Enhancing Quality through Innovation

Presentation to the National Cancer Advisory Board

on behalf of
The American Society of Clinical Oncology

Douglas W. Blayney, MD
ASCO President

September 15, 2009
Objectives

- Provide basic information on ASCO
- Our view of challenges facing our research and health care systems
- Discuss how innovative approaches may offer solutions
- Describe how NCI, researchers, clinicians, and professional societies are working together and can enhance collaboration to address the challenges
- Suggest areas for NCAB focus
ASCO’s Mission

• **Improving** cancer care and prevention
• **Advancing** education and training
• **Fostering** communication
• **Advocating** sound policy
• **Assisting** oncologists with challenges of modern practice

**2009 Presidential Theme:**
Advancing Quality through Innovation
The Professional Home for Clinical Oncology Worldwide

- 27,700 members in 126 countries
- Multi-specialty
- Education, Publications, Policy, and Communications
- Meetings:
  - Annual Meeting: 4,039 abstracts & ~30,000 attendees
  - Thematic: GI, Breast, GU
  - Cooperative Group & NCI Partnerships: NCI/EORTC/ASCO Tumor Markers and ASCO/COG
Challenges

- **Health Care Reform**
  - Concern about growth in health spending
  - Desire for cost savings
  - Clinical trial infrastructure is vulnerable

- **Search for value in clinical care and research**
  - Personalized care vs. today’s practice climate
  - Knowing and using the most effective treatment
  - Regulatory burden

- **Oncology workforce shortages**
Opportunities: Create Value

- Molecular biology has identified targets for therapeutic development → patient populations more tightly defined
- Public attention to cancer
- Interest in Comparative Effectiveness Research
- Emphasis on and support for “learning healthcare systems”
Learning Healthcare System

How We Get Quality Through Innovation

- Bench Research
- Outcomes & Health Services Research
- Translation & Clinical Research
- Clinical Care
## Elements of A Learning Healthcare System for Quality Cancer Care

<table>
<thead>
<tr>
<th>Elements</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strong basic, translational, and clinical research enterprise</td>
<td>Existing but threatened</td>
</tr>
<tr>
<td>Robust research and clinical workforce</td>
<td>Existing but threatened</td>
</tr>
<tr>
<td>Rational regulatory and policy environment</td>
<td>Needs improvement</td>
</tr>
<tr>
<td>Real time data on quality and outcomes</td>
<td>Being developed</td>
</tr>
</tbody>
</table>
Examples of ASCO Support for Research

- **Policy Advocacy for NIH/NCI Budget**
  - Annual *Clinical Cancer Advances* report
  - Collaboration with oncology and research organizations to make case for funding

- **Providing Funding through The ASCO Cancer Foundation**
  - Young Investigator Award (1984-2009) = 578
  - Career Development Award (1992-2009) = 166
  - Advanced Clinical Research Award (2004-09) = 11
  - Translational Research Professorship (2008-09) = 3
ASCO Collaborations to Promote Research

• Innovative Trial Designs
  – Partnerships with FDA Critical Path Initiative: Alternative Designs Working Group; Pre-Phase III Working Group; Clinical Trials in Small Populations

• Clinical Trials Data Collection
  – With FDA and NCI: Standardized Case Report Form
  – With CCHIT: Electronic Health Record Standards

• Recognition and Support of Quality Research Sites
  – ASCO/TACF Clinical Trials Participation Award
  – ASCO/TACF Community Oncology Research Grant

• Effective Regulations
  – HIPAA Study; Data Optimization Working Group; Summit Task Force
Translational and Clinical Research
ASCO Membership Survey

“Educational resources and tools to increase oncologists’ participation in clinical research”

ASCO members gave high ranking to the importance of involvement in clinical trials in practice and academic settings.
Federally-Funded Clinical Research—Findings are Important to Innovation

- Ask important questions not asked elsewhere
- Generate practice-changing science
- Critical for recruiting subpopulations

However, these trials are at risk due to concerns about pace of trial development and accrual.

- Across all NCI phase I, II & III trials, Only 50-60% achieved minimal accrual\(^1\)

---

\(^1\) Curt GA, Chabner BA. *The Oncologist*, September 2008
Translational and Clinical Research
Poll of Cooperative Group Participants

- 155 (32%) Decided to limit Cooperative Group Participation (n=478); 38 sites considering placing limits
- 116 (75%) Cite Inadequate Per-Case Reimbursement (n=155)
- 49 (42%) Increasing Industry Participation (n=116) (6 no industry)
- 26 (68%) cite per-case reimbursement (n=38)

Many respondents indicated preference for participation in Cooperative Group trials
NCI Steps to Improve

- Prioritizing science
  - Disease-specific Steering Committees
- Improving operational efficiency
  - Operational Efficiency Working Group
- Examining Cooperative Group System
  - IOM Committee
- NCI-ASCO Clinical Trials Accrual Symposium

But Key Issue Remains Unaddressed:

- Funding
  - Inadequate per case reimbursement (flat since 2000)
  - Inadequate support for investigators, staff, and infrastructure
Research and Clinical Care
Innovation in Training

• Rapid pace of discovery requires continuous learning\(^2\)
• CME/Training Model:
  – Web-based
  – Interactive
  – Evidence-based
  – Self-assessment

• ASCO University
• QOPI Online Community
• Social Networking Sites
• Virtual Meeting

2 John S, Niederhuber JE; Oncologist; January 2008
Clinical Care and Outcomes
Innovation and Quality

Evidence-based Guidelines
Provisional Clinical Opinions
Provider tools and patient information

Quality Oncology Practice Initiative (QOPI®)
Breast Cancer Registry
Standards for Electronic Health Records

Assess & Improve
Cancer Care in your Hematology-Oncology Practice
Partnering to Assure Quality through Innovation

- Researchers, Clinicians, Policymakers, and Patients
- Between Federal Agencies
- Among Scientific Organizations and Patient Advocacy Groups
We Encourage NCAB to be Proactive Regarding …

1. Support for Clinical Trials
   - Increase per-case reimbursement and flexibility for Cooperative Groups to support investigators

2. Training
   - Enhance innovative partnerships with organizations like ASCO

3. Harmonize regulatory requirements

4. Leverage Existing Data Collection Projects