Oncology Value Framework in the Era of Digital Health Technology: A Patient-Centric Approach

Won Chan Lee, PhD; **R. Scooter Plowman, MD, MBA, MHSA**; **George M. Savage, MD, MBA**, Proteus Digital Health Inc, Redwood City, CA, USA

KEY POINTS

Oncology health apps have a great potential to be widely adopted by healthcare systems, payers, pharmacy benefit managers, specialty pharmacies, and drug manufacturers in the coming years.

Optimal digital health solutions should ultimately seek to bridge the current patient-clinician communication gaps, particularly for symptom management outside of the immediate care environment. Achieving this reduces unnecessary clinical visits, particularly to emergency department and hospitals.

Digital health technologies can fill current gaps in delivering care to oncology patients, constructively disrupting the current health delivery environment while rebalancing the existing oncology value framework.

RISING TIDE IN THE SEA OF DIGITAL HEALTH APPLICATIONS

They are within easy reach. They are ubiquitous. Intertwined within mobile devices, they enable access to timely health information and care team communication, mimicking behavioral coaches. Indeed, digital health technologies and health applications ("apps") have begun transforming the modern healthcare ecosystem. According to IQVIA, more than 318,000 health apps and 340 consumer-wearable devices are now available worldwide, with more than 200 health apps being added each day.[1] While there are myriad apps focusing primarily on chronic care management, such as diabetes, hypertension, and asthma, more than 1000 oncology-specific apps are already available.[2]

> It is an ideal time for digital health technologies to assume a value-based role in generating sufficient clinical, real-world evidence demonstrating improved patient care, and quality of life and satisfaction while reducing healthcare costs.

These oncology-focused digital technologies attempt to address the various needs of cancer patients and their care communities. Many focus on disease management, while some promote side effect reporting and others address survivorship. Most of these apps and tools are not seeking approval through the US Food and Drug Administration (FDA) regulation or pursuing interoperability with electronic medical records (EMRs). As such, patients, caregivers, and care teams find it confusing to distinguish toys and tools from treatments and medical devices. The current flood of new entrants into the oncology care paradigm fails to complete the communication loop linking patients and their clinicians. Many oncology patients and caregivers are increasingly burdened by assuming the role of nurses as they care for themselves or loved ones. From the time of filling and taking prescriptions until their next clinical visit, many challenging clinical decisions may arise for patients. Between visits, there is a dearth of communication, with most interactions initiated by patient and caregiver. Almost nowhere is this problem more pronounced than with oral oncolytics. In the growing transition from intravenous (IV) to oral chemotherapy, many patients are left to their own devices when navigating the often complex dosing regimens, challenging and sometimes debilitating side effects, and complicated prognostic criteria. Considering that 8 out of the 14 new active substances launched in 2017 for oncology were oral therapies, these concerns are not trivial.[2]

New entrant apps, those in development, and the incumbents gaining in popularity claim to address pieces of this fragmented communication chain. Telemedicine and virtual patient visits have become increasingly common, especially for those who live in remote areas or for postsurgical patients less able or willing to travel long distances. Particularly for symptom management outside of the immediate care environment, digital and mobile outreach are becoming commonplace. Such digital solutions offer even more potential when the data captured in the apps are shared with care teams and integrated into EMRs. This offers clinicians easy access to relevant and timely patient health data to inform appropriate and opportune interventions. Based on the intrinsic value that can be captured by the current oncology care environment, these connected health apps have a great potential to be widely adopted by healthcare systems, payers, pharmacy benefit managers, specialty pharmacies, and drug manufacturers in the coming years. There seems to be "a rising tide" in the digital era of oncology care delivery. A key question remains: How will digital health technologies fit into the value stream in the current US oncology care models? >

CURRENT GAPS IN THE ONCOLOGY VALUE ASSESSMENT FRAMEWORKS

How is the value of oncology care or oncolytic therapy being evaluated in the US healthcare environment? For cancer care in particular, assessing "value" has long been a conundrum. Several countries ascribe to quality-adjusted life year (QALY) benchmarks to define thresholds of value by which to justify scarce resource allocations. Yet, value varies by stakeholder and is inherently individual. There is a divergence of views because perceived value depends on the evaluating stakeholders, unique characteristics of patients and caregivers, and how the evidence of value is captured. Given the strain that oncology costs are placing on the overall healthcare value chain, there is a clear need to refine the value assessment frameworks (VAFs). According to recent estimates from the National Cancer Institute, cancer care-related costs are projected to grow by 39% ($172.8 billion) by 2020.[3] Cancer drug spending was estimated at $37.8 billion in 2016, representing a 33% increase ($9.4 billion) for new drugs alone since 2010.[4]

Beginning around 2010, the increasingly high cost of oncology drugs and obvious trend toward precision medicine resulted in greater value, and subsequent interest in the development and application of cost-effectiveness tools and VAFs. These have focused mostly on payers and providers at large health systems and integrated delivery networks with an eye towards outcomes-based pricing arrangements with manufacturers, (eg, the DrugAbacus developed at Memorial Sloan Kettering Cancer Center and frameworks developed by the American Society for Clinical Oncology [ASCO], the National Comprehensive Cancer Network [NCCN], and the Institute for Clinical and Economic Review [ICER]). In the 5 years, we have firmly entered the "value era" in oncology, with VAFs now serving as a mechanism for payers, providers, and healthcare systems to systematically incorporate varying value-based contributors into the discussion when considering expensive therapeutic options.[7]

All too often, however, the value assessment viewpoints and criteria of payers and health systems are misaligned with those of patients and their caregivers. Often, the foremost features and elements of compassionate care are the first to miss the cut of reimbursement. Many VAFs do not include all the benefits that are important to patients. What matters most to a patient with cancer who is going through a complex and intimidating regimen? How can we maximize the patient's quality of life, regardless of the prognosis? How should these value frameworks consider patients' day-to-day concerns and their willingness to make trade-offs? In 2016, through partnership with FasterCures, Avalere developed a Patient-Perspective Value Framework.

> The digital era creates an opportunity to more closely align multistakeholder value with the patient at the center.

Although this value framework was primarily developed by incorporating patient-centered outcomes, preferences, and patient/caregiver costs, even this VAF in its current form falls short of adequately being specific in many key factors of primary interest to patients. This includes ability for adequate and timely reporting of symptoms and outcomes, monitoring and demonstrating laudable adherence, choosing between medication convenience factors (oral versus IV), communicating with their care team, and ultimately capturing their satisfaction for overall care delivered to them.

Undoubtedly, these frameworks will become more sophisticated as payers and policy makers begin integrating them into episodic and global payment models and clinical and reimbursement protocols. It is an ideal time for digital health technologies to assume a value-based role in generating sufficient clinical, real-world evidence demonstrating improved patient care, and quality of life and satisfaction while reducing healthcare costs. This in turn promotes the integration of more patient-centric value metrics into future VAFs.

"VALUE ERA" + "DIGITAL HEALTH ERA" = THE FUTURE OF PATIENT CARE IN ONCOLOGY

Digital health technologies can fill current gaps in delivering care to oncology patients, constructively disrupting the current health delivery environment while rebalancing the existing oncology VAFs.

An appropriate starting point is to ask how we best take care of patients, adding emphasis on the patient experience — what they go through, how they feel, and how they live when they are not in the clinic. Cancer patients spend the vast majority of their time outside the clinic; this is where digital health can be impactful in amplifying the patient voice, providing the care team visibility into the patient experience and incorporating it into routine care.

Recent studies have demonstrated the survival benefits of recording patient-reported outcomes (PROs). Delivering these insights back to care teams in a timely manner enables precision intervention. One landmark study by Basch, et al showed how electronic data from a questionnaire of 12 common symptoms when transmitted back to the care team enabled timely management and augmented overall survival. Closer management and coordination reduced the frequency of emergency department (ED) visits and hospital admissions for patients and health systems. More importantly, it reduced the symptom burden between office visits of patients and facilitated increased regimen completion. This intervention led to improvements in overall quality of life, fewer ED visits, and a greater than 5-month survival benefit.[8]

Only through the recent arrival of digital health technologies has it become possible to transmit near real-time PROs, combined with objective data on medication-taking behaviors. With the advent of digital medicines (medications with sensors), such seemingly impossible real-world data that records chemotherapy tolerability and adherence is becoming a reality. Now the objective reliability of IV infusion therapy can be added to the convenience of oral medicines. Objective data is provided by (vs) digital medicines to the patient's mobile app. From there, with patient permission, the data is sent on to their clinicians. With the use of digital medicines, this closed-loop feedback of impatient therapy administration can now be replicated in ambulatory settings. Through enhanced "completion of therapy," patient quality of life and reduced symptom burden can be maximized, ideally leading to increased survival rates. Importantly, the care teams' juggling act (eg, symptom management,

dose titration, adherence verification, and cycle documentation) can be grounded in consistent, objective data. This facilitates greater adherence to therapy and further attention to meaningful PROs, enhancing therapy completion.

The optimal digital health solutions should ultimately seek to bridge the current patient-clinician communication gaps. Achieving this reduces unnecessary clinical visits, particularly to the ED and hospitals. Likewise, optimizing the proportion of doses ingested reduces medication wastage and unnecessary overtreatment. As such, the value for both the patients and healthcare stakeholders (eg, clinicians, caregivers, payers) can be simultaneously captured and rebalanced in favor of treatments with demonstrable real-world effectiveness. The *digital era* creates an opportunity to more closely align multistakeholder values with the patient at the center. This in turn helps future value assessment frameworks incorporate the latest elements of precision care delivery for the *value era* in oncology.

REFERENCES

1. IQVIA Institute. The Growing Value of Digital Health Evidence and Impact on Human Health and the Healthcare System November 2017. Available at: https://www.iqvia.com/institute/reports/the-growing-value-of-digital-health. Accessed June 19, 2018.
2. IQVIA Institute. Global Oncology Trends 2018. Available at: https://www.iqvia.com/institute/reports/global-oncology-trends. Accessed June 19, 2018.
3. National expenditures for cancer care. National Cancer Institute website. Available at: costprojections.cancer.gov/expenditures.html. Accessed November 27, 2017.
4. Johnson CY. We're spending $107 billion on cancer drugs, but is it worth it? *Washington Post.* Available at: washingtonpost.com/news/wonk/wp/2016/06/02/were-spending-107-billion-on-cancer-drugs-but-is-it-worth-it/?utm_term=.92c7d620ee69. Published June 2, 2016. Accessed June 19, 2018.
5. Snow J, Migliaccio-Walle K, Cameron A. Personalized Medicine Coalition. Available at: http://www.personalizedmedicinecoalition.org/Userfiles/PMC Corporate/file/PM_and_VAFs.pdf. Accessed June 28, 2018.
6. ASCO value framework update [press release]. Alexandria, VA: ASCO Press Center; May 31, 2016. Available at: asco.org/about-asco/press-center/news-releases/asco-value-framework-update. Accessed November 27, 2017.
7. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines) with NCCN Evidence Blocks. National Comprehensive Cancer Network website. Available at: nccn.org/evidenceblocks/. Accessed November 27, 2017.
8. Basch EM, Deal AM, Dueck AC, et al. Overall survival results of a randomized trial assessing patient-reported outcomes for symptom monitoring during routine cancer treatment. *J Clin Oncol.* 2017; DOI 10.1200/JCO.2017.35.18_suppl.LBA2 (epub ahead of print).