Title:
How can we ensure that the benefit to risk ratio of anti-cancer therapies is favourable?

Full Name:
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Name of the Institution:
Kidwai Memorial Institute of Oncology, Bengaluru

State:
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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):
Cancer treatment must be equitable right to all individuals. We as oncologist must be vigilant enough to triage and tailor treatment of each individual taking into consideration performance state, comorbidities, financial, family support, nutrition and patient preference. Standard of care and international guidelines cannot be incorporated in majority of patients owing to various secondary factors and hence tailored approach to cancer care is crucial. At the same time, we as cancer physician must be appropriate in triaging patient according to consideration of definitive treatment versus palliative care.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):
At times we do see patients in our OPDs and clinics who have received multiple lines of treatment and are still vigilant for continuation of treatment despite previous grade3/4 adverse events. It is our responsibility to counsel patient and attenders regarding risk and benefit of further continuation of treatment. Hence quality counselling and confidence building is very crucial. Counselling not just about the disease but in detail counselling and patient education is crucial.
There are many factors which must be taken into consideration while ensuring benefit to risk ratio consideration which mainly include age, comorbidities, frailty index, financial consideration, prior lines of treatment, performance status, family and social support, compliance to treatment, nutritional and psychological support, if elderly we must have geriatric assessment scale. We as oncologist must provide holistic care to our patients rather than just treating the disease. We must have a checklist in electronic medical record of the above-mentioned parameters and tick those in every visit to provide wholesome cancer healing programme. Although at times it might feel a bit tedious for individual patient, routine practice might expediate the process and strength quality care.
The biggest barrier towards providing quality care in resource limited centres is majority financial toxicity. We as oncologist must be updated of existing government schemes, Ngo support, clinical support services, clinical trial enrolment to ensure equitable quality cancer to all. At the same time, it is equally essential for regular advertisements through social media channels about the availability of existing services.
It is impossible to educate all the patients, caregivers and hence in modern era of digitalisation and AI, social media we must design dedicated clinician approved Apps which encourage patient and caregiver education and bridge the gap between the physician and patient. These apps must be wholesomely designed with correct information, disease nature, treatment options, adverse events, nutritional counselling, calorie intake, physical exercise monitoring, psychological support. Having such common platforms can solve the biggest problem of doctor shopping, Google and Chatgpt mastered patients and attenders and encourage building the mutual trust between patient and doctor and off course the caregivers.

In the era of precision medicine and evolving cancer care with availability of targeted molecules, oral and subcutaneous formulation and modified chemotherapy preparations to minimise toxicity maintain efficacy with significant prolongation in overall and progression free survival with enormous response rate it is possible to include a larger cohort in treatment strata and hence quality counselling is crucial to encourage subset of population who deny treatment over palliative care due to stigmata of cancer in society. There is hence a urgent need for standardised awareness programmes facilitating these strategies.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):
The physician factors in multiple parameters to assess benefits and risks of a particular regimen. The intended treatment should give more benefits, than the risk associated and it should be worth taking a risk in order to achieve a curative benefit—by reducing the number of supportive care admissions, but improving cancer related outcomes.
Outcomes of the therapy may be assessed by—remission rates, ORR, PFS, OS, QoL scores.
A comprehensive pre-chemo and post chemo list workup checklist can be prepared to assess chemo eligibility and assess short term toxicity and then a structured schedule for long term toxicity assessment also to be designed and followed.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):
In the clinic, regimen-based pre- chemo and post chemo checklist can be prepared, which can also be integrated with the HMIS software. It can be integrated in such a way that, any problem or deviation is flagged immediately and physician can take appropriate action and reduce the dose or defer giving chemo accordingly. Softwares may also be build in such a way that it identifies CTCAE grading of the toxicity and suggest suitable standard operating procedures to be done for the same.
Also patient may be provided with a 24/7 helpline number / mail id—where they can say their hospital ID and inform their problems or complaints. These can be managed by a dedicated paramedical staff under the guidance of duty doctors in the corresponding health centres. In this way, patients can be identified in the initial period of developing grade 1 toxicity itself and supportive care initiated at the earliest or if no alarming symptoms, they can be managed with reassurance and thereby preventing unnecessary hospital visits and anxiety.
To assess long term toxicity, patient may be informed of the parameters to be followed up in long term and reminders can be setup in their calendars for follow up without defaulting, also follow up dates can be noted down by receptionist and they can call the patient on the specified date for timely follow up.

If resource constraints is not an issue, an app can be created, with a patient and doctor interface, which enables the above said features in a seamless manner. The patient can be asked to fill the checklist by themselves, can be allowed to ask their doubts and queries, which will be assessed by the doctor in real time basis and appropriate action can be taken accordingly. For long term toxicity assessment, the same app may be used to integrate into patient's calendar and give timely reminder for follow-up, thereby reducing the default rate. App effectiveness can be assessed by case basis and periodic update and audit done to maintain the effectiveness.

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Habeeb K A

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

- Ensure continuous evaluation of benefit-risk balance throughout cancer treatment, not just at initiation
- Optimize treatment selection based on expected survival, response, and quality-of-life outcomes
- Individualize therapy by integrating patient-specific risk factors (age, comorbidities, performance status, organ function)
- Improve toxicity prediction, early detection, and timely dose modification to reduce treatment-related harm
- Strengthen structured documentation and multidisciplinary review of benefit-risk decisions at each treatment stage
- Enhance patient-centered decision-making through clear communication and shared understanding of goals of care
- Improve overall outcomes by ensuring treatment is tolerable, feasible, and aligned with patient priorities

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

In oncology, the goal is not just to treat cancer, but to ensure that the benefit of treatment clearly outweighs its risks for the individual patient. This balance is not fixed at the start; it must be reassessed continuously throughout the course of therapy.

Clinicians begin by evaluating the expected benefit in terms of survival outcomes such as overall survival and progression-free survival, along with response rates and the intent of treatment. In curative settings, even modest survival gains may justify significant toxicity, whereas in palliative settings, improvement in symptoms, quality of life, and functional independence often becomes equally important. The strength and consistency of evidence supporting the treatment also influence confidence in the expected benefit.

At the same time, risks are carefully assessed. These include the severity, reversibility, and cumulative nature of toxicities, along with patient-specific vulnerabilities such as age, performance status, organ function, nutritional status, and comorbid conditions. Drug interactions, prior treatment exposure, and pharmacogenomic factors further refine the risk profile. In practice, the key question is whether the patient is likely to tolerate, adhere to, and complete the planned treatment safely.

Once treatment begins, outcomes are monitored beyond tumour response alone. Clinicians track toxicity patterns, dose modifications, hospitalizations, quality of life, functional status, and patient satisfaction. Early recognition of toxicity allows timely dose adjustment or supportive care, preventing serious complications.
A structured approach improves consistency. Before starting therapy, expected benefits and major risks should be clearly documented and discussed. During treatment, toxicity and response should be reviewed at each cycle, with predefined reassessment points. Multidisciplinary input and active patient involvement ensure that decisions remain aligned with clinical goals and personal priorities.
Ultimately, a favourable benefit-risk ratio is achieved when treatment is individualised, continuously reviewed, and adapted based on real-time clinical and patient-reported outcomes.

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Dr Mohamed Thanish

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Tamil Nadu

Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):
To establish a structured, clinician driven evaluation schema for assessing the benefit to risk ratio of anticancer therapies across both short term and long-term outcomes, and to translate this schema into a practical clinical implementation tool.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):
When a clinician decides whether to recommend a treatment, they are implicitly running a benefit to risk calculation but in most clinical settings, that calculation is informal, inconsistent, and poorly documented. Making it explicit and systematic is what separates good oncology practice from excellent oncology practice. The major parameters on the benefit side include overall survival, progression free survival, objective response rate, and depth of response but increasingly, the question of whether a survival benefit translates into meaningful functional improvement matters as much as the number itself. A six-week median OS benefit with grade 3-4 toxicity in 40% of patients is a very different proposition from the same benefit in a well-tolerated regimen. This is precisely what frameworks like ESMO-MCBS and ASCO-VF were designed to quantify, and they should be used routinely in institutional treatment decisions, not reserved for academic publications. On the risk side, the parameters that matter clinically are acute toxicity burden by grade and frequency, treatment related mortality, impact on performance status trajectory, and late effects relevant to the patient's expected survival duration. A 30-year-old woman receiving anthracycline-based chemotherapy needs a different cardiac risk conversation than a 70-year-old man with preexisting left ventricular dysfunction. The objective clinical parameters for outcome evaluation should include CTCAE toxicity grading prospectively collected at every cycle, validated QoL instruments EORTC QLQ-C30 is the standard administered at baseline and at defined intervals, patient reported outcome (PRO) measures for symptoms that don't show up on blood tests, and functional status assessed with ECOG PS or Karnofsky PS at each contact. The implementation schema is simple- at treatment initiation, document the baseline benefit risk justification explicitly in the case record. At each restaging, formally reassess whether the original calculus still holds. At toxicity or progression, a structured discontinuation or de-escalation decision should be documented with the same rigor as the original treatment decision. The goal is that benefit risk evaluation becomes a living clinical document, not a one-time justification written at diagnosis and never revisited.

Full Name:
Monish Balaji S

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):
How to optimize risk benefit ratio with systemic therapy

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

1. Major parameters clinicians use to judge risk-benefit of anticancer regimens include tumour biology (stage, molecular markers), treatment intent (curative vs palliative), expected response rate, survival benefit (OS/PFS), toxicity profile (grade, reversibility), patient comorbidities, performance status (ECOG), pharmacogenomics, drug interactions, organ function reserve, and patient values/preferences including fertility and QoL priorities including socioeconomic factors, adherence likelihood, prior therapy exposure, tumour heterogeneity measures, and real-world evidence benchmarks.
2. Clinical parameters to objectively evaluate outcomes include tumour response (RECIST), biomarker dynamics, progression-free survival, overall survival, toxicity grading (CTCAE), hospitalization rates, dose intensity delivered, patient-reported outcome measures (PROMS), quality of life indices (EORTC QLQ-C30), fatigue scales, functional status, and treatment satisfaction scores including longitudinal monitoring, symptom burden trajectories, caregiver-reported outcomes, capturing dynamic response over time and relapse indicators.
3. A comprehensive schema for risk evaluation can integrate a dual-axis temporal model: acute toxicity window (0-30 days), subacute (1-6 months), and chronic/late effects (>6 months to years). Each axis captures organ-specific toxicity, cumulative dose exposure, immune-related adverse events, and latent risks such as secondary malignancies. A weighted risk score can be generated combining severity, reversibility, and duration. Digital phenotyping and real-time biosensor data can enrich prediction. This framework supports early warning systems, personalized toxicity forecasting, and adaptive dosing strategies guided by machine learning risk stratification models and continuous learning health systems.
4. Clinical implementation can be achieved via embedding the schema into electronic health records with decision-support algorithms, multidisciplinary tumour boards, and AI-assisted risk calculators. Continuous patient-reported data integration through mobile platforms enables adaptive therapy modulation. Feedback loops from outcomes refine predictive models, enabling precision oncology governance and iterative safety optimization ensuring regulatory compliance, equity in care delivery, and improved population-level safety surveillance analytics feedback loops.

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Jarfin I M

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):
To choose anti-cancer treatment that gives meaningful survival or symptom benefit without exposing patients to disproportionate toxicity, cost or loss of dignity.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):
A clinician judges benefit and risk using intent of treatment, expected survival gain, response rate, disease burden, performance status, age, comorbidities, organ function, biomarkers, prior therapy, toxicity profile, patient preference, logistics and affordability. In oncology, “can be given” is not the same as “should be given”.
Objective outcome measures should include tumour response, PFS/OS where relevant, treatment completion rate, grade 3/4 toxicities, hospitalization, infections, dose reductions, treatment-related mortality, pain control, nutritional status, QoL scores, financial toxicity, patient satisfaction and caregiver burden.
A practical schema should assess three time points. Before treatment: baseline fitness, geriatric assessment, organ function, fertility concerns, psychosocial and financial status. During treatment: toxicity checklist, lab monitoring, symptom scoring, emergency admissions and adherence. After treatment: cardiac, renal, neuropathy, endocrine, fertility, second malignancy and survivorship issues.
In Tamil Nadu, this can be implemented through chemotherapy day-care checklists, nurse-led toxicity calls, palliative-care referral triggers and standardized consent forms explaining both benefit and harm in simple language.
Roche can support through patient education tools, adverse-event reporting systems, affordability programs and real-world safety registries.
The most humane oncologist is not the one who gives the maximum treatment, but the one who gives the right treatment, at the right intensity, to the right patient, with the courage to stop when treatment harms more than it helps.

Full Name:
Dr. Chilamkurty Maitreyi

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Stanley Medical College

State:
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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

Problem statement: In oncology, treatment decisions are often made under urgency where the focus is on "what can be given “rather than "what should be given”. While efficacy data is available, structured benefit risk reflection is rarely embedded before treatment initiation, This can lead to aggressive therapies with marginal benefit, severe toxicity, poor quality of life, financial distress and avoidable hospitalizations. The absence of a standardized pre-treatment decision pause creates variability especially in complex or borderline patients.

Objective: To Institutionalize a mandatory structured pre-treatment benefit risk pause before initiating anti-cancer therapy, ensuring that every regimen is clinically justified, patient appropriate and outcome conscious.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Solution: Oncology Therapy Time out (clinical Decision Pause). Before starting of the treatment, the treating team should perform a 5-minute structured decision checkpoint.

1.Benefit questions

- Is this treatment curative, life prolonging or symptom relieving?
- What is the realistic, expected benefit?
- Is biomarker evidence supporting benefit?

2.Risk questions

- What severe toxicity is likely?
- Can this patient physiologically tolerate treatment?
- What are long term survivorship risks?

3.Patient cantered Questions

- Will this compromise quality of life?
- Is treatment financially sustainable?
- Does the patient understand trade-offs?

4.Objective Monitoring Plan:

- Toxicity thresholds for modification
- Quality of life reassessment timeline
- Hospitalization triggers
- Stopping rules if benefit absent

Example: A 74-year-old male patient diagnosed with metastatic lung cancer presented with performance status 2, known case of COPD and financial limitations planned for aggressive chemotherapy. During Therapy Time out, the team recognizes limited survival gain versus high toxicity risk. Treatment is shifted to a low burden evidence-based option aligned with patient goals. Because effective treatment should also be tolerable.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):
To determine whether a low-cost, app-based electronic patient-reported outcome monitoring system can reduce unplanned chemotherapy-related hospitalizations among patients receiving curative-intent adjuvant or neoadjuvant chemotherapy for stage I-III breast cancer.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):
Background:
Chemotherapy for early-stage breast cancer is frequently associated with treatment-related toxicities leading to unplanned hospitalizations, emergency visits, treatment delays, and compromised quality of life. International studies have demonstrated that electronic patient-reported outcome monitoring can improve symptom recognition and reduce healthcare utilization; however, prospective evidence from low- and middle-income countries remains limited. This study aims to evaluate the impact of a low-cost app-based symptom monitoring strategy in patients receiving curative-intent chemotherapy for breast cancer in India.
Methods:
This is a single-centre, open-label, parallel-group randomized controlled trial. Adult patients (â‰¥18 years) with stage I-III breast cancer receiving adjuvant or neoadjuvant chemotherapy will be randomized 1:1 to either app-based symptom monitoring or standard care. The intervention arm will use a smartphone-based platform enabling daily or at least thrice-weekly symptom reporting, automated red-flag alerts, self-management guidance, and rapid oncology nurse notification for severe toxicities. The control arm will receive routine cycle-based review and standard emergency instructions. The primary endpoint is occurrence of at least one unplanned chemotherapy-related hospitalization from treatment initiation until 30 days after the final cycle. Secondary endpoints include treatment delays, dose reductions, emergency department visits, healthcare utilization, quality-of-life outcomes using EORTC QLQ-C30 with breast-specific modules, and app feasibility metrics including adherence and alert response rates.
Results:
Approximately 400 patients will be enrolled to detect a 50% relative reduction in hospitalization rates (20% vs 10%) with 80% power at a two-sided α of 0.05. Data will be captured using Research Electronic Data Capture with blinded outcome adjudication and planned intention-to-treat analysis.
Conclusions:
This pragmatic, randomized trial will provide the first prospective Indian evidence evaluating real-time app-based symptom monitoring during curative breast cancer chemotherapy. If effective, this scalable digital intervention may improve treatment continuity, reduce toxicity-related hospitalizations, and strengthen supportive oncology care delivery in resource-constrained settings.

Full Name:
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Madhya Pradesh

Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):
Main purpose of increasing Benefit to Risk would be better Survival , Quality of Life , Therapy Morbidity , Ease of access to therapy , Psychological comfort (counselling) , Affordability at the same time Precision therapy delivery and also to establish a structured, patient-centered benefit-risk evaluation framework in oncology that improves treatment selection, minimizes avoidable toxicity, enhances quality of life, and enables evidence-based personalized cancer care through continuous assessment of therapeutic efficacy, safety, and long-term survivorship outcomes.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):
To ensure the most optimal Benefit to Risk , evidence based medicine , various parameters (PFS, EFS , OS , DFS, FFTF , iDFS , QOL , Death due to any events), Statistical measures (p value , HR , CI , Kaplan Meir Interpretation and other tools), Therapy response measurement (Recist and iRECIST criteria). A framework should evaluate both treatment efficacy and toxicity before, during, and after therapy.
Risk assessment should include acute toxicities, late adverse effects, hospitalization rates, financial burden, treatment discontinuation, functional decline, and impact on survivorship. A model that interprets & Evaluate at onset - performance status, frailty, comorbidities, organ function, nutritional status, psychosocial support, biomarker profile, and patient goals. Risk prediction tools such as toxicity calculators, geriatric assessments, and thromboembolism models can support decision-making. Secondly on treatment monitoring by using standardized toxicity grading systems, laboratory monitoring, imaging response assessment, patient-reported outcome measures, and quality-of-life questionnaires. Digital symptom-tracking platforms and AI-assisted alerts can help identify complications early and prevent severe toxicity. Practice of Precision Oncology & Agnostic therapy, MDT discussion.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):
We need hard data to prove a protocol is actually working. We track clinical toxicity using rigid CTCAE criteria. And should rely on Patient-Reported Outcome Measures to figure out what their daily quality of life actually looks like outside the hospital.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

Figuring out if pushing a massive systemic regimen or attempting a radical resection is actually going to help the patient is always a massive balancing act. As a surgical oncologist, the very first thing I look at is the patient's ECOG performance status. And you obviously have to weigh their specific tumor biology directly against whatever baseline comorbidities they walked into the OP. But we simply cannot just guess the benefit-to-risk ratio.

We need hard data to prove a protocol is actually working. We track clinical toxicity using rigid CTCAE criteria. And should rely on Patient-Reported Outcome Measures to figure out what their daily quality of life actually looks like outside the hospital.

Building a realistic schema to evaluate all this risk basically means splitting the timeline up. You have to lock down a rigid physiological baseline before we even prep them for the OR. Then comes the acute phase. This is exactly where we aggressively monitor for immediate surgical complications or acute chemo toxicities during those initial cycles. But you absolutely cannot abandon them in the initial phase. Because that is exactly when we need to be look for late-onset disasters like chronic neuropathy or secondary malignancies.

To actually make this massive schema work in a packed outpatient clinic, you have to automate the friction out of the system. We desperately need digital symptom questionnaires hardwired straight into the hospital's electronic health record. Patients can just tap through them on a tablet in the waiting room. And if an adverse reaction score suddenly spikes, the system should immediately ping the clinical nurse navigator. This completely stops us from missing creeping toxicities between formal scan dates. It forces the multidisciplinary team to adjust the ESMO or NCCN-based protocol using real-time data, rather than just asking how they feel during a rushed five-minute follow-up.

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

Every week in our OPDs we start patients on treatments whose benefit may be a few extra months and whose harm can be sudden, permanent, or slowly corrosive yet the decision is rarely made on structured data. We lean on the headline number from a registration trial, glance at the toxicity table, and trust experience. How large the benefit actually is, how frail the patient is, what the family can realistically afford, and what the patient himself wants seldom get written down anywhere. In India the problem is sharper. Most trial evidence comes from fitter, Western cohorts our late-presenting patients do not resemble, frailty is almost never formally measured in a crowded clinic, and the cost of treatment is itself a toxicity that can push a household into debt. Without a reproducible way to weigh benefit against the full spectrum of risk, our decisions stay inconsistent and hard to audit.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

When we weigh a regimen, the benefit side comes down to how large and how durable the gain is overall and progression-free survival, response rate and its depth, whether we treat for cure or for comfort, and how many patients we must treat for one to benefit. The risk side is treatment-related death, organ-specific and cumulative toxicity, performance status and organ reserve, the line of therapy, and, in our setting, the financial burden to the family. To judge outcome objectively we can track CTCAE-graded and serious adverse events, the dose intensity actually delivered, treatment discontinuation, a validated quality-of-life tool such as the EORTC QLQ-C30, performance-status trajectory, hospital and ICU days, and patient satisfaction and decisional regret. Financial toxicity belongs here as a real endpoint, measured as out-of-pocket spend against household income.

For risk I would use a two-part appraisal.

First, grade the benefit with the ESMO-MCBS or the ASCO value framework, so we respond to the size of the gain and not merely a significant p-value.

Second, set the risk out in three layers

- acute (the first cycle or two: infusion and immune events),
- subacute (cumulative marrow, cardiac and nerve toxicity), and
- late (second cancers, endocrine and fertility damage)

each read against a quick frailty screen such as the G8 and the family's ability to pay. In a busy Indian clinic this has to be fast. Make it a short, structured note in the chart and a standing line in the tumour board using the National Cancer Grid's virtual boards where a peripheral centre has none backed by scheduled quality-of-life capture, pharmacy and geriatric input for high-risk patients, and a quarterly audit of toxicity, dropouts and cost that feeds back into how we prescribe.

Full Name:
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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):

To identify and evaluate key efficacy, safety, and patient-centered parameters that determine the benefit-to-risk ratio of anti-cancer therapies.

To develop a comprehensive framework for assessing both short-term and long-term treatment-related risks, including toxicity, quality of life, functional outcomes, and survivorship issues.

To implement a patient-centered benefit-risk assessment model in clinical practice through standardized monitoring, multidisciplinary review, and integration of patient-reported outcomes to support informed treatment decisions.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):

The goal of cancer treatment is to maximize clinical benefit while minimizing toxicity, preserving quality of life, and improving survival outcomes.

1. Major Parameters Used to Judge Risks and Benefits

Clinicians evaluate:

- Overall Survival (OS)
- Progression-Free Survival (PFS)
- Disease-Free Survival (DFS)
- Objective Response Rate (ORR)
- Duration of Response (DoR)
- Performance status (ECOG/Karnofsky)
- Age, comorbidities, and frailty
- Tumour burden and disease biology
- Biomarker and molecular profile
- Treatment-related toxicities
- Patient preferences and treatment goals

2. Clinical Parameters to Objectively Assess Outcomes

Efficacy Parameters

- OS, PFS, DFS
- ORR and Complete Response (CR) rates
- Minimal Residual Disease (MRD) status where applicable
- Time to Treatment Failure

Safety Parameters

- Incidence of Grade 3-4 adverse events (CTCAE)
- Hospitalizations and emergency visits
- Treatment discontinuation rates
- Dose reductions and treatment delays

Patient-Centered Parameters

- Quality of Life (QoL) scores (EORTC QLQ-C30, FACT-G)
- Patient-Reported Outcome Measures (PROMs)
- Satisfaction scores
- Functional status and return to daily activities

3. Schema for Comprehensive Risk Evaluation

Short-Term Risks (During and up to 1 Year)

- Acute toxicities (hematologic, gastrointestinal, dermatologic)
- Treatment-related mortality
- Hospital admissions
- Early QoL deterioration
- Financial toxicity

Long-Term Risks (>1 Year)

- Cardiotoxicity
- Secondary malignancies
- Neurocognitive dysfunction
- Infertility and sexual dysfunction
- Chronic fatigue and neuropathy
- Psychosocial impact and survivorship issues

A structured Benefit-Risk Scorecard can combine efficacy, toxicity, QoL, patient preference, and cost considerations to support treatment decisions.

4. Implementation in Clinical Practice

- Establish baseline assessment before treatment initiation.
- Use standardized toxicity grading and QoL questionnaires at regular intervals.
- Incorporate patient-reported outcomes into electronic medical records.
- Review benefit-risk profiles during multidisciplinary tumor board meetings.
- Utilize digital dashboards and AI tools to identify patients at risk of severe toxicity.
- Reassess treatment goals at each disease milestone.

Traditionally, oncology has focused heavily on survival outcomes. However, a therapy that extends survival by a few months but significantly impairs quality of life may not represent a favorable benefit-risk ratio for every patient. Therefore, future cancer care should adopt a patient-centered benefit-risk framework, where survival, toxicity, quality of life, functional independence, and patient preferences are evaluated together. This approach will help ensure that treatment decisions are not only effective but also meaningful to patients and their families.

Full Name:
Dr. Chirag Gajera

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):
To establish a comprehensive framework for evaluating the benefit-risk ratio of anti-cancer therapies by integrating clinical efficacy, toxicity assessment, quality-of-life outcomes, and patient-centered factors to ensure safe, effective, and personalized cancer treatment.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):
Clinicians assess the benefit-risk ratio of anti-cancer therapies using parameters such as overall survival, progression-free survival, response rate, disease control, treatment intent, patient performance status, comorbidities, tumor biology, biomarker profile, expected toxicity, and available alternative treatments.

Objective clinical outcome parameters include treatment response, survival outcomes, recurrence rates, adverse event frequency and severity, dose modifications, hospitalization rates, treatment discontinuation, patient-reported outcomes, quality-of-life scores, symptom control, functional status, and patient satisfaction measures.

A comprehensive evaluation schema should include four domains:

1. Efficacy assessment: tumor response, survival outcomes, disease control, and long-term remission.
2. Safety assessment: acute toxicities, immune-related adverse events, organ dysfunction, treatment-related complications, and mortality.
3. Quality-of-life assessment: physical functioning, psychological well-being, symptom burden, and patient preferences.
4. Long-term monitoring: late toxicities, secondary malignancies, survivorship outcomes, and impact on daily living.

Implementation in clinical practice requires standardized toxicity grading, routine quality-of-life assessments, electronic medical record documentation, multidisciplinary review, and periodic treatment response evaluation. Shared decision-making should involve patients in weighing expected benefits against potential risks.
Real-world evidence collection, clinical audits, and continuous guideline updates can further improve treatment selection and ensure that anti-cancer therapies provide maximum benefit with acceptable risks.

Full Name:
Joshua John Uzagare

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Objective of your solution: (Briefly define the primary outcome of your solution to this challenge):
To ensure every patient receiving fluoropyrimidine chemotherapy in India has access to biologically-guided dosing, irrespective of geography/treatment setting. PRAGATI (Precision Risk Assessment Guided Approach for Therapy Individualization) aims to establish a nationally scalable precision-dosing framework using dried blood spot-based DPD phenotyping to identify patients at high risk of severe toxicity, enable risk-stratified treatment initiation, and improve treatment efficacy. By reducing severe toxicity, financial and time toxicity, and barriers to specialized testing, PRAGATI seeks to increase access to personalized cancer care across India, with the opportunity for future expansion to other anticancer therapies.

Describe your solution / proposal: Provide a detailed account of your solution/ proposal to this challenge. You could type your solution/ proposal here. (Disclaimer: Solution/proposal should not exceed more than 300 words.):
PRAGATI (Precision Risk Assessment Guided Approach for Therapy Individualization) is a decentralized precision-dosing framework developed to make safer fluoropyrimidine (FP) therapy accessible across India. Upto 1/3rd patients experience severe FP toxicity (1). Pretreatment DPYD genotyping is recommended, but applicability is limited by cost, availability, and the ability to predict only a minority (<10%) of Actionable toxicity events (2). DPD phenotyping using Uracil and Uracil/Dihydrouracil(U/UH2) provides a direct functional assessment of FP metabolism, is cheaper(5Ã—) and faster (7Ã— shorter TAT) than genotyping, but is limited by complex sample-handling requirements (3,4). PRAGATI leverages dried blood spot (DBS) to overcome these barriers and transform emperical BSA based approach to biologically guided precision-dosing.
A simple (50 Âµl) venous DBS sample can be collected at any oncology center and transported via existing postal/cou rier networks to regional LC-MS/MS laboratories without necessitating rapid plasma processing or cold-chain infrastructure. This will provide access to biologically guided fluoropyrimidine dosing without traveling to specialized centers for patients treated in resource-limited settings. Evidence supporting DBS stability and feasibility was presented at the IATDMCT,2025 conference (5).

Using validated uracil thresholds, patients can be stratified before treatment initiation according to toxicity risk. Data from our center has shown a strong association between elevated pretreatment uracil levels and severe toxicity, while many toxicity events were not identified by DPYD genotyping alone(6). High-risk individuals may receive individualized starting doses, followed by fluoropyrimidine therapeutic drug monitoring (TDM) by the same DBS platform to reduce severe fluoropyrimidine-related toxicity, prevent avoidable hospitalizations, enable exposure-guided dose optimization during subsequent treatment cycles to improve efficacy while reducing toxicity (7).
By reducing financial and time toxicity, treatment-related morbidity, and dependence on centralized testing infrastructure, PRAGATI offers an affordable, scalable, and patient-centered solution that can bring precision fluoropyrimidine therapy to every patient/cancer center in India. The same framework could subsequently be expanded to other anticancer therapies, creating a foundation for accessible precision oncology nationwide.

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