

Common Sense Oncology: outcomes that matter

Oncology needs a recalibrated approach that is more patient centred and prioritises equitable cancer care. An approach that prioritises patients' needs with treatments that improve survival and quality of life, promotes informed decision making, and ensures these treatments are accessible to all patients.

For both patients and clinicians, cancer treatment decisions are increasingly complicated. While some cancer treatments provide large benefits, many new approved treatments do not help patients live longer or better.^{1,2} All cancer treatments have side-effects, can cause substantial financial burden, and can result in lost time for patients spent in hospital rather than with friends and family. Thus, it is important to not only study and promote treatments that improve survival or quality of life (or both), but also to identify treatments that do not. Cancer systems now face a troubling paradox. In some circumstances there is substantial overuse of treatments with very small benefits, and at the same time many patients worldwide do not have access to the treatments that can make a very meaningful difference in their lives.

How have these problems arisen in modern cancer care? The reasons are multifactorial, but one key factor is the shift over the past few decades from predominantly publicly funded clinical trials designed to answer questions important to patients, to industry funded trials designed to achieve regulatory approval or commercial advantage.¹ Often the goal of improving and lengthening the lives of patients and that of making a profit for commercial organisations are not concordant. Industry's control of the research agenda has created a system that is predominantly focused on new cancer medicines at the expense of investigating new approaches to surgery, radiotherapy, palliative care, and prevention. This model is problematic for several reasons. Surgery and radiotherapy cure many more patients than cancer medicines, yet receive much less funding for research and delivery of care. Moreover, in many parts of the world the majority of individuals diagnosed have incurable cancer, yet lack access to adequate pain relief and palliative care.

Commercial interests, rather than patient interests, often drive cancer care and research, as seen by the mismatch between research spending on some cancers and their associated mortality and societal impact.³ In

some countries, new cancer medicines cost more than US\$200 000 per year, including those that do not help patients live longer.^{4,5} A substantial proportion of industry revenue is used for marketing campaigns to influence patients, policy makers, and oncologists, irrespective of clinical need.⁶ Industry marketing campaigns and media reports often hype marginal treatments, which contribute to overuse of cancer treatments with small or negligible benefits.⁷

Another factor that contributes to these problems is the absence of clear communication regarding the magnitude of benefit and risks associated with therapies. In the context of incurable cancer it is difficult for both oncologists and patients to balance hope with reality when discussing prognosis and treatment options. Patients and clinicians often feel compelled to do something when faced with progressive disease, even if that something has minimal benefit and causes side-effects. Clear and compassionate communication is necessary to ensure that patients make informed treatment choices, supported with honestly reported, evidence-based guidance from health-care teams that match individual goals and values.

Patients deserve better information and better care. To achieve this, paradigm shifts will be needed in education, research design and investment, policy, media and communication, and delivery of care.⁸ In April, 2023, global oncologists, academics, and patient advocates met at Queen's University (Kingston, ON, Canada). The objectives of this meeting were to establish core tenets to guide development of a patient-centred Common Sense Oncology (CSO) movement, develop goals and an action plan, and disseminate CSO guiding principles so that oncology trials and treatments are focused on outcomes that matter.

The mission, vision, and guiding principles of CSO are shown in the panel. CSO will focus initially on three pillars: evidence generation, evidence interpretation, and evidence communication. This work will be patient centred and emphasise health equity. CSO projects will seek solutions for problems with measurable targets to influence cancer research, education, delivery of care, and policy.

The first pillar is evidence generation, which aims to ensure that clinical trials use and report outcomes



Published Online
July 16, 2023
[https://doi.org/10.1016/S1473-2045\(23\)00319-4](https://doi.org/10.1016/S1473-2045(23)00319-4)

For more on **Common Sense Oncology** and to get involved see www.common-sense-oncology.org

Panel: Common Sense Oncology: outcomes that matter

Mission

To ensure that cancer care focuses on outcomes that matter to patients

Vision

Patients have access to cancer treatments that provide meaningful improvements in outcomes that matter, irrespective of where they live or their health system. To realise this vision, we aspire that:

- Patient outcomes that matter must be at the centre of every drug registration trial; and patient outcomes that matter should be the standard for every drug regulatory decision
- Reporting of trials is transparent and uses language that can be understood clearly by oncologists and patients
- Patients receive clear communication regarding treatment options that enables them to make informed decisions that are aligned with their personal goals and values
- The only treatments that are registered, reimbursed, and recommended are ones that meaningfully improve patients' lives
- Common Sense Oncology that is grounded in evidence-based medicine and critical appraisal becomes a core curricular component for oncology training programmes
- Health systems invest in both developing new treatments and ensuring that patients have access to and benefit from proven effective treatments

Guiding principles

- 1 Access to quality cancer care is a basic human right—no patient should be denied access to effective therapy or forced into financial catastrophe to access meaningful cancer care
- 2 Patient and societal needs should drive cancer research and delivery of care
- 3 Patient and public involvement is essential when making policy decisions
- 4 Patients should expect that recommended cancer treatments meaningfully improve their survival or quality of life
- 5 Shared decision making between patients and oncologists should be based on patient values and grounded in evidence-based medicine and critical appraisal
- 6 Cancer treatments should be fairly priced for the context in which they are used
- 7 Equity in access to high quality care should be prioritised as much as innovation and new treatments
- 8 Comprehensive patient-centred cancer care includes timely integration of psychosocial oncology, survivorship, and palliative care

that matter to patients. The randomised controlled trial (RCT) remains the gold standard to evaluate efficacy of new cancer therapies. Although meaningful improvements in patient outcome have come from pivotal trials, there are growing concerns about problems in design and reporting of some RCTs.⁹ This work stream will seek to offer solutions to improve trial design and reporting to ensure they prioritise outcomes that matter to patients.

The second pillar is evidence interpretation, which aims to foster critical thinking by clinicians. To assist patients in decision making, oncologists must be well-trained in critical appraisal. Individual oncologists and guideline committees should not recommend

treatments that are based on poorly designed or poorly reported trials that show marginal benefits. This work stream will aim to empower oncologists to make sound clinical decisions aligned with outcomes that matter to patients.

The third pillar is evidence communication, which aims to improve patient, public, and policy maker understanding of cancer treatment options. The clinical and research communities in oncology must communicate clearly with all stakeholders in the cancer system. Lack of clear communication can lead to unrealistic expectations among patients and hype within oncology societies and the media; this in turn can drive promotion of treatments that provide marginal clinical benefits to patients.¹⁰ This work stream will look at ways of facilitating better informed decision making with patients; engagement with policy makers; and work with journalists to ensure that media reports are balanced, contextualised, and less sensational.

CSO will promote interventions that measurably improve the lives of patients. We will celebrate well conducted trials and promote effective treatments but we will also speak up about and challenge interventions that might cause more harm than good. CSO welcomes engagement from all stakeholders—especially patient advocacy groups. CSO will educate and empower the next generation of oncologists to push our field to do better for patients. We will seek to decrease global and regional inequities in access to affordable high-quality care. Improvements in the generation, interpretation, and communication of evidence will help close these gaps and move our field closer to a future in which a patient's outcome is not determined by where they live, what they can afford, or the strength of a marketing campaign. The CSO initiative will undoubtedly evolve over time, but our core mission will continue to ensure that cancer care and innovation is focused on outcomes that matter to patients rather than the commercial bottom line.

AG reports consulting fees from Seattle Genetics and speaking honoraria from Curio. BW reports research funding from Bristol Myers Squibb, Ontario Institute of Cancer Research, Queen's University, National Breast Cancer Foundation of Australia, and the Kidney Cancer Research Network of Canada; and honoraria from AstraZeneca. WvdG reports institutional research grants from Eli Lilly, Boehringer Ingelheim, and SpringworksTx; and institutional consulting fees from SpringworksTx, PTC Therapeutics, and Agenus. ES-P-d-C reports speaking honoraria from Lactrealis and is on the Board of Directors of the American Society of Clinical Oncology. SS reports travel support from Queen's University. FYM reports consulting fees from Cancer em foco, AstraZeneca, and IASLC. BLM reports speaking honoraria from Servier Pharmaceuticals. SB reports

honoraria for advisory boards from Taiho, Astellas, Merck, and Amgen. DG reports consulting fees from Vivio Health; stock ownership in TailorMed and Vivio Health; and serves as Board Member of Optimal Cancer Care Alliance. BG reports consulting fees from Vivio Health. KH reports research support from Pfizer. DK reports speaking honoraria from Amgen and MSD. KK reports consulting fees from Vivio Health and stock ownership in Vivio Health and Cadex Genomics. DC is the Editor-in-Chief of *The Lancet Oncology*. All other authors declare no competing interests. The opinions expressed by the authors are their own and this material should not be interpreted as representing the official viewpoint of the US Department of Health and Human Services, the National Institutes of Health, or the National Cancer Institute.

The CSO organising committee gratefully acknowledges Robert J Shillman PhD (Doctor Bob) for his support of the initial planning meeting in April, 2023.

**Christopher M Booth, Manju Sengar, Aaron Goodman, Brooke Wilson, Ajay Aggarwal, Scott Berry, David Collingridge, Avram Denburg, Elizabeth A Eisenhauer, Ophira Ginsburg, Daniel Goldstein, Sanjeeva Gunasekera, Nazik Hammad, Kazunori Honda, Christopher Jackson, Deme Karikios, Kevin Knopf, Rachel Koven, Bernard L Marini, Deborah Maskens, Fabio Y Moraes, Ghulam Rehman Mohyuddin, Bishesh Sharma Poudyal, C S Pramesh, Felipe Roitberg, Fidel Rubagumya, Sally Schott, Bhawna Sirohi, Enrique Soto-Perez-de-Celis, Richard Sullivan, Ian F Tannock, Dario Trapani, Michelle Tregear, Winette van der Graaf, Verna Vanderpuye, Bishal Gyawali*
booth@queensu.ca

Queen's University, Kingston, ON, K7L 3N6, Canada (CMB, BW, SB, EAE, NH, FYM, BG); Tata Memorial Hospital, Mumbai, India (MS, CSP); University of California San Diego, San Diego, CA, USA (AG); King's College London, London, UK (AA, RS); The Lancet Oncology, London, UK (DC); Hospital for Sick Children, Toronto, ON, Canada (AD); National Cancer Institute, Rockville, MD, USA (OG); Rabin Medical Center, Tel Aviv, Israel (DG); National Cancer Institute, Maharagama, Sri Lanka (SG); Aichi Cancer Centre, Nagoya, Japan (KH); University of Otago, Dunedin, New Zealand (CJ); University of Sydney, Sydney, NSW,

Australia (DK); University of California San Francisco, San Francisco, CA, USA (KK); Kingston, ON, Canada (RK); University of Michigan, Ann Arbor, MI, USA (BLM); Guelph, ON, Canada (DM); University of Utah, Salt Lake City, UT, USA (GRM); Civil Service Hospital, Kathmandu, Nepal (BSP); Hospital S rio-Liban s, S o Paulo, Brazil (FRo); Rwanda Military Hospital, Kigali, Rwanda (FRu); Medford, OR, USA (SS); Balco Medical Centre, Raipur, India (BS); Instituto Nacional de Ciencias Medicas y Nutricion Salvador Zubiran, Mexico City, Mexico (ES-P-d-C); Princess Margaret Cancer Centre, Toronto, ON, Canada (IFT); University of Milan, Milan, Italy (DT); National Breast Cancer Coalition, Washington, DC, USA (MT); Netherlands Cancer Institute, Amsterdam, Netherlands (WvdG); National Center for Radiotherapy, Oncology, and Nuclear Medicine, Accra, Ghana (VV)

- 1 Del Paggio JC, Berry JS, Hopman WM, et al. Evolution of the randomized clinical trial in the era of precision oncology. *JAMA Oncol* 2021; **7**: 728–34.
- 2 Michaeli DT, Michaeli T. Overall survival, progression-free survival, and tumor response benefit supporting initial US Food and Drug Administration approval and indication extension of new cancer drugs, 2003–2021. *J Clin Oncol* 2022; **40**: 4095–06.
- 3 Wells JC, Sharma S, Del Paggio JC, et al. An analysis of contemporary oncology randomized clinical trials from low/middle-income vs high-income countries. *JAMA Oncol* 2021; **7**: 379–85.
- 4 Del Paggio JC, Sullivan R, Schrag D, et al. Delivery of meaningful cancer care: a retrospective cohort study assessing cost and benefit with the ASCO and ESMO frameworks. *Lancet Oncol* 2017; **18**: 887–94.
- 5 Beasley D. New U.S. cancer drug prices rise 53% in five years -report. 2022. <https://www.reuters.com/business/healthcare-pharmaceuticals/new-us-cancer-drug-prices-rise-53-five-years-report-2022-11-02/> (accessed June 13, 2023).
- 6 Booth CM, Detsky AS. From the \$80 hamburger to managing conflicts of interest with the pharmaceutical industry. *BMJ* 2019; **365**: l1939.
- 7 Rubagumya F, Galica J, Rugengamanzi E, et al. Media coverage of cancer therapeutics: a review of literature. *J Cancer Policy* 2023; **36**: 100418.
- 8 Gyawali B, Booth CM. Cancer treatments should benefit patients: a common-sense revolution in oncology. *Nat Med* 2022; **28**: 617–20.
- 9 Tannock IF, Amir E, Booth CM, et al. Relevance of randomised controlled trials in oncology. *Lancet Oncol* 2016; **17**: e560–67.
- 10 Weeks JC, Cook EF, O'Day SJ, et al. Relationship between cancer patients' predictions of prognosis and their treatment preferences. *JAMA* 1998; **279**: 1709–14.

Establishing a *Lancet Oncology* Commission on the humanitarian crisis of cancer



The idea for this *Lancet Oncology* Commission on the humanitarian crisis of cancer emerged in 2022 in response to the shared concerns of a group of clinicians, scholars, and health policy leaders about the growing imbalance in the attention and resources directed to the biomedical and technological aspects of cancer care, compared with its humanitarian dimensions.¹ It was clear that enormous resources had been invested in biomedicine in the 50-year-old “war on cancer”, a global quest for its cure launched by an act of legislation in the USA.² However, it appeared that the relative neglect of the human dimensions of cancer care during this period had resulted in what we have termed a “humanitarian crisis of cancer”. This crisis has

been amplified throughout the world by the growing burden of cancer, particularly in low-income countries where costly therapies are a distant dream.

The aims of this Commission are threefold. First, we aim to document and quantify the imbalance in resources directed to elucidating the causes of cancer, improving detection, and prolonging survival, compared with those primarily intended to enhance quality of care, relieve suffering, and improve the well-being of individuals with cancer and their families. This documentation will include an examination of the lived experience of these individuals and their families and the psychological, financial, sociocultural, and political factors that shape the experience and outcomes of