

VALUE BASED CARE IN HEPATOLOGY

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ABSTRACT

The migration from legacy fee-for-service reimbursement to payments linked to high value health care is accelerating in the United States because of new legislation and re-design of payments from the Centers for Medicare and Medicaid Services (CMS). Since patients with chronic diseases account for substantial use of health care resources, payers and health systems are focusing on maximizing the value of care for these patients. Since chronic liver diseases impose a major health burden worldwide affecting the health and lives of many individuals and families as well as substantial costs for individuals and payers, hepatologists must understand how they can improve their practices. Hepatologists practice a high-intensity cognitive sub-specialty, using complex and costly procedures and medications. High value patient care requires multi-disciplinary coordination, labor-intensive support for critically ill patients and effective chronic disease management. Under current fee for service reimbursement, patient values, medical success and financial success all can be misaligned. Many current attempts to link health outcomes to reimbursement are based on compliance with process measures with less emphasis on outcomes that matter most to patients, thus slowing transformation to higher-value team-based care. Outcome measures that reflect the entire cycle of care are needed to assist both clinicians and administrators in improving quality and value of care. A comprehensive set of outcome measures for liver diseases is not currently available. Numerous researchers now are attempting to fill this gap by devising and testing outcome indicators and patients reported outcomes (PROMs) for the major liver conditions. These indicators will provide tools to implement a value-based approach for patients with chronic liver diseases to compare results and value of care between referral centers, to perform health technology assessment and to guide decision-making processes for health authorities. This review sets the groundwork for implementing a value-based, patient-centered approach to chronic liver diseases within a health system.

The practice of Hepatology, once dominated by supportive treatment, has evolved into a highly complex discipline able to offer prevention and effective care for most acute and chronic liver diseases. In several geographic regions, including some western countries, the prevalence of liver disease is still significantly high. Despite availability of novel and effective treatments, the burden of liver diseases remains elevated, as access to new treatments is limited and not universally sustainable. Treatment of viral hepatitis, liver cancer, end-stage liver disease, alcoholic or metabolic or biliary liver diseases, requires costly medication and/or surgical procedures, including transplantation. Treatment of rarer chronic liver conditions is labor intensive and often requires specialized multi-disciplinary centers and orphan drugs

Unfortunately, as therapy for liver disease blossoms, health care systems worldwide are facing problems sustaining support, and a significant number of patients may not receive appropriate treatment. As a further complication, measures taken by most health care systems to improve sustainability focus on cost-containment, reduction of coverage and system capacity. As pointed out in foundational work on Value-Based Health Care, health care operates within a “zero sum competition” where fixed sums of resources are divided among providers, hospitals, pharmaceutical companies and other components of a disjointed health care system (1,2). As Albert Einstein remarked ‘we cannot solve a problem with the same thinking we used to create it.’ In the last decade, a number of innovative solutions have been proposed by applying approaches and technologies typical of other economic and social disciplines. An important example is value-based health care delivery that calls for re-orienting health care delivery towards value for patients (defined as outcomes that matter to patients per cost sustained to deliver the care) (1,2). Value-based health care delivery is increasingly becoming the dominant logic and strategy of health decision making, at every level, local practice, hospital, state and national and examples can be found in hepatology and other medical practices (3-8).

Population health seeks the triple aim of better outcomes for a population, better experience for the patient and lower per capita costs (9). VBHC measures outcomes for each patient and these outcomes cumulate to affect population health. Thus, Value-based health care delivery is consistent with policy aiming to improve the health of the population. VBHC delivery attempts to understand the cost of care for each patient, providing insight that can be used for care process improvement and waste reduction. Those outcomes costs can be aggregated to show the average (or per capita) costs across a population. In fact, clinical decision-making and improvement require data on the outcomes and costs of patients with similar conditions, in addition to population averages. So through systematic meaningful outcome measurement the value-based delivery links to population health.

Health care for a given condition can be assessed using several measures of structure, process and outcome. The reader is referred to review articles detailing the differences among these measures (34). In brief, structure measures relate to the attributes of the setting in which care occurs and if these are conducive to safe and good care, while process measures inform about what is actually done to provide care based on best evidence or practice available. Finally, outcome measures capture the effects of care processes on the actual health and well-being of patients and populations (34) (respectively clinical outcomes and patient-relevant outcomes).

“Reimbursement and regulatory incentives for participating in VBHC.

The concept that provider payment should be linked to patient outcomes can be traced to Ernest Codman (1869-1940), a surgeon who first advocated “End Result” reimbursement. His ideas resulted in his loss of hospital privileges (Massachusetts General Hospital) and his being characterized by his colleagues as being “maniacally obsessed” with the idea that every hospital should follow every patient long enough to determine whether their treatment was successful (10). Modern advocates of value-based health care include Porter and Teisberg who have illustrated how current healthcare delivery systems fail to focus on competition at a disease or condition level and therefore raise barriers to high-value coordinated care, especially of complex conditions such as chronic liver diseases (1,2). Despite enormous efforts to shift from volume-based strategy and fragmented care delivery service to value-based strategy with integrated care delivery teams, progress has been slow because measures of health outcomes that reflect what matters to patients and that track these outcomes throughout the full cycle of care are scarce (11). As an example, the National Quality Measures Clearinghouse contains nearly 2000 quality indicators, but 7% are actual outcomes and less than 2% are patient-reported outcomes (12). The Hospital Compare website maintained by Centers for Medicare and Medicaid Services (CMS) includes 123 different measures, of which 102 track process compliance (13).

In the United States, infrastructures designed to link patient and population health outcomes to provider reimbursement has been defined in several publications and legislative acts. In March 2011, the Agency for Health Care Research and Quality published the National Quality Strategy for Quality Improvement in Health Care , in response to a mandate contained within the Patient Protection and Affordable Care Act (ACA). The overarching recommendations from this report include a) a commitment to a defined national strategy for achieving highest value, b) a process to implement and refine that strategy, c) proposals for care delivery through systems that emphasize clinical coordination, and d) a movement to value-based reimbursement based on metrics that reflect health outcomes, quality of care, access to care, population-based disparities, and efficiency

(14). Additionally, ACA mandated that the CMS become a proactive driving force in moving away from fee for service payment to providers. As such, CMS changed from a passive payer to the key driver towards value-based health care, as Porter and Teisberg discussed (2). After the November 2016 election results, the ACA may be repealed or significantly altered, but legislation mandating the migration to value-based care (Medicare Access and CHIP Reauthorization Act or MACRA) was passed with bi-partisan support and may remain in force (see below).

The National Quality Strategy, published in 2011, helped corral multiple disparate quality improvement initiatives into a more coordinated effort with six domains (priorities) as organizing principles (14). Interestingly, none of the principles focused on patients' functional outcomes or relief from pain and suffering that occurs during or due to their health care (8). The National Quality Forum, National Priorities Partnership and the Measures Application Partnership (see ref 7 for further discussion) worked to develop quality indicators and outcome measures. Unfortunately, as Porter et al have pointed out, the measures were created by specialty societies working independently and emphasizing process metrics strictly within control of their constituent providers at single points of care (2,17). Generally, process measures are easier to achieve agreement upon since they are controllable by care providers (2). Clinical teams surely need to understand their processes and ensure that these processes are safe and appropriate; however, process measures track inputs rather than results for patients. Process measures may not be indicative of patients' outcomes, nor do they follow results throughout the entire cycle of care for complex patients such as those with chronic liver diseases.

MACRA, signed into law in 2015, accelerated the shift towards value-based reimbursement. On May 9, 2016, CMS published a "Proposed Rule" open for public comment detailing the structure of Medicare value-based reimbursement and metrics that will be used. As a result of public commentary and feedback, CMS modified the ultimate structure of MACRA as published in the "Final Rule" in October 2016. Essentially, providers that care for a threshold number of Medicare beneficiaries are mandated to participate in one of two options that link payment to clinical results or face substantial payment reductions for Part B Medicare payments. (<https://www.federalregister.gov/documents/2016/11/04/2016-25240/medicare-program-merit-based-incentive-payment-system-mips-and-alternative-payment-model-apm>)

The first option is termed Merit-based Incentive Payment System. This option rests on existing incentive programs and combines three aspects of a provider's care into a single value that is used to modify Part B Medicare payments. The four components are a) the clinician's participation in Medicare's Physician Quality Reporting System, b) adoption of electronic medical records as defined by Meaningful Use (MU) and c) a practice improvement program and d) an

assessment of cost derived from Medicare claims called a Quality and Resource Use Report (QRUR). Medicare initially estimated that 12,608 gastroenterologists (including hepatologists) will have allowed Part B charges totaling \$1.6 billion and the MIPS program will have an aggregate positive payment adjustment of \$34 million compared to historical trends. Thirty-eight percent of gastroenterologists were estimated to have a negative payment adjustment. (data on file at www.gastro.org). With publication of the Final Rule, requirements eased somewhat so the burden on providers was lessened.

The second option practices may choose for Medicare reimbursement is termed an “Alternative Payment Model” (APM). While still being fully defined, practices can choose to assume financial risk for outcomes by using bundled payments, belonging to an accountable care organization or incorporating other emerging financial and clinical risk models. As defined in the Final Rule, neither MIPS nor APM’s truly capture digestive disease-related health outcomes that are important to patients, payers and purchasers of care. External payment incentive programs are difficult to define and administer and are subject to constraints mandated by medical specialty societies that are responsible for creating metrics. The Department of Health and Human Services has set goals of having 90% of Medicare’s traditional fee-for-service payments linked to quality by 2018 and of shifting 50% of all reimbursement into APM’s by the same date (18). Despite these goals, current programs still fall short of the ultimate goal of supporting value-based care with valid outcome measures that are meaningful and clear to patients as well as providers, and that separate excellent from merely competent care.

Shifting from volume to value-based care using the current infrastructure and process measures will continue to be fraught with difficulties and will engender cynicism and frustration among providers. Physician burnout, resulting from multiple new regulations included in the MACRA legislation, conversion to a new diagnostic coding system and adoption of electronic medical records, is real and jeopardizes the quality of patient care. If, however, hepatologists can shift the focus away from rewards for volume and towards rewards for providing high value care that fosters competition to improve outcomes for patients across the full cycle of their care, we believe a sense of professionalism and satisfaction can be restored.

Clinical Outcome indicators for Value-Based Care in Hepatology

Measures specific to hepatology have been virtually non-existent within the current incentive payment structure (19), so developing a new set of measures is important to advance value-based care and accelerate improvement in the measured outcomes. Hepatitis C-specific measures have

been part of Physician Quality Reporting Systems since 2008 but are all process measures. These are currently under review and none reflect long-term patient outcomes or outcomes during care. Others have developed preliminary recommendations focused on managing a population with chronic liver disease over a year's episode and utilizing the strength of health system-wide electronic records (20). Work to develop valid assessment of outcomes for patients with cirrhosis has been advanced by rigorous definition and the creation of new measures are in development (see below).

Value-Based Medicine is entering the field of Hepatology. Studies applying these concepts to liver diseases have begun to appear in high impact specialty journals (21-25), and ad hoc symposia have been organized by major international (AASLD and EASL) and national (AISF) liver societies. The concept of VBHC is different from that of evidence-based medicine (EBM), as it is based on outcome data, rather than guidelines. EBM and VBHC, though are not mutually exclusive, as the first is used to define procedures, while the second tests the clinical and economic outcomes of those procedures. EBM, and the concept of appropriateness, had an important impact in reducing the risks and the costs associated with the management of patients with liver diseases. A range of process indicators for liver disease is also available. Among others, the study from Kanwal et al(22,23) deserves a special mention for its effort to provide evidence-based process indicators for the treatment of patients with liver cirrhosis. While useful to guide treatment, process indicators do not provide information about clinical outcome and have a short life-span due to learning and innovation, and may have a weak correlation with the actual outcomes. On the other hand, the systematic measurement of clinical outcomes over an adequate period of observation provides the information needed to drive practice improvement and cost reduction at the patient level, and ultimately increase the sustainability of care (1-3,15).

To be applicable for VBHC, outcomes measures need to capture the full cycle of care, not just a single encounter and not only at a distant time. For example, measuring only the inpatient mortality in cirrhotic patients with spontaneous bacterial peritonitis would miss the three-month mortality due to kidney failure that is preventable using albumin infusion during the acute episode. At the other extreme, waiting until end of life to assess avoided disease progression would delay the learning about improved functional outcomes and reduced pain during the patients' lives. Furthermore, indicators should be easy to collect and be generated from data obtained from the daily practice and from patients (1-4,11-13, 16).

Because of the long natural history of liver diseases, in addition to long-term outcomes, such as transplantation or death, surrogate end-points are needed. Unfortunately, these are available and validated only for a few conditions. The problem can be approached by tracking patient-reported

functional outcomes throughout the cycle measuring not only if, but how well the patient lives(15,16).

Progression to intermediate stages also represents outcomes during the cycle. In most chronic liver conditions, no matter the etiology, the patient progresses through a series of defined stages from chronic hepatitis to compensated cirrhosis, to decompensated cirrhosis or/and hepatocellular carcinoma and eventually transplant or death. The risk of progressing from one stage to the other varies according to the specific etiology, treatment, and comorbidities. Each of these stages represents a measurable outcome to avoid and is characterized by a specific functional status.

For example, in Type 2 diabetes, long natural history elapses before kidney failure, blindness or gangrenous foot ulcers develop. Rather than wait for these major events, relevant outcomes during care can be tracked over time, measuring the changes in patients' functional capabilities over time during care. These measures shed light for patients and their care teams on improvement or reduction in health outcomes over time and throughout the care cycle without waiting for years to make meaningful assessments (8). Patient reports of these measures can be collected as part of ongoing clinical practice. These ongoing assessments are particularly important because Type 2 diabetes is a reversible disease, so outcomes during care indicate whether the patient is succeeding with management or progressing to more advanced stages disease.

Similarly, in most liver diseases, (from viral hepatitis, to alcoholic and metabolic and autoimmune liver diseases), effective treatment is possible and leads to significant reduction in the risk to progress to cirrhosis and its complications. Also in patients that have already progressed to cirrhosis, etiologic treatment, life-style changes and treatment of comorbidities can significantly reduce the risk of decompensation, whereas, management of complications, early referral for transplantation and critical care management, will improve survival.

A comprehensive set of outcome measures compatible with VBHC requirements is not yet available, but work is in progress and several studies have been reported at international meetings (26-30). Liver units interested in adopting a VBHC approach need outcome measurements to document their own improvement over time, for comparing outcomes and value of care between referral centers, as well as for fact-based decision-making. Each institution should collect measures that can better capture each specific organizational reality. Even though the numerical value of each measure clearly varies according to local practices and organizations, its measurement is key to performing local, national and international benchmarking. Plus, every organization can benchmark against its own previous measures to track improvement. Moreover, as these measures are used, they evolve as clinical teams suggest refinements to the measures as well as ways to improve patients' outcomes (11-17).

A comprehensive set of outcome measures for hepatologists could be used for a range of purposes, from implementation of quality improvements to measuring results among tertiary centers, sharing learning among centers, making referrals or seeking telemedical consults and reimbursing based on value of care. Last, but not least, outcome measures are a strong instrument to evaluate the value of novel drugs and technologies.

Patient-level Value-Based Health Care Delivery

In VBHC, clinical outcome indicators are usually one component of a multidimensional outcome measure set, paired with a parsimonious choice of patient-reported outcome (PROs) for each major condition or stage. For example, The International Consortium of Outcome Measurement (www.ichom.org) has convened groups of clinicians and patients to choose validated measures for a number of conditions, not yet including liver disease.

Establishing measure sets is a major undertaking. Only a few studies have focused on liver disease; however, the benefit to both the patients and the system, of developing or choosing validated PROs will be enormous. New studies will need to augment the existing quality of life metrics to capture the patient perspective on meaningful outcomes for specific conditions or specific sets of medical circumstances.

The existential purpose of health care is to help patients improve their quality of life and dignity of death. The goal of increasing value for patients recognizes both the purpose of health care and the need to manage costs. At the level at which value is created, patients usually can readily identify the outcomes that matter (31). For patients with a particular condition, a handful of functional outcomes describe significant differences in their quality of life – during the care experience and after completion. Patients with head and neck cancer are concerned not only with survival, but also with retaining the abilities to swallow, eat and talk. Patients with osteoarthritis want to be free of pain and able to pursue their normal activities. Measuring a small set of functional outcomes, not hundreds of processes, allows teams to accelerate improvement of those results. This supports professional excellence.

Outcomes during care are critical measures for patients with chronic or lifelong conditions or patients at the end of life since the duration of care may be the rest of these patients' lives. For every patient, the clinical team can track success with a small set of patient reported outcomes that reveal improvement or decline. From the patient perspective, three categories of outcomes are robust: capability (or functional outcomes), comfort (reduction in pain and anxiety due to the disease) and calm (reduction in the chaos of appointments, instructions and bills to regain time focusing on one's life)(15). In practice, comparison of these measures for individuals over time,

and analysis of trends across patients accelerates professional learning and improvement in value for patients(15,31).

With appropriate risk adjustment, the multidimensional outcomes for patients as well as costs of care can be compared across different protocols, different clinicians, different clinical teams or different locations. By looking at results from many patients, physicians and teams can gain insight on whether their patients fare better or worse than similar patients that they have treated, than patients treated elsewhere or than patients treated with different care processes. This learning and the improvement it drives are the primary reasons for outcome measurement. Competition to improve results for patients with similar circumstances or conditions, rather than competition to have the most or best hospital facilities, drives ongoing improvement in value for patients and supports the inherent professional incentives of physicians and other clinicians.

Because outcome measurement appeals to professionalism, it inspires improvement. The Martini Klinik, which has measured the functional outcomes of each of its prostate cancer patients for the past 10 years, has achieved remarkable improvement in its patients' functional outcomes.(32). Its patients suffer from incontinence and impotence at roughly one-fifth of the national average for prostate cancer patients, despite Gleason scores indicating appropriate (and arguably even too-delayed) use of surgery (33). Its surgeons enjoy shared excellence and resulting professional satisfaction; though they are regularly recruited to be department chairs elsewhere, none have left the team. In contrast, trying to create quality-based pay before developing meaningful measures can create resistance to change. Rather than paying for process compliance (P4P), payment can support transition to value-based care delivery by enabling bundled payment for clinical teams that integrate patient care and measure outcomes. Bundled payment allows the teams to attract volume by achieving excellence, and benefiting from the efficiencies they gain through higher margins(2). Team-based pay also enables alignment of incentives within organizations paid by capitation, though most payer-provider systems still use fee for service or volume-based rewards for payment within their systems. The potential to align medical success with financial success makes value a sustainable goal for patients, clinicians and society, supporting the triple aim of population health.

Conclusions

The time has come for value-based health care principles in the field of hepatology to augment our current Evidence-based Medicine. Much remains to be done, in terms of developing patient-level outcomes and cost analysis. Investments are needed in terms of informatics

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infrastructure and for funding outcomes research and the development of condition-specific Patient Reported Outcomes of capability, comfort and calm. The reward however will be huge, as this approach will re-orient competition and decision-making in health care from increasing volume of treatments to improving the value of the care for the patient. No matter how simple and obvious this statement may seem, its implications are enormous for the patients, for physicians and for society. Hepatologists also must work with health care systems to provide data on costs of care, the denominator of the value equation (4). They must become leaders to generate and monitor both clinical and patient-reported outcomes that represent the numerator of value for patients and the professional aspirations of hepatologists.

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Table 1 Frequently Used Acronyms

AASLD	American Association for the Study of Liver Diseases
ACA	Affordable Care Act
AHRQ	Agency for Health Care Research and Quality
CHIP	Children's Health Insurance Program
CMS	Centers for Medicare and Medicaid Services
EASL	European Association for the Study of the Liver
EBM	Evidence-Based Medicine
MACRA	Medicare Access and CHIP Reauthorization Act
MIPS	Merit-based Incentive Payment System
MU	Meaningful Use
P4P	Pay for Performance
PRO	Patient-Reported Outcome
PROMs	Patient Reported Outcome Measures
QRUR	Quality and Resource Use Report
SBP	Spontaneous Bacterial Peritonitis
VBHC	Value-Based Health Care

For the benefit of the reader the table lists a series of acronyms that are frequently used in publications and legislation concerning value-based health care. Not all of them are used in this manuscript