4

Looking ahead, CCMC recognizes the importance of developing a case management workforce that is diverse, both culturally and professionally. By spreading the word about case management to the traditional disciplines of nursing and social work, as well as other disciplines in the practice (mental health counselors, rehabilitation counselors, occupational therapists, pharmacists, and others), the field is further enriched for the future.

Another aspect of CCMC's Develop Others outreach is offering customized training for organizations. The Commission provides professional development resources, delivered face-to-face, online and for self-learning, to help meet the demand for highly trained, competent case managers.

Promoting Interprofessional Cooperation

Hand-in-hand with mentoring and developing others is the second goal of fostering greater collaboration among organizations in health and human services. The Commission already works closely with the Case Management Society of America (CMSA) and the National Association of Social Workers (NASW).

CCMC is engaged in regular outreach with other consumer and diversity-based organizations as well. On the consumer side, this includes promoting awareness of how case managers advocate for the needs of individuals and their families/support systems.

CCMC is also committed to increasing diversity. With greater professional, cultural, and ethnic diversity among case managers, there is a greater chance of establishing connection and rapport with the individual who is always at the center of the interdisciplinary team. To increase diversity in our ranks, CCMC is reaching out to groups that focus on diversity within the professional fields of nursing, social work, and other healthcare disciplines to better educate and inform their leadership and constituents about CCMC and the field of case management.

Looking ahead, it's important for professional organizations to seek more opportunities to work together. Greater collaboration across organizations elevates all of us, increasing the value of interdisciplinary teams to serve the needs of individuals.

As 2019 unfolds, we are excited about more opportunities to increase dialogue and awareness to ensure the case management talent pipeline is robust, diverse, and well equipped for the years ahead. CM

CE 1 **The Value of Fracture Liaison Services as Experienced by People with Osteoporosis: An Exploratory Focus Group Study** *continued from page 17*

Disclosure

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- Dyskinesia
- Bronchospasm in patients with lung disease
- Glaucoma

DRUG INTERACTIONS

Monoamine Oxidase (MAO) Inhibitors

The use of nonselective MAO inhibitors with Inbrija is contraindicated. Discontinue use of any nonselective MAO inhibitors at least two weeks before initiating Inbrija. The use of selective MAO-B inhibitors with Inbrija may be associated with orthostatic hypotension. Monitor patients who are taking these drugs concurrently.

Dopamine D2 Receptor Antagonists and Isoniazid

Dopamine D2 receptor antagonists (e.g., phenothiazines, butyrophenones, risperidone, metoclopramide) and isoniazid may reduce the effectiveness of levodopa. Monitor patients for worsening Parkinson's symptoms.

Iron Salts

Iron salts or multivitamins containing iron salts can form chelates with levodopa and consequently reduce the bioavailability of levodopa.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no adequate data on the developmental risk associated with the use of Inbrija in pregnant women. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2%–4% and 15%–20%, respectively. The background risk of major birth defects and miscarriage for the indicated population is unknown.

Geriatric Use

Of the Parkinson's disease patients in Study 1 who took Inbrija 84 mg, 49% were ≥65 years of age and 51% were <65 years of age. Of these patients, the following age-related differences in adverse reactions were reported in patients ≥65 years of age vs. in patients <65 years of age, respectively: cough 25% vs. 5%; upper respiratory tract infection 11% vs. 2%; nausea 7% vs. 3%; vomiting 4% vs. 2%; pain in the extremities 4% vs. 0%; and discolored nasal discharge 4% vs. 0%.

CLINICAL STUDIES

The efficacy and safety of Inbrija for the treatment of OFF episodes in patients with Parkinson's disease treated with oral carbidopa/levodopa was evaluated in a 12-week, randomized, placebo-controlled, double-blind study (Study 1; NCT02240030). The effect of Inbrija on pulmonary function was evaluated in patients with Parkinson's disease treated with oral carbidopa/levodopa in a 12 month, randomized, controlled, open-labeled study (Study 2: NCT02352363).

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

Inbrija 42 mg contains foil blister strips of Inbrija (levodopa inhalation powder) white capsules with two black bands on the body and "A42" in black on the cap, and one Inbrija inhaler.

- Carton containing 60 Inbrija capsules (15 blister cards containing 4 capsules each) and 1 Inbrija inhaler: NDC 10144-342-60
- Carton containing 92 Inbrija capsules (23 blister cards containing 4 capsules each) and 1 Inbrija inhaler: NDC 10144-342-92
- Inbrija inhaler consists of a blue cap, blue handle with "Inbrija" imprinted on it, and white mouthpiece covering the capsule chamber.

Storage and Handling

Store in a dry place between 20°C to 25°C (68°F to 77°F), excursions permitted to 15°C to 30°C (59°F to 86°F). Inbrija capsules should always be stored in the blister packaging and only removed immediately before use. Inbrija capsules should not be stored inside the Inbrija inhaler. Inbrija capsules should be used only with the Inbrija inhaler. The Inbrija inhaler should not be used to administer any other medicines.

Imbrija is manufactured by Acorda Therapeutics, Inc.

Case Managers a Catalyst for Patient Activation *continued from page 12*

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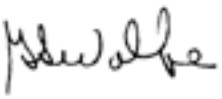
Digital Health and Case Management: The Future is Now
continued from page 2

private. Blockchain using cryptography is an incorruptible digital ledger of transactions that can be programmed to record everything of value. Blockchain, which was invented in 2008, was initially developed to serve as the transition ledger for cyptocurrency bitcoin. Blockchain technology is now being integrated into multiple areas to protect data and transactions including digital health.

Digital health has and will continue to have an impact on case management. Case managers will use technology to improve patient engagement, track data, monitor health, improve access, and reduce costs. Digital health continues to grow at an astonishing pace, with innovative solutions for diagnosing, monitoring and treating illnesses as well as advancing healthcare delivery and ensuring better lifestyles.

Case managers must embrace digital health if case management is to continue to grow and be at the center of patient-centered health. For most, embracing digital health means new knowledge and education. Seek out opportunities to educate yourself about digital health. If you don't, you will be left behind, and in the end it will be your patients that lose. Digital health is the future, but it is happening now!



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CE II Top Trends in Digital Health in 2019 *continued from page 21*

cryptocurrency or the chain as a decentralized way of transacting in health data. We will likely first see use of bitcoin (or other coins) as an incentive system to engage and motivate users.

These trends in digital care show an important shift in the industry and a significant development in how we connect with patients. Going forward, consumer-focused strategies will set the standard for creating solutions to patient-provider connectivity, improving care, and driving outcomes. CE II

Readers

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

How Accreditation Supports Child Welfare's Shift to Prevention
continued from page 8

risk factors and improve family resiliency and wellness. They are services that focus on changing the outcome for families by targeting the antecedents of identified problems. Then, if a child has to be removed, our standards address issues of follow-up, inclusion of family, and ultimately return to family or to a family-like setting.

This access to a full suite of services is what had me thinking of my car door. Certainly investing in prevention, intervention, and diversion is best for the child, but a lack of funding closes those doors before they can be explored. We grow accustomed to options in front of us and make do. Now that FFPSA aims to open these doors, CARF is excited to see how it drives the field. CM

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