RETHINKING HTA

DO WE NEED A MORE PATIENT CENTRIC APPROACH TO HTA

JUNE 2025

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GIVING A VOICE TO CANADIANS LIVING WITH DISEASE

In recent years, the concept of patient centeredness has gained significant traction across various domains of healthcare. This paradigm shift has prompted a critical examination of how we evaluate the value of healthcare technologies and interventions. One area that warrants particular attention is Health Technology Assessment (HTA), a process widely used to inform decision making regarding the adoption and reimbursement of interventions (drugs/technologies). Recognizing the need to align HTA decision making with the needs and values of patients, there is a growing call to establish a patient centric approach to HTA. Reorienting the evaluation process to reflect the diverse perspectives, experiences, and priorities (values, unmet needs) of patients, empowering them as active partners in shaping healthcare policy and decision making.

While some progress has been made in recognizing the importance of patient input in the HTA processes, a comprehensive discussion and consensus on a patient centric HTA framework remains elusive. To ensure meaningful improvements in healthcare decision making, it is imperative that we collaboratively engage to reshape the way HTA is conceptualized, conducted, and applied for the shared goal of improving patient outcomes in a resilient and sustainable health system.

This *colab.paper* serves as a catalyst for rethinking HTA and seeks to ignite a call to action among the stakeholders involved in the process. Through partnerships and co-creation we can improve and strengthen the HTA process while also aligning to more patient centric values. We aim to develop shared goals that prioritize the patient's voice, perspective, wants, experiences, outcomes and unmet needs within the HTA process and encourage innovation in the methods employed to gather and incorporate this invaluable information. By integrating patient centricity into the HTA process, we can unlock the potential for more informed, equitable, inclusive and patient centric healthcare decision making.

Together, we can forge a path towards improved patient outcomes, enhanced patient partnerships in healthcare innovation, and a more responsive and inclusive healthcare system that truly places patients at the heart of the decision making process.

RETHINKING HTA. DO WE NEED A MORE PATIENT CENTRIC APPROACH

Health technology assessment (HTA) is defined as a multidisciplinary process that uses explicit methods to determine the value of a health technology at different points in its lifecycle. Informing decision making in order to promote an equitable, efficient, and high quality health system.[1] HTA is widely employed to support policy decisions regarding healthcare interventions, considering the balance between the benefits derived from new technologies and their associated costs. Currently, over 30 countries have implemented HTA, which relies on rigorous scientific evidence and expert deliberation to assess the clinical and cost effectiveness of emerging health technologies.[2]

Historically, HTA processes have focused primarily on clinical outcomes and economic metrics, such as cost-effectiveness analyses and quality-adjusted life years (QALYs). This approach has tended to overlook the experiences, values, and priorities of patients, families, and caregivers—the primary end users of health technologies.

In recent years, international and national initiatives have sought to address this gap. In 2014, the Health Technology Assessment International (HTAi) Interest Group on Patient and Citizen Involvement (PCIG) developed a set of values and quality standards to guide patient involvement in HTA processes. These standards have informed efforts in Canada, including the Canadian Drug Agency (CDA-AMC)'s development of a formalized framework for patient engagement.[3] In Québec, the Institut national d'excellence en santé et en services sociaux (INESSS) introduced a structured process for involving patients in the evaluation of medicines in 2017, which has since been refined following consultations with patient advocacy groups..

Despite these developments, significant variability remains in how HTA agencies define, implement, and operationalize patient involvement. While both CDA-AMC and INESSS have established standardized submission processes for patient input, these mechanisms are often limited in scope. They are currently not designed to capture the diversity of patient experiences or account for equity considerations in a systematic way. The current reliance on templated submissions constrains the ability of patients and advocacy groups to articulate nuanced, contextualized perspectives, particularly from underrepresented populations. Moreover, broader challenges persist in aligning HTA mandates, research agendas, and payer decision-making with patient defined needs.

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[1] O'Rourke, B., Oortwijn, W., & Schuller, T. (2020). The new definition of health technology assessment: A milestone in international collaboration. International Journal of Technology Assessment in Health Care. May 2020

[2] WHO. Health Technology Assessment

[3] CADTH framework for Patient Engagement in Health Technology Assessment. January 2022

Although several organizations across Canadian provinces are engaged in HTA, this paper will focus on the two national organizations, CDA-AMC and INESSS.

Current CDA-AMC value frameworks encompass the following dimensions

1. Clinical value
2. Unmet clinical need
3. Distinct social and ethical considerations
4. Economic considerations
5. Impacts on health systems

The previous framework included clinical benefit, adoption feasibility, economic evaluation, and patient based values

INESSS utilizes therapeutic value frameworks that consider the following aspects

1. Improves the health and well being of its users
2. Contributes to a better state of health and well being for the population in keeping with equity considerations
3. Optimises the use of resources to support their responsible and sustainable management
4. Fits into the organisational context of care and service delivery in a manner that contributes to strengthening the health and social services system
5. Fits into the societal context in such a way that it promotes its evolution towards the common good

The previous framework included the therapeutic value, reasonableness of the price charged, cost effectiveness ratio of the medication, impact that entering the medication on the list will have on the health of the general public and on the other components of the health and social services system; and advisability of entering the medication on the list, given the purpose of the basic prescription drug insurance plan of Quebec.

Health Technology Assessment (HTA) frameworks traditionally assess new technologies based on clinical outcomes and economic value, using tools like quality adjusted life years (QALYs) and incremental cost effectiveness ratios (ICERs). While these measures remain central to decision making, they often overshadow broader dimensions of value that matter to patients—including lived experience, treatment burden, and long term quality of life (QoL).

Both CDA-AMC and INESSS formally include patient input in the HTA process. However, the current frameworks lack clear thresholds or criteria for how this input is evaluated or weighed alongside clinical and economic evidence. As a result, patient perspectives—including value, needs, experience, and voice—remain peripheral to final decisions. Engagement often occurs at a single point in the process, and in the absence of feedback mechanisms or transparency, patients are left uncertain about how their contributions inform outcomes.

The lack of a formalized structure for integrating patient experience data contributes to a process where subjective and qualitative insights are undervalued. Without clarity on how elements such as treatment preferences, out of pocket costs, or caregiver burden are used in deliberations, patient contributions risk being perceived as symbolic rather than substantive. The HTA process still lacks the transparency to show how these insights influence recommendations.

Yet, patients and their representative groups consistently evaluate healthcare interventions through a much broader lens—one that includes quality of life, emotional and mental health, family impact, social and financial burden, and the ability to function in daily life. They consider not only survival but also how care is delivered, whether it is accessible, if it respects individual priorities, and how it aligns with personal and cultural values. These factors are often excluded from economic models, leading to decisions that fail to reflect the realities of those affected.

Current evaluations rarely capture the patient journey in full—from diagnostic delays to long term outcomes—and often omit the indirect and societal costs of illness, especially for conditions lacking measurable biomarkers or standardized outcomes (e.g., mental health or rare diseases). Tools used to measure QoL frequently miss the outcomes most relevant to patients. Moreover, real world data (RWD), patient reported outcomes (PROs), and patient generated evidence are often underutilized, despite their potential to enrich assessments with real life impact data.

To create a more patient responsive system, HTA must move toward an iterative, structured, and transparent model where patients are not just an input but active participants throughout the process. This means establishing clear frameworks for integrating patient experience data, recognizing the value of qualitative and social determinants of health, and ensuring alignment between patient preferences and reimbursement decisions. Without these reforms, we risk perpetuating a model of healthcare that is efficient on paper, but misaligned with the people it is meant to serve

The increasing cost of therapeutic innovations, alongside Canada's high per capita pharmaceutical expenditure and the growing demands on a resource constrained health system, underscores the imperative to reassess how value is defined and operationalized in healthcare decision making. Current Health Technology Assessment (HTA) frameworks predominantly assess value through the lens of economic efficiency—most notably via cost effectiveness analysis (CEA), incremental cost effectiveness ratios (ICERs), and quality adjusted life years (QALYs). While these tools offer a structured approach to evaluating trade offs, their centrality within HTA has inadvertently marginalized critical dimensions of patient centered care.

This economically driven paradigm constrains the ability to recognize and prioritize attributes of health technologies that are most relevant to patients, such as quality of life, convenience, personal values, equity considerations, and broader social impacts. As such, these frameworks often fail to align with the foundational principles of patient centricity, which call for the integration of diverse lived experiences, needs, and preferences into all stages of assessment and decision making.[4]

To advance a truly patient centric HTA model, value must be reconceptualized as a multidimensional construct. This requires moving beyond rigid, single metric approaches and embracing a more holistic and flexible framework—one that accommodates qualitative evidence, real world outcomes, and the contextual realities of patients and caregivers. A value framework that fails to reflect these elements risks reinforcing systemic inefficiencies and inequities, and ultimately, undermines the legitimacy and utility of HTA in supporting equitable access to innovation.[5]

THE PROBLEM. WHO DEFINES VALUE

The HTA process considers different stakeholder perspectives in the process, including payors, healthcare providers, manufacturers and patients and caregivers. These stakeholders may hold differing and potentially conflicting views on what constitutes value in a technology.[6] Reconciling these divergent perspectives becomes crucial for fostering a sustainable health system. So how do we define value?

In an article published in 2018 on ISPOR's initiative on value frameworks, the author (Eleanor M. Perfetto) claims that it did not sufficiently incorporate a patient perspective and suggested that this was a missed opportunity for assessing the value

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[4] Goetghebeur M.M., Wagner M., Khoury H. et al. Bridging health technology assessment (HTA) and efficient health care decision making with multicriteria decision analysis (MCDA): applying the EVIDEM framework to medicines appraisal. Med Decis Making. Mar-Apr 2012

[5] Thokala P, et al. Multiple Criteria Decision Analysis for Health Care Decision Making--An Introduction: Report 1 of the ISPOR MCDA Emerging Good Practices Task Force. Value Health. January 2016

[6] Wale, J.L., Thomas, S., Hamerlijnck, D. et al. Patients and public are important stakeholders in health technology assessment but the level of involvement is low – a call to action. Res Involv Engagem January 2021

of healthcare interventions.[7] Similar to the integration of real world evidence (RWE) alongside traditional trial data, we must also learn to include complementary subjective data within the value framework.[7]
To capture the complexity of health technologies and address methodological challenges involving diverse stakeholder opinions, HTA needs to adopt multidimensional and transdisciplinary methods. However, the absence of a framework aligning the needs and interests of these stakeholders presents a challenge in achieving this comprehensive approach, even if the desire to do so was strong.

Currently, patients are requested to provide input into the HTA process at a time that is too late to revisit the design of the study, the data being collected or the primary endpoint(s). Implementing patient perspectives earlier into the process, (a proactive rather than the current reactive approach) can potentially influence the scope and outcome of the study.

REDEFINING VALUE

HTA has historically grounded its understanding of value in clinical and economic metrics—most commonly, cost effectiveness analyses and quality adjusted life years (QALYs). While such metrics offer a standardized foundation for comparison, they reflect a narrow interpretation of value, one that too often overlooks the lived experience of patients. Concepts such as 'value,' 'unmet need,' and 'value judgments' remain ill defined within many HTA frameworks, and their interpretation tends to default to budget impact thresholds or willingness to pay models that prioritize system level affordability over individual level benefit.[8]

Patient perspectives—where they are included—are typically captured through patient reported outcomes (PROs) in clinical trials or through observational and qualitative studies. While informative, these mechanisms are rarely integrated into deliberative decision making in a way that meaningfully shifts the outcome.The role of experiential value judgments, especially in cases of incomplete or uncertain evidence, remains underdeveloped and inconsistently applied.[9]

The pandemic offered a critical inflection point—laying bare the profound interdependence between health, the economy, and social stability. It underscored

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[7] Perfetto, E.M.. ISPOR's Initiative on US Value Assessment Frameworks: A Missed Opportunity for ISPOR and Patients. February 2018.
[8] Grammati S., et al. The Role of Patient Experience in the Value Assessment of Complex Technologies – Do HTA Bodies Need to Reconsider How Value is Assessed? Health Policy. March 2021
[9] A call to action to harmonize patient-reported outcomes evidence requirements across key European HTA bodies in oncology

that the value of healthcare interventions cannot be measured by clinical efficacy and cost alone. It must also account for broader societal and economic impacts: workforce participation, caregiver burden, mental health, and long term quality of life.

For example, a cancer drug with a high upfront cost may substantially reduce disease burden, allowing patients to return to work, reduce reliance on emergency services, or avoid long term disability—benefits that are seldom captured in conventional assessments. A cost based analysis may flag such a therapy as unaffordable, while a broader value lens would recognize its potential for long term savings and improved population health.[10] A truly patient centered approach to value reframes the core questions of HTA. Rather than asking solely, *“Does this technology work, for whom, and at what cost?”*, we must ask, *“For whom does this intervention meaningfully improve life, and how well does it address the lived realities of those affected?”* This shift demands a framework that is as invested in quality of life and equity as it is in fiscal sustainability—a model that reflects not just the system’s willingness to pay, but society’s responsibility to care.

CLOSING THE GAP ON PATIENT CENTRICITY

Over the past decade, there has been a growing emphasis on patient centricity across healthcare systems—shaping research agendas, policy development, regulatory frameworks, and models of care. However, in the context of Health Technology Assessment (HTA), this shift has yet to translate into a coherent, consistent, or actionable framework. While the inclusion of patient input has been formally recognized within Canadian HTA processes, a truly patient centric approach—one that meaningfully shapes how value is defined and assessed—remains elusive.

Patient perspectives offer critical insights that extend beyond clinical outcomes and economic modeling. They illuminate the realities of treatment burden, quality of life, unmet needs, and the broader social context in which health technologies are used. Yet these insights continue to be underutilized. To close the gap, HTA stakeholders—including agencies, health economists, industry, and patient organizations—must move beyond procedural inclusion and work collaboratively to redefine the parameters of value. This paper calls for coordinated action: to align on shared goals, modernize HTA methodologies, and embed patient experience as a core pillar of value assessment.

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[10] Hanna, S. Crisis to Catalyst. Using lessons learned from COVID19 to prioritize cancer care in Canada. May 2023

THE CHALLENGE. CLEAR DEFINITIONS.

PATIENT INVOLVEMENT. ENGAGEMENT. PARTNERSHIPS

A foundational barrier to advancing patient centric HTA is the lack of clarity around key terms such as *involvement*, *engagement*, and *partnership*. These terms are often used interchangeably, despite referring to distinct models of interaction. Without clear, shared definitions, stakeholders risk misalignment in both intent and execution.

Establishing precise definitions is not a semantic exercise—it is a necessary step toward operationalizing meaningful engagement. Doing so helps delineate expectations, structures, and outcomes across the HTA continuum. Whether patients are contributing evidence, advising on process design, or co-developing frameworks, the mechanisms of participation must be clearly articulated. Only then can the full scope of patient, caregiver, and community perspectives be equitably integrated into decision making processes.

THE PURPOSE

This paper seeks to challenge conventional HTA practices by initiating a national dialogue on what it truly means to embed patient centricity into healthcare decision making. As oncology and rare disease landscapes evolve—with increasingly targeted therapies, adaptive trial designs, and smaller patient populations—the limitations of existing HTA frameworks become more apparent.

Embedding patient centricity is not simply about incorporating patient perspectives as an additional input. It demands a structural reorientation of how value is conceptualized and evaluated. It requires moving beyond singular metrics like QALYs and ICERs and building multidimensional frameworks that account for what patients prioritize: quality of life, timely access, equity, autonomy, and societal impact. The goal is to construct a more inclusive, transparent, and responsive system that aligns better with the values of all stakeholders and delivers outcomes that matter.

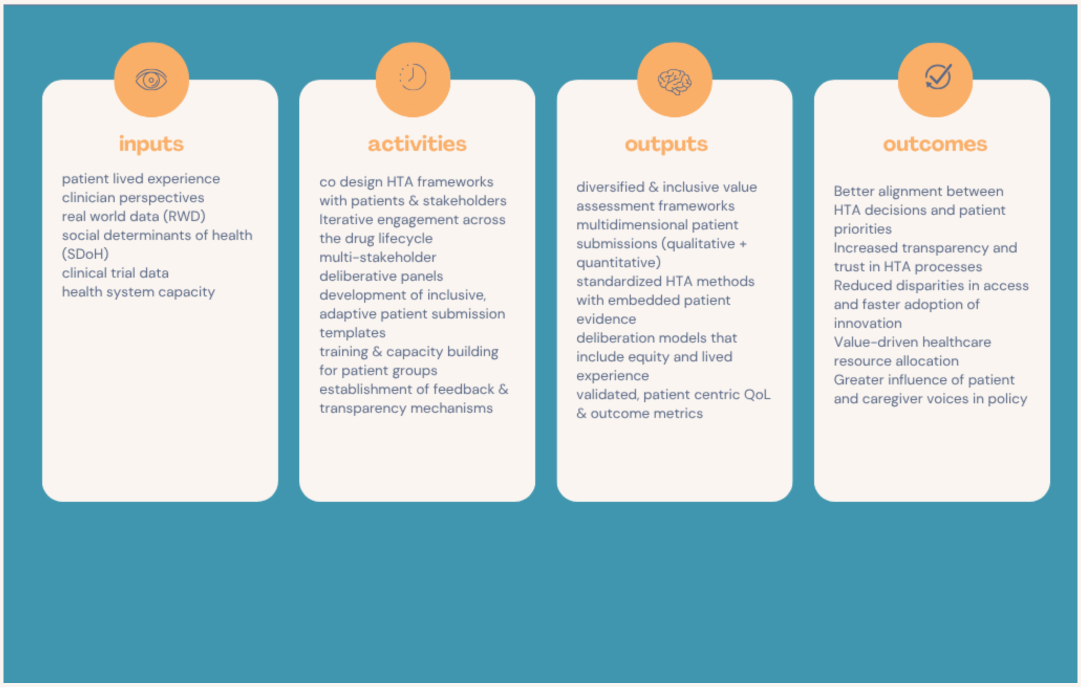
THE QUESTIONS WE MUST ASK

This work invites critical reflection on the foundational assumptions of HTA:

1. Whose definition of value is reflected in current HTA processes? Do patient and clinician perspectives carry meaningful weight, or are they treated as peripheral to economic analysis?
2. Are current patient submission templates adequate? Do they reflect the diversity of patient populations and experiences, or do they inadvertently privilege certain voices while excluding others?

3. How can we collect richer, more relevant patient data? Are surveys sufficient, or do we need new tools—such as social listening, patient journey mapping, or real time qualitative feedback—to truly understand patient experience?
4. Do current HTA frameworks adequately reflect quality of life, caregiver burden, and treatment impact? How can these outcomes be systematically evaluated and incorporated into recommendations?
5. How are social determinants of health integrated into value assessment? Do HTA processes expose or obscure disparities in access, outcomes, and costs—particularly for marginalized or underserved populations?
6. Is HTA equipped to evaluate therapies developed through non traditional clinical trials? Should clinical research evolve to better support the needs of HTA, and should HTA evolve to better accommodate emerging evidence models?
7. Can uncertainty be managed through stakeholder alignment? What role can patient and clinician input play in reducing uncertainty, and how might shared goals be developed to support decisions that reflect broader societal value?
8. What would it mean to involve patient experts and advocates across the lifecycle—from drug discovery to reimbursement? How can we move toward co-creation, rather than consultation, in shaping the future of health technology assessment?

patient centric logic model for HTA



inputs

patient lived experience
clinician perspectives
real world data (RWD)
social determinants of health (SDoH)
clinical trial data
health system capacity

activities

co design HTA frameworks with patients & stakeholders
Iterative engagement across the drug lifecycle
multi-stakeholder deliberative panels
development of inclusive, adaptive patient submission templates
training & capacity building for patient groups
establishment of feedback & transparency mechanisms

outputs

diversified & inclusive value assessment frameworks
multidimensional patient submissions (qualitative + quantitative)
standardized HTA methods with embedded patient evidence
deliberation models that include equity and lived experience
validated, patient centric QoL & outcome metrics

outcomes

Better alignment between HTA decisions and patient priorities
Increased transparency and trust in HTA processes
Reduced disparities in access and faster adoption of innovation
Value-driven healthcare resource allocation
Greater influence of patient and caregiver voices in policy

MAKING THE CASE

Despite significant discourse around patient engagement in healthcare, Health Technology Assessment (HTA) continues to lag in embedding patient experience as a formalized, valued input. Patients are often expected to participate in a system not designed for them—a system where even a positive HTA recommendation may not translate into meaningful or timely access. As noted in *Patient centered health technology assessment: a perspective on engagement in HTA* (2020), "even a favorable HTA decision does not guarantee access, but being involved and heard is crucial, regardless of the outcome." This insight captures a fundamental truth: engagement is not solely about influence—it is about legitimacy, trust, and ethical practice.

Patient involvement should not be contingent on the ability to change outcomes, but on the principle that those most affected by health system decisions deserve a seat at the table. Their inclusion fosters transparency, strengthens accountability, and ensures that decisions are rooted not only in data, but in lived reality.

Moreover, as seen in the development of recommendations for Lyme disease management (*Developing recommendations for the diagnosis and treatment of Lyme disease*, 2020), the integration of diverse patient perspectives—through varied qualitative and deliberative methods—helped navigate a controversial and complex evaluative context. This example illustrates that structured, well facilitated patient engagement can enhance—not hinder—the integrity and comprehensiveness of HTA. It provides a roadmap for how inclusive dialogue can support consensus building, especially in areas marked by uncertainty or fragmented evidence.

In both examples, engagement was not tokenistic. It was integral to the assessment process itself—bringing clarity, legitimacy, and nuance to evaluations that might otherwise remain abstract or overly technical.

Patient centered health technology assessment: a perspective on engagement in health technology assessment by three patient organizations and a health technology assessment body October 2020
'For patients, they know even a favourable HTA decision does not guarantee access but being involved and heard is crucial, regardless of the outcome. Collaboration enables consideration of their priorities'.

Developing recommendations for the diagnosis and treatment of Lyme disease: the role of the patient's perspective in a controversial environment December 2020
'The combination of methods to collect and integrate patients' knowledge and patient associations' perspectives helped develop a comprehensive understanding of a controversial object of evaluation'

THE CALL TO ACTION

If we are serious about building a healthcare system that delivers meaningful outcomes, advances equity, and reflects the lived realities of patients, then we must fundamentally rethink how value is defined and assessed. Health Technology Assessment (HTA) remains a powerful mechanism for shaping access to innovation, but its prevailing frameworks continue to privilege narrow, system centric metrics over patient informed insights.

A patient centric approach to HTA is not simply a matter of improved communication or increased transparency—it demands structural transformation. This includes realigning incentives across the healthcare ecosystem; modernizing data collection to capture real world experience, caregiver burden, and social context; defining outcome measures that reflect what patients actually value; and embedding patient input at the earliest stages of evidence development and deliberation.

Such transformation requires deliberate, coordinated action among HTA bodies, payors, regulators, researchers, clinicians, industry, and patient organizations. The current model—reliant on outdated assumptions and disconnected engagement mechanisms—is no longer fit for the complexity of today's therapies or the diversity of patient populations they are meant to serve.

We do not need another framework for consultation. We need a commitment to co-creation. That begins with asking better questions—not only about cost and clinical efficacy, but about impact, equity, and lived experience. It means committing to shared goals and building the infrastructure, capacity, and culture to elevate patient knowledge as essential evidence.

Now is the time to act—not incrementally, but decisively. A patient centric HTA system is not just more just; it is more effective, more trusted, and ultimately more capable of guiding sustainable, responsive innovation in healthcare.

CONCLUSION. RETHINKING HTA FRAMEWORKS

The need to reform HTA is not theoretical—it is practical, urgent, and grounded in the changing landscape of health innovation. As therapies grow more personalized, populations more diverse, and outcomes more complex, our methods of evaluating value must evolve in kind.

This paper offers a logic model for a patient centric HTA framework, one that builds upon existing infrastructure but reorients its core assumptions. It requires:

1. Recognizing the multiplicity of value from the patient's perspective,
2. Embedding engagement at all stages of the HTA lifecycle,
3. Creating inclusive and equitable mechanisms for input, and
4. Operationalizing trust through transparency and feedback.

We must move from seeing patient perspectives as complementary to clinical and economic data, to recognizing them as essential evidence in their own right. Only then can HTA fulfill its promise: to guide health system investments that are not only cost effective, but meaningful, equitable, and just.

As the health system stands at the intersection of economic constraint and scientific promise, we must ask ourselves not only what technologies we fund, but whom the system is designed to serve. A patient centric HTA is not an aspiration—it is an imperative.

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