Conducting Health Economics Research to Enhance Cancer Equity: Clinical Trials

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Clinical trials are critical for advancement of cancer care

12,361 pts in 23 positive SWOG trials
3.34 million life-years gained

Unger, J et al. JAMA Oncol 2017;3:1345-51
BUT…

- Adult cancer clinical trial participation is **suboptimal**
  - 5% of all adult cancer patients in the United States
  - Less than 2% on cooperative group trials
- Older patients, minorities, women, lower SES, and rural pts are underrepresented
  - *Results less generalizable*
  - *Social justice: deprived of some of the best therapies*
- While Black people are ~20% of Boston’s population, they are underrepresented (3.3%) among those accrued to clinical trials.

**We have to do better!**

What leads to disparities in trial participation?

• **Protocol requirements** – *age limits, strict exclusion criteria (e.g. labs, co-morbidities, brain mets, HIV+)*

• **Attitudinal** – *lack of knowledge, fear of side effects, ‘guinea-pig’ perception*

• **Access** – *insurance coverage, slow financial clearance process, trial availability at community cancer centers*

• **Other Financial** – *out-of-pocket $, travel, housing/food, lost income*

Nipp R,...Moy B. Oncologist 2016;20:572-5
Coverage of clinical trials under ACA

- ACA Section 2709 – Required coverage of routine health care costs for patients participating in clinical trials
- ‘Grandfathered plans’ – existing health plans as of 3/23/10
- Covers out-of-state but not necessarily out-of-network

- Medicare National Coverage Determination (Sept 2000)

- No requirement for Medicaid coverage of routine patient costs on clinical trial – ASCO Policy Statement on Medicaid Reform

### Barriers to clinical trial participation

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>OR (95% CI)</th>
<th>P value</th>
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<tbody>
<tr>
<td>Age ≥ 65</td>
<td>0.79 (0.58-1.08)</td>
<td>0.14</td>
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<tr>
<td>Female gender</td>
<td>0.93 (0.58-1.49)</td>
<td>0.75</td>
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<tr>
<td>African American race</td>
<td>1.31 (0.74-2.33)</td>
<td>0.35</td>
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<tr>
<td>Income &lt; $50,000</td>
<td>0.73 (0.57-0.94)</td>
<td>0.01</td>
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<tr>
<td>Education &lt; college</td>
<td>0.92 (0.73-1.16)</td>
<td>0.49</td>
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<tr>
<td>Comorbidity score ≥ 2</td>
<td>0.81 (0.65-1.02)</td>
<td>0.07</td>
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<tr>
<td>Distance to clinic ≥ 13 mi</td>
<td>0.66 (0.54-0.81)</td>
<td>&lt;0.001</td>
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Other financial barriers to clinical trial participation

• Out-of-pocket spending – deductibles, copayments, coinsurance ‘routine care’ is $$
• Travel to clinical trial center
• Housing / Meals
• Lost work / income

Patients may be considering trial enrollment in the context of significant previous cancer-related spending
Patient Selection:
• enrolled in or being screened for a clinical trial
• referred to CCEP by their cancer team

Patient Referral
Oncology provider • Social work • New patient access nurse • Research nurse

Lazarex Foundation
Determines need for assistance
• Reimburses patients monthly

CCEP
• Liaise with Lazarex Foundation, patient & team
• Track patient outcomes and collect data

Nipp R,..Moy B. Oncologist 2016;20:572-5
Baseline Financial Barriers

- Bothered by any financial concerns: 56.3%
  - CCEP (N=49): 56.3%
  - non-CCEP (N=38): 46.9%
- Concerned about travel costs for the trial: 69.4%
  - CCEP (N=49): 69.4%
  - non-CCEP (N=38): 60.4%
- Concerned about lodging costs for the trial: 9.1%
  - CCEP (N=49): 9.1%
  - non-CCEP (N=38): 11.1%
- Worried about affording medical costs of trial: 46.9%
  - CCEP (N=49): 46.9%
  - non-CCEP (N=38): 42.9%
- Afraid health insurance would not pay for trial: 14.3%
  - CCEP (N=49): 14.3%
  - non-CCEP (N=38): 14.3%
- Thought I wouldn't be able to keep up with trial schedule: 38.8%
  - CCEP (N=49): 38.8%
  - non-CCEP (N=38): 8.6%
- Thought I wouldn't be able to find transportation to trial center: 34.7%
  - CCEP (N=49): 34.7%
  - non-CCEP (N=38): 2.9%
### Monthly Reimbursement per Participant

<table>
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<tr>
<th></th>
<th>Local</th>
<th>Regional</th>
<th>National</th>
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<tr>
<td></td>
<td>$185</td>
<td>$300</td>
<td>$900</td>
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• Goal: to better define the scope of financial burdens on clinical trials and identify solutions both at the policy and clinical level
• Participants: Clinicians, researchers, NCI, payers, industry, Biden Moonshot Initiative, FDA,
Recommendations (1)

- Improve payer clinical trial coverage policies
  - Clinical trial cost payment policies should be revised so that they are made consistent, streamlined, and transparent to all stakeholders
- During the clinical trials development and enrollment process, provide patients with clear, transparent information about potential trial-related patient out-of-pocket costs, and include mechanisms to support patient financial/health literacy.

Winkfield K...Moy B. J Clin Oncol 2018
Recommendations (2)

- Remove impediments to ethically appropriate financial compensation for trial-related out-of-pocket costs. Provision of such financial support should not be considered undue inducement.

- Incentivize research that will better characterize patient costs incurred for participating in cancer clinical trials and support the longer-term development of tools to identify and mitigate the risk of trial-associated financial hardship.
AN ACT TO IMPROVE PATIENT ACCESS TO CANCER CLINICAL TRIAL PROGRAMS

Sponsor: Joint Committee on Public Health
Status: Referred to Joint Committee on Health Care Financing

Date    Branch          Action
11/19/2019 House     Reported from the committee on Public Health
11/19/2019 House     New draft of H1933
11/19/2019 House     Reported favorably by committee and referred to the committee on Health Care Financing
3/23/2020  House     Reporting date extended to Friday May 1, 2020, pending concurrence
3/26/2020  Senate    Senate concurred
4/29/2020  House     Reporting date extended to Friday June 19, 2020, pending concurrence
4/30/2020  Senate    Senate concurred
6/22/2020  House     Reporting date extended to Thursday December 31, 2020, pending concurrence