THE FORDS REVISION PROCESS
NAACCR ANNUAL MEETING—2016

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Cancer Programs

- Commission on Cancer
- Clinical Research Program of the Alliance
- American Joint Committee on Cancer
- American Accreditation Program for Breast Centers
- National Cancer Data Base
- Cancer Liaison Program
Introduction to FORDS

- FORDS manual
  - Facility Oncology Registry Data Standards
  - Implemented 2003
  - Minor clinical revisions 2004-2013

- Section One
  - General rules and principles

- Section Two
  - Details majority of data items collected in registries
  - Provides instructions and code structures
Introduction to FORDS

- Cancer registrar manual for shared data collection for NCDB, NPCR, SEER

- Contains
  - General rules and principles for data collection
  - Data item instructions and coding structure

- Used by CoC accredited and non-accredited facilities

- SEER manual is similar
  - Shares most data fields with CoC
  - Instructions and guidelines may differ
  - Coding structure is same
The Relevance of FORDS

- FORDS – Facility Oncology Registry Data Standards
  - Implemented in 2003, updated annually, 2014 in process
  - Replaced ROADS - Registry Oncology and Data Standards
    • Implemented in 1996 with major changes in 1998

- Currently 459 pages, available online in pdf format

- Identifies rules for coding and codes for all CoC required items

- Determines what CoC can measure
  - Quality measures used in RQRS, CQIP, CP3R

- Determines what questions NCDB data can answer
  - Participant User Files (PUF)

- Determines CoC’s relevance and ability to influence quality care
Established in 1989 as a joint program between CoC and the American Cancer Society, the NCDB is a nationwide oncology database that includes data for all CoC-accredited cancer programs.

Collects information annually on ~ 70% of all newly diagnosed cancer cases.

New cancer patients cases in 2014: 1,665,540*

NCDB contains approximately 30 million records from hospital cancer registries across the US and PR.

*Cancer Facts and Figures, American Cancer Society*
Data Collection and Submissions

Hospital Registrar

State Registry

NCDB

NPCR

SEER

CoC Hospital Registrar
Purpose of FORDS Revision Project

- Realign data collection with
  - Contemporary multidisciplinary medical practice

- Enable physicians and researchers to analyze entire continuum of care
  - Diagnostic workup
  - Treatment
  - Prognostic factors
  - National quality measures
  - Guidelines
Key Objectives

- Seek input from relevant groups – physicians (including AJCC Expert Panels), registrars, researchers, quality improvement groups
- Understand different perspectives from surveillance community and clinical professionals
- Identify issues with existing data fields
- Realign data collection with contemporary medical practice
- Create instructions and code structures
- Achieve consensus among partners
- Provide end product to software vendors & training to registrars
FORDS Revision Project

• Changes affect
  – Other registry standard-setters
    • National Program of Cancer Registries at CDC
    • SEER at NCI
    • Canadian registries
  – Software providers
  – State central registries
  – Hospital registries and non-CoC cancer abstractors

• Changes coordinated by North American Association of Central Cancer Registries committees
  – Input from National Cancer Registrars Association
  – Once accepted by NAACCR committees, implementation can take 1-2 years
Overview of Data Items Collected for Each Case

- First Course of Treatment
  - Dates of: first treatment, first surgery, most definitive surgery, radiation begin, radiation end, chemotherapy begin, hormone therapy begin, immunotherapy begin, first systemic therapy begin, other treatment begin
  - Treatment Status: treated, not treated, active surveillance
  - Surgery type: primary site, regional lymph node, other regional or distant site (all here, anywhere); reason for no surgery
  - Radiation: location (here, elsewhere), volume, modality, dose, boost modality, boost dose, number treatments to this volume, radiation/surgery sequence, reason for no radiation
  - Systemic types: Chemotherapy, hormone therapy, immunotherapy (biologic modifier), hematologic transplant and endocrine procedures; systemic/surgery sequence; reasons for not giving each of those modalities
Possible Directions

- Require more complete clinical and pathologic staging
- Better recurrence data collection
- Collect screening and workup methods
- Specific systemic treatments
  - imatinib, ipiligumab, trastuzumab, paclitaxel, etc.
- Subsequent treatment - beyond first course
- CPT and/or ICD-10-PCS treatment codes
- Pediatric-relevant data
- Eliminate unimportant data: registrar workload
  - 18 items deleted 2011-2014
- Add new clinically relevant data to keep up
FORDS Revision Project

- Review current data items
  - Do rules and coding options need revision
  - Remove items no longer necessary

- Explore need for new data items

- Steering Committee encompasses all partners

- Subcommittees to review data item details
  - Physician specialties: Surgery, Pathology, Radiology, Medical & Radiation Oncology
  - Disease site specialties: assistance from CoC QIC and AJCC Expert Panel Leaders
  - Surveillance, central, and hospital registrars

- Request input from physicians and registrars through surveys
Survey for FORDS Revision Project

- Survey link available on CoC Web page

- One suggestion per survey
  - May submit multiple surveys

- Survey categories for suggestion
  - Change existing data item
  - Add new data item
  - Remove existing data item

- Questions similar but unique to each category

- Specifics needed to understand and evaluate suggestion
Survey for FORDS Revision Project

One suggestion per survey

- May submit multiple surveys

Survey categories for suggestion

- Revise existing data item—171 recommendations
  - Most recommendations in treatment categories
- Add new data item—46 specific recommendations
- Remove existing data item—32 recommendations

Specifics needed to understand and evaluate suggestion

Results: 800+ responses
What Else is Happening

- Expert site panels chosen
- Complete in Fall 2016
- Begin use January 1, 2017
Collaboration with AJCC Expert Panels

- Data needed for AJCC staging analysis collected by registrars
- More than just stage
- Includes
  - Diagnostic approaches
  - Tumor size
  - Lymph nodes positive and examined
  - Stage elements: T, N, M, stage group
  - Type of treatment: surgery, radiation, systemic
  - Outcomes
  - Prognostic factors & predictive factors
Issues Important to PPS Exempt Institutions

Coding for patient metrics for COC Standards:
(1) patient refusal  (2) Rx contraindicated (co-existing disease, co-morbidities)  (3) age exclusion  (4) delay secondary to patient choice

Date of Clinical vs Pathologic diagnosis

Date of First Contact

Coding for clinical trial participation and agents used
RECURRENCE DATA COLLECTION and the FORDS REVISION PROJECT
The Lack Of Reliable Information Regarding Cancer Recurrence Is A Major Limitation of Existing Cancer Registries Including The National Cancer Data Base
Important Questions:

What is a “recurrent cancer”?

What is the relationship of a “recurrence” to the primary cancer presentation?

What should be the timeframe between eradication of the primary cancer and the discovery of a “recurrence”?
FORDS Revision Project--Strategy

- Review current data items
  - Do rules and coding options need revision?
  - Remove items no longer necessary
  - Re-evaluate “ambiguous terminology”

- Explore need for new data items

- Subcommittees to review data item details
  - Physician specialties: Surgery, Pathology, Radiology, Medical & Radiation Oncology, Pediatric Oncology, Recurrence workgroup
  - Disease site specialties: assistance from CoC QIC and AJCC Expert Panel Leaders
  - Surveillance, central, and hospital registrars

- Request input from registrars through surveys
Recurrence Capture for FORDS
(A work in progress)

Make it possible to:

Calculate recurrence rate and time-to-recurrence

Track quality of cancer follow-up and promote quality data collection

Allow for collection of locoregional recurrence, distant recurrence and new primary cancers separately
Opportunities for Recurrence Coding

Date of last cancer (tumor) status

Date of first local/regional recurrence

Type of local/regional recurrence

Date of first distant recurrence/metastasis

Type of distant recurrence/metastasis

Date of new primary cancer

Type of new primary cancer
Identifying Cancer Recurrence within the NCDB
Cancer Recurrence

• Cancer recurrence- indicates the cancer has come back after a period of remission

• Recurrence is a critical outcome in cancer care
  – Proxy to evaluate treatment efficacy
  – Assess patient outcomes
  – Predict future recurrences
  – Discover alternative treatments
None of the 3 major cancer registries in the United States report cancer recurrence information:
- American College of Surgeons’ (ACS) Commission on Cancer (CoC)’s National Cancer Data Base (NCDB)
- National Cancer Institute (NCI)’s Surveillance Epidemiology and End Results (SEER) program
- Centers for Disease Control and Prevention (CDC)’s National Program of Cancer Registries (NPCR)

Registries focus on gathering reliable information for the peri-diagnostic period.
Collect very little information about later events except death.

NCDB requests date of first recurrence and type of recurrence (local, regional, distant)
However, the data have not been validated, and questions remain about the quality of the cancer recurrence information.
Phase 1: NCDB data analysis

**Incomplete information**

<table>
<thead>
<tr>
<th></th>
<th>Thyroid (n=50,243)</th>
<th>Colon (n=153,192)</th>
<th>Melanoma (n=79,600)</th>
<th>Pancreas (n=9,727)</th>
<th>Breast (n=408,826)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rates</td>
<td>21.5%</td>
<td>24.0%</td>
<td>20.2%</td>
<td>34.8%</td>
<td>18.2%</td>
</tr>
</tbody>
</table>

Stage I-III cancer patients, diagnosis years 2002-2005.

**Hospital distribution of reported rates of incomplete information**

In et al. Ann Surg Onc 2014
Phase 2: Hospital Visits

- 14 hospitals visited
  - 2 NCI
  - 5 Academic
  - 5 Comp Community
  - 2 Community

- Interviews with cancer registry manager, lead CTR and follow-up clerk
- Observation of follow-up
Phase 3: Survey

• Sent to all CoC hospitals
• 35 multiple choice and 2 free text questionnaire

• Goal
  – Test hypotheses
  – Examine variability in coding
  – Examine potential resource needs

• 1,417 hospitals → 845 responses (59%)
What we found out

• Many hospitals are collecting recurrence information
• Recurrence information was obtained in different ways
• Most registrars felt recurrence information was important
• Concerned about resources available for this task
• Definitions for recurrence are underdeveloped
• Currently available data fields are inadequate to calculate recurrence rate or time-to-recurrence**
Limitations of Current Data

- Uncertain whether everyone who developed recurrence has been identified
- Uncertainty as to who did NOT develop recurrence
- Lack of information about disease status
- Time-to-recurrence
  - Need to know long a person was tracked, and what the latest information is

Time to Recurrence

Data fields needed for above:
- Date of diagnosis
- Date of event
- Date when info was last checked ("Censoring variable")
What are we currently unable to do?

- When new tumor develops after a cancer free interval, it can be a locoregional recurrence, distant recurrence or a new primary
  - Current: *recurrence is collected as any 1st recurrence.*
    - Not able to calculate
      - Locoregional recurrence rate
      - Distant recurrence rate

- Current: *new entry is created for new primary, but not recorded into the analytic case*
  - Case abstraction appears incomplete.
  - Not able to calculate rate of new primaries.
Improving Ascertainment of Recurrence Information within Cancer Registries
Study Objectives

• Determine the feasibility of improving recurrence ascertainment for three major cancer disease sites: breast, colorectal, and lung

• Estimate the additional resources that would be required for widespread implementation of more complete recurrence data collection

• Use the information to provide evidence to inform the development of a *risk-stratified* tailored approach to surveillance following active treatment for breast, colorectal, and lung cancer
Study Preparation

- Study investigators were awarded funding from Patient-centered Outcomes Research Institute (PCORI) to study and develop better approaches to post-treatment surveillance.
  - George J. Chang MD MS
  - Caprice C. Greenberg MD MPH
  - Benjamin D. Kozower MD MPH

- Investigators partnered with CoC to develop approaches to improve ascertainment of recurrence information within the NCDB.

- Investigators met with cancer registrars during development of the procedures and piloted the study at 18 sites.
Data Collection
NCDB Special Study

• Study development: 3/2014-3/2015
• Study timeline: April 1st – July 15th 2015
• 10 patients selected at random per facility for breast, colorectal and lung
  – Updated vital status, comorbidities, and first course treatment fields as needed
  – Collected imaging study, biopsy & recurrence information
• Secure, web-based data collection portal
• Detailed abstraction instructions provided
• Approximately 1215 sites participated
Communication during Study

• Study staff available for questions via email
• Weekly webinars with registrars
  – ~450 registrars in attendance at each
• Online CoC CAnswer Forum
  – Threads for each cancer site
  – Posted webinar content & study documents
Collection of Recurrence Data

- Recurrence defined as: identification of recurrent tumor >90 days after surgery performed as part of first course of treatment
- Suggested high yield locations in medical records
  - Pathology reports
  - Radiology/imaging reports
  - Notes from clinic/consult visits (PCP, medical oncologist, radiation oncologist, surgical oncologist, other provider)
- Hierarchy for determining date of recurrence
  1. Pathology date
  2. Date of imaging study used to confirm suspected recurrence
  3. Date of clinical diagnosis
Study Results: Breast Cancer

† New breast events include diagnoses of a locoregional recurrence or new breast primary. In PCORI study both new breast events and distant recurrences were recorded. NCDB includes first recurrence only.

- Published national recurrence estimates: 11-13% for new breast events and distant recurrence for Stage II. (1985-2001; Brewster 2008, JNCI)

- 2015 JCO publication suggests recurrence HR reduction of 0.5 between 1986-1992 and 2004-2008 (Corsetti)
Study Results: Colorectal Cancer

- Published recurrence estimates based on clinical trial data: 16-17% (Tsikitis 2009, JCO; Primrose 2014, JAMA)
Published national recurrence estimates: 30-75% after complete surgical resection with curative intent, depending on stage. (Colt 2013, Chest)
Special Study Conclusions

• Demonstrated the feasibility of improving the collection of recurrence data in the NCDB

• Provided important information to guide FORDS manual updates for defining recurrence fields

• Studies will help determine optimal follow-up strategy for patients
Post-Study Evaluation

• Survey of participating cancer registrars to assess potential
  – Difficulties with disease-specific data items
  – Challenges in obtaining follow-up information
  – Responsiveness of providers and other registrars to requests for records
  – Perceptions of recurrence data in the NCDB

• 575 respondents
Collecting Recurrence Data is Important

- 80% of registrars felt that improving the collection of recurrence data is important to the mission of the CoC
  - 53% said it was vital
Ease of Data Collection

- Comorbidity: 51%
- Radiation/chemotherapy: 56%
- Imaging: 30%
- Biopsy: 53%
- Recurrence: 24%
- New primary cancer: 35%
EHR Transition

- Proportion of facilities that transitioned after 2006: 60%
Challenges to Data Collection

• Finding where patients received follow-up care after active treatment: 76%
• Retrieving complete follow-up information from outside providers: 86%
• Timely receipt of information from outside providers: 77%
• The amount of time to enter data: 40%
• Records available in paper form only/limitations of EHR: 57%
Time Spent for Follow Up

• 43% of registrars spent 1-2 hours following up on each patient in the study
• Registrars in the pilot study estimated about 45 minutes-1 hour per patient
• Median estimate of hours required to perform the level of follow up on recurrence required for this study for all NCDB patients prospectively: 25
Facilitating Data Collection

- 64% felt if data collection for recurrence were done prospectively, outside records would be easier to obtain.
- 69% felt if data collection for recurrence were done prospectively, recurrence data would be easier to collect.
Improving NCDB Data Quality

• Median percentage of NCDB records that registrars changed or updated during the study: 10%
  – Incorrect sequence number
  – Incorrect class of case
  – Incorrect type of cancer
  – Incorrect date of diagnosis/date of surgery
  – Patients with undocumented metastasis/new primary cancers at time of diagnosis
  – Recurrence variable issues with disease-free status code
Summary of Findings

• Post-treatment cancer recurrence can be reliably recorded in cancer registries
• Feasibility and ease of data collection will be improved by transition to EHR with compatible platforms
• Providers at all CoC accredited programs should be encouraged to respond to registrar requests for data
• Cancer registrars are dedicated to improving the quality of cancer care
2014-2017

NCDB Research

National Quality Measures, Guidelines, Prognostic Factors

Clinical Care

Cancer Registry

Surveillance Community (NPCR, SEER, NAACCR)

AJCC 8th Edition

CS Transition to AJCC Staging
CREATION WITHOUT EXECUTION IS HALLUCINATION

Thomas A. Edison
FACILITY ONCOLOGY REGISTRY
DATA STANDARDS

FORDS

To
STANDARDS FOR ONCOLOGY REGISTRY ENTRY

STORE
“All organizations need to know that virtually no program or activity will perform effectively for a long time without modification and redesign. Eventually every activity becomes obsolete....”

—Peter Drucker