Improving the Evidence Base for Treating Older Adults with Cancer

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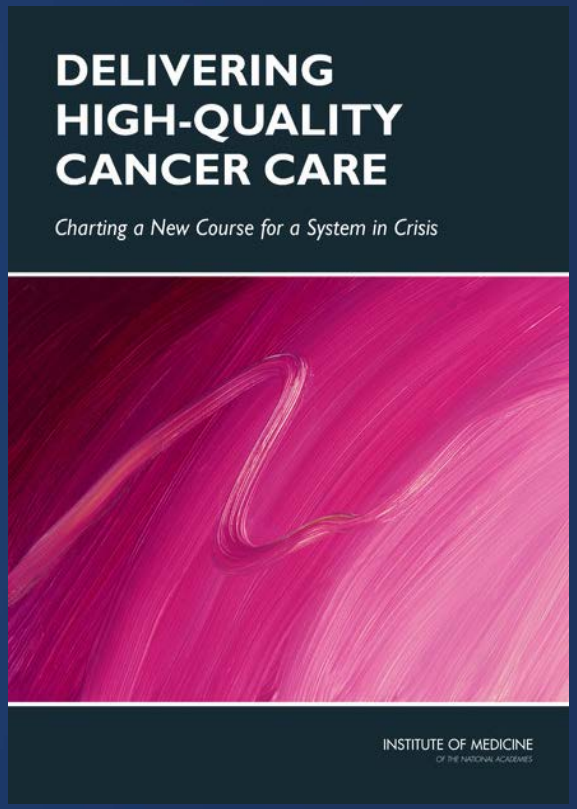
2013 Institute of Medicine Report
Delivering High-Quality Cancer Care: Charting a New Course for a System in Crisis

- Number of cancer cases on the rise
- Majority of cancers occur in older adults
- Older adults are under-represented in research
- Projected shortage of healthcare providers with geriatrics expertise
- IOM Committee makes recommendations to improve our evidence base and strengthen the national workforce that cares for older patients with cancer



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Improve Evidence-Based Care of Older Adults

IOM Committee Recommendations:

Increase breadth of collected data by matching the characteristics of the study population to that of patients with the disease (i.e. enroll more elderly patients onto clinical trials)

Increase depth of collected data by capturing a more detailed characterization of the study population through evaluation tools such as a comprehensive geriatric assessment

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JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

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

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Recommendation 1

Improve the evidence base for treating older adults from clinical trials.

Action Items

- Consider the necessity of eligibility criteria based on age, performance status, or comorbid conditions.
  - Researchers should provide a rationale when trials include eligibility criteria based on these factors.
- Funders should ensure that the common set of data elements that researchers collect include geriatric assessment measures.
- Funders should require researchers to report on the age distribution of tumor samples studied and whether they reflect the age distribution of the population enrolled in the trial and with the disease.
- NCI should encourage and incentivize research on older adults.

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Recommendation 2

Leverage research designs and infrastructure to improve the evidence base for treating older adults.

Action Items

- Researchers and funders should use the full range of research designs, including innovative trial designs.
- Funders of CER should require researchers to include a plan to study a population that mirrors the age distribution and health risk profile of patients with the disease.
- Clinical databases should collect data for geriatric assessments and have the functionality to support studies of older adults.
- CMS should use coverage with evidence development to cover off-label use of drugs in select RCTs.

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Recommendation 3

Increase FDA's authority to incentivize and require research on older adults.

Action Items

- Congress should provide FDA the authority to:
  - Require drug or biologic marketing applications to contain data and recommendations regarding the safety, efficacy, and dosing in older adults.
  - Create incentives for companies that conduct clinical trials of new cancer treatments in older adults.
- FDA should include experts in aging and geriatric oncology on its advisory boards.

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Recommendation 4

Increase clinician recruitment of older adults to clinical trials.

Action Items

- Professional societies should develop and promote educational materials to overcome clinicians' biases to recruiting older adults to clinical trials.
- The AMA should establish new CPT codes to reimburse clinicians who offer, enroll, manage, and follow patients on clinical trials for the additional time and effort involved.
  - These codes should be reimbursed by CMS and third-party payers.

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Recommendation 5

Utilize journal policies to incentivize researchers to consistently report on the age distribution and health risk profiles of research participants.

Action Items

- Include geriatric oncology experts in the pool of editorial board members who serve as peer reviewers.
- Require authors to submit and report:
  - The detailed age distribution of the study population.
  - Data analyses that could potentially yield valuable age-related information.
- Instruct peer reviewers to consider whether authors adequately reported on:
  - The age distribution of the population included in the study and the generalizability of the results.
  - Data analyses that could potentially yield valuable age-related information.

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Efforts to Improve the Evidence Base Timeline

2012

- Institute of Medicine forms “Committee on Improving the Quality of Cancer Care Addressing the Challenges of an Aging Population”

2013

- Committee Reviews Evidence and Drafts Recommendations
- IOM Committee Recommendations Published

2014

- ASCO Reviews IOM Recommendations
- Formation of the Older Adults and Research Working Group
- Conference calls held to discuss and form recommendations

2015

- Manuscript drafted of ASCO Statement
- Approval by ASCO CRC and Board Executive Committee
- Publication in Journal of Clinical Oncology (July, 2015)

2016 - 2017

- Disseminate the ASCO statement
- ASCO-FDA Workshop on Geriatric Oncology

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