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### FORDS to STORE: The Evolution of Cancer Registry Coding

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ajcc American College of Surgeons Commission on Cancer NAPBC NCCDS

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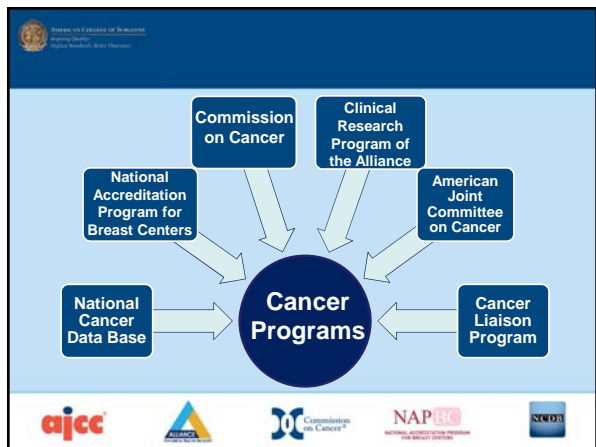
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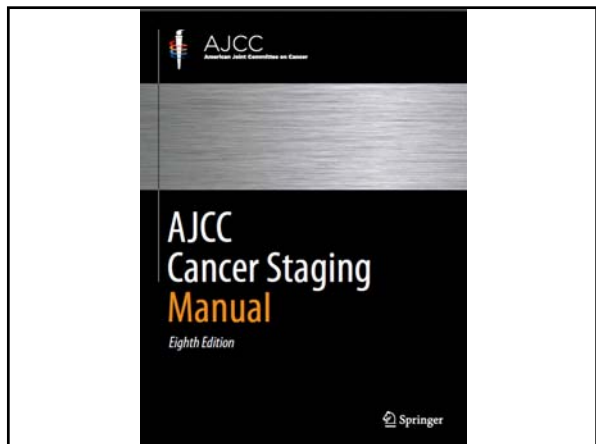
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### 8<sup>th</sup> Edition Dedication

The AJCC Cancer Staging Manual, Eighth Edition is dedicated to all **CANCER REGISTRARS** in recognition of their:

- education and unique commitment to the recording and maintenance of data that are so vital for the care of the cancer patient;
- professionalism in the collection of factors that are fundamental to sustaining local, state and national cancer registries;
- dedication to the cataloging of information crucial to cancer research;
- leadership, support and promulgation of the principles of cancer staging;
- AND THEIR POSITIVE IMPACT ON CANCER PATIENT OUTCOMES

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### The FORDS Revision Project Frederick L. Greene, MD FACS Chair, FORDS Revision Workgroup



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### 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

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### 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

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### 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
  - <http://www.facs.org/cancer/coc/fordsmanual.html>
- 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

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## National Cancer Database (NCDB)






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.

Estimated new cancer cases in 2018: 1,735,350\*

NCDB contains approximately **39 million records** from hospital cancer registries across the US and PR.

\*Cancer Facts and Figures, American Cancer Society

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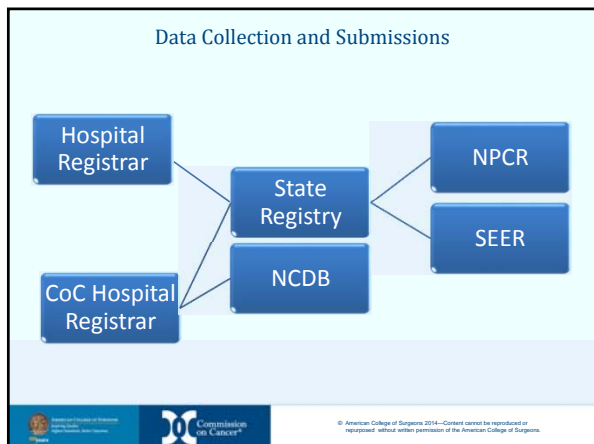
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- ### Purpose of FORDS Revision Project
- Realign data collection with
    - Contemporary multidisciplinary medical practice
  - Enable physicians and researchers to analyze entire continuum of care
    - Diagnostic workup
    - Treatment
    - Prognostic factors
    - National quality measures
    - Guidelines
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- ### 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
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### 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



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### 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



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### Possible Directions

- Require more complete clinical and pathologic staging
- Better recurrence data collection
- Collect screening and workup methods
- Specific systemic treatments
  - imatinib, ipilimumab, 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



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**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



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**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



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**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**



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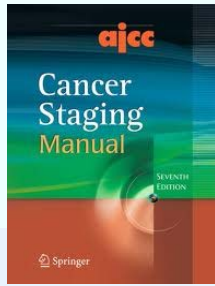
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### What Else is Happening

- Development of 8<sup>th</sup> Edition *AJCC Cancer Staging Manual*
- Expert site panels chosen
- Multi-specialty plus registrar involvement



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### 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

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### Issues Important to Prospective Payment System (PPS) Exempt Institutions (NCIPs)

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

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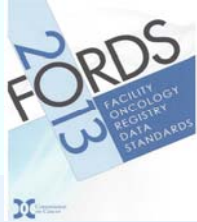
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**RECURRENCE DATA  
COLLECTION and the FORDS  
REVISION PROJECT**



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**The Lack Of Reliable  
Information Regarding Cancer  
Recurrence Is A Major  
Limitation of Existing Cancer  
Registries Including The  
National Cancer Data Base**

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**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”?**

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**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



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**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



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**Identifying Cancer Recurrence within the NCDB**



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Improving Quality  
Raising Standards. Better Outcomes.  
100 years

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## 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

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## Commission on Cancer National Cancer Data Base

- 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

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## Phase 1: NCDB data analysis

- Incomplete information

	Thyroid (n=50,243)	Colon (n=153,192)	Melanoma (n=73,600)	Pancreas (n=9,727)	Breast (n=408,826)
Rates	21.5%	24.0%	20.2%	34.8%	18.2%

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

- Hospital distribution of reported rates of incomplete information

In et al. Ann Surg Onc 2014

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### 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



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### 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%)



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### 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\*\*

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## 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**

Survival probability (%)

Time

Data fields needed for above

- Date of diagnosis
- Date of event
- Date when info was last checked ("Censoring variable")

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## 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 1<sup>st</sup> 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.

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## Improving Ascertainment of Recurrence Information within Cancer Registries

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**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

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**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

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**Data Collection  
NCDB Special Study**

- Study development: 3/2014-3/2015
- Study timeline: April 1<sup>st</sup> – July 15<sup>th</sup> 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

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## 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

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## 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

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## Study Results: Breast Cancer

Stage	Category	NCDDB (%)	Special Study (%)
All Cases	Overall	12.2%	16.9%
	Local/Regional	3.7%	6.3%
	Distant	8.6%	13.0%
	Unknown	5.1%	14.0%
Stage 2	Overall	9.0%	12.7%
	Local/Regional	0.2%	5.4%
	Distant	5.8%	8.8%
	Unknown	5.2%	13.6%
Stage 3	Overall	20.7%	27.6%
	Local/Regional	4.8%	8.4%
	Distant	3.7%	15.8%
	Unknown	4.8%	14.9%

\* New breast events include diagnosis of a second primary, in PCORF study both new breast events and distant recurrences were recorded. NCDDB includes first recurrences 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)

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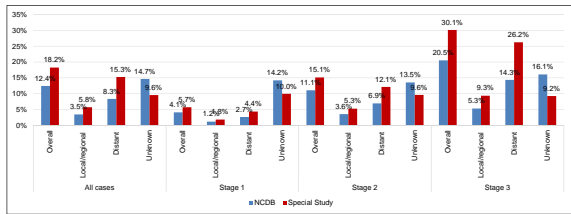
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## Study Results: Colorectal Cancer



Published recurrence estimates based on clinical trial data: 16-17% (Tsikitis 2009, JCO; Primrose 2014, JAMA)

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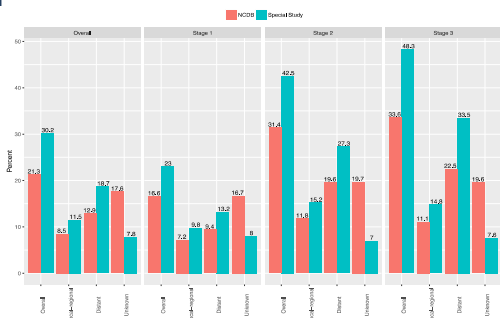
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## Study Results: Lung Cancer



Published national recurrence estimates: 30-37% after complete original resection with curative intent, depending on stage. (Colt 2013, Chest)

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## 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

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**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

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**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**

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**Ease of Data Collection**

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

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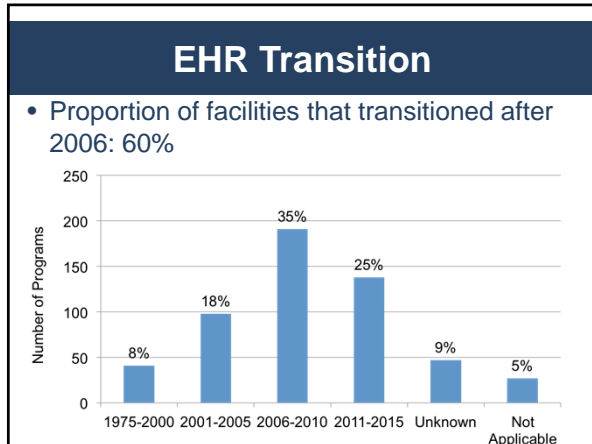
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- ### Challenges to Data Collection
- Finding where patients received follow-up care after active treatment: 76%
  - Retrieving complete follow-up information from outside providers: 86%
  - Timely receipt of information from outside providers: 77%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

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- ### 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

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### 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

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### 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

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### 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

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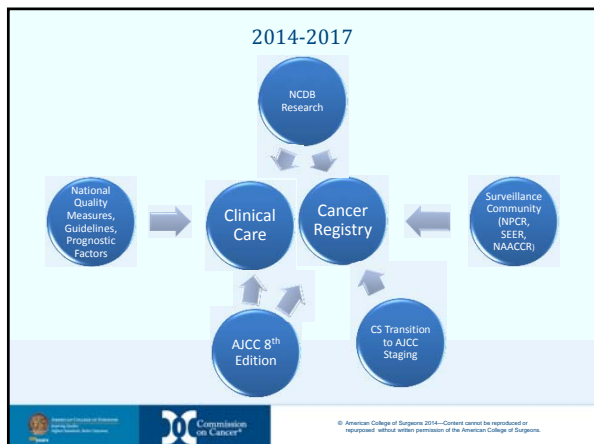
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**CREATION WITHOUT EXECUTION IS HALLUCINATION**

Thomas A. Edison

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**FACILITY ONCOLOGY REGISTRY DATA STANDARDS**

**FORDS**

To

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**Major Changes to STORE Manual**

- Implementation of AJCC 8<sup>th</sup> Edition
- Sentinel and Regional lymph nodes
- Site Specific Factors → Site Specific Data Items
- Grade
- Radiation data items, by phase
- Some Surgical codes
- Recurrence Date

- No new changes in 2019

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**Major Changes to STORE Manual**

- **Sentinel and Regional lymph nodes**

Because sentinel lymph node biopsies have been generally under-reported and the timing and results of sentinel lymph node biopsy procedures are used in multiple CoC Quality of Care Measures, the CoC developed six new data items for collection of more specific information on sentinel and regional nodes.

**Date of sentinel node biopsy required for breast and cutaneous melanoma cases only.**

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Major Changes to STORE Manual

**Cancer PROGRAMS**  
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- **Site Specific Factors → Site Specific Data Items**

The *majority* of these data items have not changed in terms of the information collected, except for the codes used to document the data. In addition, all of the CS SSFs were reviewed and aligned with CAP Protocols. It is the CoC's hope that this will facilitate the abstraction work necessary for the Site-Specific Data Items (SSDI), enabling rapid abstraction into the hospital registry from the CAP checklist. This alignment will become instrumental to the eventual direct filling of values from the electronic health record (EHR) into the registry and will eventually *save* abstraction efforts and time.

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Major Changes to STORE Manual

**Cancer PROGRAMS**  
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- **Grade**

The new way of collecting grade will greatly simplify the abstractor's task. There is no more guessing at whether you are dealing with a 2, 3, or 4 level grading system; there will be no more manual "calculation" of what value to enter for grade. The new site-specific look-ups for grade leave no room for error and will result in high quality grade data.

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Major Changes to STORE Manual

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- **Radiation data items**

When the CoC re-engineered the way radiation data are collected, we did so with several higher goals in mind. At the same time that CoC developed the new data items, we have been working with radiation oncology groups at the national level to adopt and implement a **standard End of Treatment Summary (EOTS)** to be used by all radiation oncologists and by all EHRs.

This standardized template is directly aligned with the new radiation data items and, when fully implemented, will greatly facilitate abstraction of radiation therapy and communication between registrars and radiation oncologists. As with the SSDIs, this alignment will become instrumental to the eventual direct filling of values from the EHR into the hospital registry database and will *save* abstraction efforts and time.

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## Why a Radiation Treatment Summary template?

- Initiative born from the RO subgroup of the FORDS manual update committee
  - NCDB will collect 31 RO data items.
- But not just about registry! A standardized RTS template could:
  - Improve the completeness and accuracy of communication
  - Improve the efficiency of charting
  - Improve the completeness and accuracy of registry abstraction

C2 and P1 - Restricted Information and Basic

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### STEP 1: Create/maintain a standardized Synoptic Radiation Treatment Summary template

Patient and Disease Information	
Report Date	2018-12-05
Name	Jane Susan Doe
Date of Birth	1950-03-29
Medical Record Number	1234567
Treatment indication	C50.312, pT1, pN0, M0; Mrs. Doe is a 68 year old woman with high grade carcinoma of the breast s/p lumpectomy with negative margins, who v adjuvant radiation.
Phase I Radiation	
Phase I Primary Treatment Volume	Breast - whole
Phase I to Draining Lymph Nodes	No Radiation Treatment to Draining Lymph Nodes
Phase I Treatment Modality	External beam, photons
Phase I External Beam Planning Technique	3-D conformal therapy
Phase I Dose Per Fraction (cGy)	267 cGy
Phase I Number of Fractions	15
Phase I Total Dose (cGy)	4000 cGy
Phase II Radiation	
Phase II Primary Treatment Volume	Breast - partial
Phase II to Draining Lymph Nodes	No Radiation Treatment to Draining Lymph Nodes

C2 and P1 - Restricted Information and Basic

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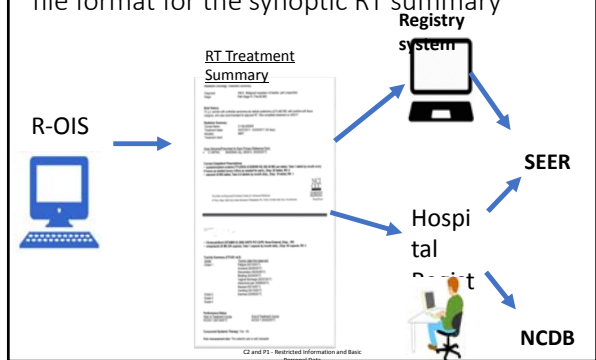
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### STEP 2: Create/maintain a standardized digital file format for the synoptic RT summary



C2 and P1 - Restricted Information and Basic

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Major Changes to STORE Manual

Cancer PROGRAMS  
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- **Surgical Codes**
  - Surgical Margins of the Primary Site [1320]
  - Scope of Regional Lymph Node Surgery [1292]
  - Scope of Regional Lymph Node Surgery at this Facility [672]
  - Surgical Procedure/Other Site [1294]
  - Surgical Procedure/Other Site at this Facility [674]

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Major Changes to STORE Manual

Cancer PROGRAMS  
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- **Recurrence Date:**
  - Date of Last Cancer (tumor) Status [1772]
  - Date of Last Cancer (tumor) Status Flag [1773]

Date of last cancer (tumor status) of the patient's malignant or non-malignant tumor.

**No Major Changes in STORE 2019**

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Change

“There is nothing more difficult to carry out, nor more doubtful of success, nor more dangerous to manage, than to initiate a new order of things.”  
—Machiavelli

International union  
against cancer

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