The National Oncologic PET Registry

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A National Cancer Institute Comprehensive Cancer Center
Evolution of Clinical PET

- PET well established as a research tool since its development in mid 1970s
- Research applications evolved into clinical applications
- Improvements in PET scanners made clinical studies practical
- However, acceptance into clinical practice occurred very slowly
PET & PET/CT Utilization (USA)

TECHNOLOGY DRIVERS
- DETECTOR DESIGN
- WHOLEBODY IMAGING
- PET/CT HYBRID IMAGING

CLINICAL DRIVERS
- NEUROLOGY
- CARDIOLOGY
- ONCOLOGY

PROCEDURES (000)
- 1981: 10
- 1991: 20
- 2001: 200
- 2011: >3000

Administrative Radiology, 2.92; Market for PET Radiopharmaceuticals and PET Imaging, 2004; Frost and Sullivan 2004; IMV PET Census Report 2003; Siemens Medical Solutions Molecular Imaging Strategic Planning
Factors Facilitating Growth of Clinical PET in USA

- Gamma camera coincidence imaging
- Commercial distribution of FDG by regional cyclotron/production facilities
- Mobile PET services
- FDA Modernization Act of 1997 (FDAMA)
- Coverage decisions by Medicare and other carriers
- PET/CT
PET Reimbursement

- Complex, slowly evolving process
- Dependent on FDA approval of PET drugs
  - Facilitated by FDAMA (1997)
- Reimbursable clinical indications
  - Determined by technology assessment panels of third-party payers
  - Process dominated by Centers for Medicare and Medicaid Services (CMS)
• Standard for new drug approval is “safe and effective” based on “adequate and well controlled studies”

• NDA for FDG for epilepsy approved in 1994
  – Evidence from the scientific literature
  – Licensed at a single site (N = 2 as of Nov 2008)

• Approved FDG for broad oncologic and cardiac applications in 2000
  – Also based on evidence from the scientific literature
Food and Drug Administration

- **1997 Food & Drug Modernization Act (FDAMA)**
  - Congress mandated that FDA develop a mechanism for approval of PET tracers
  - PET tracers listed in the U.S. Pharmacopoeia given equivalence of FDA approval
  - FDA given *2 years* to develop mechanisms, after which PET community will have 2 years to be in compliance
  - Draft Good Manufacturing Practice guidance issued September 20, 2005
  - *Broad application of FDA authority still has not occurred*
Medicare Coverage of PET

- Centers for Medicare and Medicaid Services (CMS)
  - Formerly Healthcare Financing Administration (HCFA)
- Standard for reimbursement is “reasonable and necessary”
- In 1990s, CMS adopted a new evidence-based approach for making coverage determinations
  - Requires peer-reviewed scientific evidence to document that new technology leads to changes in patient management and to improved health outcomes for Medicare beneficiaries
Medicare Coverage of PET

- CMS elected not to consider oncologic indications for PET broadly
- Rather evaluated the evidence on a cancer-specific and indication-specific basis
- Problematic because the specific evidence typically has not been very robust
- “Catch 22”
Medicare Coverage of Oncologic PET

1998  Evaluation of solitary pulmonary nodules and initial staging of NSCLC

1999  Suspected recurrent colorectal cancer, lymphoma, melanoma (covered after public meeting, with considerable restrictions)

2001  Further expanded coverage for six prevalent cancers after new request for broad coverage and public meeting
(PET must either resolve inconclusive results of standard test or replace standard test)
Medicare Coverage of Oncologic PET

2002  Individual requests submitted for several other cancers

2004  Proposed mechanism for expanded coverage
Medicare Reimbursement for Oncologic PET (2005)

• Diagnosis, staging, and restaging of:
  - Non-small cell lung cancer
  - Esophageal cancer
  - Colorectal cancer
  - Lymphoma
  - Malignant melanoma
  - Head and neck cancer
• Staging, restaging, and Rx monitoring of breast cancer
• Detection of TG+/RAI– thyroid cancer
• Staging of cervical cancer (– CT/MRI outside pelvis)
• **All other cancers/indications**
  - National registry
National Oncologic PET Registry
NOPR

- Is a CMS-approved
  - “Coverage with Evidence Development” Program
- Developed for the November 2004 expansion by CMS
  - All other cancers and indications except:
    - Breast cancer diagnosis and axillary staging
    - Melanoma regional nodal staging
- All Medicare-eligible PET facilities can participate (for a fee)
- Requires timely Pre-PET and Post-PET information
- All data will be submitted to CMS
- Cases with patient and physician consent will be used by the NOPR to assess change in intended management
NOPR: A Nationwide Collaborative Program

Sponsored by AMI

Managed by ACR

Endorsed by ACR, ASCO, SNM

Advisor CMS

Chair, Bruce Hillner, MD, Virginia Commonwealth University
Co-chair, Barry A. Siegel, MD, Washington University
R. Edward Coleman, MD, Duke University
Anthony Shields, MD, PhD Wayne State University
Statistician: Dawei Liu, PhD, Brown University
Epidemiologist: Ilana Gareen, PhD, Brown University
Objectives & Goals

• Objectives
  – Assess the effect of PET on referring physicians’ plans of intended patient management
    • across a wide spectrum of cancer indications for PET that are currently not covered by the Medicare program, and
    • in relation to cancer-type, indication, performance status, physician’s role in management, and type of PET.

• Goal
  – Acquire data that can be used to evaluate PET in a manner that does not interfere with patient clinical care and minimizes the burden to the patient, PET center, and referring physician.
Prototype for NOPR Design

• “Clinical decisions associated with positron emission tomography in a prospective cohort of patients with suspected or known cancer at one United States center.”

• Referring physicians’ intended management plans assessed by questionnaires before and after PET

• Change in intended management occurred in:
  – 61% of patients overall
  – 79% of patients where original plan was more testing or biopsy
  – 32% of patients, from a non-treatment to a treatment strategy
Data Analysis Plan and Expected Results

• Data analyzed by cancer type and indication (reason for PET).
• For the most frequent cancer indications, interim analysis will be performed at N=200 to refine sample size estimates.
• Results to be published in peer-reviewed literature.
• If the frequency of change in intended management for a particular cancer indication is sufficient to suggest benefit, data (along with summary of published literature) will be provided to CMS with request for coverage.
• Eventual goal is to achieve broad coverage through analysis of data across all cancers and indications.
Another Expected Benefit

- Reimbursement for PET under NOPR overcomes “Catch 22”

- Now possible to develop more rigorous evidence concerning accuracy and utility of PET for previously non-covered cancers
Participation Requirements/Responsibilities - PET Facilities

- Any PET facility approved to bill CMS for either technical or global charges can participate in the NOPR.
- Willingness to take on the burden and additional cost of collecting data and sending to NOPR

Participation Requirements - Patients

- Medicare beneficiaries, including those with Medicare HMO coverage, who are referred for FDG-PET for essentially all oncologic indications that are not currently reimbursable under Medicare.
- **Oral consent** is necessary for inclusion in the NOPR research dataset; however, no consent is necessary to submit data to NOPR that must be sent to CMS.
Referring Physician Responsibilities

• Complete Pre-PET Form and return it to PET Facility prior to PET scan.

• Complete Post-PET Form and return it to PET Facility within 30 days of PET scan.

• No Medicare payment to referring physicians for completing the Pre- and Post-PET Forms.

• Referring MD cooperation is essential to the success of this CED project!
NOPR Web Site

- Information for
  - PET Facilities
  - Referring Physicians
  - Patients
- Blank Forms
- Register PET Facilities
- Register Patients
- PET Facility Tools
  - Case Status Reports
  - Account Balance
  - Fund Account by Credit Card

http://www.cancerPETregistry.org
Pre-PET Form – 5 Questions

- Reason for the PET Scan
- Cancer Site/Type
- Summary of Disease Stage
  - NED, Localized, Regional, Metastatic, Unknown
- Performance Status
  - Asymptomatic, Symptomatic, Bedridden
- Intended Patient Management Plan
Pre-PET Form: Specific Reason For PET

1. Check the **single best** match for the reason for the PET.

- Diagnosis: To determine if a suspicious lesion is cancer
- Diagnosis
  - Unknown primary tumor: To detect a primary tumor site in a patient with a confirmed metastatic lesion
  - Paraneoplastic: To detect a primary tumor site in a patient with a presumed paraneoplastic syndrome
- Initial staging of histologically confirmed, newly diagnosed cancer
- Monitoring treatment response: during chemotherapy, radiotherapy, or combined modality therapy
- Restaging after completion of therapy
- Suspected recurrence of a previously treated cancer
Pre-PET Form: Intended Patient Management Plan

5. If PET were not available, your current management strategy would be (select one)?
   - Observation (with close follow-up)
   - Additional imaging (CT, MRI) or other non-invasive diagnostic tests
   - Tissue biopsy (surgical, percutaneous, or endoscopic).
   - Treatment (if treatment is selected, then also complete the following)
     - Treatment Goal: (check one)  
       - Curative
       - Palliative
     - Type(s): (check all that apply)
       - Surgical  Chemotherapy (including biologic modifiers)
       - Radiation  Other  Supportive care
Post-PET Form – 4 to 7 Questions

• Questions Customized by Specific Reason for PET (Indication)
• 3 - 6 Questions per Indication
• Most Require a Yes or No Answer
• 2 Questions are Repeated from the Pre-PET Form
  – Intended Patient Management Plan
  – Planned Cancer Care Provider
• Referring Physician Consent
Pitfalls of PET under NOPR Coverage

- Relatively low FDG uptake in some previously non-covered cancers
  - Prostate cancer, hepatoma, mucinous GI-tract cancers, neuroendocrine tumors, low-grade gliomas
  - Baseline study at initial staging will help to define those tumors for which FDG-PET not suitable
- Limited published data to guide use for some previously non-covered cancers
- Learning curves expected for both referring physicians and interpreting physicians
NOPR Status (as of October 31, 2008)

- Opened for patient accrual on May 8, 2006
- **1,629** PET facilities nationwide participating (nearly 90% of all sites)
- **56,684** patients registered
- **54,553** patients - data entry completed
- Approximately **92% of patients and 96% of referring physicians** are consenting to research use of data
NOPR Accrual (Cases Completed/Business Day)
Location of Participants (as of October 31, 2008)
## NOPR Working Group Prioritization

<table>
<thead>
<tr>
<th>Priority and Relative Frequency</th>
<th>Diagnosis</th>
<th>Staging</th>
<th>Restaging/ Suspected Recurrence</th>
<th>Treatment Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Pancreas Cancer</td>
<td>Pancreas Cancer</td>
<td>Ovarian Cancer</td>
<td>Lymphoma</td>
</tr>
<tr>
<td>2</td>
<td>Cancer/ Unknown Primary</td>
<td>SCLC</td>
<td>Brain Tumors</td>
<td>NSCLC</td>
</tr>
<tr>
<td>3</td>
<td>Ovarian Cancer</td>
<td></td>
<td>Cervical Cancer</td>
<td>Metastatic Colorectal Cancer</td>
</tr>
<tr>
<td>4</td>
<td>Multiple Myeloma</td>
<td></td>
<td></td>
<td>Head and Neck Cancer</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td></td>
<td></td>
<td>Esophageal Cancer</td>
</tr>
</tbody>
</table>
Top Ten NOPR Cancer Sites

- **Prostate**
- Ovary / Uterine Adenexa
- Pancreas
- Bladder
- Kidney / Other Urinary Tract
- Small Cell Lung
- Stomach
- **Non-small Cell Lung**
- Myeloma
- Uterus, body
Top Ten NOPR Cancer Sites/Indications

• Ovary / Uterine Adnexa – Restaging / Recurrence
• **Prostate – Restaging / Recurrence**
• **Prostate – Initial Staging**
• Bladder – Restaging / Recurrence
• Kidney / Other Urinary Tract – Restaging / Recurrence
• Ovary / Uterine Adnexa – Treatment Monitoring
• Small Cell Lung – Restaging / Recurrence
• Pancreas – Restaging / Recurrence
• Stomach – Initial Staging
• Pancreas – Initial Staging
NOPR Results

Overall Impact on Patient Management
  – Diagnosis, Staging, Restaging, Recurrence
  – Data on 22,975 scans from May 8, 2006 – May 7, 2007

Treatment Monitoring
  – In press in Cancer

Impact on Patient Management for by Cancer Type
  – Staging, Restaging, Recurrence
  – Data on 40,863 scans from May 8, 2006 – May 7, 2008
Impact of Positron Emission Tomography/Computed Tomography and Positron Emission Tomography (PET) Alone on Expected Management of Patients With Cancer: Initial Results From the National Oncologic PET Registry

Bruce E. Hillner, Barry A. Siegel, Dawei Liu, Anthony F. Shields, Ilana F. Givens, Lucy Hanna, Sharon Hartson Stine, and R. Edward Coleman

ABSTRACT

Purpose
Under Medicare’s Coverage with Evidence Development policy, positron emission tomography (PET)/computed tomography (CT) and PET became covered services for previously noncovered cancer indications if prospective registry data were collected. The National Oncologic PET Registry (NOPR) was developed to meet these coverage requirements and to assess how PET affects care decisions.

Methods
The NOPR collected questionnaire data from referring physicians on intended patient management before and after PET. After 1 year, the cohort included data from 22,975 studies (83.7% PET/CT) from 1,178 centers. The numbers of scans performed for diagnosis of suspected cancer (or unknown primary cancer), initial cancer staging, restaging, and suspected cancer recurrence were approximately equal. Prostatic, pancreatic and ovarian cancers represented approximately 30% of cases.

Results
If PET data were not available, the most common pre-PET plan would have been other imaging. In these patients, the post-PET strategies changed to watching in 37% and treatment in 48%. In patients with planned biopsy before PET, biopsy was avoided in approximately 70%. If the pre-PET strategy was treatment, the post-PET strategy involved a major change in type in 8.7% and goal in 5.6%. When intended management was classified as either treatment or nontreatment, the post-PET plan was three-fold more likely to lead to treatment than nontreatment (28.3% vs 8.2%; odds ratio = 3.4; 95% CI, 3.2 to 3.6). Overall, physicians changed their intended management in 36.5% (95% CI, 35.9 to 37.2) of cases after PET.

Conclusion
This large, prospective, nationally representative registry of elderly cancer patients found that physicians often change their intended management on the basis of PET scan results across the full spectrum of its potential uses.

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Cohort Profile

- First year of NOPR (5/8/06 to 5/7/07)
- 22,975 “consented” cases from 1,519 facilities
- Technology profile
  - 84% PET/CT
  - 71% non-hospital
  - 76% fixed sites

Hillner et al., J Clin Oncol 2008
PET Changed Intended Management in 36.5% of Cases

### Clinical Indication for PET Study (Percent)

<table>
<thead>
<tr>
<th>Pre-Pet Plan</th>
<th>Post-PET Plan</th>
<th>Dx n=5,616</th>
<th>Staging n=6,464</th>
<th>Restaging n=5,607</th>
<th>Recurrence n=5,388</th>
<th>All n=22,975</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treat</td>
<td>Same</td>
<td>16.0</td>
<td>46.5</td>
<td>15.8</td>
<td>20.4</td>
<td>25.5</td>
</tr>
<tr>
<td>Non-Treat</td>
<td>Same</td>
<td>52.9</td>
<td>14.0</td>
<td>48.0</td>
<td>40.7</td>
<td>37.9</td>
</tr>
</tbody>
</table>

|                | Non-Treat     | Treat      | 23.2            | 31.6              | 28.6              | 29.2         | 28.3         |
| Non-Treat      | Non-Treat     |            | 7.9             | 7.9               | 7.5               | 9.7          | 8.2          |
| Patients with change post-PET (%) | 31.1 | 39.5 | 36.1 | 39.0 | **36.5** |

Hillner et al., J Clin Oncol 2008
## Changes in Intended Management (%)
### Stratified by Pre-PET Plan

| Pre-PET Plan | Image  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=9,518</td>
</tr>
</tbody>
</table>
| Post-PET Plan | Biopsy  
| Image | n=3,552|
| Biopsy | n=2,199|
| Watch | n=7,706|

| Post-PET Plan | Image  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5.8</td>
</tr>
</tbody>
</table>
| Post-PET Plan | Biopsy  
| Image | 6.0 |
| Biopsy | 24.0 |
| Watch | 62.3 |

| Post-PET Plan | Watch  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Image</td>
<td>4.6</td>
</tr>
<tr>
<td>Biopsy</td>
<td>9.0</td>
</tr>
<tr>
<td>Watch</td>
<td>15.6</td>
</tr>
</tbody>
</table>

| Post-PET Plan | Treatment  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Image</td>
<td>3.0</td>
</tr>
<tr>
<td>Biopsy</td>
<td>6.8</td>
</tr>
<tr>
<td>Watch</td>
<td>15.6</td>
</tr>
<tr>
<td>Same Rx</td>
<td>42.4</td>
</tr>
</tbody>
</table>

| Post-PET Plan | New or Major Change in Rx  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Image</td>
<td>47.6</td>
</tr>
<tr>
<td>Biopsy</td>
<td>36.3</td>
</tr>
<tr>
<td>Watch</td>
<td>24.1</td>
</tr>
</tbody>
</table>

| Post-PET Plan | Minor change Rx  
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Image</td>
<td>NA</td>
</tr>
<tr>
<td>Biopsy</td>
<td>NA</td>
</tr>
<tr>
<td>Watch</td>
<td>NA</td>
</tr>
</tbody>
</table>

Hillner et al., J Clin Oncol 2008
## Major NOPR Cancer Types vs. Incidence (Patients Over Age 65)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prostate</td>
<td>3,769</td>
<td>116,659</td>
<td>3.2%</td>
</tr>
<tr>
<td>Ovary and Adnexa</td>
<td>3,706</td>
<td>9,625</td>
<td>38.5%</td>
</tr>
<tr>
<td>Pancreas</td>
<td>3,561</td>
<td>21,962</td>
<td>16.2%</td>
</tr>
<tr>
<td>Bladder</td>
<td>2,665</td>
<td>44,570</td>
<td>6.0%</td>
</tr>
<tr>
<td>Kidney/Other Urinary Tract</td>
<td>2,623</td>
<td>20,886</td>
<td>12.6%</td>
</tr>
<tr>
<td>Small Cell Lung</td>
<td>2,390</td>
<td>19,657</td>
<td>12.2%</td>
</tr>
<tr>
<td>Stomach</td>
<td>2,349</td>
<td>13,048</td>
<td>18.0%</td>
</tr>
<tr>
<td>Myeloma</td>
<td>1,336</td>
<td>10,194</td>
<td>13.1%</td>
</tr>
</tbody>
</table>

*Excluded Scans done for treatment monitoring
## Change in Management by Cancer Type

<table>
<thead>
<tr>
<th>Cancer Type</th>
<th>Diagnosis</th>
<th>Staging</th>
<th>Restaging</th>
<th>Suspected Recurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bladder</strong></td>
<td>44.3%</td>
<td>39.9%</td>
<td>36.4%</td>
<td>36.7%</td>
</tr>
<tr>
<td></td>
<td>(174)</td>
<td>(1,461)</td>
<td>(1,239)</td>
<td>(878)</td>
</tr>
<tr>
<td><strong>Brain</strong></td>
<td>31.6%</td>
<td>--</td>
<td>--</td>
<td>40.5%</td>
</tr>
<tr>
<td></td>
<td>(158)</td>
<td></td>
<td></td>
<td>(222)</td>
</tr>
<tr>
<td><strong>Cervix</strong></td>
<td>---</td>
<td>36.1%</td>
<td>26.9%</td>
<td>35.9%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(341)</td>
<td>(353)</td>
<td>(290)</td>
</tr>
<tr>
<td><strong>Kidney</strong></td>
<td>25.4%</td>
<td>41.1%</td>
<td>34.4%</td>
<td>32.4%</td>
</tr>
<tr>
<td></td>
<td>(710)</td>
<td>(895)</td>
<td>(979)</td>
<td>(1,059)</td>
</tr>
</tbody>
</table>

% (patients)

Hillner et al., J Nucl Med 2008
## Change in Management by Cancer Type

<table>
<thead>
<tr>
<th></th>
<th>Diagnosis</th>
<th>Staging</th>
<th>Restaging</th>
<th>Suspected Recurrence</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ovary</strong></td>
<td>35.3</td>
<td>43.2</td>
<td>37.7</td>
<td>44.5</td>
</tr>
<tr>
<td></td>
<td>(306)</td>
<td>(378)</td>
<td>(1,971)</td>
<td>(2,160)</td>
</tr>
<tr>
<td><strong>Pancreas</strong></td>
<td>30.2</td>
<td>39.2</td>
<td>38.3</td>
<td>39.3</td>
</tr>
<tr>
<td></td>
<td>(1,190)</td>
<td>(1,491)</td>
<td>(1,021)</td>
<td>(802)</td>
</tr>
<tr>
<td><strong>Prostate</strong></td>
<td>28.0</td>
<td>32.0</td>
<td>34.0</td>
<td>39.4</td>
</tr>
<tr>
<td></td>
<td>(321)</td>
<td>(2042)</td>
<td>(1,477)</td>
<td>(1,790)</td>
</tr>
<tr>
<td><strong>Small Cell Lung</strong></td>
<td>21.7</td>
<td>43.3</td>
<td>40.8</td>
<td>38.1</td>
</tr>
<tr>
<td></td>
<td>(281)</td>
<td>(1,082)</td>
<td>(1,357)</td>
<td>(544)</td>
</tr>
<tr>
<td><strong>Myeloma</strong></td>
<td>--</td>
<td>52.2</td>
<td>46.4</td>
<td>50.9</td>
</tr>
<tr>
<td></td>
<td></td>
<td>(402)</td>
<td>(1009)</td>
<td>(373)</td>
</tr>
</tbody>
</table>

Hillner et al., J Nucl Med 2008
Imaging-adjusted Change in Management

- Inclusion of cases where the pre-PET plan was alternative imaging (CT or MRI) may overestimate the impact of PET.
- As a lower boundary of the impact of PET on intended management, we re-analyzed the data assuming no benefit from the information provided by PET in cases with a pre-PET imaging plan (all such cases were included in the denominator).
Change in Management by Cancer Type

• The average overall change was 38.0%  
  – Range: 48.7% in myeloma to 31.4% in non-melanoma skin cancer

• Across indications (staging, restaging, recurrence) PET only had a greater impact in myeloma

• The average imaging adjusted impact was 14.7%  
  – Range: 16.2% in ovarian cancer to 9.6% in non-melanoma skin cancer

• Imaging adjusted change for myeloma was 11.5%

Hillner et al., J Nucl Med 2008
Impact of PET Used for Treatment Monitoring

- Chemotherapy 82%, chemoRT 12%, RT 6%
- Ovarian, pancreas, NSCLC, SCLC most frequent
- Metastatic disease in 54%
- PET findings led to:
  - Switch to another therapy in 26%
  - Adjust dose or duration of therapy in 17%
  - Switch from therapy to observation/supportive care in 6%
- Management change more often if post-PET prognosis worse rather than improved/unchanged (70% vs. 40%)
Strengths of the NOPR Data

- “Real world” data
- Timely data
- Very large patient cohorts
- Current technology (≥ 85% PET/CT)
- Good observational studies usually match controlled studies in magnitude and direction of effect (Concato NEJM 2000; Benson NEJM 2000; Ionnanidis JAMA 2001)
- Results similar to more tightly managed single-institution studies (e.g., Hillner 2004) and to new Australian studies with outcome validation
Limitations of the NOPR Data

- Collected change in “intended” management, not actual management
- Unknown if management changes were in the correct direction or improve long-term outcomes
- NOPR does not address:
  - Whether PET should be used in lieu of or as a complement to other imaging techniques
  - The optimal sequencing of CT, MRI and PET.
  - How much ‘better’ PET is than next best legacy method
Summary of NOPR Results

• Change in intended management associated with PET in previously non-covered cancers similar to that reported in single-institution studies of covered cancers.

• ~1/3 of older patients undergoing PET for cancer types covered under Medicare’s CED policy had a major change in intended management, including type of treatment.

• Examination of individual cancers did not find a significant difference in treatment changes between cancer.

• NOPR has not yet examined if PET actually changed patient management or if PET improved outcome (can be examined in future studies).
NOPR “Forecast”

- Request submitted to CMS on March 25, 2008 to expand coverage for diagnosis, staging, restaging and detection of suspected recurrence for all cancers
- Requested that NOPR continue for treatment monitoring
- NCD process to date has included two public comment periods, technology assessment, and MedCAC meeting
- Draft decision memorandum due January 10, 2009
- Final national coverage determination due April 9, 2009
- Stay tuned!!