The Provisional Clinical Opinion

Based on strong evidence from a phase III randomized clinical trial (RCT), patients with metastatic non-small cell lung cancer should be offered concurrent palliative care and standard oncologic care at initial diagnosis. While a survival benefit from early involvement of palliative care has not yet been demonstrated in other oncology settings, substantial evidence demonstrates that palliative care – when combined with standard cancer care or as the main focus of care – leads to better patient and caregiver outcomes. These include improvement in symptoms, quality of life (QOL), and patient satisfaction, with reduced caregiver burden. Earlier involvement of palliative care also leads to more appropriate referral to and use of hospice, and reduced utilization of futile intensive care.
While evidence clarifying optimal delivery of palliative care to improve patient outcomes is evolving, no trials to date have demonstrated harm to patients and caregivers, or excessive costs from early involvement of palliative care. Therefore, it is the Panel’s expert consensus that combined standard oncology care and palliative care should be considered early in the course of illness for any patient with metastatic cancer and/or high symptom burden. Strategies to optimize concurrent palliative care and standard oncology care, with evaluation of its impact on important patient and caregiver outcomes (e.g. QOL, survival, healthcare services utilization, costs) and society, should be an area of intense research.
Introduction

• The American Society of Clinical Oncology (ASCO) has established a rigorous, evidence-based approach—the provisional clinical opinion (PCO)—to offer a rapid response to emerging data in clinical oncology.

• The PCO is intended to offer timely clinical direction to ASCO members following publication or presentation of potentially practice-changing data from major studies.

• This PCO addresses the integration of palliative care services into standard oncology practice at the time a person is diagnosed with metastatic or advanced cancer.
Statement of the Clinical Issue

• Population: patients with metastatic disease whose disease is incurable— but have range of life expectancies

• Unmet needs include:
  – Care for advanced illness
  – High symptom burden
  – Late referrals to hospice when the person is actively dying.

• Palliative management emphasizes:
  – medically-appropriate goal setting
  – honest and open communication with patients and families
  – meticulous symptom assessment and control
  – Support across all domains of the cancer experience for patients and caregivers
Literature Review and Analysis

• Emerging data from 7 recent published randomized clinical trials that include a standard care group and a concurrent palliative care plus standard care group

• Temel et al. initially reviewed by NCI’s PDQ Supportive and Palliative Care Editorial Board
  – Additional studies suggested

• An ASCO Ad Hoc Expert Panel considered the PDQ review, as well as results of ASCO and panel member literature searches for randomized clinical trials and relevant reviews
Literature Review and Analysis: Temel et al.

- This study was a phase III randomized, controlled, single institution, non-blinded clinical trial comparing palliative care plus standard oncology care, begun at the time of diagnosis, to standard oncology care.
- 151 patients with newly-diagnosed metastatic non-small cell lung cancer.
- Intervention: a baseline evaluation and follow-up, at least once per month, by members of a multidisciplinary PC team comprised of 7 palliative care clinicians.
- Primary Outcome: Quality of life.
- Secondary outcomes: Mood, Aggressiveness of end of life care.
Literature Review and Analysis: Temel et al.

- Results in intervention arm:
  - Better understanding of the disease, prognosis, and options
  - Significantly higher QOL scores p=0.03
  - Fewer depressive symptoms p=0.01
  - Less aggressive end of life care p=0.05
    - Less use of chemotherapy near end of life
    - Less hospitalization and intubation
    - More and longer use of hospice
  - Survival 2.7 months longer p=0.02
Literature Review and Analysis: Temel et al., cont’d

• Strengths of study included:
  – Recruitment at time of diagnosis
  – Low attrition rate
  – Power to detect change in primary outcome

• Weaknesses of study included:
  – Single institution, single diagnosis, limited diversity
  – Not blinded
  – Lack of control for palliative intervention
  – Survival outcomes need confirmation
  – Community-based interventions not routinely available
## Included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Intervention</th>
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<tbody>
<tr>
<td>Bakitas, M: 2010</td>
<td>multicomponent psycho-educational intervention</td>
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<tr>
<td>JAMA 302: 741</td>
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<tr>
<td>Brumley, R: 2007</td>
<td>Interdisciplinary home-based care healthcare program</td>
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<tr>
<td>J Am Geriatr Soc 55:</td>
<td></td>
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<tr>
<td>993</td>
<td></td>
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<tr>
<td>Gade, G: 2008</td>
<td>Interdisciplinary palliative care service, consultations, with home service</td>
</tr>
<tr>
<td>J Pall Med 11: 180</td>
<td>extension</td>
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<tr>
<td>Meyers, FJ: 2011</td>
<td>Simultaneous Care Educational Intervention (SCEI): Linking Palliation and</td>
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<tr>
<td>J Pall Med 14: 465</td>
<td>Clinical Trials. Educational sessions</td>
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<tr>
<td>Pantilat, SZ: 2010</td>
<td>Daily palliative medicine consultation</td>
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<tr>
<td>Arch Int Med 170: 2038</td>
<td></td>
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<tr>
<td>Rabow, MW: 2004</td>
<td>Seven interdisciplinary component interventions (home visits, phone calls)</td>
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<tr>
<td>Arch Int Med 164: 83</td>
<td></td>
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<tr>
<td>Temel, JS: 2010</td>
<td>Outpatient palliative care team</td>
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<tr>
<td>NEJM 363: 733</td>
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Integrative Discussion and Analysis

• Studies heterogeneous
  – Meta-Analysis not conducted
• Overall, the addition of palliative care interventions to standard oncology care, delivered via different models to patients with cancer, provided evidence of benefit
• No harm was observed in any trial, even those with discussions of end-of-life planning
• Most trials showing benefits ranging from:
  – equal to improved overall survival
  – reduced depression
  – improved caregiver and/or patient quality of life
  – overall lower resource use and cost
Integrative Discussion and Analysis, cont’d

- # of studies showing statistically significant improvements with palliative care in measurements of:
  - 2/5 - symptoms
  - 2/5 - QOL
  - 2/3 - patient/caregiver satisfaction
  - 1/3 - survival
  - 3/6 - mood
  - 2/5 - resource use
  - 1/4 - advance care planning

- Modern studies that used a defined intervention including better communication and a team approach:
  - all showed substantial benefit
  - 2/3 measuring cost showed lower cost with intervention
More research is needed to:

- Evaluate the optimal timing and venue for provision of palliative care (inpatient, outpatient / community)
- Evaluate evidence-based reimbursement models to support palliative care provision
- Evaluate which components of palliative care have impact
- Evaluate interventions in other diseases besides lung cancer
- Evaluate the impact of palliative care across the continuum of care, especially during the delivery of anti-tumor therapy
Other priorities

• Health policy and reimbursement mechanisms to facilitate efficient implementation early in the disease trajectory
• More clinic-based palliative care and community-based non-hospice palliative care service
• More palliative care physicians and multidisciplinary providers – workforce development
• Demonstration programs
What can ASCO members do today?

- Consider early referral to palliative care
- Establish working relationships with local hospice and palliative care providers.
- Monitor important Quality Oncology Practice Initiative (QOPI) metrics
  - Their own referrals and length of patient stay in hospice
  - How many patients get chemotherapy within 2 weeks of death
  - Evaluation of pain by the second visit
- Consider a “hospice information visit” 3-6 months before the patient is expected to die, to ease the transition later
What can ASCO members do today?

• Discuss, early in the course of illness, rather than when there is no more chemotherapy to give:
  – Prognosis, with the most likely outcome
  – Medically appropriate goals (risks and benefits)

• Establish
  – Advance medical directives
  – Durable Power of Medical Attorney
  – Involvement of hospice as the best way of taking care of people at the end of life, when prognosis warrants

• Present palliative care as an added layer of support for patients and families
## PCO Methodology: Ad Hoc Expert Panel Members

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<tr>
<th>Panel Members</th>
<th>Affiliation/Institution</th>
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Additional ASCO Resources

• The PCO was published in the *Journal of Clinical Oncology* <placeholder>

• The PCO, patient guide, and additional resources are available at www.asco.org/pco/palliativecare

• The patient guide is also available at http://www.cancer.net
This resource is a practice tool for physicians based on an ASCO® Provisional Clinical Opinion (PCO). The PCO and this presentation are not intended to substitute for the independent professional judgment of the treating physician. PCOs do not account for individual variation among patients and may not reflect the most recent evidence. This presentation does not recommend any particular product or course of medical treatment. Use of the PCO and this resource is voluntary. The full PCO and additional information are available at http://www.asco.org/pco/palliativecare. Copyright © 2012 by American Society of Clinical Oncology®. All rights reserved.