Article published online: 2025-10-30

Data-Driven Realism: Why Every Oncologist Must Analyze and Publish Their Clinical Outcomes

Sandeep Muzumder[1]

[1] Department of Radiation Oncology, Apollo Hospital, Bhubaneswar, Odisha, India

Ind J Med Paediatr Oncol

Address for correspondence Sandeep Muzumder, MD, Department of Radiation Oncology, Apollo Hospital, Bhubaneswar, Odisha, India (e-mail: sandeepmuzumder@gmail.com).

Introduction

Oncologists are at the front lines of cancer care. They navigate a complex landscape of rapidly changing treatments, technologies, and patient expectations. In this dynamic environment, it is essential for oncologists to carefully examine and share their clinical data. This practice is not just an academic task; it is vital for fostering a realistic understanding of cancer outcomes. It helps prevent undue influence from market-driven innovations and ensures optimal patient-centered care. Such care focuses on prevention and early intervention instead of resorting to last-minute technological fixes that can often be misleading.

Validation for Real-World Outcomes

The primary reason for oncologists to conduct thorough data analysis and publication is to build a grounded and realistic perspective on cancer outcomes. This perspective should remain clear of theories and marketing hype from the pharmaceutical and medical device industries. An oncologist's real-world data (RWD) provides a clear view of treatment effectiveness within their specific patient population.[1]

The pharmaceutical and medical device industries are powerful innovators, but they also respond to market forces. New drugs and technologies often launch with great fanfare and impressive efficacy rates from highly controlled clinical trials. While these trials are crucial for regulatory approval, they frequently operate under strict criteria that might not apply to the diverse patient populations encountered in everyday practice. Without solid internal data, oncologists risk being influenced by market narratives, which could lead to an overly optimistic and unrealistic view of treatment success for their patients. For example, a new targeted therapy might show excellent response rates in a clinical trial. However, an oncologist who analyzes its own patient group—made up of individuals with various health challenges, genetic differences, or different levels of access to care—could discover that the actual outcomes are less impressive.

While randomized controlled trials (RCTs) are considered the gold standard for evaluating drug efficacy, real-world evidence (RWE) analyses are increasingly challenging their findings, as seen in recent literature. For example, in clinical trials, sorafenib was shown to substantially improve the overall survival of patients with advanced hepatocellular carcinoma, extending it by 2 to 3 months compared to a placebo.[2,3] A later Surveillance, Epidemiology, and End Results (SEER)-Medicare database analysis of patients receiving sorafenib in clinical practice, a less selective group, found that their survival was much shorter.[4] Similarly, patients with castration-resistant prostate cancer who received docetaxel plus prednisone in a clinical trial had considerably better outcomes, including improved survival and less toxicity, than those who received the same treatment outside of a trial.[5,6] Again, when cetuximab combined with radiotherapy was shown an alternate standard of treatment for locally advanced head and neck squamous cell carcinoma with lesser toxicity since the Bonner study (IMCL 9815).[7] But subsequent clinical practice showed inferior outcome with increased toxicities.[8,9] This was confirmed in recent trials not supporting the routine use of cetuximab in a curative setting.[10] This finding supports the idea that the positive results from RCTs for new cancer treatments may not be fully replicated in routine clinical practice, where patients are less selected and can experience worse outcomes and more side effects.

This does not overlook the value of new therapies; it aims to provide a realistic view of their effectiveness in real life. By publishing these real-world outcomes, oncologists enrich

DOI https://doi.org/10.1055/s-0045-1812850.
ISSN 0971-5851.

Thieme Medical and Scientific Publishers Pvt. Ltd., A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

the understanding of a drug's performance, highlighting potential gaps between trial results and everyday practice. This openness encourages better conversations with patients about their prognosis and treatment expectations, building trust and enabling shared decision-making based on a complete, honest picture. Their data acts as a reality check, helping oncologists stay grounded in their expectations for their unique patient population instead of being swayed by theoretical maximums.

Prioritizing Prevention Over Futile Technological Interventions

The second important reason for oncologists to audit and share data is to improve patient care. This approach helps prevent unnecessary toxicity and challenges the dangerous misconception that technology can merely "fix anything" when problems arise. The true error lies not just in the technological design but in the serious mistake of depending on a safety system to make up for ignoring established protocols. The blind trust in technology or advanced interventions without fully understanding their utility and potential may risk patients in real-time treatment.[11]

In oncology, the urge to use every available technological advancement or cutting-edge drug, especially as a patient's condition worsens, can be overwhelming. Oncology today features modern imaging, complex molecular diagnostics, advanced radiation systems, and strong systemic therapies. While these advances are transformative, they can also pose risks and lead to toxicities. Without carefully analyzing their clinical data, oncologists may overly rely on these tools, mistakenly assuming that more technology guarantees better outcomes, especially in critical situations. Importantly, we also have strong supportive care options like intensive care units (ICUs), powerful antibiotics, and advanced life support. These tools are vital and they can help within their established limits.

However, problems occur when oncologists treat these supportive measures and advanced technologies as an ultimate safety net, thinking they can rescue any situation without considering the patient's vulnerabilities. Medical professionals sometimes push patients to their physical limits. This may involve ignoring a patient's age or health issues, missing early warning signs, and relying on rescue measures instead of prevention.

A systematic review showed underreporting of toxic deaths in clinical oncology trials possibly due to low autopsy rates.[12] These might overestimate the effects of newer intervention while underreporting toxic deaths. In a SEER database analysis of 7,366,229 patients, 241,575 noncancer deaths (15.9%) were recorded in the first year following a cancer diagnosis. Patients have a 2.34-fold higher risk of dying from noncancer causes, such as cardiovascular and infectious diseases, compared to the general population. This risk is highest in the first month following a cancer diagnosis.[13] These may suggest probable deaths related to cancer-directed therapies. The side effects of cancer treatments should be prevented or detected early with monitoring, not just addressed after they become severe. An oncologist who carefully tracks and evaluates their patients' experiences with treatment side effects might notice trends that enable earlier interventions or even proactive measures. Their data could show, for example, that certain patient profiles face higher risks for specific adverse events, leading to closer monitoring or different treatment plans from the beginning. For example, by employing sepsis surveillance and the prompt use of antibiotics and Granulocyte colony-stimulating factor (G-CSF), along with early hospitalization, when necessary, reduced the occurrence of sepsis-related early deaths in patients with head-and-neck undergoing chemoradiation.[14] This forward-thinking approach, driven by RWD, is far superior and kinder than depending on ICU admission as a last resort. Another study examined the benefit of the audit in decreasing 30-day mortality by considering factors that may be associated with an increased risk of chemotherapy-related death.[15]

By sharing these real-world insights, especially about managing side effects, early warning signs, and the appropriate boundaries of supportive care, the broader oncology community gains greatly. It fosters sharing practical knowledge that reveals what truly works and what can be an ineffective or even harmful technological illusion when pushed too far.[14,15] Feliu et al developed and validated a highly accurate tool which can help physicians making decisions in elderly patients with cancer planned for chemotherapy using simple parameters like stage, Eastern Cooperative Oncology Group Performance Status, activities of daily living, serum albumin, body mass index, and hemoglobin.[16] This shared understanding can help develop more effective, evidence-based guidelines for preventing or managing crises, leading to safer, timely patient care focused on true benefits instead of last-minute, misleading "fixes" born from overreliance on an imagined safety net.

Ultimately, oncologists' commitment to examining and sharing their clinical data is not just an academic task; it is a deep commitment to truth, realism, and patient safety. By grounding themselves in their own data, they gain a realistic view of what treatments can genuinely achieve. By recognizing limitations and potential for harm, they avoid the illusion of technological perfection, focusing on prevention and early intervention. This dedication to insights based on data empowers oncologists to provide more transparent and effective patient-centered care, ultimately changing what it means to practice optimally in the complex world of oncology. In this direction, the U.S. Food and Drug Administration (FDA) had issued a document named "Framework for FDA's Real-World Evidence Program" to evaluate and use RWE to support regulatory decisions for drugs and biological products.[17] Also, to evaluate the potential use of RWE to help support the approval of new indications for already-approved drugs or to satisfy postapproval study requirements.

Patient Consent
Patient consent is not required.

Funding
None.

Conflict of Interest
None declared.

Acknowledgments
The author would like to acknowledge and thank all staff at the Department of Radiation Oncology, Apollo Hospital, Bhubaneswar, Odisha, India.

References

1 Wilson BE, Booth CM. Real-world data: bridging the gap between clinical trials and practice. EClinicalMedicine 2024;78(78):102915
2 Cheng AL, Kang YK, Chen Z, et al. Efficacy and safety of sorafenib in patients in the Asia-Pacific region with advanced hepatocellular carcinoma: a phase III randomised, double-blind, placebo-controlled trial. Lancet Oncol 2009;10(01):25–34
3 Llovet JM, Ricci S, Mazzaferro V, et al; SHARP Investigators Study Group. Sorafenib in advanced hepatocellular carcinoma. N Engl J Med 2008;359(04):378–390
4 Sanoff HK, Chang Y, Lund JL, O'Neil BH, Dusetzina SB. Sorafenib effectiveness in advanced hepatocellular carcinoma. Oncologist 2016;21(09):1113–1120
5 Templeton AJ, Vera-Badillo FE, Wang L, et al. Translating clinical trials to clinical practice: outcomes of men with metastatic castration resistant prostate cancer treated with docetaxel and prednisone in and out of clinical trials. Ann Oncol 2013;24(12):2972–2977
6 Tannock IF, de Wit R, Berry WR, et al; TAX 327 Investigators. Docetaxel plus prednisone or mitoxantrone plus prednisone for advanced prostate cancer. N Engl J Med 2004;351(15):1502–1512
7 Bonner JA, Harari PM, Giralt J, et al. Radiotherapy plus cetuximab for squamous-cell carcinoma of the head and neck. N Engl J Med 2006;354(06):567–578
8 Albarmawi H, Cullen KJ, Mehra R, Onukwugha E, Goloubeva O. Cost-effectiveness of concurrent radiation with cetuximab or chemotherapy in older patients with oropharyngeal cancer. J Comp Eff Res 2022;11(08):595–607
9 Stanbouly D, Philipone E, Morlandt AB, Kaleem A, Chuang SK, Patel N. Adverse events secondary to cetuximab therapy in head & neck cancer therapy and risk factors for serious outcomes. Oral Oncol 2022;131:105952
10 Krishnamurthy S, Ahmed I, Bhise R, et al. The dogma of cetuximab and radiotherapy in head and neck cancer - a dawn to dusk journey. Clin Transl Radiat Oncol 2022;34:75–81
11 Prakash G, Bakhshi S, Raina V, et al. Characteristics and pattern of mortality in cancer patients at a tertiary care oncology center: report of 259 cases. Asian Pac J Cancer Prev 2010;11(06): 1755–1759
12 Penninckx B, Van de Voorde WM, Casado A, Reed N, Moulin C, Karrasch M. A systemic review of toxic death in clinical oncology trials: an Achilles' heel in safety reporting revisited. Br J Cancer 2012;107(01):1–6
13 Yang P, Zheng Y, Chen J, et al. Immediate risk of non-cancer deaths after a cancer diagnosis. BMC Cancer 2021;21(01):963
14 Babu A, Noel Alexander F H, Muzumder S, Srikantia N, Udayashankar AH. Sepsis surveillance in patients with head-and-neck cancer undergoing chemo-radiation. Support Care Cancer 2024; 32(11):724
15 Khoja L, McGurk A, O'Hara C, Chow S, Hasan J. Mortality within 30 days following systemic anti-cancer therapy, a review of all cases over a 4 year period in a tertiary cancer centre. Eur J Cancer 2015;51(02):233–240
16 Feliu J, Pinto A, Basterretxea L, et al. Development and validation of an early mortality risk score for older patients treated with chemotherapy for cancer. J Clin Med 2021;10(08):1615
17 https://www.fda.gov/media/120060/download

