

National Oncologic PET Registry

Present and Future

Barry A. Siegel, M.D.

Mallinckrodt Institute of Radiology

R. Edward Coleman, M.D.

Duke University Medical Center

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**

NOPR

NATIONAL ONCOLOGIC PET REGISTRY

National Oncologic PET Registry

CANCERPETREGISTRY.ORG

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

NATIONAL ONCOLOGIC PET REGISTRY

NOPR: A Nationwide Collaborative Program

Sponsored by 
ACADEMY OF MOLECULAR IMAGING

Advisor 
CENTERS for MEDICARE & MEDICAID SERVICES

Managed by  
AMERICAN COLLEGE OF RADIOLOGY AMERICAN COLLEGE OF RADIOLOGY IMAGING NETWORK

Endorsed by    
AMERICAN COLLEGE OF RADIOLOGY AMERICAN SOCIETY of CLINICAL ONCOLOGY Advancing Molecular Imaging and Therapy Molecular Imaging

- 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

CANCERPETREGISTRY.ORG

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.”
Hillner, et al. *J Clin Oncol* 2004; 22;4147-56.
- 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

Institutional Review Board (IRB) Approval & Subject Informed Consent

- Is this research? Yes, but only for the NOPR. Individual PET facilities and referring physicians are not engaged in research.
- Is IRB approval needed? Yes. ACR IRB has approved the NOPR. Individual PET facilities and referring physicians do not need to obtain IRB approval to participate.
 - All data will be sent to CMS. CMS is not engaged in research.
 - Patients and referring physicians will be given an IRB-approved information sheet and asked for consent to have their data included for NOPR research.
 - Only cases where both patient and physician give consent will be included in the NOPR research dataset.

Consent Procedure

- Patient
 - Patient Information Sheet provided to patient by PET facility
 - Patient gives oral consent
- Referring Physician
 - Physician Information Sheet included with Post-PET Form
 - Consent noted on that form

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

NOPR
NATIONAL ONCOLOGIC PET REGISTRY

Home
[What Is The NOPR](#) ▼
[NOPR Forms](#) ▼
[Info For PET Facilities](#) ▼
[Info For Referring Physicians](#) ▼
[Info For Patients](#)
[PET Facility Registration](#)
[Registered Users](#)
[Frequently Asked Questions](#)
[Educational Materials](#)
[News](#)
[Monthly Status Report](#)
[Contact Us](#)

Welcome to the NOPR
 The National Oncologic PET Registry (NOPR) is a collaboration of the American College of Radiology Imaging Network (ACRIN), the American College of Radiology (ACR), and the Academy of Molecular Imaging (AMI), to ensure access to Medicare reimbursement for certain types of positron emission tomography (PET) scans.

Denial of Claims with the Q0 Modifier (7/24/08)
CMS Convenes MedCAC Panel (7/21/08)
Denial of Claims with the Q0 Modifier (7/14/08)
NOPR Billing Alert (4/09/08)
QR Modifier Deleted Effective 2008 (12/31/07)
Covered Indications (11/2/07)
Referring MD Responsibilities (9/20/07)
NOPR Presents at 2007 RSNA (8/15/07)
CMS MLM Matters on Reimbursement (5/19/2006)
CMS Transmittal 956 (5/19/2006)

Individual Cancers Paper Published in JNM
NOPR Initial Results Published in JCO
Design & Analysis Plan Paper Published
NOPR Design and Methods Paper in JNM
NOPR Overview in the AJR

VeriSeal Security

http://www.cancerPETregistry.org

Sponsored By:

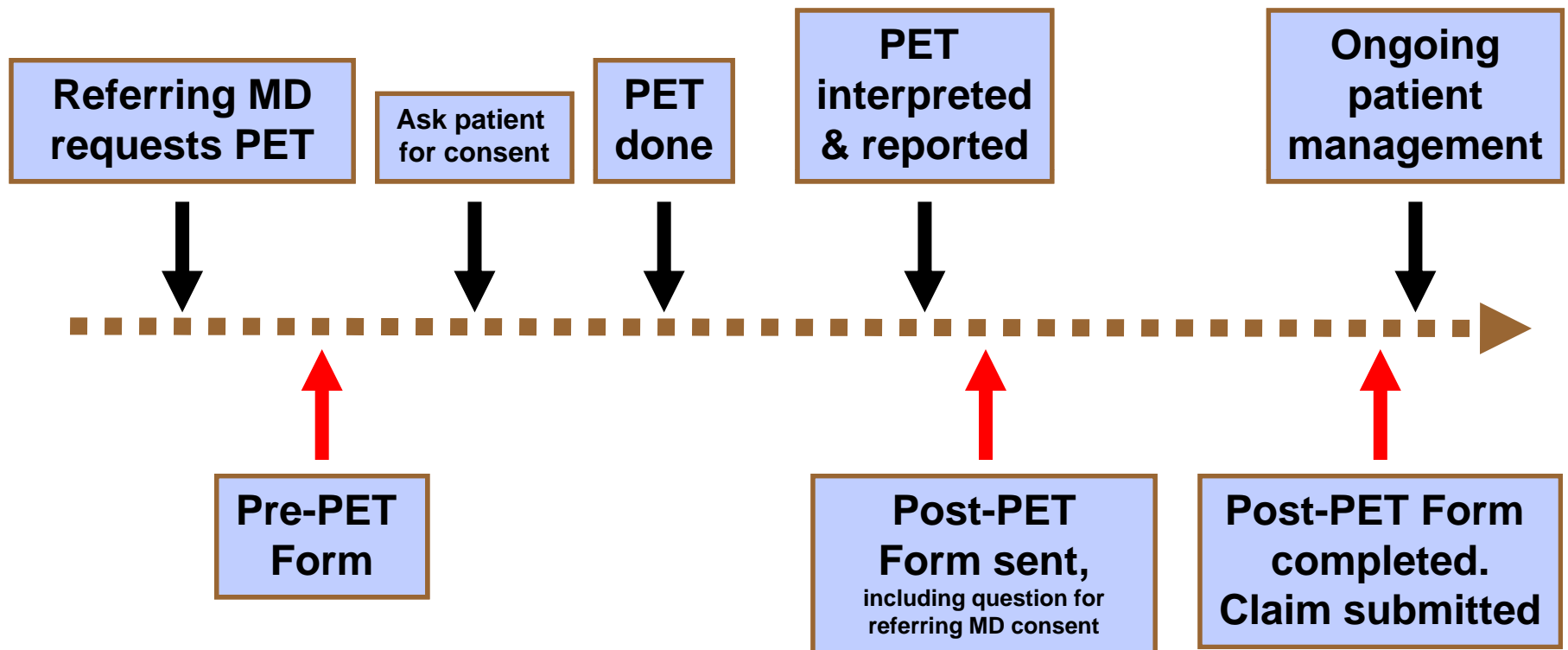
Managed By:

Endorsed By:

Advisor:

1818 Market Street, Suite 1600, Philadelphia, PA 19103 | 215.717.0859 | pet_registry@phila.acr.org

NOPR Workflow



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

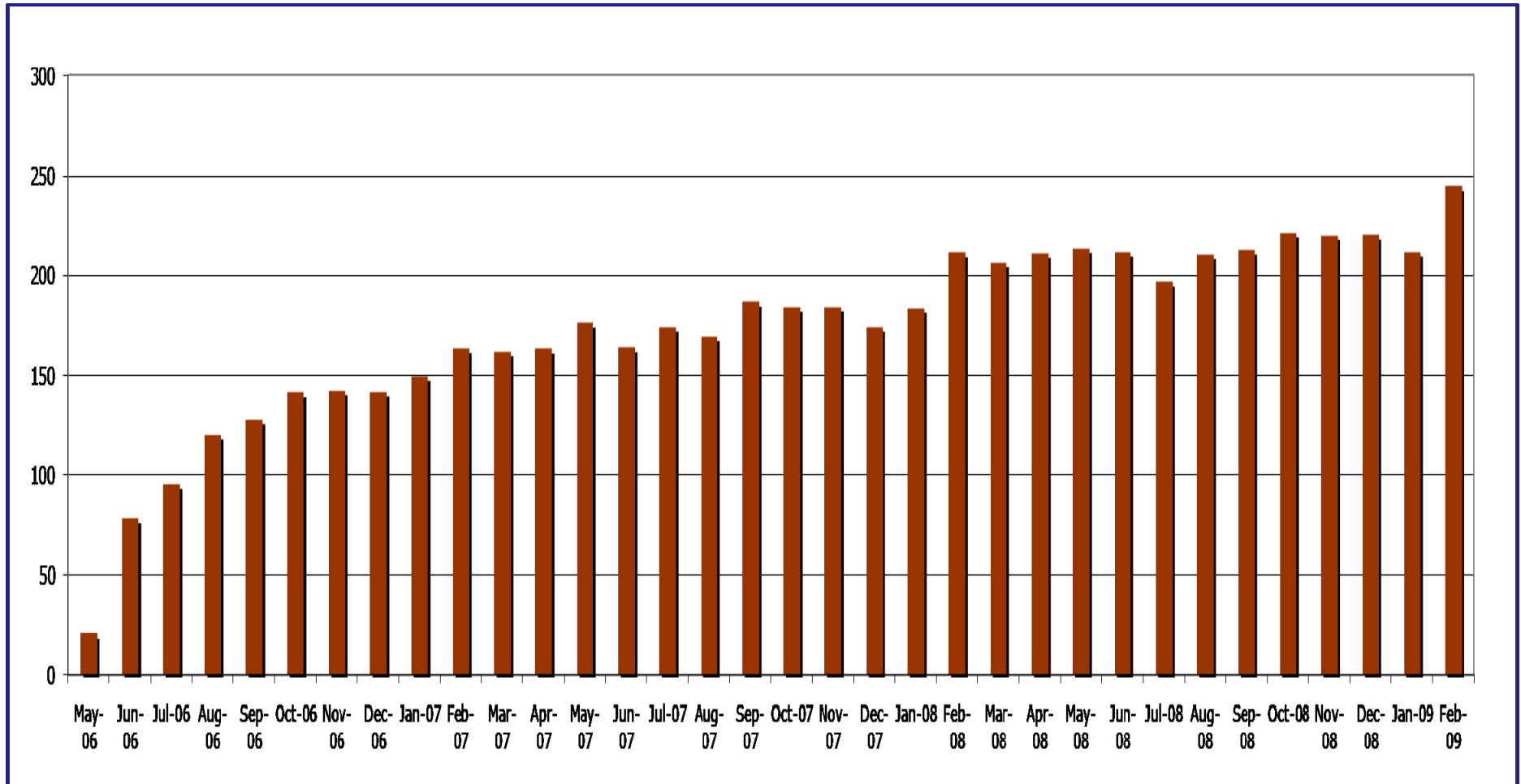
Pitfalls of PET under NOPR Coverage

- 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 March 31, 2009)

- Opened for patient accrual on May 8, 2006
- 1,891 PET facilities nationwide participating (over 90% of all sites)
- 130,167 patients - data entry completed
- Approximately 92% of patients and 96% of referring physicians are consenting to research use of data

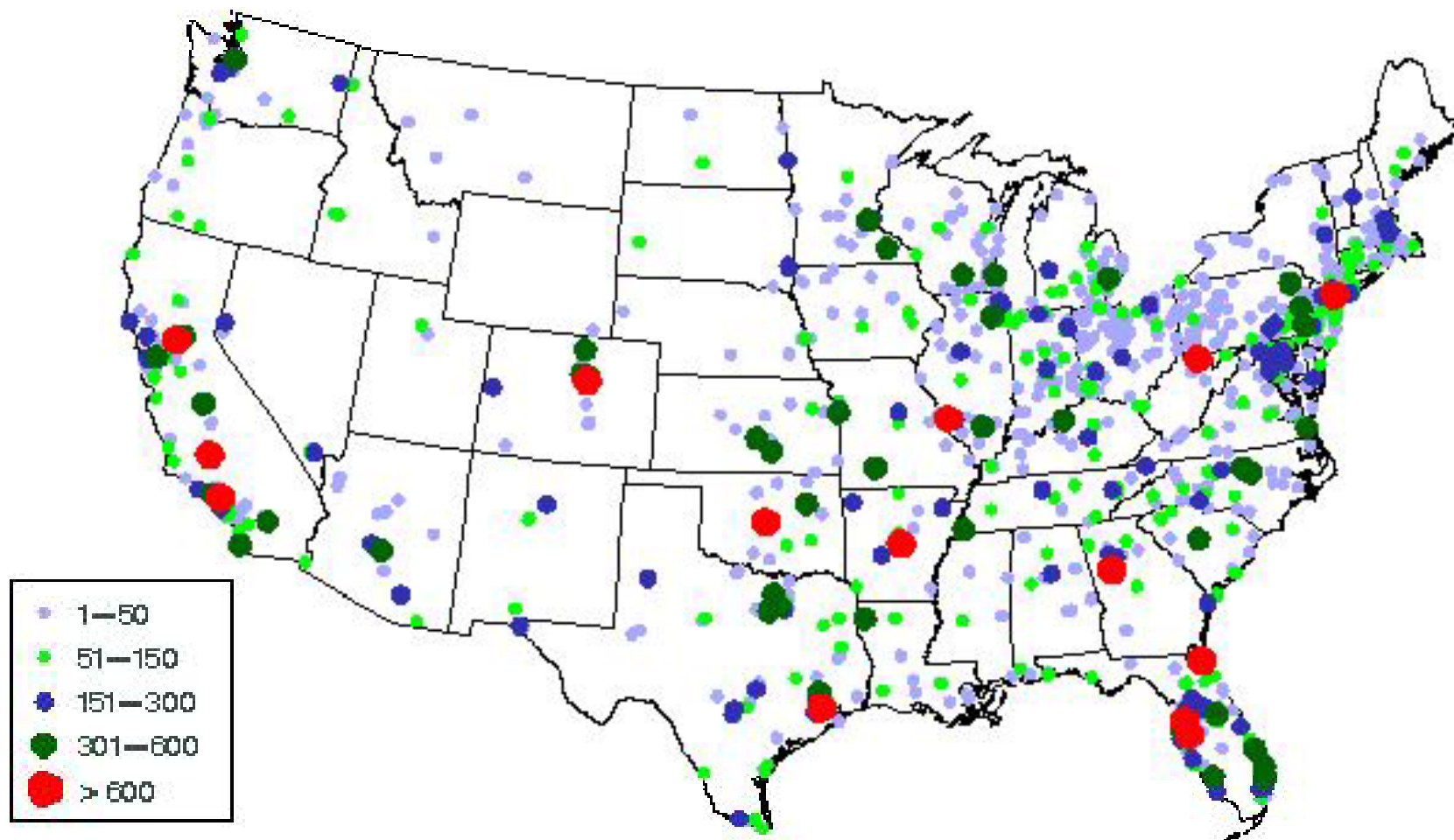
NOPR Accrual (Cases Completed/Business Day)



NOPR

NATIONAL ONCOLOGIC PET REGISTRY

Location of NOPR Participants



Top Ten NOPR Cancer Sites

- Ovary / Uterine Adenexa
- **Prostate**
- Pancreas
- Kidney / Other Urinary Tract
- Bladder
- Small Cell Lung
- Stomach
- Myeloma
- Non-small Cell Lung
- Uterus, body

Top Ten NOPR Cancer Sites/Indications

- Ovary / Uterine Adnexa – Recurrence
- Ovary / Uterine Adnexa – Treatment Monitoring
- Ovary / Uterine Adnexa – Restaging
- **Prostate – Initial Staging**
- **Prostate – Recurrence**
- Pancreas – Initial Staging
- Stomach – Initial Staging
- Bladder – Initial Staging
- **Prostate – Restaging**
- Small Cell Lung – Restaging

NOPR Results

Overall Impact on Patient Management

- Diagnosis, Staging, Restaging, Recurrence
- Data on 22,975 scans from May 8, 2006 – May 7, 2007
- *J Clin Oncol* 2008; 26:2155-61

Treatment Monitoring

- Data on 10,447 scans from May 8, 2006 – Dec 31, 2007
- *Cancer* 2009;115:410-18

Impact on Patient Management for by Cancer Type

- Staging, Restaging, Recurrence (proven cancer type)
- Data on 40,863 scans from May 8, 2006 – May 7, 2008
- *J Nucl Med* 2008; 49:1928-35

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. Gareen, Lucy Hanna, Sharon Hartson Stine, and R. Edward Coleman

From the Department of Internal Medicine and the Massey Cancer Center, Virginia Commonwealth University, Richmond, VA; Division of Nuclear Medicine, Mallinckrodt Institute of Radiology and the Siteman Cancer Center, Washington University School of Medicine, St. Louis, MO; Center for Statistical Sciences, Brown University, Providence, RI; Karmanos Cancer Institute, Wayne State University, Detroit, MI; American College of Radiology, Philadelphia, PA; and the Department of Radiology, Duke University School of Medicine, Durham, NC.

Submitted October 3, 2007; accepted December 4, 2007; published online ahead of print at www.jco.org on March 24, 2008.

Authors' disclosures of potential conflicts of interest and author contributions are found at the end of this article.

Corresponding author: Bruce E. Hillner, MD, Virginia Commonwealth University, 1101 E Marshall St, Room 7013, Richmond, VA 23298-0170; e-mail: Hillner@vcu.edu.

© 2008 by American Society of Clinical Oncology

0732-183X/08/2613-2155/\$20.00

DOI: 10.1200/JCO.2007.14.5631

A B S T R A C T

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% v 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.

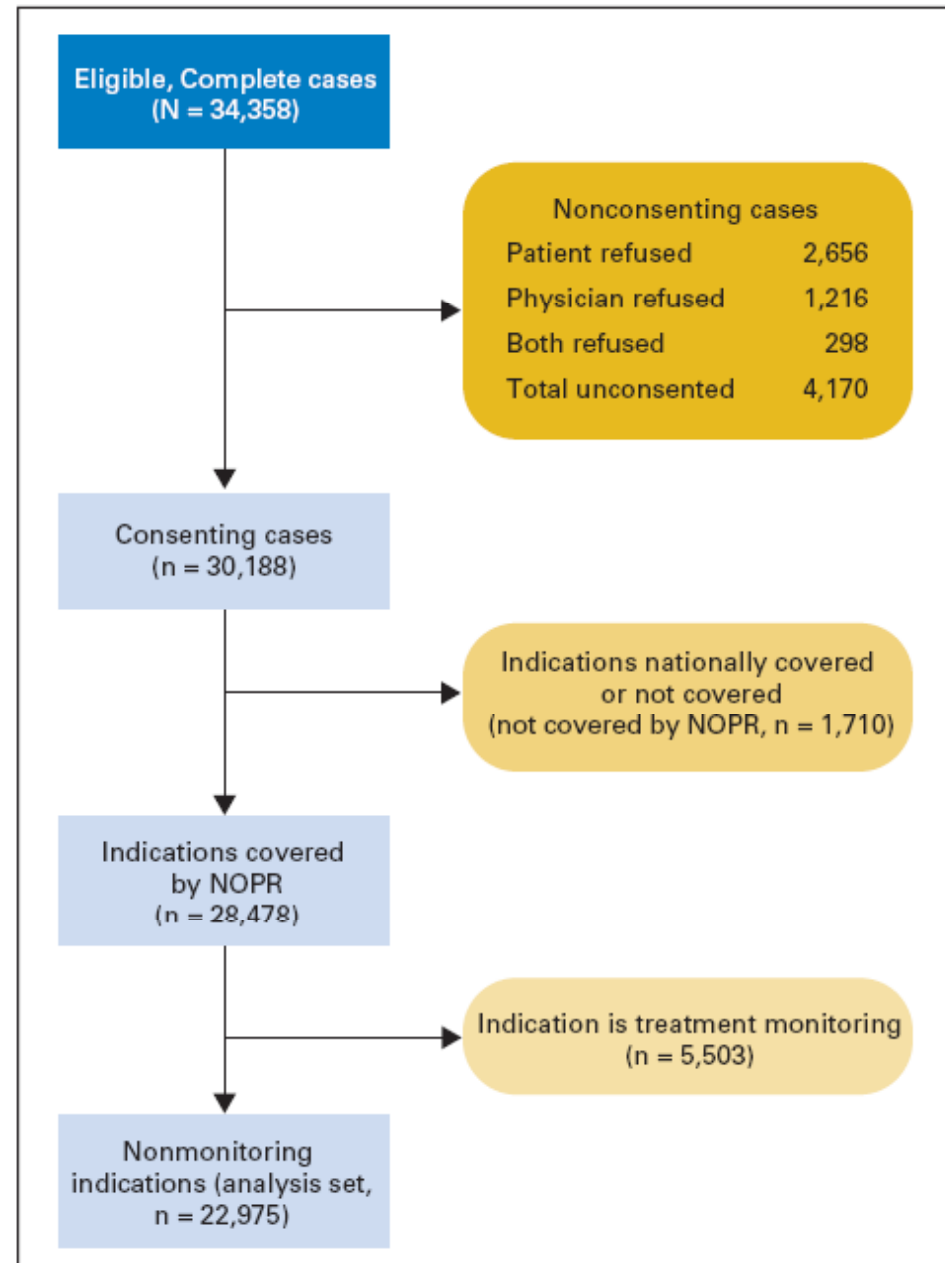
Conclusion

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.

J Clin Oncol 26:2155-2161. © 2008 by American Society of Clinical Oncology

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



PET Changed Intended Management in 36.5% of Cases

		Clinical Indication for PET Study (Percent)				
Pre-Pet Plan	Post-PET Plan	Dx n=5,616	Staging n=6,464	Restaging n=5,607	Recurrence n=5,388	All n=22,975
Treat	Same	16.0	46.5	15.8	20.4	25.5
Non-Treat	Same	52.9	14.0	48.0	40.7	37.9
Non-Treat	Treat	23.2	31.6	28.6	29.2	28.3
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 n=9,518	Biopsy n=3,552	Watch n=2,199	Treatment n=7,706
Post-PET Plan				
Image	5.8	6.0	4.6	3.0
Biopsy	9.5	24.0	9.0	6.8
Watch	37.2	33.6	62.3	15.6
Same Rx	NA	NA	NA	42.4
New or Major Change in Rx	47.6	36.3	24.1	8.7
Minor change Rx	NA	NA	NA	23.5

Hillner et al., J Clin Oncol 2008

Major NOPR Cancer Types vs. Incidence (Patients Over Age 65)

Cancer Type	Total NOPR Scans (2007)*	Incidence (CDC 2004)	Scans per Incidence (2007)
Prostate	3,769	116,659	3.2%
Ovary and Adnexa	3,706	9,625	38.5%
Pancreas	3,561	21,962	16.2%
Bladder	2,665	44,570	6.0%
Kidney/Other Urinary Tract	2,623	20,886	12.6%
Small Cell Lung	2,390	19,657	12.2%
Stomach	2,349	13,048	18.0%
Myeloma	1,336	10,194	13.1%

*Excluded Scans done for treatment monitoring

Change in Management by Cancer Type

	Staging	Restaging	Suspected Recurrence
Bladder	39.9 (1,461)	36.4 (1,239)	36.7 (878)
Brain	--	--	40.5 (222)
Cervix	36.1 (341)	26.9 (353)	35.9 (290)
Kidney	41.1 (895)	34.4 (979)	32.4 (1,003)

% (patients)

Hillner et al., J Nucl Med 2008

Change in Management by Cancer Type

	Staging	Restaging	Suspected Recurrence
Ovary	43.21 (378)	37.7 (1,971)	44.5 (2,160)
Pancreas	39.2 (1,491)	38.3 (1,021)	39.3 (802)
Prostate	32.0 (2042)	34.0 (1,477)	39.4 (1,790)
Small Cell Lung	43.3 (1,082)	40.8 (1,357)	38.1 (544)
Myeloma	52.2 (402)	46.4 (1009)	50.9 (373)

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
 - i.e., outcome might be the same if CT or MRI had been done instead 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%)

Hillner et al., Cancer 2009

Strengths of the NOPR Data

- “Real world” data
- Timely data
- Very large patient cohorts
- Current technology ($\geq 85\%$ PET/CT)
- Good observational studies usually match controlled studies in magnitude and direction of effect
(Concato NEJM 2000; Benson NEJM 2000; Ionnidis 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

NOPR and the New NCD

- **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 issued January 6, 2009
- Final national coverage determination issued April 3, 2009

CMS Decision

- ***New framework*** differentiates PET imaging into use for:
 - **initial treatment strategies**
(formerly diagnosis and initial staging)
 - **subsequent treatment strategies**
(formerly treatment monitoring and restaging/
detection of suspected recurrence)

Expanded Coverage by CMS

- As part of initial treatment evaluation, a single PET scan will be covered for all cancers with the exception of **prostate cancer**, breast cancer diagnosis and axillary nodal staging, and melanoma regional nodal staging
- For subsequent treatment evaluation, expanded coverage for PET in legacy conditions to include treatment monitoring
- New coverage for subsequent treatment evaluation of cervical cancer, **ovarian cancer, and myeloma**

Continuation of Coverage with Evidence Development (CED) Program

- For subsequent treatment evaluation (restaging, suspected recurrence or treatment monitoring) for most cancers included in the initial NOPR study, PET will be continue to be available only through a CED program (also necessary for thyroid cancer not meeting current coverage requirement—Tg > 10, neg I-131 scan)
- CED also required for initial treatment strategy of cervical cancer (not meeting current coverage requirements—neg CT/MRI for extrapelvic metastasis) and for leukemia .

	Previous Framework				New Framework	
	Dx	Staging	Restaging	Treatment Monitoring	Initial Rx	Subseq. Rx
Breast	N/C	1	Cover	Cover	1	Cover
Colorectal	Cover	Cover	Cover	CED	Cover	Cover
Esophagus	Cover	Cover	Cover	CED	Cover	Cover
Head Neck	Cover	Cover	Cover	CED	Cover	Cover
Lymphoma	Cover	Cover	Cover	CED	Cover	Cover
Melanoma	Cover	2	Cover	CED	2	Cover
NSCLC	Cover	Cover	Cover	CED	Cover	Cover
Thyroid	Cover	Cover	3	CED	Cover	3

- 1: Covered for metastatic disease. Non-covered for staging of axillary lymph nodes.
- 2: Melanoma: Non-covered for initial staging of regional lymph nodes
- 3: Thyroid: Covered for restaging of follicular cell types

	Previous Framework				New Framework	
	Dx	Staging	Restaging	Treatment Monitoring	Initial Rx	Subseq. Rx
Brain	CED	CED	CED	CED	Cover	CED
Cervix	CED	Cover/CED	Cover/CED	CED	Cover/CED	Cover
Ovary	CED	CED	CED	CED	Cover	Cover
Myeloma	CED	CED	CED	CED	Cover	Cover
Pancreas	CED	CED	CED	CED	Cover	CED
Prostate	CED	CED	CED	CED	N/C	CED
Small cell	CED	CED	CED	CED	Cover	CED
Testis	CED	CED	CED	CED	Cover	CED
All other solid tumors	CED	CED	CED	CED	Cover	CED

Expanded coverage is significant gain, but:

- Single-scan limit for initial treatment evaluation illogical and problematic for:
 - RT planning
 - Evolving cancer
- Potential coverage gap for cancers requiring CED

No “Coverage Gap”

- NOPR 2009 operational on April 6, as soon as NCD effective
- Very similar data collection as for NOPR (2006)
 - Additional questions related to treatment monitoring
 - Requirement for referring MD signature attesting to data accuracy
- Will include linkage to Medicare claims data in collaboration with AHRQ