

SPECIAL ARTICLES

Potential Impacts of the Affordable Care Act on the Clinical Practice of Hepatology

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The Patient Protection and Affordable Care Act (ACA), along with the Health Care and Education Reconciliation Act, was signed into law and upheld by the Supreme Court earlier this year. The ACA contains a variety of reforms that, if implemented, will significantly affect current models of healthcare delivery for patients with acute and chronic hepatobiliary diseases. One of the Act's central reforms is the creation of accountable care organizations (ACOs) whose mission will be to integrate different levels of care to improve the quality of services delivered and outcomes among populations while maintaining, or preferably reducing, the overall costs of care. Currently, there are clinical practice areas within hepatology, such as liver transplantation, that already have many of the desired features attributed to ACOs. The ACA is sure to affect all fields of medicine, including the practice of clinical hepatology. This article describes the components of the ACA that have the greatest potential to influence the clinical practice of hepatology. **Conclusion:** Ultimately, it will be the responsibility of our profession to identify optimal healthcare delivery models for providing high-value, patient-centered care. (HEPATOLOGY 2014;59:1681-1687)

The Patient Protection and Affordable Care Act (referred to as ACA), along with the Health Care and Education Reconciliation Act, was signed into law on March 23, 2010.¹ It is considered the largest overhaul of the U.S. healthcare system since Lyndon Johnson authorized the Medicare and Medicaid programs in 1965.² The stated aims of the ACA are to expand coverage, improve quality, and reduce costs. Though several organizations challenged the ACA in state and federal courts, the Act was ultimately upheld by the Supreme Court, including the "individual mandate" that requires all Americans to purchase insurance or pay a penalty.^{2,3}

Affordable Care Act

Section 3022 of the ACA describes the need to "promote accountability for a patient population and

coordinate items and services under the provision of insurance coverage, and to encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery."¹ The first way the law achieves these goals is by expanding Medicaid eligibility to include Americans in a wider income bracket. The ACA also expands coverage through a series of new regulations limiting insurance exclusions, preventing the use of lifetime caps on insurance, making it illegal to deny coverage because of preexisting conditions (as of 2014), and to allow insurance coverage for children on parental plans through age 26. The law also expands insurance access by creating state-run insurance marketplaces (or exchanges) that are to offer a choice of insurance plans for consumers. Finally, the ACA expands coverage by establishing two different mandates to buy

Abbreviations: ACA, affordable care act; ACO, accountable care organizations; AMCs, academic medical centers; CHC, chronic hepatitis C; CLD, chronic liver disease; CMS, Centers for Medicare and Medicaid Services; DHHS, Department of Health and Human Services; DSH, disproportionate share hospital; HHS, Health and Human Services; IPAB, independent payment advisory board; LT, liver transplantation; NQF, National Quality Forum; PGP, Physician Group Practice; PQRS, Physician Quality Reporting System.

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insurance, which is either through an employer or as an individual. These changes essentially require that nearly everyone will have a minimum level of healthcare insurance coverage.^{3,4}

The ACA is estimated to increase the number of people with health insurance by 32 million by the year 2019. It is hoped that 16 million of these individuals will receive coverage from an expansion of Medicaid, although this is will be determined by state governments who may choose to participate or not participate in the expansion process. Failing to obtain insurance coverage will result in a fine, which will increase from the greater of \$95 or 1% of taxable income in the first year. These fines increase in 2016 to a maximum of \$695 for individual adults and \$2,085 for families. To expand coverage to the “near-poor,” Medicaid coverage eligibility will be expanded to up to 133% of the U.S. poverty line. Furthermore, for people with an annual income between 100% and 400% of the poverty line, tax credits will be available for the purchase of health insurance.²⁻⁹ In turn, the Congressional Budget Office¹¹ has predicted that legislation within the ACA mandating the purchase of health insurance will provide coverage to more than 95% of all Americans while reducing the federal deficit by \$138 billion over the next 10 years with additional reductions in subsequent years. Under the new legislation, the Centers for Medicare and Medicaid Services (CMS) will reduce payments to hospitals by \$158 billion over 10 years to also help cover the cost of the newly insured.

Despite its controversy, there is a nationally agreed-upon agenda to enhance the value of healthcare delivery by improving patient-centered outcomes for larger patient populations while reducing costs.⁵ Specific details regarding the effect of addressing access, cost, and quality on the clinical practice of hepatology are described below.

Access

With respect to clinical hepatology, it is conceivable that the ACA will lower barriers to access and expand health coverage to large uninsured populations, including those with, or at increased risk for, chronic liver disease (CLD). Subsequent referral of an increased population with CLD may become financially challenging for some clinical practices, including those housed within academic medical centers (AMCs).^{7,9}

Furthermore, an influx of patients with hepatobiliary disease traditionally observed in safety-net hospitals will likely be accompanied by reductions in payment for medical services with elimination of the dispropor-

tionate share hospital (DSH) payments traditionally paid by Medicare and Medicaid. This could greatly affect the ability of hepatology providers to provide safe, efficient care for this population if resources become constrained. Furthermore, it is reasonable to expect that more individuals obtaining health insurance through the ACA will access safety-net hospitals to receive care for liver disease, which will only serve to exacerbate this situation further.⁹ Given the continued demand for trained clinical hepatologists who will be needed more than ever to meet a potential increased demand for services, opportunities to develop new care models, including of the use of mid-level providers⁴ and more established partnerships with primary care providers, will be possible.^{4,11} Further aggravating the potential for a supply-demand mismatch between providers and patients is the possibility of reduced payments in support of graduate medical education training programs, including fewer hepatologist training positions.⁷

Cost

Another innovation of the ACA is the proposed creation of the Independent Payment Advisory Board (IPAB). This federally appointed committee is directed to maintain Medicare spending below specific growth targets. If these goals are missed, the Board is empowered to reduce expansion by policy mechanisms that affect up to 1.5% of the Medicare budget. However, the IPAB is prevented from reducing Medicare benefits, raising premiums or taxes, and rationing care. It also may not lower payments to hospitals or hospices before 2020 or lower payments to clinical laboratories before 2016.^{2,3}

In general, the ACA does not contain provisions for restructuring the fee for the service reimbursement model used by Medicare and other insurance carriers. However, the ACA authorizes the Secretary of Health and Human Services (HHS) to adjust “misvalued” fee schedules for procedures and services that have experienced high growth rates or advances in technology.

Although no overarching consequence has been described for reimbursement of care to patients with CLD following passage of the ACA, this is not the case in gastroenterology with respect to colorectal cancer screening. For example, if a patient is referred for a positive fecal immunochemical test or undergoes polyp removal during a screening colonoscopy, the procedure becomes reclassified as a therapeutic procedure, and beneficiaries will likely pay an out-of-pocket cost.⁴ Upper endoscopy, colonoscopy, and endoscopic retrograde cholangiopancreatography are among the

numerous procedures under review, and Medicare reimbursement for these services will probably decrease. It is expected that advanced imaging techniques, including computed tomography and magnetic resonance imaging, may also come under review with subsequent reductions in reimbursement to follow. The importance of these diagnostic tools in clinical hepatology cannot be overstated, which suggests that our field will also be affected.

Quality

Beginning in 2013, the CMS will give out an estimated total of \$850 million to hospitals across the United States as rewards for meeting a series of quality measures. The funding will come from the savings expected from reforms implemented by the ACA. The metrics used will focus on processes associated with high-quality patient care, such as prevention of venous thromboembolism in patients undergoing surgery as an example.²

The Department of Health and Human Services (DHHS) is tasked with creating assessments of health outcomes, care transitions, and measures of efficiency, safety, equity, timeliness, and patient satisfaction. These tools will be developed in conjunction with the National Quality Forum (NQF). The NQF is an independent, nonprofit organization of multiple stakeholders with the mission of improving healthcare quality by generating consensus on national healthcare priorities, advocating performance improvements, creating quality measures, and promoting goals through education and outreach. Information gleaned from these metrics will be combined in a database that will ultimately be used for public reporting of physician and hospital performance.¹²

By creating an Innovation Center at the CMS, the goal of achieving higher-quality, cost-effective care with improved coordination between providers may be realized through the ACA. A major focus will be on developing “bundled payment” systems for entire episodes of care involving multiple providers and settings, rather than for discrete services by individual providers. Thus, there would be an alignment of incentives for hepatologists to coordinate care more closely with colleagues in primary care and other specialty areas to care for patients with CLD. However, the processes involved with coordinating care and sharing in the reimbursement of services provided remains to be determined.⁴ Examples with use of bundled payments in the care for patients with end-stage renal disease may be a relevant example to draw from in designing bundles for patients with CLD and decompensated cirrhosis.^{2,4}

To date, the CMS has introduced the Physician Quality Reporting System (PQRS) to deliver incentives to providers that submit quality data for review. For our gastroenterology colleagues, the ACA has extended the PQRS under which gastroenterologists who voluntarily report select performance measures by using Medicare Part B claims, a qualified registry, or an electronic health record. When reporting to the PQRS, gastroenterologists can receive an additional 0.5% bonus payment.⁵ Current PQRS measures for diagnosis and treatment include CRC screening, inflammatory bowel disease, and chronic hepatitis C (CHC).² It is expected that these and future performance measures will be used for value-based payments to accountable care organizations (ACOs).⁵ If these measures prove effective in terms of enhanced quality and economic benefits, the DHHS may expand the scope of these pay-for-performance processes in 2018 to involve other disease-based areas within specialties, including hepatology.²

It has been described that requiring adherence to certain quality measures could incentivize provider groups to avoid caring for certain population subsets (i.e., those with complex diseases or noncompliance issues) where an increased risk of being perceived as delivering lower-quality care could occur. Furthermore, current pay-for-performance models do not actually tell consumers how good healthcare delivery systems are in terms of fragmentation, duplication of services, and coordination of care between the hospital, outpatient clinic, and home. Because of these pitfalls in assessing individual provider performance, it is likely that quality will be assessed at the delivery system level rather than the individual provider. Ongoing pilot initiatives, such as the Pioneer ACO and Shared Savings Programs sponsored by the CMS Innovation Center, exemplify this concept.

Accountable Care Organization

An ACO is currently defined as a network of healthcare providers that assumes joint accountability for coordinating and delivering efficient, high-quality healthcare through more-efficient uses of resources.^{2-9,14} The ACA includes specific requirements that ACOs must meet, which include (1) a minimum of 5,000 Medicare beneficiaries with a strong core of primary care physicians, (2) a legal structure to receive and allocate payments, and (3) a management structure that includes physicians and administrators (Table 1).³ Recognition of ACOs is in response to current trends in Medicare spending, which are unsustainable.

In contrast to managed care organizations, which utilized ineffective strategies to control healthcare

Table 1. Criteria for Designation as an ACO*

Express willingness to be accountable for quality, cost, and overall care of Medicare fee-for-service beneficiaries for a minimum of 3 years
Have a formal legal structure to receive and distribute shared savings
Have at least 5,000 assigned beneficiaries with a sufficient number of primary care ACO professionals
Report on quality, cost, care coordination measures, and meet patient-centeredness criteria set forth by the HHS secretary
May initially focus on one-sided shared savings models

*Adapted from Goodney et al.¹⁴

costs,¹⁵ patients cared for within an ACO are free to choose their providers, do not have to change their insurance, and can stay in the Medicare program. By making improvements in quality and slowing resource utilization to improve population health, ACOs will receive money from the government equal to a percentage of estimated money saved through cost-efficiency (to be determined by the DHHS). Remuneration to the organization will be realized through a CMS-directed shared savings program, which is linked to demonstrating quality of care.² In this concept, performance measurement and quality markers are used to reward physicians and hospitals that provide cost-effective, evidence-based care.¹⁵

Two large efforts have been undertaken to demonstrate the feasibility of ACOs (Table 2). In the Physician Group Practice (PGP) Demonstration, all providers during their fourth year showed improvements in 29 of the 32 quality measures assessed. Unfortunately, cost savings were more difficult to achieve, with only 2 of 10 PGP participants exceeding the 2% savings threshold in the first year of the demonstration. However, by year 4 of the program, 5 of the 10 participating providers reduced costs enough to receive a shared savings payment.¹⁴ Notably, the cost savings may have been more the result of earlier cost trends than actual changes in care delivery after subsequent analysis.¹⁶ Nevertheless, the criteria identified for successful implementation of the program were (1) electronic medical records and an extensive administrative structure with defined quality measures, (2) organ-

izational commitment to improving performance, and (3) provision of resources to measure and improve healthcare delivery.¹⁵

Beyond the demonstration projects, there remains little evidence as to how ACOs will be structured or created. It also remains unclear how organizations will support the significant up-front resource costs necessary to build the information technology and infrastructure required to facilitate quality measurement and improvement within an ACO. This sizeable investment will likely restrict ACO creation to large health systems where many of these elements are already in existence.¹⁵ Unlike gastroenterology, where several business models exist, including physician-owned practices of varying sizes, the majority of hepatology care in the United States has been focused within large AMCs and health systems that now serve the basis for future ACOs.

Impact of ACA Policies on AMCs With Hepatology Expertise

AMCs will need to address both financial and cultural barriers to implementation of new care and payment models contained within ACOs.^{7,17} For example, the Medicare shared savings program payment model is likely to be pursued by a number of AMCs. However, the AMC will receive less money, compared to the traditional fee-for-service reimbursement. In addition, only half of what is saved in addition to a previously agreed upon target would likely be given back to the AMC.⁷ Furthermore, AMCs will need to invest in creating meaningful use of electronic health records to measure and define high-quality care,¹⁸ which requires a sizable up-front cost by these institutions. More importantly, AMCs will need to provide leadership and direction in growing the influence of primary care medicine to facilitate coordination of care with specialty practices (which has not been a traditional focus for AMCs).

Despite the barriers to becoming an ACO, healthcare reform brings opportunities for AMCs to

Table 2. Summary of PGP Plan and Advocate Physician Partners

Project/Site	No. of Hospitals	No. of Physicians	No. of Patients	Primary Payer	Examples of Quality Markers	Savings Returned to ACO Providers
Physician Group project	10 large group practices	5,000 physicians ranging from 232 to 1,291 per practice	223,204	CMS	Beta-blocker therapy for post-MI patients	\$31.7 million distributed back to five sites that met quality goals
Advocate physician partners	10 affiliated group and private practices	3,500 physicians; 2,700 in group practice, 900 in solo practice	>1 million	Blue Cross/Blue Shield	eICU capability for all ICU beds	\$38 million in incentive payments distributed to 3,700 physicians across 10 sites

ICU, intensive care unit; eICU, enhanced ICU.

modernize their approaches to research, education, and patient care. Efforts to stem the use of unwarranted services (e.g., duplicative testing, emergency department visits for chronic conditions, and repeat hospitalizations) through care management protocols are most likely to come from AMCs as well.¹⁶ Innovation within the medical school and graduate medical environments for developing curriculum centered on quality and efficiency in delivering healthcare will emerge from these institutions. Research in the science of healthcare delivery is just beginning, and AMCs are well positioned to spearhead efforts to develop, pilot, and disseminate new patient-focused measures and models of care.^{7,17} Examples of funding sources include the Patient-Centered Outcomes Research Institute, a nonprofit entity focusing on comparative-effectiveness research that will provide annual research funding of \$500 million by 2015, and the Center for Medicare and Medicaid Innovation, with its \$10 billion for innovation grants to evaluate and implement effective delivery models.¹⁷

Impact of ACA Policies on Hepatology Subspecialty Care

Whereas policies of the ACA are focused on strengthening the network of services delivered at the primary care level, there will continue to be an important role for specialists in identifying novel, innovative strategies for providing high-value healthcare for individuals with complex chronic diseases.⁷

As mentioned earlier, individuals with CLDs labeled as have preexisting conditions will now have access to health insurance, which may increase the volume of patients observed by hepatology providers. For example, uninsured patients with cancer represent a particularly vulnerable population, with demonstrated differences in incidence, prevalence, burden, and mortality.² This is also likely to be the case for patients with hepatobiliary malignancy. Under the ACA, these patients will now have access to medical care in a more timely fashion. Expanded coverage for patients with end-stage organ failure has the potential to improve early access to transplant services leading to better care.¹⁸ Again, the question as to whether increased access will result in improved health outcomes in the face of declining reimbursement remains unanswered.⁷

Given the chronic nature of hepatobiliary diseases that are diagnosed and treated by hepatology providers, it is very likely that these populations will be served within ACOs. Though this will result in more

specialists being employed by hospitals or integrated delivery systems, this phenomenon could be much less impactful than anticipated in the discipline of clinical hepatology, based on the organizational structure already established for performing liver transplantation (LT) in the United States.

To date, solid organ transplantation (including liver) is the most applicable, existing model for accountable care given the charge of maximizing clinical benefit in the face of limited resources. Transplant centers routinely provide multidisciplinary care, report outcomes in a transparent manner, and function as a "medical home" that coordinates care for its populations. Moreover, the AMCs that house most transplant programs will exist at the core of many of the ACOs and will be the focus of other models of care. These circumstances uniquely position many of the institutions that house transplant centers to become leaders in the evolution of ACOs.¹⁹ Furthermore, many transplant centers are already receiving bundled payments for the entire episode of transplant services. Additional financing of pilot programs will develop bundled payments for hospital and posthospital care for specific conditions (e.g., acute myocardial infarction) and will look very similar to many current transplant contracts.²⁰

The Need for Data in Support of High-Value, Patient-Centered Hepatology Care

Whereas LT programs can help to identify the organizational approaches for reassembling hepatology care within an ACO framework, serious attempts to improve quality and reduce costs must be pursued as well. Within AMCs that reorganize as ACOs, it is expected that hepatologists will continue to provide consultative services and perform procedures. However, there will also be a greater need for clinical input regarding the development of clinical processes and protocols.¹⁶ Chronic hepatobiliary care requires a multidisciplinary approach that often results in wide variation in resource utilization and costs. In an effort to control these factors, bundled payments would likely be tied to specific outpatient diagnoses and management strategies. Therefore, it will be critical for hepatology providers to participate in the development of these payment schemes to ensure appropriate allocation of resources and care for their patients. In turn, hepatology-based providers will likely see an increase in data collection requirements to ensure that reimbursement is appropriate.²

Clearly, the ability to measure quality and redesign care processes to improve patient-centered care

expectations within the ACO model will be linked to reimbursement. For the moment, there are few performance measures reflecting the quality of subspecialty care in hepatology, yet this may change in the future. For example, the national problem of 30-day hospital readmission is no stranger to the discipline of hepatology as well. Thirty-day hospital readmission has become an important metric in establishing the presence of high-quality medical care, which will remain important in the upcoming ACO era. National administrative data confirm that the number of hospitalizations for cirrhosis and its complications is increasing with time.²¹ Though few medical record-based studies have been published to date, the data point toward observing increased 30-day readmission rates based on variability in medical care services provided during the index hospitalization.^{22,23} Legislation within the ACA recommends combining acute and postacute care episodes (i.e., skilled nursing facilities, home health care, and so on) as part of bundled payments, with the acute care provider bearing responsibility for the bundle. Therefore, rates of rehospitalization may become even more carefully scrutinized as a factor in deciding which postacute setting to use.²

Another example where clinical hepatology is involved with the development of innovative care delivery models is the patient-centered medical home. This is a team-based approach led by a personal physician who provides and directs continuous and coordinated care to enhance access, quality, and safety. These depend on an emerging nonphysician workforce that is capable of delivering much of the care needed by patients, but not necessarily responsible for face-to-face care.²⁴ An example of this approach can be seen in the Extension for Community Healthcare Outcomes project of New Mexico. This model uses videoconferencing technology to train primary care providers on treatment of patients with CHC. Outcomes from this project were substantial, with high rates of cure within community-based settings that are similar to those seen in AMCs.²⁵

Future Challenges and Opportunities

The ACA will have significant implications for the field of clinical hepatology. Clinical programs housed within institutions organized as ACOs will also be asked to focus their missions on care coordination, performance measurement, and quality improvement to demonstrate high-value healthcare.⁴ Efforts to reduce excessive utilization would also ideally occur in

the context of tort reform, given the influence of "defensive" medicine on test ordering practices, yet this feature of the medicolegal landscape has not been specifically addressed by the ACA.

Notably, this provides an opportunity for hepatology-based providers to develop innovative approaches and care delivery models for managing patients with acute and chronic hepatobiliary diseases. A number of clinical hepatology providers have "grown up" in this recent era of healthcare reform, and the resource constraints related to LT as a whole represent a microcosm of several ongoing policy issues the entire U.S. health care system is currently experiencing. Hepatologists should take the lead in defining which conditions and services are central to our profession as well as continue to develop trustworthy evidence-based guidelines, in addition to valid and measureable performance metrics in these areas. It will almost be certain that clinical hepatology practices that develop the capability to measure and report their results will demonstrate value-based care.^{16,25} Similar challenges are being faced by our nephrology colleagues, who are meeting these initiatives successfully to date.¹⁴

Specific goals for a "roadmap" to guide hepatology in the current atmosphere of healthcare reform would include the following: (1) seek educational opportunities to learn the principles of health policy implementation and delivery system organization; (2) participate in local institution quality improvement and external measures workgroup activities; (3) reinforce the importance of improving and maintaining efficiency of clinical practice operations with respective leadership structures while assessing the value of care processes toward maximizing patient-centered outcomes; (4) encourage investigators at all career levels to pursue training in methods for conducting healthcare delivery research using patient-centered outcomes and comparative effectiveness research techniques; and (5) conduct research that examines the impact of health policy interventions on the organization, financing, and delivery of medical care to populations affected by CLD, including long-term survivors subsequent to LT.

The tradition of leadership in advancing the science of patient care, providing advocacy for disease prevention, and the pursuit of initiatives in clinical practice guideline development will position the discipline of hepatology to take the next step in this new world of accountable care. In contrast, lack of action in this space will create opportunities for others to dictate what should be measured and paid for in the future.

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