EDITORIAL



Monitoring for Ascites in Cirrhosis Using Patient-Generated Health Data: No Longer a Remote Possibility

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Cirrhosis is a chronic condition with a well-documented high symptom burden, morbidity, mortality and costs [1–3]. Asrani et al. reported that in-hospital mortality from cirrhosis exceeds that from other serious comorbidities such as congestive heart failure or chronic obstructive pulmonary disease [1]. Ascites is a particularly common and costly cirrhosis complication that has been the target of several interventions aimed to reduce hospitalization frequency and length by improving timely access to paracentesis and redesigning acute models of care [4, 5]. Though telemedicine and "automated hovering" interventions are particularly promising modalities that can improve access to care and inbetween visit monitoring, the evidence base for their clinical effectiveness and optimal implementation is still building for cirrhosis [6, 7].

In this issue of *Digestive Diseases and Sciences*, Bloom et al. evaluated the costs and outcomes of a telemonitoring intervention for ascites in cirrhosis [8]. The authors developed a decision-analytic model that examined payerperspective costs of a standard-of-care compared with a telemonitoring intervention among 100 simulated patients at a tertiary care center over a 6-month horizon. The model was based on the premise of an initial hospital admission for tense ascites. Model assumptions were straightforward: the standard-of-care model assumed a rehospitalization for gradually reaccumulated ascites after the index

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admission. The telemonitoring intervention model assumed that patients would receive a Bluetooth-connected scale to monitor weight after the index hospitalization and alert clinical staff about weight re-accumulation at a prespecified threshold. This proactive management would trigger outpatient up-titration of diuretics, timely outpatient paracentesis, and/or additional outpatient visits as needed. Model inputs were based on the location of the first encounter, ascites volume, treatment response, and complications. Based on the available evidence, the authors assumed that a telemonitoring program would modestly increase outpatient utilization while decreasing inpatient utilization by about 15%. The costs of telemonitoring were assumed to be \$50,000 USD for 6 months, accounting for staffing and technology. The authors, using the most likely outcome probabilities, concluded that the telemonitoring intervention would be \$167,500 less expensive than standard-of-care. Sensitivity analyses that varied the outcome probabilities and costs by $\pm 10\%$ and $\pm 20\%$, respectively, also yielded cost savings ranging from \$9400-\$340, 200 for the entire program.

The authors are to be applauded for this detailed analysis that provides an initial evidence base for potential cost savings of telemonitoring for ascites in cirrhosis. As with any modeling exercise, the results are based on the robustness of model assumptions and inputs, which are always simpler and more idealized than in the real world. This simplicity does not detract from the major conclusions but does raise additional questions worthy of future study.

As with any such analysis, the authors do acknowledge important limitations when interpreting their results, namely that hospital costs, clinical practice, and patient/program adherence may vary. Beyond the noted limitations, there are multiple unknown variables that should be studied in the future in order to add robustness to such analyses. For example, model inputs of the clinical effectiveness of remote monitoring are based on small, largely single center studies based at tertiary care centers. Larger, randomized studies in real-world settings or detailed program evaluations in settings where remote monitoring is accepted as the standardof-care are in order. Care fragmentation (patients seeking care at multiple hospitals), variable hospital resources (e.g., availability of outpatient paracentesis), and patient/caregiver digital literacy and comfort with technology are difficult to measure in real-world settings; these factors can impact cost assumptions, patient adherence to technology, healthcare utilization, and outcomes. Care model alternatives without the need for nonstandard equipment such as Bluetooth scales can also be evaluated. For example, a simple text message with a photo of a patient's weight from a traditional scale or a telephone call with a self-reported weight sent to the clinical team could yield even more cost savings and be more broadly acceptable to patients struggling with technology. Additionally, patient comorbid conditions and complications such as encephalopathy could alter their ability to self-manage, thereby challenging model assumptions and inputs. Since broader societal costs such as patient and caregiver costs with required time off work, transportation, absenteeism, and impact on quality-of-life are unknown, these factors could render remote monitoring-based models even more cost-effective if measurable. Finally, impacts on clinician workflow such as additional time spent in managing clinical alerts or time saved by telephone calls or patient counseling with automated functions could be factored into cost-effectiveness analyses.

Despite the many unknowns, Bloom et al. have taken an important initial step into analyzing the utility of remote monitoring in cirrhosis. Their data, which are particularly timely, invite a broader discussion of the use of patientgenerated health data (PGHD) in clinical care for cirrhosis and other high-cost chronic conditions. PGHD are defined as health-related information created, gathered, or inferred from patients or caregivers to address a health concern [9]. Though the increased uptake of consumer technologies such as smartphones and wearables has increased the availability of PGHD, best practices addressing how to combine clinical data with PGHD remain to be determined.

The potential of PGHD is remarkable in cirrhosis since it enables in-between visit monitoring of weight, clinical symptoms, quality-of-life, and other meaningful outcomes. Nevertheless, there are multiple patients/caregivers, technological, clinician, and health-system challenges to the implementation of PGHD into the standard-of-care. Patients and caregivers may face technological challenges and may have privacy concerns about data transmission; without clear guidance, it is not evident whether PGHD would belong to the patient, healthcare system, or developer, and whether or not the data could be shared with payers or other third parties. There may be concerns about the validity and accuracy of data transmitted from patient devices; most home health monitoring devices are not regulated by the Food and Drug Administration. If not integrated efficiently, PGHD may disrupt clinician workflow and add to their clinical workload, discouraging use. Health systems may lack the information technology infrastructure needed to ensure secure data storage and transmission, trained personnel to manage the data, and institutional buy-in needed to integrate such programs into clinical care. Furthermore, in the current state, welldefined economic incentives for using PGHD await evidence that their use is cost or time saving and is adequately reimbursed. To overcome these challenges, researchers, healthsystems, payers, and policymakers need to collaborate in order to generate a solid evidence base for the optimal implementation of these technologies from a clinical, technological, and cost perspective, all within a patient-centered, ethical and legal framework. Decompensated cirrhosis presents an ideal complex, chronic, and high cost condition to test these new models of care.

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Declarations

Conflict of interest The authors declare that they have no conflict of interest.

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