

Select Blue Ribbon Panel Recommendations

For CTAC Discussion

A. Network for Direct Patient Engagement

Develop a federated, large-scale patient participation network to offer patients comprehensive tumor profiling. Allow patients to “pre-register” for clinical trials.

Why It's Important

- By linking existing pilot programs, comprehensive tumor profiling could be provided for a large-scale cohort of cancer patients.
- Genomic profiling data could be combined with immunological profiling data for easier data sharing and deep analysis.
- Profiling data at various time points during treatment could help understand and overcome resistance to targeted therapies.
- This could lead to more precise knowledge about what works, in whom, and in which cancers.

A. Network for Direct Patient Engagement

What It Will Achieve

- Improve the precision and categorization of cancers.
- Engage patients and accelerate the enrollment of patients into clinical trials by providing a network of previously tested patients willing to enroll in a trial.
- Enhance diversity, providing a truer representation of the American population and improving therapy options for all.
- Ultimately, it could lead to integration of precision oncology into everyday cancer care.

The Challenges

- Cost, lack of standardization, insufficient evidence of broad-based clinical utility, and barriers to data sharing.
- Personal, genetic, and clinical information must be protected.
- Patients must believe the info will be useful, which could be facilitated by education of community oncologists.

F. Symptom Management Research

Accelerate research to monitor and manage patient reported symptoms. Update national guidelines for symptom control and support. Improve quality of life and ensure patient adherence to treatment, improving outcome, especially for children.

Why It's Important

- Systems for routine monitoring and management of patient-reported symptoms as the standard of care in all settings are needed.
- Symptom management programs could be tailored to differing patient and survivor needs.
- With symptoms controlled, patients would continue treatment, optimize well-being, and stay engaged in family and societal roles.
- Costs related to emergency department visits, urgent care, and unplanned hospitalizations and readmissions will decrease.

F. Symptom Management Research

What It Will Achieve

- Accelerate development of systems to collect patient-reported symptoms as part of all national cancer databases.
- A database of symptoms could be used to:
 - Revise and update evidence-based guidelines on symptom management
 - Track patient-reported outcomes
 - Make comparisons, share best practices, and encourage the attainment of a high standard for symptom control and supportive care nationally
 - Identify gaps and new scientific questions that could be addressed through symptom management science

The Challenges

- Research is needed on how to deploy patient-reported outcome (PRO) tools, which will provide a mechanism to report poorly controlled symptoms.
- PRO tools need to be incorporated into overall care delivery.

H. Retrospective Analysis of Biospecimens from Patients Treated with Standard of Care

Conduct retrospective analyses of tumor samples from patients treated with standard of care and whose outcomes are known in order to better understand the mechanisms driving individual tumor types. This will help optimize tumor classification and indicate whether standard of care is likely to be beneficial or identify a potential experimental therapy.

Why It's Important

- We need to understand why similar patients with similar treatments have different outcomes.
- A thorough analysis of archival samples to determine the underlying cellular, genetic, inflammatory/immune, and molecular events that drive a tumor's response or resistance to therapy will help refine patient sub-classification at the molecular level.
- We need information on which patients are likely to benefit from standard of care and which patients require additional or novel interventions.

H. Retrospective Analysis of Biospecimens from Patients Treated with Standard of Care

What It Will Achieve

- Establish a large scale network of cancer researchers and clinicians.
- Develop better risk stratification of cancers and allow tailored treatments for patients based on disease characteristics.
- Identify efficient ways to conduct faster and smaller precision-based trials on patients with the appropriate biological parameters.

The Challenges

- Large-scale retrospective analyses of tumor samples.
- Regulatory pathways commonly altered in cancer and their surrounding supportive cells also should be characterized.
- Clinical infrastructure, medical oncologist reimbursement and patient reluctance to enroll in trials.



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