Improving the Evidence Base for Treatment Decision-Making for Older Adults with Cancer: A Virtual Workshop

Session 3: Study designs and policy opportunities to benefit older adults: Approaches to clinical trials designed for registrational intent

ASCO Policy Perspective

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January 25, 2021

Financial Disclosure

- I am an employee of the American Society of Clinical Oncology
- ASCO receives grants from the following pharmaceutical companies to support the TAPUR study:
  - Astra-Zeneca
  - Bayer
  - Boehringer-Ingelheim
  - Bristol Myers Squibb
  - Eli Lilly and Co.
  - Genentech
  - Merck
  - Pfizer

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Improving the Evidence Base for Treating Older Adults With Cancer: American Society of Clinical Oncology Statement

Recommendation
To improve the conduct of research
Use clinical trials to improve evidence for treating older adults with cancer
Leverage research designs and infrastructure for generating evidence on older adults with cancer
To improve the research environment
Increase FDA authority to incentivize and require research involving older adults with cancer
Increase clinicians' recruitment of older adults with cancer to clinical trials
Use journal policies to improve researchers' reporting of age distribution and health risk profiles of research participants

Hurria et al, JCO, 2015

OXFORD

JNCI J Natl Cancer Inst (2018) 110(11): djy169

doi: 10.1093/jnci/djy169
First published online October 17, 2018
Commentary

COMMENTARY

Expanding the Evidence Base in Geriatric Oncology: Action Items From an FDA-ASCO Workshop

Laura A. Levit, Harpreet Singh, Heidi D. Klepin, Arti Hurria

Action Items:

1. Increase enrollment of older adults on trials
2. Collect more information on older adults from treatment trials
3. Expand the use of real-world data in research on older adults
4. Strengthen the collaboration between stakeholders to develop advocacy and policy solutions

VOLUME 36 · NUMBER 22 · AUGUST 1, 2018

JOURNAL OF CLINICAL ONCOLOGY

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Practical Assessment and Management of Vulnerabilities in Older Patients Receiving Chemotherapy: ASCO Guideline for Geriatric Oncology

Supriya G. Mohile, William Dale, Mark R. Somerfield, Mara A. Schonberg, Cynthia M. Boyd, Peggy S. Burhenn, Beverly Canin, Harvey Jay Cohen, Holly M. Holmes, Judith O. Hopkins, Michelle C. Janelsins, Alok A. Khorana, Heidi D. Klepin, Stuart M. Lichtman, Karen M. Mustian, William P. Tew, and Arti Hurria

American Society of Clinical Oncology Road to Recovery Report: Learning From the COVID-19 Experience to Improve Clinical Research and Cancer Care

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Road to Recovery: Research Goals

Goal 1: Ensure that clinical trials are accessible, affordable, and equitable for patients

Goal 2: Design more pragmatic and efficient clinical trials that are better integrated into routine clinical care

Goal 3: Simplify, streamline, and standardize protocol requirements and trial operations to minimize administrative and regulatory burdens on research sites

Goal 4: Recruit, retain, and support a well-trained clinical trial workforce that is committed to providing patients with access to high-quality research

Goal 5: Promote appropriate oversight and review of clinical trial conduct and results

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Broadening Eligibility Criteria to Make Clinical Trials More Representative: American Society of Clinical Oncology and Friends of Cancer Research Joint Research Statement

Edward S. Kim, Suanna S. Bruinooge, Samantha Roberts, Gwynn Ison, Nancy U. Lin, Lia Gore, Thomas S. Uldrick, Stuart M. Lichtman, Nancy Roach, Julia A. Beaver, Rajeshwari Sridhara, Paul J. Hesketh, Andrea M. Denicoff, Elizabeth Garrett-Mayer, Eric Rubin, Pratik Multani, Tatiana M. Prowell, Caroline Schenkel, Marina Kozak, Jeff Allen, Ellen Sigal, and Richard L. Schilsky

Researchers and Funders

- Create targeted funding opportunities to support research involving older adults and include experts in geriatrics and geriatric oncology on review panels.
- Require researchers to include a plan to study a population that mirrors the age distribution and health profile of patients with the disease and report results accordingly.
- Develop a common set of data elements to be collected in all trials including elements from the geriatric assessment domains to help identify which older adults are most likely to benefit or not from treatment.
- Design more pragmatic, efficient and decentralized clinical trials.

Regulatory Agencies

- Require that registration-directed trials contain a plan to gather data and develop recommendations on safety, efficacy, and dosing in older adults (in pre- or post-market setting). Adjust drug label accordingly.
- Create incentives for conducting clinical trials in older adults, such as additional months of market exclusivity or transferable vouchers for expedited review of marketing applications.
- Include experts in aging and geriatric oncology on its advisory boards.

Payers

- Use “coverage with evidence development” strategies to cover the off-label use of marketed drugs in cancer clinical trials in older individuals while gathering data.

Physicians

- AMA should establish new CPT codes to reimburse clinicians for the additional time and effort involved to enroll, manage and follow-up older patients on clinical trials.
- These CPT codes should be reimbursed by Medicare, Medicaid, and third-party payers.

Summary

- Coordinated efforts among researchers, funders, regulators and payers can improve the evidence base for treating older adults.
- Policy initiatives at several levels are necessary to provide incentives to do so.