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P R E S E N T S

The American Journal of Accountable Care®

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ONLINE COVERAGE

Matt Salo Discusses Concerns Associated With Medicaid Expansion
http://goo.gl/KM6w3T

Matt Salo, executive director, National Association of Medicaid Directors, says there are many concerns associated with Medicaid expansion.

Change across the healthcare landscape means change for us, too, at *The American Journal of Managed Care*. With this issue, we launch *The American Journal of Accountable Care*, a publication that will both advance and respond to the revolution in the ways we care for patients and measure how well we do that. *AJAC* will draw its inspiration from the word "accountable," as physicians, health plans, and patients adjust to the world of metrics and all they mean. For most of its history, healthcare has been a profession with no way to prove which doctor or practice is the best (or the worst). Now that is changing, and with livelihoods on the line, the stakes have never been higher. Yet the first priority must be better care for patients, especially those with chronic conditions like diabetes or respiratory conditions whose treatment may be as much art as science. The 2010 Affordable Care Act offers the promise of rewarding those who offer better treatment for populations, but for months those on the front lines have told us that payment models including those run by government have been slow to move from fee-for-service to focusing on consumers. *AJAC* will highlight models, pilot programs, and concepts that merit attention, ask which patient groups might be winners or losers in the new healthcare paradigm, and seek input from healthcare leaders at conferences, in commentary, and in interviews. The introductory piece by Donovan T. Maust, MD, on the accountable care organization "movement" asks the important questions that *AJAC* will cover in the coming months. It is required reading for all who are concerned about what is happening in the market. Our goal for *AJAC* is to respond quickly to emerging issues surrounding the most ambitious attempt in our lifetime to rebuild the healthcare system. Your feedback and contributions can help us succeed in our mission to bring you the latest ideas on the frontier of managed care.

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"Many provider organizations are looking for ways to enhance their ability not only to deliver high-quality, low-cost clinical care, but also to streamline their many non-clinical lines of operation as a stepping-stone to an ACO, piloting and testing critical competencies first."

—from Collaborative Care Before Accountable Care: Achieving Low-Cost, High-Quality Care Through a Regional Collaborative in Florida

The American Journal of Accountable Care™

Accountable Care Organizations:

Looking for Answers to an Overspending, Underachieving System

A. MARK FENDRICK, MD & DONOVAN T. MAUST, MD

While the concurrent implementation and ongoing attempts to repeal the Patient Protection and Affordable Care Act (ie Obamacare) dominate headlines, 2 independent yet closely related storylines drive the national dialogue. The most prominent is the healthcare providers' pursuit of the "triple aim,"[1] which includes enhancing the care experience, improving population health, and reducing healthcare expenditures. Equally important is the changing face of the healthcare consumer as access to care grows, demographics change, and engagement increases. In this time of contention, there seems to be a growing consensus among stakeholders that the traditional, volume-based, fee-for-service (FFS) care is an untenable strategy to deliver evidence-based care that is both fiscally sustainable and able to meet the clinical needs of Americans. As we look for a solution to an overspending, underachieving system, the concept of "accountable care" has received much attention as a potential mechanism to better align provider financial incentives with high-quality care.

In light of these national trends and in response to multi-stakeholder interest, *The American Journal of Managed Care* is pleased to launch *The American Journal of Accountable Care*. The content in this inaugural and future issues aims to highlight the opportunities and challenges faced by providers, payers, and patients as delivery systems, payment models, and consumer engagement initiatives are redesigned. Realizing that there is more than enough money in the system, we hope to steer the conversation from how much to how well we spend our healthcare dollars.

It is our hope and expectation that *The American Journal of Accountable Care* will address several important themes, including:

- Is the accountable care movement increasing the use evidence-based, high-value care? For example, the evidence is overwhelming that chronic care models can improve management of multiple chronic conditions (eg, diabetes, congestive heart failure, depression) and yet such models are rarely implemented in FFS settings. The population-based approach of accountable care organization (ACO) payment could help provide resources up front to implement chronic care models. And, for the first time, reducing the volume and cost of clinical services through successful chronic care management would actually generate revenue for providers through shared savings.
- Are specific patient populations being left out of the accountable care movement? Before population-based models are implemented, someone has to determine the population for which the providers are accountable. The report by Perry et al[2] on building infrastructure for a safety net ACO highlights the need to consider the experience of vulnerable populations in ACOs. Do patient attribution methods used by payers even capture vulnerable patients, who potentially have the most to gain from participation in an ACO?
- What aspects of ACO implementation are replicable in other settings? The reports in this issue by Patel[2,3] and Perry highlight the fact that ACO implementation is proceeding with unique sets of patients, providers, and payers in diverse settings across the country. To what extent can the success or failure of a given ACO inform the efforts of other ACOs given their fundamental differences?
- What is the role of consumers in accountable care? While most of the discussion about ACOs has focused on the roles and responsibilities of payers and providers, success of accountable models will require active consumer participation. ACOs will need to work with patients to develop common goals and be sure that consumer engagement initiatives (eg, benefit design, shared decision-making programs) match the needs of their aligned consumers.
- Where do public health initiatives fit into the accountable care movement? Population health is largely driven by factors beyond the control of ACO payers and providers. Truly improving the health of an aligned population will require ACOs to move away from a purely medical model.

And finally: What are the effects of accountable care on direct medical expenditures and the economy as a whole? Albert Einstein's quote, "In the middle of difficulty lies opportunity," is often applied to United States healthcare. While the accountable care movement will not—on its own—provide the cure for what ails healthcare in the United States, its implementation marks a critical step in the evolution of healthcare from volume to value. We intend that *The American Journal of Accountable Care* will promote innovative ideas and inform, stimulate, and advance the dialogue on the healthcare transformation process. We welcome your comments on the papers included in this issue and encourage submissions for future issues.

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Collaborative Care Before Accountable Care:

Achieving Low-Cost, High-Quality Care Through a Regional Collaborative in Florida

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As accountable care organizations proliferate across the nation, delivery systems still struggle to balance quality improvement, cost containment, and migration toward accountable care. This paper describes the phased approach where the University of Florida Health Science Center and Shands Teaching Hospital and Clinics, Inc, and Orlando Health have jointly developed a series of clinical and health services that are of the highest quality and are offered at the lowest cost. The result is a regional collaborative that will be the foundation for a regional accountable care organization, first leveraging clinical core competencies, then moving to a more integrated model.

In this era of healthcare reform which is focused on cost containment and quality improvement, health systems are struggling to provide the right balance between quality and cost-efficient services. At the same time, advancements in biomedical knowledge and technological innovation are changing standards for the composition and volume of healthcare that can and should be delivered.[1] As such, healthcare providers are working to develop alternative delivery and financing models that enable the provision of high-quality, high-value patient care.

Accountable care organizations (ACOs) hold promise as a model for the financing and delivery of high-value care.[2] Since the passage of the Affordable Care Act, there has been a dramatic increase in ACO activity. In a comprehensive report that canvassed media releases, reports, and private payer activities, over 164 ACO entities were identified across the country.[3] These entities include those that are actively bearing risk and coordinating care, and those that are still implementing such programs. Additionally, the Centers for Medicare & Medicaid services (CMS) recently announced that 27 entities covering 375,000 beneficiaries in 18 states had been selected to form ACOs under the Medicare Shared Savings Program (MSSP).[4] The MSSP ACOs will add to the 32 organizations participating in CMS' Pioneer ACO Program, which involves a more aggressive payment model and is designed for healthcare organizations and providers that are already experienced in coordinating care for patients across care settings.[5] Together with ACOs in the private sector, these Medicare programs put the national total of operating or planned ACOs at well over 200.

However, many organizations are not yet prepared to pursue a full ACO contract with a payer. Moreover, there is no consensus on the optimum design or development path for an ACO. Many provider organizations are looking for ways to enhance their ability not only to deliver high-quality, low-cost clinical care, but also to streamline their many non-clinical lines of operation as a stepping-stone to an ACO, piloting and testing critical competencies first. Thus, providers are looking for innovative intermediate steps that can begin to achieve some of the aims of an ACO: better care for patients, at a lower cost.[6] Many are looking for a strategic approach to begin integrating clinical and operational processes aimed at saving on cost and improving the care patients receive. Depending on their particular circumstances, these strategic approaches might involve creative partnerships between entities who realize that patient care could benefit from the steps that lead to accountable care.

"Many provider organizations are looking for ways to enhance their ability not only to deliver high-quality, low-cost clinical care, but also to streamline their many non-clinical lines of operation as a stepping-stone to an ACO, piloting and testing critical competencies first."

The University of Florida Health Science Center and Shands Teaching Hospital and Clinics, Inc, (University of Florida and Shands) has taken a unique and innovative approach to addressing the increasingly complex needs of patients while being conscious of cost constraints: a regional collaborative with Orlando Health. This collaborative leverages each organization's comparative advantage in the delivery of a number of clinical services and combines efforts in some non-clinical operations. This paper describes the phased approach of the 2 organizations in achieving efficiencies and cost savings. First, we discuss a series of clinical and health services (phase 1) that University of Florida and Shands and Orlando Health have jointly developed over the past

12 months which allow the organizations to share resources in order to offer a comprehensive range of clinical services at the lowest cost of the highest quality. Second, we discuss the University of Florida and Shands and Orlando Health Clinical Integration Network (phase 2), governed by both University of Florida and Shands and Orlando Health executives, which and deepens the collaborative efforts of the 2 organizations.

The result is a unique regional collaborative between 2 contiguous, non-competitive health systems that will serve as the foundation for the development of a "regional accountable care organization" (phase 3), first leveraging clinical core competencies of each organization, then moving to a more integrated model that includes operational and governance integration. This collaborative has allowed both organizations to offer better care, in a leaner, more efficient fashion. Moreover, the organizations' continued integration plans make possible even greater cost savings and quality improvements by combining the inherent advantages of an academic medical center with a non-academic, non-profit organization.

An Opportunity for Collaboration

The University of Florida Academic Health Center comprises the research institutes and professional schools of the University of Florida and the Shands Teaching Hospital and Clinics, Inc. Known collectively as University of Florida and Shands, it is a $2.7 billion organization under the governance of the University of Florida. University of Florida and Shands operates across 2 campuses—Gainesville and Jacksonville, Florida. Like many academic medical centers, University of Florida and Shands serves a disproportionately impoverished population, with over one-third of their payer mix coming from Medicaid, as well as an additional 9% uninsured.

Its partner, Orlando Health Inc, is an approximately $2 billion not-for-profit corporation, with 1738 licensed beds in 6 hospitals, and is one of Florida's most comprehensive medical systems, offering a wide range of tertiary and secondary healthcare services to approximately 1.8 million residents of Orange, Seminole, and Osceola Counties in Central Florida, its primary service area. Specialized treatment includes medicine, surgery, cardiology, oncology, pediatrics, orthopedics, obstetrics, and emergency care.

The 2 institutions operate in contiguous and almost entirely non-competitive markets. Beginning over 2 years ago with informal conversations between the Orlando Health senior vice president and the University of Florida and Shands CEO, the idea of a partnership to bring better care to Floridians materialized into an action plan. In October 2010, Orlando Health and University of Florida and Shands signed a memorandum of understanding to develop joint clinical and non-clinical programs, as well as explore the possibility of creating a clinically integrated network (CIN). The affiliation progressed rapidly as evidenced by joint clinical programs such as: teleconferences for heart failure patients requiring ventricular assist devices (VADS) or transplant; staffing of pediatric orthopedics at University of Florida by Orlando Health physicians; and a proposal for a joint personalized cancer care program and non-clinical activities, such as joint supply purchasing decisions, combining reference laboratories, and evaluation of common IT analytic systems. An expressed intent of these programs is the transparent sharing of data to critically evaluate which system has the best program in order to learn from each other and not duplicate costly services in which regional volumes are low.

Table 1. Identified Areas of Collaboration, December 2010

Health Services	
AREA	**GOALS/ PROGRESS**
Clinical research	Develop collaborative clinical research programs across the organizations
Graduate medical education	Develop a jointly named medical education program
Provider service network	Evaluate the creation of a non-risk-based fee-for-service model
Quality oversight	Identify opportunities combining IT quality infrastructure and joint quality improvement
Supply chain management and laboratory	Evaluate and implement a joint venture model for a regional laboratory and joint purchasing
Clinical Service Lines	
Oncology	Build an oncology network for education, research, recruiting, and clinical areas
Cardiovascular care	Create an integrated network for heart failure, ventricular assist devices, and cardiac transplant services
Behavioral health and addiction medicine	Develop a joint program for addiction medicine services and provision of behavioral health services
Pediatrics	Create a pediatric integrated network including shared high-cost, highly specialized providers
Women's health	Develop joint graduate medical education programs in obstetrics and gynecology

IT indicates information technology.
Source: Author Analysis.

In May 2011, University of Florida and Shands and Orlando Health leadership agreed to a model of regional clinical integration in order to improve quality and cost. The collaboration has been developing in size and scope for the last 12 months. This model extended and formalized the collaborative efforts to date and began a formal clinical integration network (CIN), an entity that governed joint activities between the institutions within 4 major areas: clinical integration, data analytics, contracting, and operations.

Phase 1: Identification of Opportunities for Collaboration

Early on in the effort, leaders at both institutions identified 11 initial areas of collaboration as seen in **Table 1**. The collaborative activities cover a range of health and clinical services, combining institutional efforts where possible, and leveraging each other's expertise and comparative advantage in others. For example, the 2 organizations are exploring options to combine their supply chains for various medical devices and other products. Joint pur-

Table 2. Clinical Integration Network Focus Areas, Design Principles, and Examples

Area of Focus	Design Principle	Examples
Patients	The CIN improves quality and efficiency of healthcare for patients in the CIN area, including tighter coordination, new referral patterns across institutions, and better adoption of best practices.	• Heart failure patients can now access heart failure, pre and post VAD and transplant care in Orlando as a result of the CV collaboration • Supply chain analysis is identifying how supply choice is leading to practice variations
Geography	The CIN will serve a broad geography throughout Central and North Florida.	• Coverage area from Jacksonville and Gainesville to Orlando (over 3 million people)
Quality	The CIN will establish standards of care and use advance data reporting and analytic capabilities to drive variation reduction and best practices, and mandate these standards for provider members.	• The CIN will enable the transfer of patient information between the 2 organizations • Both organizations are using Crimson to identify quality opportunities • End goal is to agree upon provider standards of care
Governance	The CIN requires a governance structure with strong physician leadership that reflects multiple constituencies of specialty, practice, and location.	• CIN executive governance already in place • Physician participation to be determined
Legal	The CIN requires a legal structure that reflects members' ability and willingness to capitalize infrastructure development.	• In progress
Members	The CIN uses a structure and governance model that accommodates other (outside University of Florida/Orlando Health) providers.	• OHPP is a separate legal organization allowing private practitioners to participate in ACO model
Information	The CIN enhances transparency and information sharing among members, utilizing an HIE to accommodate multiple EHRs for connectivity and performance reporting.	• Currently sharing patient information for heart failure collaborative
Payers	The CIN pursues an all-payer strategy with common metrics across all payers, and a consolidated performance incentive structure.	• In progress
Payment models	The CIN embraces and allows for a range of payment arrangements.	• In progress

ACO indicates accountable care organization; CIN, clinical integration network; CV, cardiovascular; HIE, health information exchange; EHR, electronic health record; OHPP, Orlando Health Physician Partners; VAD, ventricular assist device.
Source: Author Analysis

chasing and a "regional laboratory" model enable the 2 health systems to leverage their combined purchasing power to obtain cheaper device contracts and laboratory services. From a clinical standpoint, the 2 organizations maintain a shared pediatric orthopedic staff, utilize University of Florida faculty for addiction medicine services, plan to utilize telemedicine for psychiatric evaluations to clear mental health patients held by involuntary or emergency commitment from the emergency department (ED) (a provision of the Florida Mental Health Act of 1971),[7] and have 1 pediatric liver transplant surgeon, maximizing their return and eliminating the need for multiple high-cost physicians. The organizations also successfully created a single cardiovascular transplant program and instituted a second opinion/referral telemedicine program for cardiac patients.

As part of the initial effort, the following collaborative activities were implemented through 2010 to 2012 and are now beginning to show specific impact on both organizations:

1. Ability to pool expensive physician manpower in pediatric orthopedics through shared staffing and resources.
2. Ability for Orlando Health to rely exclusively on University of Florida and Shands for transplant services, thus eliminating the capital dollars budgeted to pursue its own program.
3. University of Florida and Shands-trained Orlando Health cardiologists in heart failure fellowship will subsequently run a regional heart failure program at Orlando Health, thereby eliminating the need to recruit an additional heart failure medical director at Orlando Health.
4. Weekly telemedicine conferences for heart failure patients between Orlando Health and University of Florida and Shands enable patients to receive a second opinion with minimal effort and allow Orlando-based patients to remain in Orlando for heart failure care until transfer is deemed necessary.
5. Joint ventricular assist device (VAD) program will enable organizations to purchase and share expensive equipment for a high-cost procedure such as VAD.
6. By sharing the nationally recognized addiction medicine program at University of Florida with Orlando Health and sharing in the staffing of outpatient clinics, both organizations were able to meet patient care demands as well as disseminate best practices in mental healthcare.
7. Through novel use of telemedicine, University of Florida psychiatrists are able to help triage mental health patients in the emergency department at Orlando Health, thereby improving bed capacity and staffing resources.
8. Early results of supply chain analysis indicate millions in savings for both organizations for same supplies (contracted at different rates), and similar supplies (where multiple but similar products are used and a single product could be agreed upon). Further, the analysis is identifying variations in supply choices within a single DRG (eg, hip replacement) that could result in quality improvements via standardization of product.

This initial stage of collaboration was also an important first step to a more

advanced model of integration between the 2 organizations, a CIN.

Phase 2: Establishment of a CIN

The CIN is anticipated to be formalized as an LLC that will be governed jointly by both organizations. It is responsible for expanding and deepening the collaborative efforts of the 2 organizations. **Table 2** outlines the CIN design principles and goals. The CIN is focused on 4 pillars that will collectively drive care improvements and cost reduction opportunities: clinical integration, data and analytics, contracting, and operations. Activities are under way within each of these 4 pillars driving the 2 organizations toward quality and efficiency.

Clinical Integration

University of Florida and Shands and Orlando Health are in the process of establishing patient registries and integrating patient data into a common electronic health record platform via a complete health information exchange among competing electronic health records across the members of the CIN in order to support expanded care coordination programs and facilitate care transitions. Comprehensive views of patient records will be possible, and will allow for better patient management, referrals across institutions when necessary, and tracking across the continuum to maximize patient care quality.

"The data and analytic tools also enable new chronic disease management programs for complex patients with chronic obstructive pulmonary disease, diabetes, heart failure, etc allowing both organizations to shift to an approach more focused on population health management."

Data Analytics

In addition to a common electronic health record and exchange via the health information exchange (HIE), a new data warehouse and analytical platform will push quality and performance, as well as clinical data, out into scorecards and reports used to identify variation in care and cost and drive best practice across both institutions. The platform will also enable clinical decision support, evidence-based medicine, and care management. Physicians will be empowered with routine scorecards that analyze performance, and can alter their practice accordingly based on demonstrated best practice. The data and analytic tools also enable new chronic disease management programs for complex patients with chronic obstructive pulmonary disease, diabetes, heart failure, etc, allowing both organizations to shift to an approach more focused on population health management. These tools help prevent costly ED visits and admissions, and allow for better patient management in no-cost or lower-cost settings.

Contracting

University of Florida and Shands and Orlando Health are developing a contract management platform to enable risk profiling and risk management, ultimately positioning them to engage in risk-based contracting with third-party payers. Using their platform and other jointly developed risk profiling and actuarial tools, the 2 organizations are looking to soon jointly engage in shared savings and bundled payment distribution contracts.

Operations

Finally, University of Florida and Shands and Orlando Health are planning to merge and streamline some operations specifically around supply chain management, pharmaceutical management, durable medical equipment, home and long-term health, and tertiary care provision. This will enable joint purchasing with increased consumer leverage, consolidation of post acute services where possible, and streamlined tertiary procedures that share resources rather than duplicate them.

Phase 3: A Regional ACO

Multiple areas within the CIN thus far have shown immense promise in lowering costs and improving integrated care delivery. Further, Orlando Health leadership and an Orlando-based large, private practice primary care group have agreed to file a letter of intent for an ACO in June 2012 that will include Orlando Health and the University of Florida and Shands. The expected start date will be January 2013.

Importantly for University of Florida and Shands and Orlando Health, the work to date between the 2 organizations has laid the foundation for an ACO that spans their 2 regions. A centralized office staffed by University of Florida and Shands and Orlando Health administrators who provide oversight, prioritization, and project management manages this effort. Over the past 2 years and continuing over the coming months, the 2 organizations have created a form of a "pre-ACO," focusing on the critical elements needed to transition and manage a population of patients. Investments in critical information technology infrastructure to support quality and performance reporting at the provider and physician level, clinical decision support, internal business intelligence, disease registries for chronic disease management, etc, will enable the University of Florida and Shands and Orlando Health to improve their collective population management capabilities.

Collaborative efforts around clinical integration are beginning to create the necessary provider culture that pushes for coordination across the care continuum, leverages the expertise for specific procedures between the 2 organizations, and makes use of innovative delivery system transformation efforts such as telemedicine, enhanced home health, and community-based patient management.

Conclusion and Policy Implications

ACOs have attracted considerable attention as promising vehicles for achieving better care, better population health, and lower costs. Indeed, the ability to coordinate care across a variety of settings is a trait of any successful ACO. Yet the success of ACOs—as they are defined by healthcare providers, private payers, and now CMS with its recent announcements of both the Pioneer and Medicare Shared Savings Program ACOs—will depend on whether they can enable care delivery organizations to improve care through the innovative deployment of resources, healthcare personnel, and technology.[8]

We believe that the innovative approach taken by University of Florida and Shands and Orlando Health has produced not only short-term benefits for both organizations, but also a viable path for transitioning to a more accountable payment and delivery model through a formal ACO contract in the future. Organizations contemplating their own path toward an accountable care future can learn from University of Florida and Shands and Orlando Health's approach of developing a regional collaboration as a meaningful interim step toward adopting needed accountable care processes and potentially formal accountable care structures (ie, an ACO). Policy makers and health services researchers will benefit from a better survey of the transition phases toward an ACO so that we can gain a better understanding of what the elements of accountable care are and how best they can be harmonized with other delivery system reforms such as bundled payments, patient-centered medical homes, and value-based purchasing. This particular example focuses on how organizations operating in distinct markets can collaborate to address the challenges of an evolving healthcare market, but even organizations in competitive markets and high medical growth rates and spending can adopt some of these principles as stepping-stones toward implementing accountable care models within their organization. The collaboration of University of Florida and Shands and Orlando Health is a novel example of how provider organizations can work together to achieve both short-term efficiency gains and long-term strategic transformation.

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Accountable Care:

We Have Made Progress but Need to Keep Moving the Agenda Forward

SARAH THOMAS, MS

We are in the midst of exchange implementation—the centerpiece of the affordable care act—and it seems a good time to take stock of where we are and need to go. The ACA has validated and spurred on existing efforts. We are making progress on many fronts but fundamental changes are still needed to deliver on the promise of better value.

The Affordable Care Act Reinforces and Supports Work Already Under Way

The Affordable Care Act (ACA) built from the experience of many pioneers in working toward better value—from business, states, local initiatives, multipayer initiatives, and private organizations, as well as some federal initiatives like the Physician Group Practice demonstration. In many cases, these initiatives are benefiting from funding and reinforcement from the federal government through implementation of the Affordable Care Act.

Regional initiatives have been working on safety and quality improvement together with payment reform, all intended to get to better value for the healthcare dollar. Even before the ACA passed, many local initiatives got serious about improving quality and payment reform. There are many examples of initiatives around the country—many spearheaded by business leaders committed to getting better value from the healthcare system in places like Memphis, Tennessee, and Maine. One example of these initiatives is the Pittsburgh Regional Health Initiative. Focusing first on improving hospital quality and safety (eg, reducing rates of medication errors by 86%), then moving on to reducing hospital readmissions through myriad strategies, its work is grounded in analysis of data to identify opportunities for making care better. ACA funding through the Center for Medicare & Medicaid Innovation and the Agency for Healthcare Research & Quality (AHRQ) has supported some of this work.

The ACA drew from the work of private organizations like the National Committee for Quality Assurance (NCQA). NCQA has proven approaches to defining and promoting quality improvement through accreditation of health plans, evaluating clinical practices (eg, through the patient-centered medical home [PCMH]), and standardized collection and public reporting of quality measures results. With ACA implementation, funding has been made available for developing new quality measures for children, for people with behavioral health problems, and for use in electronic health records. The number of clinicians recognized as PCMHs has grown to over 30,000 and record numbers of health plans are seeking accreditation because of participation requirements for Exchanges called for in the ACA.

We are seeing many health plans getting serious about sponsoring payment reforms. Carriers like Aetna, CIGNA, and United are entering into new types of arrangements with provider groups to form Accountable Care Organizations (ACOs). The ACA does not support these initiatives directly, but may have helped to stimulate their development together with employers' push for better results.

Promising Results From ACA Initiatives

The ACA passed in March 2010. The last 3½ years have been a long road for the legislation, which has faced multiple hurdles—the presidential election, the Supreme Court ruling, multiple votes from the House to repeal and defund, and now website problems. Despite these many tests, implementation has moved forward and we are seeing some positive results.

The ACA transformed the Medicare Star Rating program from a report card program (where results for the plans were posted to a website) to a pay for performance program that—with the addition of demonstration funds—has resulted in new attention from health plan leadership and acceleration in results. NCQA reported last year that Medicare plan performance on measures like colorectal cancer screening, body mass index assessment, and controlling high blood pressure had improved.[1] Centers for Medicare & Medicaid Services (CMS) authors reported that Medicare beneficiaries appear to be using quality information to help choose a health plan[2]; this is a major breakthrough for consumer engagement.

CMS is also reporting some positive results in the trends in hospital readmissions and improved quality in the first year of the ACO program. The agency has laid the groundwork for many potential improvements through supporting state and multipayer initiatives around primary care (including PCMH initiatives), integrating care for people with Medicare and Medicaid coverage,

and delivery system transformation. The Office of the National Coordinator for Health Information Technology is reporting increased rates of health information technology adoption covering many important elements of "meaningful use." While promising, it is too soon to see the results of these initiatives.

Healthcare spending growth is slowing down and while all economists attribute this to, at least in part, the recession, some credit the new incentives in the ACA with some effect.[3]

Where We Still Need to Go

Although we are making good and steady progress toward better value, we need more.

- **Exchanges need to realize their potential.** Although there was a lot of discussion around active versus passive purchasing models for exchanges in the early days of the ACA, most states and the federally facilitated exchanges have put their energies into offering choice of plans and negotiating over premiums. This is natural given the goal of getting these programs up and running, but we want to see more emphasis on quality and driving plans to sponsor initiatives to change the delivery system in the next couple of years.
- **We need to move away from fee-for-service payment to physicians.** Researchers surveying large multispecialty group practices found that even these organizations that are most likely to be positioned for better value are still using fee-for-service payment, which rewards volume over value.[4] The Catalyst for Payment Reform reported that in 2012, only around 11% of payments were based on value.[5] Pending legislation to address physician payment by Medicare would move in the right direction by promoting alternative payment models.
- **Engaging patients.** Changes to align incentives in the payment system and provider transparency and accountability initiatives are important, but getting to the best possible results in health outcomes will require helping consumers to take better care of themselves, whether this means diet and exercise or management of chronic conditions.
- **Improving the system for furnishing long-term services and supports.** As the US population ages, we will need to fix the current financing system for long-term services and supports and for post acute care. The program established by the ACA for addressing this was not actuarially sound. The commission established to make recommendations on how to improve care broke down when it tried to figure out how to improve financing. We hope that some of the new initiatives around providing better care for people with Medicare and Medicaid are successful, but there are many challenges to surmount.
- **Integrating behavioral health with medical healthcare.** State governments have long separated the financing and delivery of care for behavioral health issues from physical health. Experts realize that some of the "high fliers" in healthcare spending are people with both types of healthcare problems; they also realize that treatment for behavioral health conditions can lead to physical health problems. The ACA created the "health home" program in Medicaid as a way to bring primary care and behavioral health together, but it is too soon to see results. Furthermore, the funding for this program is limited to just 24 months.
- **Getting to transparency on price and quality.** Despite many all-payer database initiatives and report cards, we are a long way from real transparency about prices and quality. Private sector innovators like Castlight are leading the way in engaging consumers in information about cost and quality at the point when they need and can act on the information. But we are a long way from this type of information being widely available. Some states are hamstrung by political factors from providing useful information on healthcare prices. Robust transparency and other steps to spur competition are needed to pull down prices for both plans and hospitals with too much market power.

"Healthcare spending growth is slowing down and while all economists attribute this to, at least in part, the recession, some credit the new incentives in the ACA with some effect."

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Building the Infrastructure for a Safety-Net Accountable Care Organization

RUTH E. PERRY, MD

A young community health improvement collaborative in Trenton, New Jersey, is transforming healthcare for the community, with the community.

Ruth E. Perry, MD

The Affordable Care Act (ACA) has stimulated a tremendous amount of discussion, debate, delight, and discord across our nation. Will it improve health outcomes, and will it lower costs? Will Medicaid expansion provide improved access to care for our most vulnerable patients across urban and rural America? Will there be enough providers to provide care to an expanded base? Will I be able to adequately care for my highly complex patients when I can only spend 15 to 20 minutes with them? Will I be able to break even and maintain my practice?

These, and a host of other questions, are critically important, and the answers are not easy or clear. It is human nature to view change through the lens of danger. However, I believe that we have to look through the lens of opportunity as well and ask ourselves the following questions: "What should high-quality care look like, and how should our healthcare system function to best meet the needs of patients?" If we take time to envision the outcomes we desire, we can begin to reverse-engineer the system so that it delivers these very outcomes.

Some important elements of a new healthcare system include:

a collaboration between all healthcare providers and payers in a community; expansion of access to primary care; integration of mental health and primary care services; coordination, navigation, and management of care; implementation of evidence-based treatment plans; utilization of data to manage health at the individual and population level; participation of the community, and innovation support, from the government at all levels, for new models of care delivery and payment.

The state of New Jersey is working to redesign its healthcare system to include many of these new elements. New Jersey is the first state in the nation to pass legislation providing for safety-net accountable care organizations (ACOs). Coalitions in Camden, Trenton, Newark, and Atlantic City are poised to participate in this safety-net ACO demonstration project.

In Trenton, the work had begun long before the ACO legislation was passed in 2011. Trenton's healthcare providers realized the problems facing the community were greater than what 1 individual or organization could solve alone and decided to act on that realization in 2005. The 4 major healthcare providers—Capital Health, St. Francis Medical Center, Henry J. Austin Health Center, and the City of Trenton Department of Health and Human Services—have become collaborators and formed a community-based health improvement organization called the Trenton Health Team (THT).

To date, THT has made progress in improving healthcare for city residents, while at the same time beginning to contain, and in some cases even reduce, costs. It has expanded access to care by implementing advanced access scheduling, reduced emergency department (ED) and inpatient recidivism through a community-wide care coordination team, engaged the community by forming a community advisory board and performing a unified community health needs assessment/health improvement plan, and integrated behavioral health and trauma-informed care into primary care.

THT achieved an early success with advanced access scheduling (AAS). AAS enables outpatient clinics to offer patients appointments on the same day or the next day and has been shown to reduce use of EDs. THT involved all 7 of its outpatient clinics in this initiative, and within the first year, there were remark-

able accomplishments in the areas of patient-provider continuity, quality of care, and efficiency. For example, patients at the St. Francis Medical Center were unable to see the same provider or provider team each time they visited the clinic when this program began. Within a year, they achieved 95% patient-provider continuity. The Henry J. Austin Health Center improved its third-next available (TNA) appointment rate from 37 days at the beginning of the initiative to 2 days following the implementation of the advanced access scheduling program.

The hospital-funded high utilizer teams, coordinated through the communitywide Clinical Care Coordination Team (C4T), have had early success managing patients with high rates of ED use and in-patient recidivism. Between the 2 hospitals within the city of Trenton there was a 45% reduction in ED visits, a 56% reduction in inpatient stays, and a 48% reduction in inpatient charges for the 100 highest volume utilizers served in this program. Ten high-utilizer homeless patients with significant medical problems were connected with housing professionals and received housing vouchers. Upon receiving housing there was a 73% reduction in ED visits, a 100% reduction in inpatient stays, and a 100% reduction in inpatient charges. The significant reduction in charges for these high utilizers will be foundational to bending the cost curve as THT moves to be an accountable care organization.

To begin addressing the city's health issues, THT utilized the IRS's community health needs assessment (CHNA) and community health improvement plan (CHIP) obligation as an opportunity to complete a comprehensive health needs assessment for our geography in an innovative way. First, we performed a unified community health assessment in place of separate assessments as was done in the past. Second, we shifted our approach from one that viewed this as a "requirement" to one that engaged the community and permitted the voice of our community to illuminate the successes, as well as the barriers and challenges, that Trenton residents face in maintaining their health.

The CHNA methodology involved 3 major components. The first was to form a community advisory board (CAB). This organization was chartered in late 2011 and reports directly to the THT board of directors. This board consists of 40 unique community organizations which include municipal, county, and state government, behavioral health providers, social service agencies, academia, homeless service providers, and the faith community. Members of the CAB that possessed community data shared their information with the THT. In turn, THT committed to sharing our compiled data with the CAB. Second, THT performed a retrospective data analysis utilizing data from all of the hospitals and outpatient clinics. These data have been analyzed in a very robust manner and key healthcare trends have been geo-mapped to the zip code level. The third component involved THT contracting People Improving Communities through Organizing (PICO), to help obtain the voice of the community through one-on-one interviews and community forums across our geography. Many of the one-on-one interviews were videotaped, creating a permanent first-person narrative record of the health challenges facing our community. Twenty-five community forums were led by members of the THT executive team, which enabled us to hear the unfiltered voices of our residents. This element is unique to our methodology and demonstrated how quantitative and qualitative data can be mutually reinforcing and useful in refining our understanding of barriers to good health in our community.

Six priorities have emerged in the CHNA. Poverty, the overarching priority, influences the others, which include crime, chronic disease, substance abuse/mental health, obesity, health literacy, and health disparities. We are in the final stages of completing our CHIP and will hold a public meeting to discuss our findings and share the plan with community members and stakeholders.

A great deal of this early transformative work in Trenton and across the state preceded the ACA. Now that the ACA has passed, along with Medicaid expansion in New Jersey, we can reflect on our early successes to scale up our work to impact more individuals in our community, and serve as a model for other communities across the state and the nation.

The Chinese character for the word risk includes the characters for danger and opportunity. With the tools of courage, reason, data, and collaboration, the Trenton Health Team chose to focus on the opportunity to lay the foundation for an ACO to transform healthcare for the people of Trenton into a high-quality system, which they deserve.

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Making the Rounds

CYRIL TUOHY, BA

Hackensack Alliance ACO integrates pharmacists and adopts new technology as it joins in the bold experiment to lower costs and improve quality under health reform.

Even before the US Supreme Court ruled the Affordable Care Act (ACA) constitutional in June, the Hackensack Alliance Accountable Care Organization (ACO) was well on its way to implementing the fundamental changes required of the ACA—President Obama's landmark attempt to change the way healthcare is distributed and reimbursed in the United States.

For the Hackensack Alliance ACO and the 104 doctors who have signed on with the organization, meeting the test set forth by the ACA began in April, 2012. That was when the Medicare Shared Savings Program (MSSP) signed a contract with Hackensack Alliance ACO to share in the millions of dollars the ACO could save by delivering better healthcare services at lower prices to the 14,000 Medicare patients within the ACO network.

"With the bulk of the ACO's patient population being 65 years or older, many on limited budgets, giving them the fewest medications at the lowest cost is essential."

"In the first 5 quarters we have saved in excess of $14.5 million," said Dr Morey Menacker, president and chief executive officer of Hackensack Alliance ACO, in a telephone interview.

Hackensack Alliance administrators had targeted savings of between $5 million and $10 million across the 20 disciplines practiced by healthcare professionals with privileges at 685-bed flagship Hackensack University Medical Center (UMC) in Hackensack, NJ, and the 2 other northern New Jersey hospitals within the Hackensack University Health Network: 128-bed HackensackUMC at Pascack Valley in Westwood, NJ, and the 365-bed HackensackUMC Mountainside in Montclair, NJ (**Table 2**). Even using the most aggressive estimate, savings have exceeded Menacker's expectations by about 50%. The amount saved would have been even greater had the MSSP contract included Medicare Part D, which covers prescription medication, Menacker said. How Hackensack Alliance ACO and the 3 hospitals under its auspices far exceeded its savings target offers a case study in what one ACO has done to lower costs and improve services.

Nurse Navigators

Menacker said one of the first things Hackensack Alliance managers did was to make the 20 hospital practice areas patient-centered medical home (PCMH) compliant. Once that was sealed, the ACO then went off and trained the staff to become PCMH compliant.

Because the PCMH model is grounded in care coordination and communication among the different healthcare disciplines, each PCMH was required to have an electronic medical system, which the ACO then linked to a population management software program capable of gathering data from the separate electronic medical systems. Gathering the data allowed the ACO to target the top 10% highest cost patients for intervention using the concept of "nurse navigators" embedded within the PCMH setting, he said.

Nurse navigators at Hackensack University Medical Center (UMC) play a similar role to that of account managers in a large corporation. Like account managers responsible for every part of the client relationship across multiple departments, nurse navigators are charged with overseeing the patient's relationship with the array of services within the healthcare system: the primary care physician, the hospital, the pharmacist, and the physical therapist.

At the end of the day, these special nurses supervise the inpatient population to make sure the care they receive is "seamless."

"A big problem is that patients go from home to the hospital and all the medications get changed because they don't have the formulary with them," Menacker said. "We've created 2 major interventions that have been dramatically successful in that area."

One intervention involves following patients to make sure

their medication reconciliation is complete, he said. The second intervention allows hospitals to supply patients with 30 days' worth of medication, and patients are told to toss out what is left in their medicine cabinet. Nurse navigators, meanwhile, get in touch with hospital pharmacists and retail pharmacies to tell them about the changes.

With the bulk of the ACO's patient population being 65 years or older, many on limited budgets, giving them the fewest medications at the lowest cost is essential, said ACO director Denise Patriaco. "We continually speak to them," she said. "We have the nurse navigators come in for high-tech, high-touch with the patients. We ask, 'Did you take your meds this morning? Tell me what you took?' Patients need to be aware of what they are taking and why they are taking it."

Table 1. Hackensack University Medical Center

VITAL STATS	
Admissions	39,140
Inpatient surgeries	12,532
Outpatient visits	2.93 million
Emergency department visits	92,182
Births	6182
Beds	685
VITAL STAFF	
Employed full time	
Physicians and dentists	240
Registered nurses	1360
Licensed practical nurses	2
Employed part time	
Physicians and dentists	161
Registered nurses	654
Licensed practical nurses	0

Source: HackensackUMC, FY 2012

The number 1 cause of hospital readmittance is medication noncompliance, so the ACO follows up with a barrage of calls, from the day of discharge right through to subsequent office visits with primary care doctors and specialists, she said.

The average cost of a visit to the emergency department (ED) for more than 8000 patients in the United States was $2168.[1] Keeping patients out of the ED simply by reminding them to take their medication is the best way to zap hospital costs out of the system, literally at the price of a pill.

Hackensack UMC in Hackensack last year alone had 92,182 ED admissions, 12,532 inpatient surgeries, and 2.93 million outpatient visits, according to hospital statistics (**Table 1**).

Making the Rounds

Because Medicare Part D was not part of the MSSP contract with Hackensack Alliance, it is hard to say exactly how much the ACO's stricter pharmacy management procedures have contributed to overall savings. It is safe to say, however, that no ACO can hope to achieve the kind of big savings delivered by Hackensack without implementing reforms around the pharmacy piece of the healthcare equation.

Medication Therapy Management (MTM) techniques show treatment costs for patients were lower by as much as $5500 per patient than for patients in the control group,[2] and more than 7 out of 10 physician visits resulted in at least 1 prescription medication, according to a 2006 study.[3]

Not long ago, it was the doctors who were best known for making the rounds and visiting dozens of patients on different hospital floors. Doctors still do that, but it is now much more common to see pharmacists making the rounds as well.

"In my experience pharmacists have not traditionally come to the floor and talked to patients," Patriaco said.

At Hackensack UMC, though, pharmacists are just as likely as nurses to be appearing at patients' bedsides and talking to nurses and doctors. Nor does the pharmacist's role end at discharge following the all-important medical reconciliation.

Pharmacists, she said, "are calling nurses and physicians all day long" to make sure patients are on the proper blood thinners, and if they are on more than 1, how they got there, who made the decision, and why.

With 2014 full- and part-time registered nurses, 2 licensed practical nurses, and 401 doctors and dentists at Hackensack UMC (**Table 2**), pharmacists have a full plate coordinating medications among the patients served by the physicians and nurses.

Once primarily a dispenser of medication in the correct doses, the pharmacist has morphed into an equal of the practicing nurse and the doctor, with all the privileges and responsibilities that access to the hospital's emergency medical records system can provide.

Menacker said that with Hackensack Alliance on the verge of signing new contracts with commercial insurers, it is likely Hackensack UMC will have to hire more pharmacists or consultants to help with MTM, Menacker said.

Commercial insurers typically take a closer look than Medicare at slashing the pharmacy portion of the total medical spending pie, and Hackensack Alliance is ready to make sure Hackensack UMC leans on all their PharmD's for help.

"Doctors and the healthcare system can reduce the use of pharmacy dramatically if doctors talk and discuss the options with patients and doctors talk to other experts—nurses and pharmacists—instead of just writing a script," Menacker said.

As Hackensack Alliance grows beyond its original Medicare population and inks commercial contracts, the ACO will look

Table 2. Hackensack University Health Network

Hackensack University Medical Center, Hackensack, NJ (685 beds)
Hackensack UMC at Pascack Valley, Westwood, NJ (128 beds)
HackensackUMC Mountainside, Montclair, NJ (365 beds)

Source: HackensackUMC, FY 2012

to "wrest control" of the formulary from the insurance carriers since Part D is not part of the ACO's MSSP contract, he said.

Placing the formulary in the hands of the healthcare providers—the hospitals or nursing care facilities—only makes sense "because they know what the patients need," he said.

Touch and Tech

Elderly patients who suffer from memory lapses often forget to take their pills, or take them at the wrong time, or take them in the wrong order or doses. Particularly if patients consume a regimen of multiple prescription drugs for chronic conditions, it is not uncommon for them to mix pills.

Following a successful pilot at Hackensack UMC with software vendor Health Recovery Solutions, high-risk patients will be provided a tablet computer to keep them on track during the critical 30-day post discharge period, said Rohan Udeshi, chief operating officer of Health Recovery Solutions.

The latest 4G tablets come with integrated glucose meters and pedometers. Data medication compliance, vital signs, physical activity, and side effects are all recorded and shared with the patient's pharmacist, doctor, and nurse navigator.

"The tablet is loaded with reminder times," said Udeshi. "All these data are collected and we crunch the data and alert clinicians when they need to follow up with the patient."

Keeping patients on track with their pharmacy regimen through access to the electronic medical records is considered critical to avoiding readmission, and patients can use the tablet to record and transmit progress to their nurse navigators, Udeshi said.

Hackensack Alliance administrators originally thought the tablet would work as a hospital readmission prevention tool, but it has since developed into an ideal disease management tool and the 30-day usage period has recently been extended to 60 days, Patriaco said.

"The tablet goes with patients wherever they go," Menacker said. "It will act as an alarm clock. There's ongoing reconciliation that automatically gets forwarded to the nurse navigator. As home care comes to the house, they enter the vitals into the tablet and forward the data to the nurse navigator."

A 50-patient randomized blind trial found an 8% readmission rate after 30 days for the patients using the tablets. The control group that received the usual care suffered a readmission rate of 28% after 30 days, Udeshi said.

"We've really made a difference," said Menacker.

Quality Measures

The "dramatic changes" in Hackensack's ability to oversee medication compliance among the highest risk population is critical to meeting quality measures laid down by Centers for Medicare & Medicaid Services as part of the MSSP contract, Menacker said. With 5 quarters worth of experience, "It's a little early" to be able to track exactly how rigorously Hackensack Alliance is meeting the pharmacy quality standards set by CMS, Menacker said, but Medicare's announcement that Hackensack Alliance had saved more than $14.5 million was enough for him.

For the first time, doctors and nurses at Hackensack UMC will be rated based on the quality metrics, he said. "This will also apply to the pharmacist."

Under MSSP, ACOs have to report on a total of 33 quality-related performance measures, and Hackensack Alliance is reporting on each of the government's ACO measures: Nos. 12, 30, 31, and 33, all of which are specific to pharmacy and drug therapy.

The 4 measures range from medication reconciliation after discharge, to cholesterol management for patients with cardiovascular conditions, to beta-blocker and Warfarin therapy for patients with heart failure, to angiotensin-converting enzyme inhibitor and cholesterol-lowering therapy for patients with heart disease-to bronchodilatory therapy for patients with chronic obstructive pulmonary disease, to osteoporosis management in women suffering from fractures.[4]

Every patient will need a good reason as to why they are on a particular dose of medication, and every step in the MTM process will be documented in Hackensack UMC's electronic medical system, which was scheduled to undergo a major integration overhaul with Hackensack Alliance in October, Patriaco said.

"The job of the ACO is to look at how hospitals are spending the money," she said. "Our job is to drive down costs and keep really close track of high-risk patients who have developed high-risk diseases and to keep them healthy and happy. The more support they have the better off they are and the lower the costs."

Author Disclosure: The author reports no relationship or financial interest with any entity that would pose a conflict of interest with the subject matter of this article.

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Is the Deal Any Good?

FRANÇOIS DE BRANTES, MS, MBA

ACOs are entering into risk-based deals. Research suggests that many of these deals will have uncertain outcomes, which a new tool might help mitigate.

The implementation of the Affordable Care Act introduced new payment models that create opportunities for providers to increase their margins if they manage resources more effectively when caring for patients. By far, the focus of Medicare's Innovation Center has been in promoting various flavors of "global capitation" in which providers can form an accountable care organization (ACO) to manage a specified number of Medicare beneficiaries. There are 2 different types of ACO programs offered and the more popular is the one in which the ACO is held accountable for increases in total patient costs of care, and which can share in savings if the target trend rate is beat by a specified margin. It's what's referred to as a "one-sided" deal because the ACO will share savings if there are any but won't be penalized if there aren't. There also is a "two-sided" deal in which the ACO is at financial risk if costs exceed a specified rate.

Since Medicare's introduction of these total costs of care payment programs, private sector payers have mimicked the model and most of the national health plans have a version of this payment scheme in effect with network providers. Today there are far more than 500 ACOs in the United States and the number is growing, with the majority in "one-sided" deals as opposed to "two-sided." Are these deals any good? In other words, how confident is the payer—whether Medicare or private insurer—or the provider that retrospective calculations on actual costs of care will reflect true gains or losses?

A body of literature has examined the underlying variability in total costs of care and the potential for increases in that variability as the sample of patients decreases. This research is the foundation of the concepts of insurance in which the experience of an individual at any point in time is binary, while for cohorts of individuals the probability of a negative event is distributed along a curve. However, the specific cost of that negative event can be trivial or consequential. Overall, as the cohort size increases the variation decreases, but the opposite is also true.

In early 2012 researchers from Rutgers University published a paper that examined the potential for misclassifying ACOs as "winners" or "losers" given the underlying variability of total costs of care in a patient population. The research was based on Medicare beneficiaries but has implications for the private sector as well. Similar to the RAND study on the potential for misclassification of physicians as being efficient or inefficient, the answer lies in the size of the cohort of patients included in the contractual arrangement between the ACO and the payer.

The upshot of these studies is that there is a risk that the provider—the ACO—will be misclassified as a winner or a loser, simply due to the shift in the distribution of the probability curve of incurring a negative event for the population managed. In other words, the ACO might get lucky, or not. And unfortunately, as the size of the cohort goes down, severity adjustment or case mix adjustment models are simply not powerful enough to compensate for the random luck effect of a distribution of probabilities. As a result, depending on the specific nature of the financial deal between the payer and the ACO, as well as the size of the cohort of patients under management, the potential for misclassification can be significant, and the payer could be rewarding the ACO for savings not actually achieved or, conversely, the ACO could fail to receive a reward for savings actually realized.

That explains why a third of the "Pioneer ACOs," who had signed up for a two-sided deal, recently dropped from the program. They realized that the deal wasn't any good for them. It's likely that similar realizations will hit payers and providers in the years to come. It would be regrettable to infer from that realization that new payment programs like the Medicare Shared Savings program cannot work. Instead, we should work to better understand the uncertainty embedded in the program and mitigate it as much as possible.

Building on DeLia and colleagues' work, we've collaborated with IMPAQ International to create an online calculator that should help answer this basic but fundamental question of whether or not the deal offered is any good. There are several variables that influence the answer:

- ***The size of the population to which the deal applies***—Any payment model that is centered on total costs of care requires a large patient cohort to avoid the statistical uncertainties involved in the underlying variability of the population. DeLia

"There is much riding on the success of national and local efforts to move from volume-based payments to new models that encourage a more prudent use of resources."

points out that a reasonable sample size for Medicare patients can be as high as 50,000 plan members depending on the other variables in the deal. While that may be high for commercially insured plan members, the analytic work pretty clearly shows that the lower the number of plan members included in the deal, the greater the underlying uncertainty about the results. So plan member count matters a lot.

- ***The target trend rate and the minimum savings rate—*** These 2 combine to create the conditions under which the ACO will succeed or fail. The target trend rate is typically the expected rate of increase in medical costs during the performance year, and the minimum savings rate is the rate below which shared savings kick in. So, for example, the expected rate could be 4% and the rate under which shared savings would start could be 3%. In other words, if the ACO were to achieve a rate of increase of medical costs of less than 3%, it would share in the savings with the payer. Depending on the spread between the target and the minimum rates, the likelihood of a "false positive" increases.

Intuitively, it's easy to understand how these variables can impact the likelihood that the ACO (or the payer) will win or lose, but what's not as easily understood is the extent to which these variables combine to create uncertainty in the actual results, and that's what the calculator helps better define. With it, a user can modify these key variables and better understand the potential uncertainty in gains and losses, even if the actual results are better than what they appear to be.

There is much riding on the success of national and local efforts to move from volume-based payments to new models that encourage a more prudent use of resources. Over a decade ago, the ability of providers to understand the uncertainty of the financial risks eventually led to the demise of many and a significant setback for the country in our collective ability to rein in runaway medical costs. We cannot allow the same mistakes to happen again, and both providers and payers need to understand whether or not the deal is any good.

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INVOKANA™ is the #1 branded therapy prescribed by endocrinologists when adding or switching non-insulin type 2 diabetes medications*

ENVISION NEW **POSSIBILITIES**

Invokana™
canagliflozin tablets

*Data on file. Based on NBRx data sourced from IMS NPA Market Dynamics Database, weekly data through 9/20/13.

INVOKANA™ (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

INVOKANA™ is not recommended in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

IMPORTANT SAFETY INFORMATION

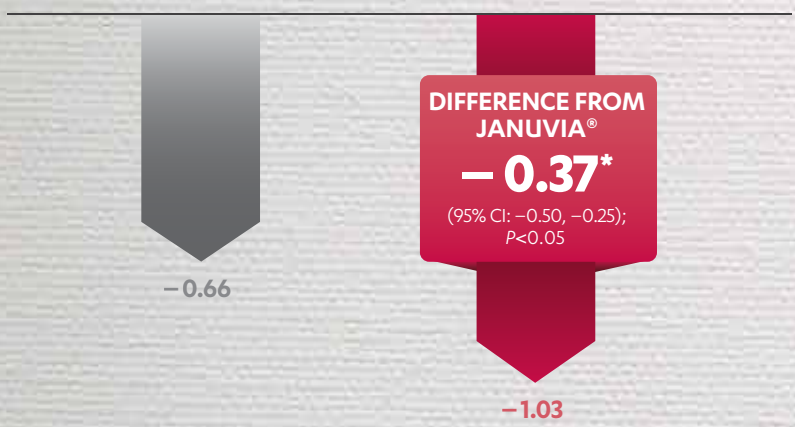
CONTRAINDICATIONS

- History of a serious hypersensitivity reaction to INVOKANA™.
- Severe renal impairment (eGFR <30 mL/min/1.73 m^2), end stage renal disease, or patients on dialysis.

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.

INVOKANA™ 300 mg demonstrated greater reductions in A1C vs Januvia® 100 mg at 52 weeks…

Adjusted Mean Change in A1C From Baseline (%): INVOKANA™ 300 mg vs Januvia® 100 mg, Each in Combination With Metformin + a Sulfonylurea[1]



Incidence of Hypoglycemia

With metformin + a sulfonylurea over 52 weeks: INVOKANA™ (canagliflozin) 300 mg: **43.2%**; Januvia® 100 mg: **40.7%**[1]

- Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue[1]

Convenient Once-Daily Oral Dosing[1]

- Recommended starting dose: INVOKANA™ 100 mg
- Dose can be increased to 300 mg in patients tolerating 100 mg who have an eGFR ≥60 mL/min/1.73 m^2 and require additional glycemic control

*INVOKANA™ + metformin is considered noninferior to Januvia® + metformin because the upper limit of the 95% confidence interval is less than the prespecified noninferiority margin of 0.3%.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS and PRECAUTIONS

- **Hypotension:** INVOKANA™ causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA™, particularly in patients with impaired renal function (eGFR <60 mL/min/1.73 m^2), elderly patients, and patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (eg, angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA™ in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.
- **Impairment in Renal Function:** INVOKANA™ increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA™. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m^2.
- **Hyperkalemia:** INVOKANA™ can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia. Monitor serum potassium levels periodically after initiating INVOKANA™ in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.

COVERED FOR >**75%** OF COMMERCIALLY INSURED PATIENTS WITHOUT PRIOR AUTHORIZATION[3]

...as well as greater reductions in body weight† and systolic blood pressure (SBP)†

Change in Body Weight†

Significant reductions in body weight at 52 weeks, each in combination with metformin + a sulfonylurea (*P*<0.001)[1]

»Difference from Januvia®‡:
300 mg: **–2.8%**

Change in SBP†

Significant lowering of SBP at 52 weeks, each in combination with metformin + a sulfonylurea (*P*<0.001)[2]

»Difference from Januvia®‡:
300 mg: **–5.9 mm Hg**

INVOKANA™ is not indicated for weight loss or as antihypertensive treatment.

†Prespecified secondary endpoint.

‡Adjusted mean.

INVOKANA™ provides SGLT2 inhibition, reducing renal glucose reabsorption and increasing urinary glucose excretion.[1]

Adverse Reactions

In 4 pooled placebo-controlled trials, the most common (≥5%) adverse reactions were female genital mycotic infection, urinary tract infection, and increased urination.[1§]

References: 1. INVOKANA™ [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals, Inc.; 2013. **2.** Schernthaner G, Gross JL, Rosenstock J, et al. Canagliflozin compared with sitagliptin for patients with type 2 diabetes who do not have adequate glycemic control with metformin plus sulfonylurea: a 52-week randomized trial. *Diabetes Care*. 2013;36(9):2508-2515. **3.** Data on file. Janssen Pharmaceuticals, Inc., Titusville, NJ. Data as of 9/17/13.

SGLT2 = sodium glucose co-transporter-2.

§Included 1 monotherapy and 3 add-on combination trials with metformin, metformin + a sulfonylurea, or metformin + pioglitazone.

Learn more at **INVOKANAhcp.com/journal**

»**Hypoglycemia With Concomitant Use With Insulin and Insulin Secretagogues:** Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA™ can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA™.

»**Genital Mycotic Infections:** INVOKANA™ increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections. Monitor and treat appropriately.

»**Hypersensitivity Reactions:** Hypersensitivity reactions (eg, generalized urticaria), some serious, were reported with INVOKANA™ treatment; these reactions generally occurred within hours to days after initiating INVOKANA™. If hypersensitivity reactions occur, discontinue use of INVOKANA™; treat per standard of care and monitor until signs and symptoms resolve.

»**Increases in Low-Density Lipoprotein (LDL-C):** Dose-related increases in LDL-C occur with INVOKANA™. Monitor LDL-C and treat per standard of care after initiating INVOKANA™.

»**Macrovascular Outcomes:** There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA™ or any other antidiabetic drug.

Please see additional Important Safety Information and brief summary of full Prescribing Information on the following pages.

ENVISION NEW
POSSIBILITIES

Invokana™
canagliflozin tablets

IMPORTANT SAFETY INFORMATION (cont'd)

DRUG INTERACTIONS

- **UGT Enzyme Inducers:** Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including UGT1A9, UGT2B4, decreased canagliflozin area under the curve (AUC) by 51%. This decrease in exposure to canagliflozin may decrease efficacy. If an inducer of these UGTs (eg, rifampin, phenytoin, phenobarbital, ritonavir) must be co-administered with INVOKANA™ (canagliflozin), consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA™ 100 mg once daily, have an eGFR greater than 60 mL/min/1.73 m^2, and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m^2 receiving concurrent therapy with a UGT inducer and requiring additional glycemic control.
- **Digoxin:** There was an increase in the area AUC and mean peak drug concentration (C_{max}) of digoxin (20% and 36%, respectively) when co-administered with INVOKANA™ 300 mg. Patients taking INVOKANA™ with concomitant digoxin should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

- **Pregnancy Category C:** There are no adequate and well-controlled studies of INVOKANA™ in pregnant women. Based on results from rat studies, canagliflozin may affect renal development and maturation. In a juvenile rat study, increased kidney weights and renal pelvic and tubular dilatation were evident at ≥0.5 times clinical exposure from a 300-mg dose.

  These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA™ should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- **Nursing Mothers:** It is not known if INVOKANA™ is excreted in human milk. INVOKANA™ is secreted in the milk of lactating rats, reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA™ showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs in utero and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from INVOKANA™, a decision should be made whether to discontinue nursing or to discontinue INVOKANA™, taking into account the importance of the drug to the mother.
- **Pediatric Use:** Safety and effectiveness of INVOKANA™ in pediatric patients under 18 years of age have not been established.
- **Geriatric Use:** Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA™ in nine clinical studies of INVOKANA™. Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA™ (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300-mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were ≥75 years of age. Smaller reductions in HbA1C with INVOKANA™ relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA™ 100 mg and -0.74% with INVOKANA™ 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA™ 100 mg and -0.87% with INVOKANA™ 300 mg relative to placebo).
- **Renal Impairment:** The efficacy and safety of INVOKANA™ were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to <50 mL/min/1.73 m^2). These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR ≥60 mL/min/1.73 m^2); patients treated with INVOKANA™ 300 mg were more likely to experience increases in potassium.

  The efficacy and safety of INVOKANA™ have not been established in patients with severe renal impairment (eGFR <30 mL/min/1.73 m^2), with end-stage renal disease (ESRD), or receiving dialysis. INVOKANA™ is not expected to be effective in these patient populations.

Janssen Pharmaceuticals, Inc.

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November 2013 004991-131021

» **Hepatic Impairment:** No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA™ has not been studied in patients with severe hepatic impairment and it is therefore not recommended.

OVERDOSAGE

» There were no reports of overdose during the clinical development program of INVOKANA™ (canagliflozin).

In the event of an overdose, contact the Poison Control Center. It is also reasonable to employ the usual supportive measures, eg, remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as dictated by the patient's clinical status. Canagliflozin was negligibly removed during a 4-hour hemodialysis session. Canagliflozin is not expected to be dialyzable by peritoneal dialysis.

ADVERSE REACTIONS

» The most common (≥5%) adverse reactions were female genital mycotic infections, urinary tract infections, and increased urination. Adverse reactions in ≥2% of patients were male genital mycotic infections, vulvovaginal pruritus, thirst, nausea, and constipation.

K02CAN13149

Please see brief summary of full Prescribing Information on the following pages.

Invokana™
canagliflozin tablets

janssen
PHARMACEUTICAL COMPANIES
OF Johnson&Johnson

INVOKANA™

(canagliflozin) tablets, for oral use

Brief Summary of Prescribing Information.

INDICATIONS AND USAGE

INVOKANA™ (canagliflozin) is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus *[see Clinical Studies (14) in full Prescribing Information]*.

Limitation of Use: INVOKANA is not recommended in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.

CONTRAINDICATIONS

- History of a serious hypersensitivity reaction to INVOKANA *[see Warnings and Precautions]*.
- Severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), end stage renal disease or patients on dialysis *[see Warnings and Precautions and Use in Specific Populations]*.

WARNINGS AND PRECAUTIONS

Hypotension: INVOKANA causes intravascular volume contraction. Symptomatic hypotension can occur after initiating INVOKANA *[see Adverse Reactions]* particularly in patients with impaired renal function (eGFR less than 60 mL/min/1.73 m^2), elderly patients, patients on either diuretics or medications that interfere with the renin-angiotensin-aldosterone system (e.g., angiotensin-converting-enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs]), or patients with low systolic blood pressure. Before initiating INVOKANA in patients with one or more of these characteristics, volume status should be assessed and corrected. Monitor for signs and symptoms after initiating therapy.

Impairment in Renal Function: INVOKANA increases serum creatinine and decreases eGFR. Patients with hypovolemia may be more susceptible to these changes. Renal function abnormalities can occur after initiating INVOKANA *[see Adverse Reactions]*. More frequent renal function monitoring is recommended in patients with an eGFR below 60 mL/min/1.73 m^2.

Hyperkalemia: INVOKANA can lead to hyperkalemia. Patients with moderate renal impairment who are taking medications that interfere with potassium excretion, such as potassium-sparing diuretics, or medications that interfere with the renin-angiotensin-aldosterone system are more likely to develop hyperkalemia *[see Adverse Reactions]*.

Monitor serum potassium levels periodically after initiating INVOKANA in patients with impaired renal function and in patients predisposed to hyperkalemia due to medications or other medical conditions.

Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues: Insulin and insulin secretagogues are known to cause hypoglycemia. INVOKANA can increase the risk of hypoglycemia when combined with insulin or an insulin secretagogue *[see Adverse Reactions]*. Therefore, a lower dose of insulin or insulin secretagogue may be required to minimize the risk of hypoglycemia when used in combination with INVOKANA.

Genital Mycotic Infections: INVOKANA increases the risk of genital mycotic infections. Patients with a history of genital mycotic infections and uncircumcised males were more likely to develop genital mycotic infections *[see Adverse Reactions]*. Monitor and treat appropriately.

Hypersensitivity Reactions: Hypersensitivity reactions (e.g., generalized urticaria), some serious, were reported with INVOKANA treatment; these reactions generally occurred within hours to days after initiating INVOKANA. If hypersensitivity reactions occur, discontinue use of INVOKANA; treat per standard of care and monitor until signs and symptoms resolve *[see Contraindications and Adverse Reactions]*.

Increases in Low-Density Lipoprotein (LDL-C): Dose-related increases in LDL-C occur with INVOKANA *[see Adverse Reactions]*. Monitor LDL-C and treat per standard of care after initiating INVOKANA.

Macrovascular Outcomes: There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with INVOKANA or any other antidiabetic drug.

ADVERSE REACTIONS

The following important adverse reactions are described below and elsewhere in the labeling:

- Hypotension *[see Warnings and Precautions]*
- Impairment in Renal Function *[see Warnings and Precautions]*
- Hyperkalemia *[see Warnings and Precautions]*
- Hypoglycemia with Concomitant Use with Insulin and Insulin Secretagogues *[see Warnings and Precautions]*
- Genital Mycotic Infections *[see Warnings and Precautions]*
- Hypersensitivity Reactions *[see Warnings and Precautions]*
- Increases in Low-Density Lipoprotein (LDL-C) *[see Warnings and Precautions]*

Clinical Studies Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to the rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

Pool of Placebo-Controlled Trials: The data in Table 1 is derived from four 26-week placebo-controlled trials. In one trial INVOKANA was used as monotherapy and in three trials INVOKANA was used as add-on therapy *[see Clinical Studies (14) in full Prescribing Information]*. These data reflect exposure of 1667 patients to INVOKANA and a mean duration of exposure to

INVOKANA of 24 weeks. Patients received INVOKANA 100 mg (N=833), INVOKANA 300 mg (N=834) or placebo (N=646) once daily. The mean age of the population was 56 years and 2% were older than 75 years of age. Fifty percent (50%) of the population was male and 72% were Caucasian, 12% were Asian, and 5% were Black or African American. At baseline the population had diabetes for an average of 7.3 years, had a mean HbA1C of 8.0% and 20% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 88 mL/min/1.73 m^2).

Table 1 shows common adverse reactions associated with the use of INVOKANA. These adverse reactions were not present at baseline, occurred more commonly on INVOKANA than on placebo, and occurred in at least 2% of patients treated with either INVOKANA 100 mg or INVOKANA 300 mg.

Table 1: Adverse Reactions From Pool of Four 26–Week Placebo-Controlled Studies Reported in ≥ 2% of INVOKANA-Treated Patients*

Adverse Reaction	Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Female genital mycotic infections†	3.2%	10.4%	11.4%
Urinary tract infections‡	4.0%	5.9%	4.3%
Increased urination§	0.8%	5.3%	4.6%
Male genital mycotic infections¶	0.6%	4.2%	3.7%
Vulvovaginal pruritus	0.0%	1.6%	3.0%
Thirst#	0.2%	2.8%	2.3%
Constipation	0.9%	1.8%	2.3%
Nausea	1.5%	2.2%	2.3%

* The four placebo-controlled trials included one monotherapy trial and three add-on combination trials with metformin, metformin and sulfonylurea, or metformin and pioglitazone.

† Female genital mycotic infections include the following adverse reactions: Vulvovaginal candidiasis, Vulvovaginal mycotic infection, Vulvovaginitis, Vaginal infection, Vulvitis, and Genital infection fungal. Percentages calculated with the number of female subjects in each group as denominator: placebo (N=312), INVOKANA 100 mg (N=425), and INVOKANA 300 mg (N=430).

‡ Urinary tract infections includes the following adverse reactions: Urinary tract infection, Cystitis, Kidney infection, and Urosepsis.

§ Increased urination includes the following adverse reactions: Polyuria, Pollakiuria, Urine output increased, Micturition urgency, and Nocturia.

¶ Male genital mycotic infections include the following adverse reactions: Balanitis or Balanoposthitis, Balanitis candida, and Genital infection fungal. Percentages calculated with the number of male subjects in each group as denominator: placebo (N=334), INVOKANA 100 mg (N=408), and INVOKANA 300 mg (N=404).

Thirst includes the following adverse reactions: Thirst, Dry mouth, and Polydipsia.

Abdominal pain was also more commonly reported in patients taking INVOKANA 100 mg (1.8%), 300 mg (1.7%) than in patients taking placebo (0.8%).

Pool of Placebo- and Active-Controlled Trials: The occurrence of adverse reactions was also evaluated in a larger pool of patients participating in placebo- and active-controlled trials.

The data combined eight clinical trials *[see Clinical Studies (14) in full Prescribing Information]* and reflect exposure of 6177 patients to INVOKANA. The mean duration of exposure to INVOKANA was 38 weeks with 1832 individuals exposed to INVOKANA for greater than 50 weeks. Patients received INVOKANA 100 mg (N=3092), INVOKANA 300 mg (N=3085) or comparator (N=3262) once daily. The mean age of the population was 60 years and 5% were older than 75 years of age. Fifty-eight percent (58%) of the population was male and 73% were Caucasian, 16% were Asian, and 4% were Black or African American. At baseline, the population had diabetes for an average of 11 years, had a mean HbA1C of 8.0% and 33% had established microvascular complications of diabetes. Baseline renal function was normal or mildly impaired (mean eGFR 81 mL/min/1.73 m^2).

The types and frequency of common adverse reactions observed in the pool of eight clinical trials were consistent with those listed in Table 1. In this pool, INVOKANA was also associated with the adverse reactions of fatigue (1.7% with comparator, 2.2% with INVOKANA 100 mg, and 2.0% with INVOKANA 300 mg) and loss of strength or energy (i.e., asthenia) (0.6% with comparator, 0.7% with INVOKANA 100 mg and 1.1% with INVOKANA 300 mg).

In the pool of eight clinical trials, the incidence rate of pancreatitis (acute or chronic) was 0.9, 2.7, and 0.9 per 1000 patient-years of exposure to comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

In the pool of eight clinical trials with a longer mean duration of exposure to INVOKANA (68 weeks), the incidence rate of bone fracture was 14.2, 18.7, and 17.6 per 1000 patient years of exposure to comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Upper extremity fractures occurred more commonly on INVOKANA than comparator.

INVOKANA™ (canagliflozin) tablets

In the pool of eight clinical trials, hypersensitivity-related adverse reactions (including erythema, rash, pruritus, urticaria, and angioedema) occurred in 3.0%, 3.8%, and 4.2% of patients receiving comparator, INVOKANA 100 mg and INVOKANA 300 mg, respectively. Five patients experienced serious adverse reactions of hypersensitivity with INVOKANA, which included 4 patients with urticaria and 1 patient with a diffuse rash and urticaria occurring within hours of exposure to INVOKANA. Among these patients, 2 patients discontinued INVOKANA. One patient with urticaria had recurrence when INVOKANA was re-initiated.

Photosensitivity-related adverse reactions (including photosensitivity reaction, polymorphic light eruption, and sunburn) occurred in 0.1%, 0.2%, and 0.2% of patients receiving comparator, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Other adverse reactions occurring more frequently on INVOKANA than on comparator were:

Volume Depletion-Related Adverse Reactions: INVOKANA results in an osmotic diuresis, which may lead to reductions in intravascular volume. In clinical studies, treatment with INVOKANA was associated with a dose-dependent increase in the incidence of volume depletion-related adverse reactions (e.g., hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration). An increased incidence was observed in patients on the 300 mg dose. The three factors associated with the largest increase in volume depletion-related adverse reactions were the use of loop diuretics, moderate renal impairment (eGFR 30 to less than 60 mL/min/1.73 m^2) and age 75 years and older (Table 2) *[see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Use in Specific Populations]*.

Table 2: Proportion of Patients With at Least one Volume Depletion-Related Adverse Reactions (Pooled Results from 8 Clinical Trials)

Baseline Characteristic	Comparator Group* %	INVOKANA 100 mg %	INVOKANA 300 mg %
Overall population	1.5%	2.3%	3.4%
75 years of age and older†	2.6%	4.9%	8.7%
eGFR less than 60 mL/min/1.73 m^2†	2.5%	4.7%	8.1%
Use of loop diuretic†	4.7%	3.2%	8.8%

***** Includes placebo and active-comparator groups

† Patients could have more than 1of the listed risk factors

Impairment in Renal Function: INVOKANA is associated with a dose-dependent increase in serum creatinine and a concomitant fall in estimated GFR (Table 3). Patients with moderate renal impairment at baseline had larger mean changes.

Table 3: Changes in Serum Creatinine and eGFR Associated with INVOKANA in the Pool of Four Placebo-Controlled Trials and Moderate Renal Impairment Trial

			Placebo N=646	INVOKANA 100 mg N=833	INVOKANA 300 mg N=834
Pool of Four Placebo-Controlled Trials	Baseline	Creatinine (mg/dL)	0.84	0.82	0.82
		eGFR (mL/min/1.73 m^2)	87.0	88.3	88.8
	Week 6 Change	Creatinine (mg/dL)	0.01	0.03	0.05
		eGFR (mL/min/1.73 m^2)	-1.6	-3.8	-5.0
	End of Treatment Change*	Creatinine (mg/dL)	0.01	0.02	0.03
		eGFR (mL/min/1.73 m^2)	-1.6	-2.3	-3.4
			Placebo N=90	**INVOKANA 100 mg N=90**	**INVOKANA 300 mg N=89**
Moderate Renal Impairment Trial	Baseline	Creatinine (mg/dL)	1.61	1.62	1.63
		eGFR (mL/min/1.73 m^2)	40.1	39.7	38.5
	Week 3 Change	Creatinine (mg/dL)	0.03	0.18	0.28
		eGFR (mL/min/1.73 m^2)	-0.7	-4.6	-6.2
	End of Treatment Change*	Creatinine (mg/dL)	0.07	0.16	0.18
		eGFR (mL/min/1.73 m^2)	-1.5	-3.6	-4.0

***** Week 26 in mITT LOCF population

In the pool of four placebo-controlled trials where patients had normal or mildly impaired baseline renal function, the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR below 80 mL/min/1.73 m^2 and 30% lower than baseline, was 2.1% with placebo, 2.0% with INVOKANA 100 mg, and 4.1% with INVOKANA 300 mg. At the end of treatment, 0.5% with placebo, 0.7% with INVOKANA 100 mg, and 1.4% with INVOKANA 300 mg had a significant renal function decline.

In a trial carried out in patients with moderate renal impairment with a baseline eGFR of 30 to less than 50 mL/min/1.73 m^2 (mean baseline eGFR 39 mL/min/1.73 m^2) *[see Clinical Studies (14.3) in full Prescribing Information]*, the proportion of patients who experienced at least one event of significant renal function decline, defined as an eGFR 30% lower than baseline, was 6.9% with placebo, 18% with INVOKANA 100 mg, and 22.5% with INVOKANA 300 mg. At the end of treatment, 4.6% with placebo, 3.4% with INVOKANA 100 mg, and 3.4% with INVOKANA 300 mg had a significant renal function decline.

In a pooled population of patients with moderate renal impairment (N=1085) with baseline eGFR of 30 to less than 60 mL/min/1.73 m^2 (mean baseline eGFR 48 mL/min/1.73 m^2), the overall incidence of these events was lower than in the dedicated trial but a dose-dependent increase in incident episodes of significant renal function decline compared to placebo was still observed.

Use of INVOKANA was associated with an increased incidence of renal-related adverse reactions (e.g., increased blood creatinine, decreased glomerular filtration rate, renal impairment, and acute renal failure), particularly in patients with moderate renal impairment.

In the pooled analysis of patients with moderate renal impairment, the incidence of renal-related adverse reactions was 3.7% with placebo, 8.9% with INVOKANA 100 mg, and 9.3% with INVOKANA 300 mg. Discontinuations due to renal-related adverse events occurred in 1.0% with placebo, 1.2% with INVOKANA 100 mg, and 1.6% with INVOKANA 300 mg *[see Warnings and Precautions]*.

Genital Mycotic Infections: In the pool of four placebo-controlled clinical trials, female genital mycotic infections (e.g., vulvovaginal mycotic infection, vulvovaginal candidiasis, and vulvovaginitis) occurred in 3.2%, 10.4%, and 11.4% of females treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Patients with a history of genital mycotic infections were more likely to develop genital mycotic infections on INVOKANA. Female patients who developed genital mycotic infections on INVOKANA were more likely to experience recurrence and require treatment with oral or topical antifungal agents and anti-microbial agents *[see Warnings and Precautions]*.

In the pool of four placebo-controlled clinical trials, male genital mycotic infections (e.g., candidal balanitis, balanoposthitis) occurred in 0.6%, 4.2%, and 3.7% of males treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. Male genital mycotic infections occurred more commonly in uncircumcised males and in males with a prior history of balanitis or balanoposthitis. Male patients who developed genital mycotic infections on INVOKANA were more likely to experience recurrent infections (22% on INVOKANA versus none on placebo), and require treatment with oral or topical antifungal agents and anti-microbial agents than patients on comparators. In the pooled analysis of 8 controlled trials, phimosis was reported in 0.3% of uncircumcised male patients treated with INVOKANA and 0.2% required circumcision to treat the phimosis *[see Warnings and Precautions]*.

Hypoglycemia: In all clinical trials, hypoglycemia was defined as any event regardless of symptoms, where biochemical hypoglycemia was documented (any glucose value below or equal to 70 mg/dL). Severe hypoglycemia was defined as an event consistent with hypoglycemia where the patient required the assistance of another person to recover, lost consciousness, or experienced a seizure (regardless of whether biochemical documentation of a low glucose value was obtained). In individual clinical trials *[see Clinical Studies (14) in full Prescribing Information]*, episodes of hypoglycemia occurred at a higher rate when INVOKANA was co-administered with insulin or sulfonylureas (Table 4) *[see Warnings and Precautions]*.

Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies

Monotherapy (26 weeks)	**Placebo (N=192)**	**INVOKANA 100 mg (N=195)**	**INVOKANA 300 mg (N=197)**
Overall [N (%)]	5 (2.6)	7 (3.6)	6 (3.0)
In Combination with Metformin (26 weeks)	**Placebo + Metformin (N=183)**	**INVOKANA 100 mg + Metformin (N=368)**	**INVOKANA 300 mg + Metformin (N=367)**
Overall [N (%)]	3 (1.6)	16 (4.3)	17 (4.6)
Severe [N (%)]†	0 (0)	1 (0.3)	1 (0.3)
In Combination with Metformin (52 weeks)	**Glimepiride + Metformin (N=482)**	**INVOKANA 100 mg + Metformin (N=483)**	**INVOKANA 300 mg + Metformin (N=485)**
Overall [N (%)]	165 (34.2)	27 (5.6)	24 (4.9)
Severe [N (%)]†	15 (3.1)	2 (0.4)	3 (0.6)
In Combination with Sulfonylurea (18 weeks)	**Placebo + Sulfonylurea (N=69)**	**INVOKANA 100 mg + Sulfonylurea (N=74)**	**INVOKANA 300 mg + Sulfonylurea (N=72)**
Overall [N (%)]	4 (5.8)	3 (4.1)	9 (12.5)
In Combination with Metformin + Sulfonylurea (26 weeks)	**Placebo + Metformin + Sulfonylurea (N=156)**	**INVOKANA 100 mg + Metformin + Sulfonylurea (N=157)**	**INVOKANA 300 mg + Metformin + Sulfonylurea (N=156)**
Overall [N (%)]	24 (15.4)	43 (27.4)	47 (30.1)
Severe [N (%)]†	1 (0.6)	1 (0.6)	0

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Table 4: Incidence of Hypoglycemia* in Controlled Clinical Studies (continued)

In Combination with Metformin + Sulfonylurea (52 weeks)	**Sitagliptin + Metformin + Sulfonylurea (N=378)**		**INVOKANA 300 mg + Metformin + Sulfonylurea (N=377)**
Overall [N (%)]	154 (40.7)		163 (43.2)
Severe [N (%)]†	13 (3.4)		15 (4.0)
In Combination with Metformin + Pioglitazone (26 weeks)	**Placebo + Metformin + Pioglitazone (N=115)**	**INVOKANA 100 mg + Metformin + Pioglitazone (N=113)**	**INVOKANA 300 mg + Metformin + Pioglitazone (N=114)**
Overall [N (%)]	3 (2.6)	3 (2.7)	6 (5.3)
In Combination with Insulin (18 weeks)	**Placebo (N=565)**	**INVOKANA 100 mg (N=566)**	**INVOKANA 300 mg (N=587)**
Overall [N (%)]	208 (36.8)	279 (49.3)	285 (48.6)
Severe [N (%)]†	14 (2.5)	10 (1.8)	16 (2.7)

* Number of patients experiencing at least one event of hypoglycemia based on either biochemically documented episodes or severe hypoglycemic events in the intent-to-treat population

† Severe episodes of hypoglycemia were defined as those where the patient required the assistance of another person to recover, lost consciousness, or experienced a seizure (regardless of whether biochemical documentation of a low glucose value was obtained)

Laboratory Tests: *Increases in Serum Potassium:* Dose-related, transient mean increases in serum potassium were observed early after initiation of INVOKANA (i.e., within 3 weeks) in a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*. In this trial, increases in serum potassium of greater than 5.4 mEq/L and 15% above baseline occurred in 16.1%, 12.4%, and 27.0% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. More severe elevations (i.e., equal or greater than 6.5 mEq/L) occurred in 1.1%, 2.2%, and 2.2% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively. In patients with moderate renal impairment, increases in potassium were more commonly seen in those with elevated potassium at baseline and in those using medications that reduce potassium excretion, such as potassium-sparing diuretics, angiotensin-converting-enzyme inhibitors, and angiotensin-receptor blockers *[see Warnings and Precautions]*.

Increases in Serum Magnesium: Dose-related increases in serum magnesium were observed early after initiation of INVOKANA (within 6 weeks) and remained elevated throughout treatment. In the pool of four placebo-controlled trials, the mean change in serum magnesium levels was 8.1% and 9.3% with INVOKANA 100 mg and INVOKANA 300 mg, respectively, compared to -0.6% with placebo. In a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*, serum magnesium levels increased by 0.2%, 9.2%, and 14.8% with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Increases in Serum Phosphate: Dose-related increases in serum phosphate levels were observed with INVOKANA. In the pool of four placebo controlled trials, the mean change in serum phosphate levels were 3.6% and 5.1% with INVOKANA 100 mg and INVOKANA 300 mg, respectively, compared to 1.5% with placebo. In a trial of patients with moderate renal impairment *[see Clinical Studies (14.3) in full Prescribing Information]*, the mean serum phosphate levels increased by 1.2%, 5.0%, and 9.3% with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively.

Increases in Low-Density Lipoprotein Cholesterol (LDL-C) and non-High-Density Lipoprotein Cholesterol (non-HDL-C): In the pool of four placebo-controlled trials, dose-related increases in LDL-C with INVOKANA were observed. Mean changes (percent changes) from baseline in LDL-C relative to placebo were 4.4 mg/dL (4.5%) and 8.2 mg/dL (8.0%) with INVOKANA 100 mg and INVOKANA 300 mg, respectively. The mean baseline LDL-C levels were 104 to 110 mg/dL across treatment groups *[see Warnings and Precautions]*.

Dose-related increases in non-HDL-C with INVOKANA were observed. Mean changes (percent changes) from baseline in non-HDL-C relative to placebo were 2.1 mg/dL (1.5%) and 5.1 mg/dL (3.6%) with INVOKANA 100 mg and 300 mg, respectively. The mean baseline non-HDL-C levels were 140 to 147 mg/dL across treatment groups.

Increases in Hemoglobin: In the pool of four placebo-controlled trials, mean changes (percent changes) from baseline in hemoglobin were -0.18 g/dL (-1.1%) with placebo, 0.47 g/dL (3.5%) with INVOKANA 100 mg, and 0.51 g/dL (3.8%) with INVOKANA 300 mg. The mean baseline hemoglobin value was approximately 14.1 g/dL across treatment groups. At the end of treatment, 0.8%, 4.0%, and 2.7% of patients treated with placebo, INVOKANA 100 mg, and INVOKANA 300 mg, respectively, had hemoglobin above the upper limit of normal.

DRUG INTERACTIONS

UGT Enzyme Inducers: Rifampin: Co-administration of canagliflozin with rifampin, a nonselective inducer of several UGT enzymes, including

UGT1A9, UGT2B4, decreased canagliflozin area under the curve (AUC) by 51%. This decrease in exposure to canagliflozin may decrease efficacy. If an inducer of these UGTs (e.g., rifampin, phenytoin, phenobarbital, ritonavir) must be co-administered with INVOKANA (canagliflozin), consider increasing the dose to 300 mg once daily if patients are currently tolerating INVOKANA 100 mg once daily, have an eGFR greater than 60 mL/min/1.73 m^2, and require additional glycemic control. Consider other antihyperglycemic therapy in patients with an eGFR of 45 to less than 60 mL/min/1.73 m^2 receiving concurrent therapy with a UGT inducer and require additional glycemic control *[see Dosage and Administration (2.3) and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Digoxin: There was an increase in the area AUC and mean peak drug concentration (C_{max}) of digoxin (20% and 36%, respectively) when co-administered with INVOKANA 300 mg *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Patients taking INVOKANA with concomitant digoxin should be monitored appropriately.

USE IN SPECIFIC POPULATIONS

Pregnancy: Teratogenic Effects: Pregnancy Category C: There are no adequate and well-controlled studies of INVOKANA in pregnant women. Based on results from rat studies, canagliflozin may affect renal development and maturation. In a juvenile rat study, increased kidney weights and renal pelvic and tubular dilatation were evident at greater than or equal to 0.5 times clinical exposure from a 300 mg dose *[see Nonclinical Toxicology (13.2) in full Prescribing Information]*.

These outcomes occurred with drug exposure during periods of animal development that correspond to the late second and third trimester of human development. During pregnancy, consider appropriate alternative therapies, especially during the second and third trimesters. INVOKANA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known if INVOKANA is excreted in human milk. INVOKANA is secreted in the milk of lactating rats reaching levels 1.4 times higher than that in maternal plasma. Data in juvenile rats directly exposed to INVOKANA showed risk to the developing kidney (renal pelvic and tubular dilatations) during maturation. Since human kidney maturation occurs *in utero* and during the first 2 years of life when lactational exposure may occur, there may be risk to the developing human kidney. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from INVOKANA, a decision should be made whether to discontinue nursing or to discontinue INVOKANA, taking into account the importance of the drug to the mother *[see Nonclinical Toxicology (13.2) in full Prescribing Information]*.

Pediatric Use: Safety and effectiveness of INVOKANA in pediatric patients under 18 years of age have not been established.

Geriatric Use: Two thousand thirty-four (2034) patients 65 years and older, and 345 patients 75 years and older were exposed to INVOKANA in nine clinical studies of INVOKANA *[see Clinical Studies (14.3) in full Prescribing Information]*.

Patients 65 years and older had a higher incidence of adverse reactions related to reduced intravascular volume with INVOKANA (such as hypotension, postural dizziness, orthostatic hypotension, syncope, and dehydration), particularly with the 300 mg daily dose, compared to younger patients; more prominent increase in the incidence was seen in patients who were 75 years and older *[see Dosage and Administration (2.1) in full Prescribing Information and Adverse Reactions]*. Smaller reductions in HbA1C with INVOKANA relative to placebo were seen in older (65 years and older; -0.61% with INVOKANA 100 mg and -0.74% with INVOKANA 300 mg relative to placebo) compared to younger patients (-0.72% with INVOKANA 100 mg and -0.87% with INVOKANA 300 mg relative to placebo).

Renal Impairment: The efficacy and safety of INVOKANA were evaluated in a study that included patients with moderate renal impairment (eGFR 30 to less than 50 mL/min/1.73 m^2) *[see Clinical Studies (14.3) in full Prescribing Information]*. These patients had less overall glycemic efficacy and had a higher occurrence of adverse reactions related to reduced intravascular volume, renal-related adverse reactions, and decreases in eGFR compared to patients with mild renal impairment or normal renal function (eGFR greater than or equal to 60 mL/min/1.73 m^2); patients treated with INVOKANA 300 mg were more likely to experience increases in potassium *[see Dosage and Administration (2.2) in full Prescribing Information, Warnings and Precautions, and Adverse Reactions]*.

The efficacy and safety of INVOKANA have not been established in patients with severe renal impairment (eGFR less than 30 mL/min/1.73 m^2), with ESRD, or receiving dialysis. INVOKANA is not expected to be effective in these patient populations *[see Contraindications and Clinical Pharmacology (12.3) in full Prescribing Information]*.

Hepatic Impairment: No dosage adjustment is necessary in patients with mild or moderate hepatic impairment. The use of INVOKANA has not been studied in patients with severe hepatic impairment and is therefore not recommended *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

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OVERDOSAGE

There were no reports of overdose during the clinical development program of INVOKANA (canagliflozin).

In the event of an overdose, contact the Poison Control Center. It is also reasonable to employ the usual supportive measures, e.g., remove unabsorbed material from the gastrointestinal tract, employ clinical monitoring, and institute supportive treatment as dictated by the patient's clinical status. Canagliflozin was negligibly removed during a 4-hour hemodialysis session. Canagliflozin is not expected to be dialyzable by peritoneal dialysis.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling (Medication Guide).

Instructions: Instruct patients to read the Medication Guide before starting INVOKANA (canagliflozin) therapy and to reread it each time the prescription is renewed.

Inform patients of the potential risks and benefits of INVOKANA and of alternative modes of therapy. Also inform patients about the importance of adherence to dietary instructions, regular physical activity, periodic blood glucose monitoring and HbA1C testing, recognition and management of hypoglycemia and hyperglycemia, and assessment for diabetes complications. Advise patients to seek medical advice promptly during periods of stress such as fever, trauma, infection, or surgery, as medication requirements may change.

Instruct patients to take INVOKANA only as prescribed. If a dose is missed, advise patients to take it as soon as it is remembered unless it is almost time for the next dose, in which case patients should skip the missed dose and take the medicine at the next regularly scheduled time. Advise patients not to take two doses of INVOKANA at the same time.

Inform patients that the most common adverse reactions associated with INVOKANA are genital mycotic infection, urinary tract infection, and increased urination.

Inform female patients of child bearing age that the use of INVOKANA during pregnancy has not been studied in humans, and that INVOKANA should only be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Instruct patients to report pregnancies to their physicians as soon as possible.

Inform nursing mothers to discontinue INVOKANA or nursing, taking into account the importance of drug to the mother.

Laboratory Tests: Due to its mechanism of action, patients taking INVOKANA will test positive for glucose in their urine.

Hypotension: Inform patients that symptomatic hypotension may occur with INVOKANA and advise them to contact their doctor if they experience such symptoms *[see Warnings and Precautions]*. Inform patients that dehydration may increase the risk for hypotension, and to have adequate fluid intake.

Genital Mycotic Infections in Females (e.g., Vulvovaginitis): Inform female patients that vaginal yeast infection may occur and provide them with information on the signs and symptoms of vaginal yeast infection. Advise them of treatment options and when to seek medical advice *[see Warnings and Precautions]*.

Genital Mycotic Infections in Males (e.g., Balanitis or Balanoposthitis): Inform male patients that yeast infection of penis (e.g., balanitis or balanoposthitis) may occur, especially in uncircumcised males and patients with prior history. Provide them with information on the signs and symptoms of balanitis and balanoposthitis (rash or redness of the glans or foreskin of the penis). Advise them of treatment options and when to seek medical advice *[see Warnings and Precautions]*.

Hypersensitivity Reactions: Inform patients that serious hypersensitivity reactions such as urticaria and rash have been reported with INVOKANA. Advise patients to report immediately any signs or symptoms suggesting allergic reaction or angioedema, and to take no more drug until they have consulted prescribing physicians.

Urinary Tract Infections: Inform patients of the potential for urinary tract infections. Provide them with information on the symptoms of urinary tract infections. Advise them to seek medical advice if such symptoms occur.

Active ingredient made in Belgium

Finished product manufactured by:
Janssen Ortho, LLC
Gurabo, PR 00778

Manufactured for:
Janssen Pharmaceuticals, Inc.
Titusville, NJ 08560

Licensed from Mitsubishi Tanabe Pharma Corporation

10282400

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Accountable Care Organizations Facing New Competency Challenges:

The "8 Habits" Required of US Health Systems

DANIEL K. ZISMER, PhD

Daniel K. Zismer, PhD

The US health system has undergone notable transformations over the last 2 decades. Independent community hospitals have consolidated horizontally with others to form hospital healthcare systems, with many of the larger ones covering wide-ranging geographies, generating billions of dollars in operating revenues. Hospitals and physicians have consolidated their businesses through vertical integrations, stemming from hospital acquisition of private medical practice assets forming various models of integrated health systems. Integrated health systems are extending clinical programming beyond acute care to create a broader reach along the continuum of care and are standardizing clinical service line models and methods across sites and geographies.[1]

The next transformation is to accountable care, and while definitions may differ, the foundation of the accountable care organization (ACO) is its ability to assume the responsibility for the health of attributed populations, over time, for known allocations of funding (financial risk transfer).

ACO structural designs exist on a continuum from "less integrated" to "fully integrated," with fully integrated defined here as all clinicians and related staff working for the same organization. The lesser integrated ACO is often aggregations of independent parties (eg, community hospitals and private practice physicians) holding stakes in a legal entity formed as the contracting mechanism between a third party payer (governmental or commercial insurer or other financial intermediary) and the participating providers.

With this transformation the business relationship between provider and payer changes fundamentally, as do related financial incentives. Systems of healthcare delivery are transformed from manufacturers of units of service sold to sick people on a per unit basis to systems of healthcare accountable for the health status of a population and all related current and future health services needed. This includes provision of preventive healthcare and care for the acutely ill. The principal difference in the financial model is the nature of the incentives: "more is better" shifts to "more is more costly to the provider."

Over the last few years, I have been examining the implications of such organizational transformations through studies funded by MedPac[2] and through unfunded work, including interviews with a number of leaders of larger, integrated health systems. What follows is a summary of that work expressed as a list of organizational competency challenges. These competency challenges represent the "where we need to go as an organization" thinking of health-system leaders.

Competency #1: Public Health Practice

Embedded or contracted competencies in the areas of: the epidemiology of attributed populations, including health cost risk profiles with evidence-based best practices applied; total costs of care for specific care episodes and for cohorts with chronic illnesses; health behavior intervention methods and models for specific populations at risk; and effective application of social media as a health behaviors management tool for specific, attributed populations. Many health-system leaders believe it is time for the convergence of principles of public health management with principles of health-system management.[3]

Competency #2: Interprofessional Team Care and Care Management

Given that skilled healthcare professionals are likely to remain in short supply for the foreseeable future, provider supply will be constrained, requiring more effective "leverage models," meaning the applications of interprofessional team care. Our study of this area shows a number of important observations: (1) many of the more integrated health systems are experimenting with models for primary and specialty care and interprofessional team care, (2) "best practices" in this regard are not likely to emerge for wide spread industry consumption anytime soon, (3) many of the models in operation are designed to optimize productivity of physicians in a fee-for-service environment, and (4) what passes as interprofessional team care is often times physicians and physician extenders doing much the same work (especially for primary care).

Competency #3: Physician Compensation Design

Many of the compensation designs for integrated health systems (those that employ physicians) are productivity based with a compensable unit of effort the work relative value unit (RVU). The number of work RVUs produced by a physician multiplied by an internally derived value equals the cash compensation paid. The model is typically indifferent to type of patient seen, type of work performed, or whether the health system is paid for the work done. The raw incentive at play is the production of "more" work RVUs. The more integrated health systems are working on the options with the goal of paying market compensation for clinical productivity that aligns the incentives of the providers and their organization with those derivative of the types of financial agreements (risk contracts) executed with the payers. Health systems that have a history of salary-based compensation plans may have an easier time with this challenge.[4]

Competency #4: Facility Asset Investments and Utilization

Integrated health systems are principally in the outpatient business; ie, most of revenue earned and clinical activity delivered is not from the acute care setting. The size, design, layout, and functionality of larger, clinically sophisticated ambulatory healthcare facilities are a fast-moving area of health-systems asset planning, development, and financing.[5] Many health-system leaders admit they are "behind the curve" with what is a new science for facilities design and application. Based upon examination of balance sheets of larger health systems there is a sizable latent demand for investments in ambulatory facility assets that serve the needs of changing health services delivery models.

Competency #5: Performance Metrics, Benchmarks, and ACO Performance Evaluations

"How do we know how we're doing in a business model with reversed incentives?" Asked another way, "what counts" for healthcare organizations that assume the costs of latent and future health risk for attributed populations, within a contracting environment where the health services organization cannot fully control the health services demand behaviors of "covered lives," including, for some, use of providers not within the identified ACO network.

Few US health systems, save for those that own health plans, possess the internal competencies, infrastructures, and required data sets to reliably forecast the health services consumption behaviors and costs of attributed, covered lives. Nor do many possess the experience, capabilities, and models to forecast health services consumption behaviors and costs under accepted, evidence-based best practices. Consequently, many health services organizations that accept financial risk for attributed populations will be "flying blind." A number of leaders of larger, more integrated health systems destined for financial risk on covered lives report the need to "buy, not make" such competencies.

"Few US health-systems, save for those that own health plans, possess the internal competencies, infrastructures, and required data sets to reliably forecast the health services consumption behaviors and costs of attributed, covered lives."

Competency #6: Balance Sheet Performance

There is a strong argument for the deterioration of balance sheet liquidity for US health systems.[6] Reasons included the dilutive effects associated with integration of physician practices with hospitals and mergers of hospitals with larger health systems, especially those with weakend balance sheets, massive investment requirements in information systems, including the electronic health record, and the negative balance sheet effects of the financial risk contracting "learning curve." An examination of the balance sheets of several of the larger US health systems shows deteriorating free cash flow productivity. Such effects bear negatively on balance sheet liquidity, restricting future investment potential. The "new" competency required is strategies to regenerate balance sheet liquidity during a transformative market cycle. Not-for-profit health systems especially may need to venture out of the traditional approaches to capital formation, especially tax-exempt debt financings, and consider alternative financing opportunities for future strategies aimed at balance sheet regeneration.[7]

Competency #7: Health-System Governing Boards as Learning Organizations

Senior leaders of US health systems, especially those with "community boards," are challenged with managing board members along a very steep learning curve. Health-system chief executive officers and board chairs will need to become students of the disciplines related to the development of "learning organizations."[8] Here, form will follow function. As US health systems transform to highly integrated organizations in the business of managing the health of attributed populations, board structure, composition, and function will necessarily change, as will required competencies of individual board members. The more integrated health systems will have employed physicians as members. Community representatives will need to bring relevant competencies to the board room. The disciplines of strategy maps and balance score cards are used by a growing number. Rapid cycle decision making is required.

Competency #8: Medical Practice Management

As community hospital systems integrate physicians with their business models most will reach a point where virtually all physicians required for missions, clinical models, financial performance, and strategies are employees of integrated systems of care delivery. Such integrations will facilitate clinical models that are conducive to the incentives and dynamics derivative of financial risk-sharing and related quality and total costs of care management.

Integrated health systems require an organized approach to the design, leadership, and operation of the physician enterprise. Optimal performance is not possible when physicians show up to work and operate on individualized practice plans. The medical enterprise is integral to the success of the integrated health system. There are 2 common organizational designs with a few viable variations on these themes. The first is the unified, multispecialty group practice with a physician-led leadership structure supported by a dyad co-management partner.[9] The alternative is an embedded "divisional model" where the integrated health system operates several wholly controlled practice entities held corporately as divisions of hospitals, the larger physician enterprise, or as controlled corporate subsidiaries.

With either organizational design, the "behaviors" of the integrated health-system physician enterprise must align with the needs of the integrated health system overall to harmonize incentives that affect overall performance mission, clinical care, strategic, and financial. Integrated health systems developed from serial acquisitions of small, independent medical practices need to determine how they will acquire or develop the required competencies of high-functioning large-scale medical practices, including the competencies related to interprofessional team care.

Conclusion

So, while few senior executives of US health-systems will argue the market demands for transformative leadership, the practical question of which competencies are required when is a debatable and debated issue. The 8 competencies presented here are not representative of an exhaustive list, but the relevancy of one and all should not be in question, or underestimated in importance, at least not according to those health system leaders queried on the topic. The practical questions are: which first, and when, how, and at what costs to other competing organizational developmental requirements and related investments.

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Relying on ACOs and TCOC Contracting to "Bend the Cost Curve"

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There is no question that the number of accountable care organizations (ACOs) in Medicare and total cost of care contracts (TCOCs) in the private sector is growing, along with the amount of care provided under these contracts.[1] Common characteristics of both types of contracts are that a provider group agrees to care for an attributed population of patients under a fixed budget, with the potential to benefit financially through "shared savings" and by meeting quality goals.[2] The hope is that paying providers in this way will improve quality of care and population health, promote efficiency in care delivery, and ultimately "bend the cost curve."[3] While all these are commendable goals, the greatest emphasis appears to be on the potential for ACOs and TCOCs to reduce the rate of growth in per capita healthcare costs, without negatively affecting quality.

In some ways, we have been down this path before. In the 1980s, when capitated contracts first came into vogue, it was argued that health plan contracts that transferred financial risk to providers would curtail provision of unnecessary services, ultimately reducing costs to payers or at least the rate of growth in their costs. There were concerns that changes in provider behavior under capitated contracts could harm quality of care, but many health plans attempted to guard against this possibility by placing quality-related bonuses in contracts, specifying upper bounds on provider gains and losses, and analyzing claims data to detect trends that might indicate inappropriate care.[4] What is different now? One important difference is that consumers do not enroll in ACOs or with provider groups being paid under TCOC contracts. Instead they are attributed to these entities based on their past history of service use and can continue to seek care from the providers of their choice. Presumably this will alleviate consumer concerns about health plan influence on provider decisions. At the same time, better data and quality measures combined with greater provider performance transparency will make it easier for health plans and consumers to identify providers who deliver poor quality care and will shame providers into improving their performance. It is clearly too early to tell if ACOs and TCOCs will improve provider efficiency without also reducing quality, although early findings from analyses of a TCOC contract between the Blue Cross and Blue Shield of Massachusetts and providers in that state certainly are promising.[5]

To date, most of the analytic attention being given to ACO and TCOC contract designs has focused on how best to encourage providers to become more efficient. This attention is certainly warranted, as there are many "moving parts" that must be in sync if contract goals are to be achieved. For instance, if attribution algorithms inappropriately assign patients to providers, incentives for efficiency are attenuated. The same is true if methods used to "risk adjust" attributed populations of patients are not adequate to avoid penalizing providers who care for sicker patients. And, there has been great debate in the design of Medicare ACOs regarding risk-sharing specifications. These decisions are complicated by the fact that provider groups vary in their experience in managing panels of patients and assuming financial risk. For instance, under private sector TCOC contracts some larger provider groups with experience managing financial risk do not see the need for "shared gain/shared loss" provisions. Instead, they prefer to adjust their degree of risk exposure through the purchase of reinsurance.

How these issues relating to contract design are resolved will have important impacts on the ability of ACO and TCOC contracting approaches to reach their goals. However, an issue that could prove more important, but has received less attention, is the setting of global budgets initially and their subsequent adjustment over time. Here it is important to distinguish between costs to providers and costs to payers. The incentives that these contracts create for providers could lead to reductions in their costs of providing care. Under typical ACO or TCOC contracts, payers can capture at least a portion of the provider cost savings (should they occur) through a combination of shared savings as specified in yearly contracts, but also—and likely more important and controversial—through adjustment of budget targets over time. There are technical aspects to the setting of budgets, of course, but for ACO contracts political clout also will play a role,

"The hope is that paying providers in this way will improve quality of care and population health, promote efficiency in care delivery, and ultimately bend the cost curve."

and for TCOC contracts market leverage will come into play. In both cases, experience suggests that, even if efficiencies are obtained without harming quality, a favorable impact on long-run cost trends for payers and, ultimately, consumers is far from certain.

There are 3 general approaches that can be taken in setting budgets and, perhaps more importantly, year-to-year increases in budgets. Using the language of health service researchers, the problem is finding an appropriate "comparison group." Some argue that the ideal comparison group would yield an exact picture of what the performance of the provider group under contract would have been if it had not signed the contract. Of course, there is no such ideal comparison group, so payers are forced to settle for proxies. In practice, there are 2 options. First, payers can set initial budgets (payments) based on a similar group of providers, tracking the performance of this group over time and adjusting budgets of contracting groups based on the rate of change in the comparison group. Because comparison groups are never perfect, some risk adjustment is required. This is essentially the approach that Medicare took in the early days of the current Medicare Advantage program, using performance in fee-for-service Medicare to set rates and make rate adjustments for contracting health plans, and in its "physician group practice demonstration."[6] There are all sorts of drawbacks to this approach, including continual disputes over the choice of the comparison group (eg, with Medicare health plans, should the fee-for-service comparison group be drawn from the same county, the same region, or nationally?), and the fact that the comparison group, and the environment in which it operates, can change in ways that make its use less defensible over time. In some cases, the comparison group can simply disappear. For example, when some Medicaid programs began contracting with health plans on an experimental basis to serve beneficiaries, they used the experience of Medicaid beneficiaries not in these plans to guide changes in contract rates. However, as they enrolled more beneficiaries in plans, the number in comparison groups shrunk. Beneficiaries in these groups became less representative of the beneficiary population in Medicaid health plans and, in some cases, too small for reliable estimates. Some health plans have used external comparison groups to inform the setting of budgets in their private TCOC contracts, but their exact methods are not clear.[7]

The second approach, a version of which was adopted in CMS' ACO program, is to use patients served by the provider group under contract to set the budget.[8] In a sense, the group is its own comparison. Historical provider expenditures for the group of patients are calculated; 2 or more years generally are included, with more weight typically given to more recent years. This historical yearly expense then is trended forward to the contract year. The choice of the trend rate is critical,[9] and it is typical to choose a trend rate that is tied to an externally calculated number, such as regional healthcare expenditures, or the trend in expenditures for health plan or public program participants not covered by the contract. Usually, in the private sector, the trend rate is negotiated as part of the contract, as it can incorporate the mutually agreed upon goals of payers and providers. As such, it has an aspirational element, while also reflecting the relative negotiating leverage of the parties involved.

A third approach relies on payers to create incentives that encourage providers to "reveal" the dollar amount that they think is adequate to provide necessary care to an attributed population. This typically has involved some sort of competitive bidding process. Medicare currently uses this approach in setting rates for medical equipment and supplies and, in the past, used its demonstration authority to test competitive bidding to set payment rates for contracting health plans.[10] Medicaid programs also have used competitive bidding approaches to set rates when contracting with health plans.

Unfortunately, experience with all 3 of these approaches is not promising with respect to the ability of ACOs and TCOC contracts to "bend the cost curve" for payers in the long run. In the public sector, the decisions about process will be complicated, they are unlikely to be made under the media spotlight, and their ultimate impact on costs over time will be difficult to establish. Much will be at stake for providers, who will push hard to see that their interests are served. The government's desire to have a "successful" program—defined year to year by retaining or increasing participants—will make it responsive to provider concerns. This is the classic "regulatory capture" scenario, which has been overused in the past, but still has some merit. Matters can be further complicated when legislators intervene to alter payments in response to provider pressure, as has been the case with passage of legislation aimed at "correcting" perceived "geographic inequities" in Medicare provider payments and Medicare Advantage payments.

With respect to private sector TCOC contracts, initial benchmarks and their rate of increase will be settled through negotiation. However, many recent studies have concluded that the leverage in payment negotiations now favors providers, because

the provider market has become increasingly consolidated at the community level, and employers have resisted offering health plans with networks that exclude key provider organizations.[11] There is no reason to believe this dynamic will be altered by changing the way in which providers are paid. In fact, concern has been expressed that ACOs and TCOC contracts will encourage further provider consolidation.[12] As the Massachusetts attorney general has observed, "A shift of payment methodology is not the panacea to controlling costs."[13]

Competitive bidding models administered by government also seem problematic as a means of setting budgets simply because government has had difficulty implementing them effectively in the past. Providers typically resist this approach, citing concerns about the impact on quality of care that could result from acceptance of bids that are "too low" and, in all likelihood, believing that they will fare better in a regulatory process. On the other hand, program administrators worry that competitive bidding processes will result in rates that are "too high" and therefore use bids to establish starting points for a negotiated rate-setting process. This strategy raises questions about the usefulness of the information contained in the initial bids, specifically whether these bids actually reflect provider estimates of the true cost of delivering care.

Despite this pessimistic assessment of the potential for ACOs and TCOCs to modify increases in payer costs in the long run, there are 2 recent developments that bear watching. McClellan and Fisher[12] observe that "It is…important to keep in mind that ACOs are not managed care insurers" but that does not mean that they will not offer insurance products. In fact, some provider organizations with ACO and/or TCOC contracts now are positioning themselves as "narrow-network" options in private health insurance exchanges or within Medicare Advantage plans. In these contexts, they compete directly for "enrollees" rather than having patients attributed to them. If this generates effective price competition for patients among ACOs and TCOC contractors and other plan options, then ACO and TCOC contracting may well contribute, albeit inadvertently, to "bending the cost curve" over time.

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IMPORTANT SAFETY INFORMATION

WARNING: (A) PREMATURE DISCONTINUATION OF XARELTO® INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA

A. PREMATURE DISCONTINUATION OF XARELTO® INCREASES THE RISK OF THROMBOTIC EVENTS

Premature discontinuation of any oral anticoagulant, including XARELTO®, increases the risk of thrombotic events. If anticoagulation with XARELTO® is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.

B. SPINAL/EPIDURAL HEMATOMA

Epidural or spinal hematomas have occurred in patients treated with XARELTO® who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- Use of indwelling epidural catheters
- Concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants, *see* Drug Interactions
- A history of traumatic or repeated epidural or spinal punctures
- A history of spinal deformity or spinal surgery

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary.

Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thromboprophylaxis.

Please see Important Safety Information on following pages.
Please see Brief Summary of full Prescribing Information, including Boxed WARNINGS, on following pages.

IMPORTANT SAFETY INFORMATION (cont'd)

CONTRAINDICATIONS

- Active pathological bleeding
- Severe hypersensitivity reaction to XARELTO® (eg, anaphylactic reactions)

WARNINGS AND PRECAUTIONS

- **Increased Risk of Thrombotic Events After Premature Discontinuation:** Premature discontinuation of any oral anticoagulant, including XARELTO®, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from XARELTO® to warfarin in clinical trials in atrial fibrillation patients. If XARELTO® is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant.
- **Risk of Bleeding:** XARELTO® increases the risk of bleeding and can cause serious or fatal bleeding. Promptly evaluate any signs or symptoms of blood loss and consider the need for blood replacement. Discontinue XARELTO® in patients with active pathological hemorrhage.
  - A specific antidote for rivaroxaban is not available. Because of high plasma protein binding, rivaroxaban is not expected to be dialyzable.
  - Concomitant use of other drugs affecting hemostasis increases the risk of bleeding. These include aspirin, $P2Y_{12}$ platelet inhibitors, other antithrombotic agents, fibrinolytic therapy, and NSAIDs.
- **Spinal/Epidural Anesthesia or Puncture:** When neuraxial anesthesia (spinal/epidural anesthesia)

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

or spinal puncture is employed, patients treated with anticoagulant agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma, which can result in long-term or permanent paralysis. An epidural catheter should not be removed earlier than 18 hours after the last administration of XARELTO®. The next XARELTO® dose is not to be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, the administration of XARELTO® is to be delayed for 24 hours.

- **Use in Patients With Renal Impairment:**
  - **Nonvalvular Atrial Fibrillation:** Avoid the use of XARELTO® in patients with creatinine clearance (CrCl) <15 mL/min, since drug exposure is increased. Discontinue XARELTO® in patients who develop acute renal failure while on XARELTO®.

SIX INDICATIONS STRONG

- To reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation (AF). There are limited data on the relative effectiveness of XARELTO® and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well controlled
- For the treatment of deep vein thrombosis (DVT)
- For the treatment of pulmonary embolism (PE)
- For the reduction in the risk of recurrence of DVT and of PE following initial 6 months treatment for DVT and/or PE
- For the prophylaxis of DVT, which may lead to PE in patients undergoing knee replacement surgery
- For the prophylaxis of DVT, which may lead to PE in patients undergoing hip replacement surgery

*Among Factor Xa inhibitors and direct thrombin inhibitors.

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IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

- **Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE:** Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population.
- **Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery:** Avoid the use of XARELTO® in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Patients who develop acute renal failure while on XARELTO® should discontinue the treatment.
- **Use in Patients With Hepatic Impairment:** No clinical data are available for patients with severe hepatic impairment. Avoid use of XARELTO® in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy, since drug exposure and bleeding risk may be increased.
- **Use With P-gp and Strong CYP3A4 Inhibitors or Inducers:** Avoid concomitant use of XARELTO® with combined P-gp and strong CYP3A4 inhibitors (eg, ketoconazole, itraconazole, lopinavir/ritonavir, ritonavir, indinavir/ritonavir, and conivaptan). Avoid concomitant use of XARELTO® with drugs that are P-gp and strong CYP3A4 inducers (eg, carbamazepine, phenytoin, rifampin, St. John's wort).
- **Risk of Pregnancy-Related Hemorrhage:** In pregnant women, XARELTO® should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO® dosing in pregnancy has not been studied. The anticoagulant effect of XARELTO® cannot be monitored with standard laboratory testing and is not readily reversed. Promptly evaluate any signs or symptoms suggesting blood loss (eg, a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).
- **Patients With Prosthetic Heart Valves:** The safety and efficacy of XARELTO® have not been studied in patients with prosthetic heart valves. Therefore, use of XARELTO® is not recommended in these patients.

DRUG INTERACTIONS

- Avoid concomitant use of XARELTO® with other anticoagulants due to increased bleeding risk, unless benefit outweighs risk. Promptly evaluate any signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs.
- XARELTO® should be used in patients with CrCl 15 to 50 mL/min who are receiving concomitant combined P-gp and weak or moderate CYP3A4 inhibitors only if the potential benefit outweighs the potential risk.

USE IN SPECIFIC POPULATIONS

- **Pregnancy Category C:** XARELTO® should be used during pregnancy only if the potential benefit justifies the potential risk to mother and fetus.

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IMPORTANT SAFETY INFORMATION (cont'd)

USE IN SPECIFIC POPULATIONS (cont'd)

There are no adequate or well-controlled studies of XARELTO® in pregnant women, and dosing for pregnant women has not been established. Use XARELTO® with caution in pregnant patients because of the potential for pregnancy-related hemorrhage and/or emergent delivery with an anticoagulant that is not readily reversible. The anticoagulant effect of XARELTO® cannot be reliably monitored with standard laboratory testing.

- **Labor and Delivery:** Safety and effectiveness of XARELTO® during labor and delivery have not been studied in clinical trials.
- **Nursing Mothers:** It is not known if rivaroxaban is excreted in human milk.
- **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established.
- **Females of Reproductive Potential:** Females of reproductive potential requiring anticoagulation should discuss pregnancy planning with their physician.

OVERDOSAGE

- Discontinue XARELTO® and initiate appropriate therapy if bleeding complications associated with overdosage occur. A specific antidote for rivaroxaban is not available. The use of activated charcoal to reduce absorption in case of XARELTO® overdose may be considered. Due to the high plasma protein binding, rivaroxaban is not expected to be dialyzable.

ADVERSE REACTIONS IN CLINICAL STUDIES

- The most common adverse reactions with XARELTO® were bleeding complications.

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Please see Brief Summary of full Prescribing Information, including Boxed WARNINGS, on following pages.

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XARELTO® (rivaroxaban) tablets

Brief Summary of Prescribing Information for XARELTO® (rivaroxaban)
XARELTO® (rivaroxaban) tablets, for oral use
See package insert for full Prescribing Information

WARNING: (A) PREMATURE DISCONTINUATION OF XARELTO INCREASES THE RISK OF THROMBOTIC EVENTS, (B) SPINAL/EPIDURAL HEMATOMA

A. PREMATURE DISCONTINUATION OF XARELTO INCREASES THE RISK OF THROMBOTIC EVENTS

Premature discontinuation of any oral anticoagulant, including XARELTO, increases the risk of thrombotic events. If anticoagulation with XARELTO is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant *[see Dosage and Administration (2.2, 2.6) in full Prescribing Information, Warnings and Precautions, and Clinical Studies (14.1) in full Prescribing Information]*.

B. SPINAL/EPIDURAL HEMATOMA

Epidural or spinal hematomas have occurred in patients treated with XARELTO who are receiving neuraxial anesthesia or undergoing spinal puncture. These hematomas may result in long-term or permanent paralysis. Consider these risks when scheduling patients for spinal procedures. Factors that can increase the risk of developing epidural or spinal hematomas in these patients include:

- **use of indwelling epidural catheters**
- **concomitant use of other drugs that affect hemostasis, such as non-steroidal anti-inflammatory drugs (NSAIDs), platelet inhibitors, other anticoagulants**
- **a history of traumatic or repeated epidural or spinal punctures**
- **a history of spinal deformity or spinal surgery**

***[see Warnings and Precautions and Adverse Reactions]*.**

Monitor patients frequently for signs and symptoms of neurological impairment. If neurological compromise is noted, urgent treatment is necessary *[see Warnings and Precautions]*.

Consider the benefits and risks before neuraxial intervention in patients anticoagulated or to be anticoagulated for thrombo-prophylaxis *[see Warnings and Precautions]*.

INDICATIONS AND USAGE

Reduction of Risk of Stroke and Systemic Embolism in Nonvalvular Atrial Fibrillation: XARELTO is indicated to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation.

There are limited data on the relative effectiveness of XARELTO and warfarin in reducing the risk of stroke and systemic embolism when warfarin therapy is well-controlled *[see Clinical Studies (14.1) in full Prescribing Information]*.

Treatment of Deep Vein Thrombosis: XARELTO is indicated for the treatment of deep vein thrombosis (DVT).

Treatment of Pulmonary Embolism: XARELTO is indicated for the treatment of pulmonary embolism (PE).

Reduction in the Risk of Recurrence of Deep Vein Thrombosis and of Pulmonary Embolism: XARELTO is indicated for the reduction in the risk of recurrence of deep vein thrombosis and of pulmonary embolism following initial 6 months treatment for DVT and/or PE.

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: XARELTO is indicated for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

CONTRAINDICATIONS

XARELTO is contraindicated in patients with:

- active pathological bleeding *[see Warnings and Precautions]*
- severe hypersensitivity reaction to XARELTO (e.g., anaphylactic reactions) *[see Adverse Reactions]*

WARNINGS AND PRECAUTIONS

Increased Risk of Thrombotic Events after Premature Discontinuation: Premature discontinuation of any oral anticoagulant, including XARELTO, in the absence of adequate alternative anticoagulation increases the risk of thrombotic events. An increased rate of stroke was observed during the transition from XARELTO to warfarin in clinical trials in atrial fibrillation patients. If XARELTO is discontinued for a reason other than pathological bleeding or completion of a course of therapy, consider coverage with another anticoagulant *[see Dosage and Administration (2.2, 2.6) and Clinical Studies (14.1) in full Prescribing Information]*.

Risk of Bleeding: XARELTO increases the risk of bleeding and can cause serious or fatal bleeding. In deciding whether to prescribe XARELTO to patients at increased risk of bleeding, the risk of thrombotic events should be weighed against the risk of bleeding.

Promptly evaluate any signs or symptoms of blood loss and consider the need for blood replacement. Discontinue XARELTO in patients with active pathological hemorrhage. The terminal elimination half-life of rivaroxaban is 5 to 9 hours in healthy subjects aged 20 to 45 years.

A specific antidote for rivaroxaban is not available. Because of high plasma protein binding, rivaroxaban is not expected to be dialyzable *[see Clinical Pharmacology (12.3) in full Prescribing Information]*. Protamine sulfate and vitamin K are not expected to affect the anticoagulant activity of rivaroxaban. There is no experience with antifibrinolytic agents

(tranexamic acid, aminocaproic acid) in individuals receiving rivaroxaban. There is neither scientific rationale for benefit nor experience with systemic hemostatics (desmopressin and aprotinin) in individuals receiving rivaroxaban. Use of procoagulant reversal agents such as prothrombin complex concentrate (PCC), activated prothrombin complex concentrate (APCC), or recombinant factor VIIa (rFVIIa) may be considered but has not been evaluated in clinical trials.

Concomitant use of other drugs affecting hemostasis increases the risk of bleeding. These include aspirin, $P2Y_{12}$ platelet inhibitors, other antithrombotic agents, fibrinolytic therapy, and non-steroidal anti-inflammatory drugs (NSAIDs) *[see Drug Interactions]*.

Concomitant use of drugs that are combined P-gp and CYP3A4 inhibitors (e.g., ketoconazole and ritonavir) increases rivaroxaban exposure and may increase bleeding risk *[see Drug Interactions]*.

Spinal/Epidural Anesthesia or Puncture: When neuraxial anesthesia (spinal/epidural anesthesia) or spinal puncture is employed, patients treated with anticoagulant agents for prevention of thromboembolic complications are at risk of developing an epidural or spinal hematoma which can result in long-term or permanent paralysis *[see Boxed Warning]*.

An epidural catheter should not be removed earlier than 18 hours after the last administration of XARELTO. The next XARELTO dose is not to be administered earlier than 6 hours after the removal of the catheter. If traumatic puncture occurs, the administration of XARELTO is to be delayed for 24 hours.

Use in Patients with Renal Impairment: Nonvalvular Atrial Fibrillation: Avoid the use of XARELTO in patients with CrCl <15 mL/min since drug exposure is increased. Periodically assess renal function as clinically indicated (i.e., more frequently in situations in which renal function may decline) and adjust therapy accordingly. Discontinue XARELTO in patients who develop acute renal failure while on XARELTO *[see Use in Specific Populations]*

Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and Reduction in the Risk of Recurrence of DVT and of PE: Avoid the use of XARELTO in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population *[see Use in Specific Populations]*.

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: Avoid the use of XARELTO in patients with CrCl <30 mL/min due to an expected increase in rivaroxaban exposure and pharmacodynamic effects in this patient population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Patients who develop acute renal failure while on XARELTO should discontinue the treatment *[see Use in Specific Populations]*.

Use in Patients with Hepatic Impairment: No clinical data are available for patients with severe hepatic impairment.

Avoid use of XARELTO in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy since drug exposure and bleeding risk may be increased *[see Use in Specific Populations]*.

Use with P-gp and Strong CYP3A4 Inhibitors or Inducers: Avoid concomitant use of XARELTO with combined P-gp and strong CYP3A4 inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, ritonavir, indinavir/ritonavir, and conivaptan) *[see Drug Interactions]*.

Avoid concomitant use of XARELTO with drugs that are combined P-gp and strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin, St. John's wort) *[see Drug Interactions]*.

Risk of Pregnancy Related Hemorrhage: In pregnant women, XARELTO should be used only if the potential benefit justifies the potential risk to the mother and fetus. XARELTO dosing in pregnancy has not been studied. The anticoagulant effect of XARELTO cannot be monitored with standard laboratory testing nor readily reversed. Promptly evaluate any signs or symptoms suggesting blood loss (e.g., a drop in hemoglobin and/or hematocrit, hypotension, or fetal distress).

Patients with Prosthetic Heart Valves: The safety and efficacy of XARELTO have not been studied in patients with prosthetic heart valves. Therefore, use of XARELTO is not recommended in these patients.

ADVERSE REACTIONS

The following adverse reactions are also discussed in other sections of the labeling:

- Increased risk of stroke after discontinuation in nonvalvular atrial fibrillation *[see Boxed Warning* and *Warnings and Precautions]*
- Bleeding risk *[see Warnings and Precautions]*
- Spinal/epidural hematoma *[see Boxed Warning* and *Warnings and Precautions]*

Clinical Trials Experience: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

During clinical development for the approved indications, 16326 patients were exposed to XARELTO. These included 7111 patients who received XARELTO 15 mg or 20 mg orally once daily for a mean of 19 months (5558 for 12 months and 2512 for 24 months) to reduce the risk of stroke and systemic embolism in nonvalvular atrial fibrillation (ROCKET AF); 4728 patients who received either XARELTO 15 mg orally twice daily for three weeks followed by 20 mg orally once daily (EINSTEIN DVT, EINSTEIN PE) or 20 mg orally once daily (EINSTEIN Extension) to treat DVT, PE, and to reduce the risk of recurrence of DVT and of PE; and 4487 patients who received XARELTO 10 mg orally once daily for prophylaxis of DVT following hip or knee replacement surgery (RECORD 1-3).

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Hemorrhage: The most common adverse reactions with XARELTO were bleeding complications *[see Warnings and Precautions]*.

Nonvalvular Atrial Fibrillation: In the ROCKET AF trial, the most frequent adverse reactions associated with permanent drug discontinuation were bleeding events, with incidence rates of 4.3% for XARELTO vs. 3.1% for warfarin. The incidence of discontinuations for non-bleeding adverse events was similar in both treatment groups.

Table 1 shows the number of patients experiencing various types of bleeding events in the ROCKET AF study.

Table 1: Bleeding Events in ROCKET AF*

Parameter	XARELTO N = 7111 n (%)	Event Rate (per 100 Pt-yrs)	Warfarin N = 7125 n (%)	Event Rate (per 100 Pt-yrs)
Major bleeding†	395 (5.6)	3.6	386 (5.4)	3.5
Bleeding into a critical organ‡	91 (1.3)	0.8	133 (1.9)	1.2
Fatal bleeding	27 (0.4)	0.2	55 (0.8)	0.5
Bleeding resulting in transfusion of ≥2 units of whole blood or packed red blood cells	183 (2.6)	1.7	149 (2.1)	1.3
Gastrointestinal bleeding	221 (3.1)	2.0	140 (2.0)	1.2

* For all sub-types of major bleeding, single events may be represented in more than one row, and individual patients may have more than one event.

† Defined as clinically overt bleeding associated with a decrease in hemoglobin of ≥2 g/dL, transfusion of ≥2 units of packed red blood cells or whole blood, bleeding at a critical site, or with a fatal outcome. Hemorrhagic strokes are counted as both bleeding and efficacy events. Major bleeding rates excluding strokes are 3.3 per 100 Pt-yrs for XARELTO vs. 2.9 per 100 Pt-yrs for warfarin.

‡ The majority of the events were intracranial, and also included intraspinal, intraocular, pericardial, intra-articular, intramuscular with compartment syndrome, or retroperitoneal.

Treatment of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), and to Reduce the Risk of Recurrence of DVT and of PE: EINSTEIN DVT and EINSTEIN PE Studies: In the pooled analysis of the EINSTEIN DVT and EINSTEIN PE clinical studies, the most frequent adverse reactions leading to permanent drug discontinuation were bleeding events, with XARELTO vs. enoxaparin/Vitamin K antagonist (VKA) incidence rates of 1.7% vs. 1.5%, respectively. The mean duration of treatment was 208 days for XARELTO-treated patients and 204 days for enoxaparin/VKA-treated patients.

Table 2 shows the number of patients experiencing major bleeding events in the pooled analysis of the EINSTEIN DVT and EINSTEIN PE studies.

Table 2: Bleeding Events* in the Pooled Analysis of EINSTEIN DVT and EINSTEIN PE Studies

Parameter	XARELTO† N = 4130 n (%)	Enoxaparin/ VKA† N = 4116 n (%)
Major bleeding event	40 (1.0)	72 (1.7)
Fatal bleeding	3 (<0.1)	8 (0.2)
Intracranial	2 (<0.1)	4 (<0.1)
Non-fatal critical organ bleeding	10 (0.2)	29 (0.7)
Intracranial‡	3 (<0.1)	10 (0.2)
Retroperitoneal‡	1 (<0.1)	8 (0.2)
Intraocular‡	3 (<0.1)	2 (<0.1)
Intra-articular‡	0	4 (<0.1)
Non-fatal non-critical organ bleeding§	27 (0.7)	37 (0.9)
Decrease in Hb ≥ 2g/dL	28 (0.7)	42 (1.0)
Transfusion of ≥2 units of whole blood or packed red blood cells	18 (0.4)	25 (0.6)
Clinically relevant non-major bleeding	357 (8.6)	357 (8.7)
Any bleeding	1169 (28.3)	1153 (28.0)

* Bleeding event occurred after randomization and up to 2 days after the last dose of study drug. Although a patient may have had 2 or more events, the patient is counted only once in a category.

† Treatment schedule in EINSTEIN DVT and EINSTEIN PE studies: XARELTO 15 mg twice daily for 3 weeks followed by 20 mg once daily; enoxaparin/VKA [enoxaparin: 1 mg/kg twice daily, VKA: individually titrated doses to achieve a target INR of 2.5 (range: 2.0-3.0)]

‡ Treatment-emergent major bleeding events with at least >2 subjects in any pooled treatment group

§ Major bleeding which is not fatal or in a critical organ, but resulting in a decrease in Hb ≥2 g/dL and/or transfusion of ≥2 units of whole blood or packed red blood cells

EINSTEIN Extension Study: In the EINSTEIN Extension clinical study, the most frequent adverse reactions associated with permanent drug discontinuation were bleeding events, with incidence rates of 1.8% for XARELTO vs. 0.2% for placebo treatment groups. The mean duration of treatment was 190 days for both XARELTO and placebo treatment groups.

Table 3 shows the number of patients experiencing bleeding events in the EINSTEIN Extension study.

Table 3: Bleeding Events* in EINSTEIN Extension Study

Parameter	XARELTO† 20 mg N = 598 n (%)	Placebo† N = 590 n (%)
Major bleeding event‡	4 (0.7)	0
Decrease in Hb ≥2 g/dL	4 (0.7)	0
Transfusion of ≥2 units of whole blood or packed red blood cells	2 (0.3)	0
Gastrointestinal	3 (0.5)	0
Menorrhagia	1 (0.2)	0
Clinically relevant non-major bleeding	32 (5.4)	7 (1.2)
Any bleeding	104 (17.4)	63 (10.7)

* Bleeding event occurred after the first dose and up to 2 days after the last dose of study drug. Although a patient may have had 2 or more events, the patient is counted only once in a category.
† Treatment schedule: XARELTO 20 mg once daily; matched placebo once daily
‡ There were no fatal or critical organ bleeding events.

Prophylaxis of Deep Vein Thrombosis Following Hip or Knee Replacement Surgery: In the RECORD clinical trials, the overall incidence rate of adverse reactions leading to permanent treatment discontinuation was 3.7% with XARELTO.

The rates of major bleeding events and any bleeding events observed in patients in the RECORD clinical trials are shown in Table 4.

Table 4: Bleeding Events* in Patients Undergoing Hip or Knee Replacement Surgeries (RECORD 1-3)

	XARELTO 10 mg	Enoxaparin†
Total treated patients	**N = 4487 n (%)**	**N = 4524 n (%)**
Major bleeding event	14 (0.3)	9 (0.2)
Fatal bleeding	1 (<0.1)	0
Bleeding into a critical organ	2 (<0.1)	3 (0.1)
Bleeding that required re-operation	7 (0.2)	5 (0.1)
Extra-surgical site bleeding requiring transfusion of >2 units of whole blood or packed cells	4 (0.1)	1 (<0.1)
Any bleeding event‡	261 (5.8)	251 (5.6)
Hip Surgery Studies	**N = 3281 n (%)**	**N = 3298 n (%)**
Major bleeding event	7 (0.2)	3 (0.1)
Fatal bleeding	1 (<0.1)	0
Bleeding into a critical organ	1 (<0.1)	1 (<0.1)
Bleeding that required re-operation	2 (0.1)	1 (<0.1)
Extra-surgical site bleeding requiring transfusion of >2 units of whole blood or packed cells	3 (0.1)	1 (<0.1)
Any bleeding event‡	201 (6.1)	191 (5.8)
Knee Surgery Study	**N = 1206 n (%)**	**N = 1226 n (%)**
Major bleeding event	7 (0.6)	6 (0.5)
Fatal bleeding	0	0
Bleeding into a critical organ	1 (0.1)	2 (0.2)
Bleeding that required re-operation	5 (0.4)	4 (0.3)
Extra-surgical site bleeding requiring transfusion of >2 units of whole blood or packed cells	1 (0.1)	0
Any bleeding event‡	60 (5.0)	60 (4.9)

* Bleeding events occurring any time following the first dose of double-blind study medication (which may have been prior to administration of active drug) until two days after the last dose of double-blind study medication. Patients may have more than one event.
† Includes the placebo-controlled period for RECORD 2, enoxaparin dosing was 40 mg once daily (RECORD 1-3)
‡ Includes major bleeding events

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Following XARELTO treatment, the majority of major bleeding complications (≥60%) occurred during the first week after surgery.

Other Adverse Reactions: Non-hemorrhagic adverse reactions reported in ≥1% of XARELTO-treated patients in the EINSTEIN Extension study are shown in Table 5.

Table 5: Other Adverse Reactions* Reported by ≥1% of XARELTO-Treated Patients in EINSTEIN Extension Study

System Organ Class Preferred Term	XARELTO N = 598 n (%)	Placebo N = 590 n (%)
Gastrointestinal disorders		
Abdominal pain upper	10 (1.7)	1 (0.2)
Dyspepsia	8 (1.3)	4 (0.7)
Toothache	6 (1.0)	0
General disorders and administration site conditions		
Fatigue	6 (1.0)	3 (0.5)
Infections and infestations		
Sinusitis	7 (1.2)	3 (0.5)
Urinary tract infection	7 (1.2)	3 (0.5)
Musculoskeletal and connective tissue disorders		
Back pain	22 (3.7)	7 (1.2)
Osteoarthritis	10 (1.7)	5 (0.8)
Respiratory, thoracic and mediastinal disorders		
Oropharyngeal pain	6 (1.0)	2 (0.3)

* Adverse reaction (with Relative Risk >1.5 for XARELTO versus placebo) occurred after the first dose and up to 2 days after the last dose of study drug. Incidences are based on the number of patients, not the number of events. Although a patient may have had 2 or more clinical adverse reactions, the patient is counted only once in a category. The same patient may appear in different categories.

Non-hemorrhagic adverse reactions reported in ≥1% of XARELTO-treated patients in RECORD 1-3 studies are shown in Table 6.

Table 6: Other Adverse Drug Reactions* Reported by ≥1% of XARELTO-Treated Patients in RECORD 1-3 Studies

System/Organ Class Adverse Reaction	XARELTO 10 mg (N = 4487) n (%)	Enoxaparin† (N = 4524) n (%)
Injury, poisoning and procedural complications		
Wound secretion	125 (2.8)	89 (2.0)
Musculoskeletal and connective tissue disorders		
Pain in extremity	74 (1.7)	55 (1.2)
Muscle spasm	52 (1.2)	32 (0.7)
Nervous system disorders		
Syncope	55 (1.2)	32 (0.7)
Skin and subcutaneous tissue disorders		
Pruritus	96 (2.1)	79 (1.8)
Blister	63 (1.4)	40 (0.9)

* Adverse reaction occurring any time following the first dose of double-blind medication, which may have been prior to administration of active drug, until two days after the last dose of double-blind study medication.
† Includes the placebo-controlled period of RECORD 2, enoxaparin dosing was 40 mg once daily (RECORD 1-3)

Other clinical trial experience: In an investigational study of acute medically ill patients being treated with XARELTO 10 mg tablets, cases of pulmonary hemorrhage and pulmonary hemorrhage with bronchiectasis were observed.

Postmarketing Experience: The following adverse reactions have been identified during post-approval use of rivaroxaban. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Blood and lymphatic system disorders: agranulocytosis

Gastrointestinal disorders: retroperitoneal hemorrhage

Hepatobiliary disorders: jaundice, cholestasis, cytolytic hepatitis

Immune system disorders: hypersensitivity, anaphylactic reaction, anaphylactic shock, angioedema

Nervous system disorders: cerebral hemorrhage, subdural hematoma, epidural hematoma, hemiparesis

Skin and subcutaneous tissue disorders: Stevens-Johnson syndrome

DRUG INTERACTIONS

Rivaroxaban is a substrate of CYP3A4/5, CYP2J2, and the P-gp and ATP-binding cassette G2 (ABCG2) transporters. Inhibitors and inducers of these CYP450 enzymes or transporters (e.g., P-gp) may result in changes in rivaroxaban exposure.

Drugs that Inhibit Cytochrome P450 3A4 Enzymes and Drug Transport Systems: In drug interaction studies evaluating the concomitant use with drugs that are combined P-gp and CYP3A4 inhibitors (ketoconazole, ritonavir, clarithromycin, erythromycin and fluconazole), increases in rivaroxaban exposure and pharmacodynamic effects (i.e., factor Xa inhibition and PT prolongation) were observed. The increases in exposure ranged from 30% to 160%. Significant increases in rivaroxaban exposure may increase bleeding risk *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

When data suggest a change in exposure is unlikely to affect bleeding risk (e.g., clarithromycin, erythromycin), no precautions are necessary during coadministration with drugs that are combined P-gp and CYP3A4 inhibitors.

Avoid concomitant administration of XARELTO with combined P-gp and strong CYP3A4 inhibitors *[see Warnings and Precautions]*.

Drugs that Induce Cytochrome P450 3A4 Enzymes and Drug Transport Systems: Results from drug interaction studies and population PK analyses from clinical studies indicate coadministration of XARELTO with a combined P-gp and strong CYP3A4 inducer (e.g., rifampicin, phenytoin) decreased rivaroxaban exposure by up to 50%. Similar decreases in pharmacodynamic effects were also observed. These decreases in exposure to rivaroxaban may decrease efficacy *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

Avoid concomitant use of XARELTO with drugs that are combined P-gp and strong CYP3A4 inducers (e.g., carbamazepine, phenytoin, rifampin, St. John's wort) *[see Warnings and Precautions]*.

Anticoagulants and NSAIDs/Aspirin: Single doses of enoxaparin and XARELTO given concomitantly resulted in an additive effect on anti-factor Xa activity. Single doses of warfarin and XARELTO resulted in an additive effect on factor Xa inhibition and PT. Concomitant aspirin use has been identified as an independent risk factor for major bleeding in efficacy trials. NSAIDs are known to increase bleeding, and bleeding risk may be increased when NSAIDs are used concomitantly with XARELTO. Coadministration of the platelet aggregation inhibitor clopidogrel and XARELTO resulted in an increase in bleeding time for some subjects *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

Avoid concurrent use of XARELTO with other anticoagulants due to increased bleeding risk unless benefit outweighs risk. Promptly evaluate any signs or symptoms of blood loss if patients are treated concomitantly with aspirin, other platelet aggregation inhibitors, or NSAIDs *[see Warnings and Precautions]*.

Drug-Disease Interactions with Drugs that Inhibit Cytochrome P450 3A4 Enzymes and Drug Transport Systems: Patients with renal impairment receiving full dose XARELTO in combination with drugs classified as combined P-gp and weak or moderate CYP3A4 inhibitors (e.g., amiodarone, diltiazem, verapamil, quinidine, ranolazine, dronedarone, felodipine, erythromycin, and azithromycin) may have increases in exposure compared with patients with normal renal function and no inhibitor use, since both pathways of rivaroxaban elimination are affected.

XARELTO should be used in patients with CrCl 15 to 50 mL/min who are receiving concomitant combined P-gp and weak or moderate CYP3A4 inhibitors only if the potential benefit justifies the potential risk *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category C: There are no adequate or well-controlled studies of XARELTO in pregnant women, and dosing for pregnant women has not been established. Use XARELTO with caution in pregnant patients because of the potential for pregnancy related hemorrhage and/or emergent delivery with an anticoagulant that is not readily reversible. The anticoagulant effect of XARELTO cannot be reliably monitored with standard laboratory testing. Animal reproduction studies showed no increased risk of structural malformations, but increased post-implantation pregnancy loss occurred in rabbits. XARELTO should be used during pregnancy only if the potential benefit justifies the potential risk to mother and fetus *[see Warnings and Precautions]*.

Rivaroxaban crosses the placenta in animals. Animal reproduction studies have shown pronounced maternal hemorrhagic complications in rats and an increased incidence of post-implantation pregnancy loss in rabbits. Rivaroxaban increased fetal toxicity (increased resorptions, decreased number of live fetuses, and decreased fetal body weight) when pregnant rabbits were given oral doses of ≥10 mg/kg rivaroxaban during the period of organogenesis. This dose corresponds to about 4 times the human exposure of unbound drug, based on AUC comparisons at the highest recommended human dose of 20 mg/day. Fetal body weights decreased when pregnant rats were given oral doses of 120 mg/kg. This dose corresponds to about 14 times the human exposure of unbound drug.

Labor and Delivery: Safety and effectiveness of XARELTO during labor and delivery have not been studied in clinical trials. However, in animal studies maternal bleeding and maternal and fetal death occurred at the rivaroxaban dose of 40 mg/kg (about 6 times maximum human exposure of the unbound drug at the human dose of 20 mg/day).

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Nursing Mothers: It is not known if rivaroxaban is excreted in human milk. Rivaroxaban and/or its metabolites were excreted into the milk of rats. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from rivaroxaban, a decision should be made whether to discontinue nursing or discontinue XARELTO, taking into account the importance of the drug to the mother.

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

Geriatric Use: Of the total number of patients in the RECORD 1-3 clinical studies evaluating XARELTO, about 54% were 65 years and over, while about 15% were >75 years. In ROCKET AF, approximately 77% were 65 years and over and about 38% were >75 years. In the EINSTEIN DVT, PE and Extension clinical studies approximately 37% were 65 years and over and about 16% were >75 years. In clinical trials the efficacy of XARELTO in the elderly (65 years or older) was similar to that seen in patients younger than 65 years. Both thrombotic and bleeding event rates were higher in these older patients, but the risk-benefit profile was favorable in all age groups *[see Clinical Pharmacology (12.3) and Clinical Studies (14) in full Prescribing Information]*.

Females of Reproductive Potential: Females of reproductive potential requiring anticoagulation should discuss pregnancy planning with their physician.

Renal Impairment: In a pharmacokinetic study, compared to healthy subjects with normal creatinine clearance, rivaroxaban exposure increased by approximately 44 to 64% in subjects with renal impairment. Increases in pharmacodynamic effects were also observed *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

Nonvalvular Atrial Fibrillation: In the ROCKET AF trial, patients with CrCl 30 to 50 mL/min were administered XARELTO 15 mg once daily resulting in serum concentrations of rivaroxaban and clinical outcomes similar to those in patients with better renal function administered XARELTO 20 mg once daily. Patients with CrCl 15 to 30 mL/min were not studied, but administration of XARELTO 15 mg once daily is also expected to result in serum concentrations of rivaroxaban similar to those in patients with normal renal function *[see Dosage and Administration (2.3) in full Prescribing Information]*.

Treatment of DVT and/or PE, and Reduction in the Risk of Recurrence of DVT and of PE: In the EINSTEIN trials, patients with CrCl values <30 mL/min at screening were excluded from the studies. Avoid the use of XARELTO in patients with CrCl <30 mL/min.

Prophylaxis of DVT Following Hip or Knee Replacement Surgery: The combined analysis of the RECORD 1-3 clinical efficacy studies did not show an increase in bleeding risk for patients with CrCl 30 to 50 mL/min and reported a possible increase in total venous thromboemboli in this population. Observe closely and promptly evaluate any signs or symptoms of blood loss in patients with CrCl 30 to 50 mL/min. Avoid the use of XARELTO in patients with CrCl <30 mL/min.

Hepatic Impairment: In a pharmacokinetic study, compared to healthy subjects with normal liver function, AUC increases of 127% were observed in subjects with moderate hepatic impairment (Child-Pugh B).

The safety or PK of XARELTO in patients with severe hepatic impairment (Child-Pugh C) has not been evaluated *[see Clinical Pharmacology (12.3) in full Prescribing Information]*.

Avoid the use of XARELTO in patients with moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment or with any hepatic disease associated with coagulopathy.

OVERDOSAGE:

Overdose of XARELTO may lead to hemorrhage. Discontinue XARELTO and initiate appropriate therapy if bleeding complications associated with overdosage occur. A specific antidote for rivaroxaban is not available. Rivaroxaban systemic exposure is not further increased at single doses >50 mg due to limited absorption. The use of activated charcoal to reduce absorption in case of XARELTO overdose may be considered. Due to the high plasma protein binding, rivaroxaban is not expected to be dialyzable *[see Warnings and Precautions and Clinical Pharmacology (12.3) in full Prescribing Information]*.

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AHIP Medicare, Medicaid, and Dual Eligibles 2013 Conference

The Medicare, Medicaid, and Dual Eligibles programs are on the verge of a significant transition under the Affordable Care Act. Coordinating care and improving population health outcomes will require these federal programs to move away from outdated fee-for-service models to ones that incent better quality and more cost-effective delivery methods. At America's Health Insurance Plans (AHIP) Medicare, Medicaid, and Dual Eligibles conference held on September 23-26 in Washington, DC, the sessions featured discussions that highlighted the role health insurance plans will play as these federal programs continue to evolve under healthcare reform.

Medicare

One might question what sustainable Medicare would look like. Historically, those who received health insurance were covered either by a private employer, or were eligible for coverage under the Medicare and Medicaid programs. Individuals who lacked access to either option fell in a gap. This disparity necessitated the implementation of the Affordable Care Act (ACA), a reform effort which intends to expand Medicaid to include more beneficiaries, and will subsidize private insurance for many others who currently remain uninsured. Yet, the health law remains a highly contested topic in Washington, especially along political party lines. Alice M. Rivlin, co-chair, Bipartisan Policy Center's Domenici-Rivlin Task Force, and interim director of Brookings' Engelberg Center for Health Care Reform, provided insight as to what elements are needed to refocus federal energies where they need to be. "It really is a very strange time to be here; the most extreme partisan politics in my memory, and I'm afraid the most broken that I've seen our democratic process," Ms Rivlin said. "Healthcare and health insurance are caught right in the middle of this dysfunctional situation."


Alice M. Rivlin

Ms Rivlin noted that despite the healthcare "fix" being complex, it must be addressed in a diplomatic and urgent way. Healthcare reform has been long overdue. "All this seems to be happening when the whole world is looking to us for stability," said Ms Riviln. "The network's broken; we ought to be able to work together across party divisions to make essential services of government work." Encouraging better-quality, higher-value healthcare as well as supporting the sustainability of the Medicare program in the long term will require a more neutral view of healthcare across party lines. Establishing accountable care organizations (ACOs), Medicare Networks (MNs), and transforming or replacing the Cadillac Tax are just some of the suggestions Ms Rivlin offered. MNs are of special interest, because unlike ACOs, they are enrollment based. Nevertheless, both models provide incentives that would help drive quality based on care guidelines and benchmarks. To control spending, reform efforts must be focused on shifting Medicare from fee-for-service to a premium support program where the government would cap its contribution at a reasonable sustainable growth rate (SGR). Medicare plays a central role in health policy, including the total spending of healthcare, as well as contributing largely to the national debt. However, whether through public or private health plans, there is an opportunity to transform the federal program and increase the efficiency of care delivery. Restructuring Medicare would slow the growth of current total healthcare spending at a national level, while reducing the potential growth of future debt.


Marilyn Tavenner

Marilyn Tavenner, administrator, Centers for Medicare & Medicaid Services (CMS), also had much to say in regard to how the Medicare program might operate in 2014 and beyond. Of course, there is the "3-legged stool" of Medicare's strategic plan: access, cost, and quality. Familiar terms, but what do they really mean? Cost containment comes from a myriad of paths, but aligning incentives and strategy starts with sharing data. Ms Tavenner suggests that CMS still has a way to go in this emerging area. Reforming existing health systems provides an opportunity for such growth and improvement. "We need to get more value for the dollars we spend," Ms Tavenner said. In fact, addressing quality and innovation on the front end saves a lot of rework on the back end. As she spoke to the medical professionals and other attendees, Ms Tavenner said she was excited and looking forward to the opening of the health insurance marketplaces in October. CMS has been actively working with the private sector to ensure that the quality of healthcare matches the costs that are being incurred to deliver it. "We're all going to make a difference, and it's going to take us a while to get there. What we're seeing is more transparency, more data, and individuals asking a lot of questions—and for me, that's what it's all about."

Medicare Advantage Plans

Dr Katherine Baicker, professor of health economics, Department of Health Policy and Management, Harvard School of Public Health, says that the 2 main goals of healthcare reform are cover-

ing the uninsured and slowing spending growth. She says while it is easy enough to cut funding in order to slow spending growth, it does little to drive value—quality care costs a significant amount of money. At the same rate, there are parts of the country where we are spending the most, yet patients are not receiving the best quality care because of fee-for-service models. Spending is wasted, and is only exasperated by a failure to coordinate care. Proton beam therapy is a strong example of expensive care that is being used even when its outcomes have no better proven outcomes than other less expensive therapies. Dr Baicker argues that as long as Medicare keeps reimbursing these types of costly treatments, providers will continue to keep using them under the fee-for-service model. "It would be nice to say, 'Well, save Medicare's problem by eliminating fraud and abuse and cut out care that had no outcomes,'" said Dr Baicker. Aligning cost sharing with value will require more incentives, like bundled payments and shared savings, as well as integrated plans like ACOs and value-based insurance design. Put simply, Medicare and other public programs cannot cover all care for all people with public money under current reimbursement models.


Paul B. Ginsburg, PhD

Paul B. Ginsburg, PhD, president, Center for Studying Health System Change, echoed Dr Baicker's comments, saying that there are diverse forces affecting the Medicare Advantage (MA) business. Medicare Advantage plans are offered through private companies that contract with Medicare to provide patients with all their Part A and Part B benefits. Dr Ginsburg says there are opportunities for enrollment growth in MA plans due to both the retirement of baby boomers and private exchanges for retirees. There are also many challenges, including potential policy changes that would affect MA plans more than traditional Medicare plans. Long-term success of the MA program requires care delivery innovation, tailored benefits for consumers, and collaborative provider partnerships. Dr Ginsburg also suggests that benefits should be more individualized, and selective about who would be entitled to coverage.

Dual Eligibles

With nearly 10 million beneficiaries who are eligible for both Medicare and Medicaid, guaranteeing access to high-quality, cost-effective healthcare is imperative. According to Melanie Bella, director, Medicare-Medicaid Coordination Office, Centers for Medicare & Medicaid Services, CMS is pursuing multiple initiatives to streamline care. Those initiatives include an Integrated Resource Center which would showcase best practices for states, initiatives to reduce unnecessary hospitalizations, and resource centers that would provide assistance to state Medicaid and Medicare agencies in sharing data. Each opportunity presents unique offerings to better coordinate care. CMS-sponsored demonstration projects, including a capitated model and a managed fee-for-service model, aim to integrate primary care, acute care, long-term services, and other important benefits for dual eligibles. These demonstrations integrate the full spectrum of Medicaid and Medicare services, in addition to ensuring beneficiaries have access to all the care they are entitled to under both programs.

As with other reform initiatives, being person-centered is crucial. Ms Bella says that simple changes, such as issuing a single insurance card to patients, could help promote coordination and continuity of care. "We are very focused on data, which may not sound like a direct benefit to beneficiaries, but getting Medicare data linked with Medicaid data and into the hands of care managers allows us to foster coordination and access for beneficiaries," Ms Bella told *The American Journal of Managed Care* during the event.

Medicaid

Controlling costs is a major issue for all state governors, especially as healthcare exponentially outpaces spending in other key areas such as K-12 education. Dan Crippen, executive director, National Governors Association (NGA), discussed the issues from the governors' perspectives, especially as they pertained to the ACA implementation and Medicaid program priorities in the states. Mr Crippen said that the elderly account for 26% of Medicaid spending, even though they are only 9% of the population. Disabled beneficiaries account for 43% of Medicaid expenditures, while they represent a mere 16% of Medicaid population. These figures show that spending is just not being utilized effectively. As well, many of these higher costs of care could be preventable. Mr Crippen relayed the example of a Medicaid patient with diabetes who was showing stable blood glucose levels at the beginning of the month, and spiked glucose levels toward the end of the month. Upon investigation into the patient's medication adherence, it was discovered that the patient did not own a refrigerator and the insulin was losing efficacy due to improper storing. In another case, the patient was frequently having severe asthma attacks because they did not have an air conditioning unit in their home. While these issues are easily resolvable with the purchase of a small refrigerator and AC window unit, there are no payment systems in place to finance non-medical items like these for patients. Small preventive measures would help patients better manage their care, but policy change at this level can be difficult despite being much needed. Mr Crippen quipped, "Don't wait for Washington, do what you can from home."

Additionally, less than 3% of funding is spent on public health, including that for clean water and vaccinations. Yet, this underfunded area is not the first place where most governors look for solutions in promoting preventive care and controlling higher costs. Mr Crippen says the governors and states are working diligently to reform along all levels of Medicaid by identifying

roadblocks that exist. It is critical to control the "super-utilizers" of Medicaid services. Super-utilizers average nearly $4000 in monthly health costs, as well as average 2.6 hospital admissions, 7 emergency department visits, 10 primary care visits, and 20 specialist visits per year. While slower that hoped, Medicaid expansion is happening, and with the governors' help, many of the barriers to realizing a more effective care delivery model will be addressed. Mr Crippen hopes that although only 29 states have chosen to expand Medicaid eligibility, eventually more states will implement expansion programs as they experience the first few months of the ACA.

Jocelyn A. Guyer, director, Manatt Health Solutions, said that outreach will be critical in educating patients about the ACA. Four out of 10 people are still uncertain if the ACA is actually an enacted law. Lack of specific funding for ACA outreach has left many consumers ill-informed about what the ACA encompasses, despite patient education being an "important piece of the puzzle." There are some initiatives in place that are working to remediate the situation. The non-profit organization Enroll America, for instance, is addressing the "enrollment gap" by ensuring that they assist as many uninsured Americans as possible in making responsible choices when choosing a health plan. As the future of care calls for collaboration and a more person-centered focus, having patients make educated decisions is important. Small efforts such as disseminating in-depth information about how and where to enroll for coverage is just 1 way to close the "enrollment gap." The exchange navigator program, which provides assistance to the uninsured in obtaining health plans on the marketplace, is also essential. But this is not enough. Ms Guyer says the states need to be more formally involved with reform by stepping forward and changing the business-as-usual attitudes. Getting insurance to those who need it most will require collaboration between the federally facilitated marketplaces (FFMs) and State Partnership Marketplaces (SPMs).

"Details aren't important things, the basic message across the health policy spectrum is we've got to move toward more collaborative care, more reward for value, and outcomes have to incent beneficiary and providers," added Chuck Milligan, deputy secretary, health care financing, Maryland Department of Health and Mental Hygiene. "Nothing is easy about it, but we can do better." MNs and ACOs are a start toward bringing groups together to collaborate on care and share savings, but the overall process of reforming the Medicaid landscape is going to be a slow and arduous process. Regardless of the time it takes, the changes are long overdue. The first necessary strides toward ensuring better-valued care in the United States are being made.

Conclusion

Reform brings challenges and questions, but more importantly, it brings promises and opportunities. Quality, value, and cost-effective healthcare delivery in the Medicare, Medicaid, and Dual Eligibles programs will require a communal effort between the healthcare industry and federal entities. Continued support and collaboration will be essential to supporting models that drive consumer knowledge while incentivizing providers to administer greater value-based care.

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ACO and Emerging Healthcare Delivery Coalition

Background

As ACOs and other emerging delivery and payment models evolve and move away from traditional fee-for-service system models towards cost-effective and value-based care, the need to understand how these models will evolve is critical to building long term strategic solutions. The mission of the coalition is to bring a diverse group of key stakeholders together, including ACO providers, payers, IDNs, specialty pharmacy and pharmaceutical manufacturers to work collaboratively to build solutions and improve the quality and overall outcomes of patient care.

Coalition Goals

- Gather insights of current "real-world" best practices and strategies for care management interventions
- Gather insights of current ACO physician challenges and best practices in executing successful ACOs, as well as new healthcare delivery models, including the impact of incentive structures for ACO providers–implementation strategies and measurement
- Identify operational lessons and best practices, including key components of transitions-of-care programs; patient and physician engagement; quality measures; formulary decisions; and protocol development.
- Translate key findings into actionable solutions for key stakeholders

Key Stakeholders

- ACO poroviders
- Payers
- Integrated Delivery Networks
- Specialty Pharmacy
- Pharmaceutical Manufacturers

Deliverables

- **Participation in two live working group sessions with coalition members:**
  - Free registration for live interactive meeting with Industry leaders across ACOs, payers, IDNs, specialty pharmacy and pharmaceutical manufacturers
  - Opportunity for exclusive breakout sessions with coalition members
- **Two virtual meetings with coalition members - free registration**
- **Ongoing collaboration opportunities with coalition members:**
  - Monthly executive interchanges with thought leaders (includes Q&A)
  - Active participation and proprietary questions in pulse surveys
- **Complimentary subscriptions:**
  - The *American Journal of Managed Care*
  - The *American Journal of Accountable Care* quarterly publication
  - **ACO and Emerging Healthcare Delivery Coalition** newsletter
- **Additional discounts:**
  - Free registration to The *American Journal of Managed Care* live events
  - Discount on HRA syndicated managed care studies and inclusion of 5 proprietary questions in 2014
- **Company/brand advertisements:**
  - The *American Journal of Managed Care*
  - The *American Journal of Accountable Care* quarterly publication
  - **ACO and Emerging Healthcare Delivery Coalition** newsletter
- **Expedited peer review for submissions to AJAC**
- **Additional Resources:**
  - Development of training modules: live, on-line, etc
  - Development of patient education
  - Access to ACO portal resource center within AJMC.com

AJMC's **ACO and Emerging Healthcare Delivery Coalition** is the premier managed care alliance for ACOs, payers, IDNs, specialty pharmacy and pharmaceutical companies. This coalition provides the platform for diverse stakeholders to collaborate and interact regarding the current and evolving healthcare delivery models–to build strategies and solutions, in addition to developing enduring materials to ensure continuous engagement and innovation for all alliance members.

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