Mission

Created 10/2005
To provide a proactive resource for all stakeholders: ASTRO members and staff, industry, commercial payers, healthcare organizations, and government, in the application and integration of new and emerging technologies (and procedures) into the practice of radiation oncology.

Organizational Challenges

- Legal implications
- Avoidance of conflict
- Maintenance of consistency
- Creation of operational structure
- Selection of key volunteers
- Clear definition of mission
- Avoidance of functional overlaps

Topics

Background
Current Activities
Coverage with Evidence Development (CED) Initiative

Clarify some misunderstanding
ETC Development Timeline

- October 2005: Initial meeting
- June 2006: Implementation plan
- Nov. 2006: Comm. convened
- Dec. 2006: CTAF request
- Jan. 2007: SC co-chairs named
- Feb. 2007: CTAF document
- Spring 2007: Evaluation initiation

ETC Primary Peril: Mission Creep

- Operational activities
- Policy development
- Code definitions (CPT®)
- Code valuations (RUC)
  - Carrier appeals
- Guideline development
- Appropriateness criteria

Organizational Structure

ETC Co-Chairs (2)
MSC Co-Chairs (2)
ESC Co-Chairs (2)
ASTRO President-Elect
ASTRO Council Chairs (4)
At-Large Members (2)
Emerging Technology Committee (ETC)
Co-Chairs: Andre Konski, MD, MBA, Paul Wallner, DO
- Set Committee policy
- Establish priorities
- Monitor progress
- Assign responsibilities
- Determine appropriate role for external support of activities
- Finalize reports

Monitoring Subcommittee (MSC)
Co-Chairs: Michael Herman, PhD, Jeff Michalski, MD
- Identify and track new and emerging technologies and procedures
- Project impact
- Recommend new evaluation projects
- Consider requests for evaluations

Evaluation Subcommittee (ESC)
Co-Chairs: Robert Price, PhD, Eleanor Harris, MD
- Establish an assessment mechanism(s),
- Establish criteria for investigation and appropriate end-points
- Convene Task Groups (TGs/TGLs) for specific evaluation project
- Prepare initial evaluation reports for ETC review and action
- Prepare manuscripts

Project Initiation
- Direct ASTRO BOD request
- Council Chair(s) request*
  - MSC referral*
  - Vendor request*
- Agency/payer request*

*Requires ETC approval
Projects

- Dose escalation/prostate cancer* ✓
- Electronic brachytherapy ✓
- Localization/tracking systems
  - Proton beam therapy
  - SBRT/prostate cancer* ✓
  - SBRT/Non-small cell lung cancer*

* ASTRO Board of Directors or HP Council request

Standard Reimbursement Nomenclature

The service(s) provided shall be “reasonable and medically necessary”

Evidence-based Medicine (EBM)

Necessary Components

Evidence
  + Judgment

Limitations of Regulatory Approval

- Decades old standards
- Low bar standards
- Restrictive legislative mandate
- Lack of reimbursement linkage
Stakeholders

- Inventors, developers, vendors, investors
- Providers
- Patients, families, caregivers
- Payers
- Policy-makers

Evaluation Concepts

- Comparative Effectiveness (CE)
- Coverage with Evidence Development (CED)
  - Coverage with appropriateness determinations (CAD)
  - Coverage with study participation (CSP)

MedPAC Annual Report to Congress
March 2008

- Concern that new modalities disseminate quickly without provider knowledge of whether they outperform existing services
- Create an entity that will sponsor comparative effectiveness research
- Create budget neutral RVUs that would be value-based: >0 only if evidence shows > effectiveness relative to alternatives

Potential Benefits of CED

Expedite development of evidence to support vendor and provider claims
CED Background

- 2005 – CMS – Web posting of CED policy draft guidance document
- 2006 – CMS – Revised guideline document
- 2006 – Cooksey Report (UK) – “Only in research” programs

CED Experiments (Successful)

- NETT LVRS Trial
- CREST Trial
- FDG-PET Trial
- ICD Trial

National Emphysema Treatment Trial (NETT) of Lung Volume Reduction Surgery (LVRS)

- Trial initiation: 1995
- Trial arms: LVRS versus aggressive pulmonary rehab
- Trial funding: CMS/NIH
- Trial Cost: $35M research/$100M clinical
- Patients accrued: 1218 over 7 years
- Impact:
  - 1996: 3000 cases @ $150M/year
  - Post publication (2003): 500 cases

Additional CED Experiments

- CREST Trial – Balloon angioplasty + carotid artery stenting versus carotid endarterectomy
- Prophylactic Intra-cardiac defibrillator (ICD) Trial for prevention of Sudden Cardiac Death
- FDG-PET Trial for evaluation of suspected dementia
CED Experiments
(Failures)

A parable of stakeholder interference

CT Angiography for diagnosis of coronary artery disease

Attack of the: vendors, lobbyists, advocacy groups

CED Policy Issues

• Stable funding mechanisms (public and private)
• Legislative, regulatory and legal mandates
• Ethical considerations
• Apparent focus on cost reduction

Potential CED Implications for Radiation Oncology

1. Early-stage, low-intermediate risk prostate cancer: Protons versus IMRT
2. ........?
3. ........?
4. ........?

Future Possibilities

Be part of the problem?
Be part of the solution?
Deny that there are problems or solutions and “don’t worry, be happy!”