



# WHAT'S NEW FOR 2013 AND V13

FCDS Annual Meeting  
 July 26, 2013  
 Sunrise, Florida



Steven Peace, CTR  
 Gary Levin, CTR

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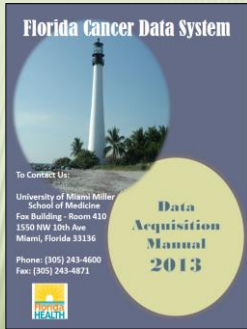
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# 2013 FCDS DATA ACQUISITION MANUAL




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# 2013 FCDS DATA ACQUISITION MANUAL

**Newly reportable data items required to be collected**

- Standard Data Item added FCDS CORE (Required for ALL Cases)

NAACCR Item #	Item Name	Start Position	Stop Position	Length
102	Addr at DX - Country	436	438	3
252	Birthplace State	442	443	2
254	Birthplace Country	444	446	3
1832	Addr Current - Country	439	441	3

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## FCDS ABSTRACTOR CODE POLICY

- ✘ This test is NOT a substitute for the CTR Examination
- ✘ CTRs and non-CTRs MUST take the FCDS Abstractor Code Test
- ✘ Every person who abstracts must have their own FCDS Code
  
- ✘ New to Florida Abstractors (no existing FCDS Abstractor Code) will take a test with 20 questions with no time limit
- ✘ Annual Renewal tests are 15 questions with 1 hour time limit
- ✘ If you fail the test twice – you must wait 7 days to take it again
- ✘ If you fail twice – you should not abstract cases until you pass
- ✘ A score of 80% is required to pass
  
- ✘ NEVER share your FCDS Abstractor Code

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## FCDS ABSTRACTOR CODE POLICY

- ✓ Sources for FCDS Abstractor Code Test Questions:
  - Current FCDS Data Acquisition Manual
  - SEER Self Instructional Manuals
    - Book 2 – Cancer Characteristics and Selection of Cases
    - Book 3 – Tumor Registrar Vocabulary: The Composition of Medical Terms
    - Book 4 – Human Anatomy as Related to Tumor Formation
  - Collaborative Stage Data Collection System
    - Collaborative Stage Core Data Items
    - Site-Specific Factors
  - ICD-O-3 and Updates
  - Multiple Primary and Histology Coding Rules – Solid Tumors
  - Hematopoietic and Lymphoid Neoplasms - MPH Rules and Data Base
  - Any NEW Rules, Tools, Instructions, Data Items, etc.

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## APPENDIX A-P

- ➡ Appendix A: Florida Healthcare Facilities Currently Reporting to FCDS
- ➡ Appendix B: Florida FIPS, USPS State Abbreviations and ISO Country Codes - NEW
- ➡ Appendix C: Glossary and Standard Abbreviations - Updated
- ➡ Appendix D: Race Coding Instructions and Race and Nationality Descriptions
- ➡ Appendix E: Census List of Spanish Surnames
- ➡ Appendix F: Site-Specific Surgery Codes
- ➡ Appendix G: FCDS 2013 Record Layout (NAACCR Version 13)
- ➡ Appendix H: 2013 FCDS Required CSv02.04 Site Specific Factors (SSFs)
- ➡ Appendix I: Free-Standing Radiation Therapy Centers Cancer Case Identification Program
- ➡ Appendix J: Height Conversion Tables - Converting Feet to Inches
- ➡ Appendix K: Weight Conversion Tables - Converting Kilograms to Pounds
- ➡ Appendix L: FCDS Text Documentation Requirements - Updated
- ➡ Appendix M: Hematopoietic and Lymphoid Neoplasm Master Code Lists (alpha/numeric)
- ➡ Appendix N: 2013 FCDS Casefinding List for Reportable Tumors
- ➡ Appendix O: 2013 Resources for Registrars
- ➡ Appendix P: FCDS Frequently Asked Questions (FAQ)

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## APPENDIX C - UPDATED

### APPENDIX C

#### BREAST CANCER PROFILE EXPLAINING ER/PR/HER2 PROGNOSTIC FACTORS

SEER PROGRAM CODING AND STAGING MANUAL 2013  
[LINK TO CODING GUIDELINES FOR SPECIFIED SITES](#)

#### GLOSSARY OF COMMON TERMS

#### STANDARD ABBREVIATIONS

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## APPENDIX C - UPDATED

#### When and Why are ER/PR/HER2 Test(s) Performed as Part of Creating Individual Breast Cancer Profile?

- **Estrogen Receptor (ER)**
  - Test routinely performed on invasive cancers
  - Test may be performed on non-invasive (in-situ) cancers
  - Result used to determine whether or not Hormonal Therapy should be considered in 1<sup>st</sup> course treatment plan
- **Progesterone Receptor (PR)**
  - Test routinely performed on invasive cancers
  - Test may be performed on non-invasive (in-situ) cancers
  - Result used to determine whether or not Hormonal Therapy should be considered in 1<sup>st</sup> course treatment plan
- **Human Epidermal growth factor Receptor 2 (HER2)**
  - Test frequently but not always performed on invasive cancers
  - Test rarely performed on non-invasive (in-situ) cancers at this time
  - Test may be performed using one or more methods (IHC, FISH, CISH, Other)
  - An equivocal or borderline result from IHC HER2 Test may trigger additional testing using FISH or CISH
  - Some facilities bypass IHC HER2 Test and perform FISH HER2 Test as part of routine Breast Cancer Profile
  - Result used to determine whether or not Herceptin (trastuzumab) or Tykerb (lapatinib) should be included in 1<sup>st</sup> course treatment plan

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## APPENDIX C - UPDATED

#### Favorable Prognostic Factors: ER, PR, HER2

- ✓ Estrogen Receptor (ER) **positive** is a favorable prognostic factor.
  - Hormonal Therapy should be considered in 1<sup>st</sup> course treatment planning.
- ✓ Progesterone Receptor (PR) **positive** is a favorable prognostic factor.
  - Hormonal Therapy should be considered in 1<sup>st</sup> course treatment planning.
- ✓ **Single Receptor positive** tumors (ER- only or PR- only) do exist but are rare with an unfavorable prognosis
  - These tumors are often large in size, are of high grade, are often HER2+, and are often lymph node +
  - Single Receptor positive tumors are usually not treated with Hormonal Therapy
- ✓ **Human Epidermal growth factor Receptor 2 (HER2) positive** is a favorable prognostic factor.
  - Herceptin (trastuzumab) or Tykerb (lapatinib) should be included as part of 1<sup>st</sup> course treatment plan

#### Unfavorable Prognostic Factors: ER, PR, HER2

- Estrogen Receptor (ER) **negative** is an unfavorable prognostic factor.
  - Hormonal Therapy usually not included as part of 1<sup>st</sup> course treatment plan
- Progesterone Receptor (PR) **negative** is an unfavorable prognostic factor.
  - Hormonal Therapy usually not included as part of 1<sup>st</sup> course treatment plan
- **Single Receptor negative** tumors (ER- only or PR- only) do exist but are rare with an unfavorable prognosis
  - These tumors are often large in size, are of high grade, are often HER2+, and are often lymph node +
  - Single Receptor negative tumors are usually not treated with Hormonal Therapy
- **Human Epidermal growth factor Receptor 2 (HER2) negative** is an unfavorable prognostic factor.
  - Herceptin (trastuzumab) or Tykerb (lapatinib) usually not included as part of 1<sup>st</sup> course treatment plan
- **Triple Negative Breast Cancer (ER neg/PR neg/HER2 neg)** is a **very unfavorable** prognostic combination.

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## APPENDIX C - UPDATED

Test	Value Range	Negative	Borderline	Positive
ER Proportion Score	0%-100%	<5%	5% - 19%	>=20%
ER Intensity Score	None, weak, intermediate, strong	None, weak	intermediate	Strong
PR Proportion Score	0%-100%	<5%	5% - 19%	>=20%
PR Intensity Score	None, weak, intermediate, strong	None, weak	intermediate	Strong
HER2 by IHC	0, 1+, 2+, 3+	0, 1+	2+	3+
HER2 by FISH	Ratio 1.00-9.79 (note decimal point)	<= 1.9	1.90-2.20	>= 2.00
HER2 by cISH	Ratio 1.00-9.79 (note decimal point)	<= 1.9	1.90-2.20	>= 2.00
HER2 by unknown	No value given	Stated by MD	Stated by MD	Stated by MD
Test Not Mentioned in Medical Record - Code as Not Done (998) or Unknown if Done (999)				

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## APPENDIX L - TEXT DOCUMENTATION

Below is a list of FCD5 Required Data Items that carry an additional requirement of complete and accurate text documentation. See Table on Following Page for Specific Examples for each Text Area.

DATA ITEMS REQUIRING COMPLETE TEXT DOCUMENTATION	
Date of DX	RX Summ - Surg Prim Site
Seq No	RX Summ - Scope Reg LN Surgery
Sex	RX Summ - Surg Oth Reg/Distant
Primary Site	RX Date - Surgery
Subsite	RX Summ - Radiation
Laterality	Rad Rx Modality
Histologic Type	RX Date - Radiation
Behavior Code	RX Summ - Chemo
Grade	RX Date - Chemo
CS Tumor Size	RX Summ - Hormone
CS Ext	RX Date - Hormone
CS Tumor Ext/Eval	RX Summ - BRM/immunotherapy
Regional Nodes Positive	RX Date - BRM/immunotherapy
Regional Nodes Examined	RX Summ - Transplant/Endocrine
CS LN	RX Date - Transplant/Endocrine
CS LN Eval	RX Summ - Other
CS Mets	RX Date - Other
CS Mets Eval	Any Unusual Case Characteristics
All FCD5 Req'd SSFs	Any Pertinent Patient/Family History

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## APPENDIX L - TEXT DOCUMENTATION

Text documentation should always include the following components:

- Date(s) - include date(s) references - this allows the reviewer to determine event chronology
- Date(s) - note when date(s) are estimated [i.e. Date of DX 3/15/2011 (est.)]
- Location - include facility/physician/other location where the event occurred (test/study/treatment/other)
- Description - include description of the event (test/study/treatment/other) - include positive/negative results
- Details - include as much detail as possible - document treatment plan even if treatment is initiated as planned
- Include "relevant-to-this-person/cancer" information only - edit your text documentation
- DO NOT REPEAT INFORMATION from section to section
- DO USE Standard Abbreviations (Appendix B)
- DO NOT USE non-standard or stylistic shorthand
- Enter "N/A" or "not available" when no information is available related to any specific text area.

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## APPENDIX P – FCDS IDEA AND ACCOUNTS

### Frequently Asked Questions

- > Do I need an FCDS IDEA User Account?
- > How do I create an FCDS IDEA User Account?
- > Procedure for Lost User ID/Password?
- > How do I renew my FCDS User Account?
- > Who can be a Facility Access Administrator (FAA)?
- > Which Facilities are Required to Establish an FAA Account?
- > How do I apply for the FAA Role?
- > How do I Manage User Role Assignments?
- > What is an FCDS Abstractor Code?
- > Do I need an FCDS Abstractor Code?
- > How do I obtain an FCDS Abstractor Code?



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## FCDS EDITS V13A METAFILE



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## NEW FCDS EDITS METAFILE V13A

Changes Made To NAACCR v13 Metafile		Released: Dec. 17, 2012
Green = deleted		
Yellow = new edits		
Blue = edit name/field name changes		
New Edit Name	Old Edit Name	Comments
addr at DX--Country (COC)		New edit
addr at DX--Country (NAACCR)		New edit
addr at DX--Country, Date of Diagnosis (COC)		New edit
addr at DX--Country, Date of Diagnosis (NAACCR)		New edit
addr at DX--Country, State (NAACCR)		New edit
addr Current--Country (COC)		New edit
addr Current--Country (NAACCR)		New edit
addr Current--Country, Date of Diagnosis (COC)		New edit
addr Current--Country, Date of Diagnosis (NAACCR)		New edit
addr Current--Country, State (NAACCR)		New edit
Chocolate Histology (COC), Date of DX (SERE)		New edit

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## IMPORTANT REMINDERS

- ✓ Astractors must have access to and use available resources such as Heme DB and SEER\*Rx and new MPH DB
- ✓ Please refer to MPH Rules and Heme MPH Rules
- ✓ Please refer to Heme DB for coding Heme/Lymph Histology
- ✓ Check your drop-down selections - not a substitute for rules
- ✓ Contact FCDS with abstracting and coding questions

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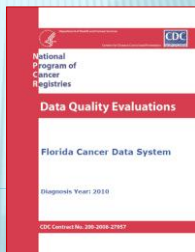
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## 2013 NPCR DATA QUALITY EVALUATION: RESULTS AND RECOMMENDATIONS

FCDS Annual Meeting  
 July 26, 2013  
 Sunrise, Florida

Steven Peace, CTR  
 Megsys Herna, CTR  
 FCDS Data Quality Staff




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## PURPOSE OF NPCR DQE

- ✦ Assess the quality of the data of NPCR-funded, statewide, population-based cancer registries.
- ✦ These data are a crucial part of cancer surveillance systems because they are used for planning, operating, funding, and evaluating cancer control programs.
- ✦ Complete and accurate data are essential to estimate variations in and changes among population subgroups over time.
- ✦ The evaluation assessment is based on the existence of appropriate policies and procedures for the following:
  - + Data consolidation
  - + Assessment of data quality
  - + Text documentation

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## ELEMENTS OF DQE

- \* Visual Editing
- \* Consolidation Validation
- \* NPCR Clinical Edit Checks
- \* FCDS Policy and Procedures Manual
- \* Final Report to NPCR and FCDS
- \* Recommendations

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## DQE METHODOLOGY - VISUAL EDITING

- \* Evaluator reviewed all data elements included in the evaluation as well as the corresponding text for each abstract-level case.
- \* Any abstract-level codes not substantiated by text were recoded
- \* Errors resulted when there was 1) a complete lack of text to support the coded data element or, 2) the text was available but the coded data element was incorrect.

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## DATA ELEMENTS REVIEWED

Cancer Identification	Collaborative Staging	Treatment 1st Course
Primary Site	CS Tumor Size	Date of Initial Rx/SEER
Subsite	CS Extension	Rx Summ-Surg Prim Site
Laterality	CS Tumor Size Extent Eval.	Rx Summ-Scope Reg/LN Sur
Histology	CS Lymph Nodes	Rx Summ-Surg Oth Reg/Die
Behavior	CS Mets at Dx	Rad-Regional Rx Modality
Grade	CS Site-Specific Factor 1	Rx Summ-Chemo
Date of Diagnosis	CS Site-Specific Factor 2	Rx Summ-Hormone
Sequence Number-Central	CS Site-Specific Factor 3	Rx Summ-BRM
	Derived SS2000	Rx Summ-Transplnt/Endocr
		Rx Summ-Other

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## DATA ELEMENTS REVIEWED

- Collaborative Staging
- SSFs for Female Breast
- CS Site-Specific Factor 1
- CS Site-Specific Factor 2
- CS Site-Specific Factor 8
- CS Site-Specific Factor 9
- CS Site-Specific Factor 10
- CS Site-Specific Factor 11
- CS Site-Specific Factor 12
- CS Site-Specific Factor 13
- CS Site-Specific Factor 14

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## DQE METHODOLOGY – CONSOLIDATION

- ✦ A total of 200 cases were reconsolidated.
- ✦ A total of 5,483 data elements could have had errors
- ✦ 181 data elements were found to have errors.

Site	Number of Elements Reviewed	Number of Elements With Errors	Number of Elements Without Errors	Accuracy Rate
Colon	480	17	463	96.46%
Rectum	216	7	209	96.76%
Lung	1,800	53	1,747	97.06%
Female Breast	1,536	49	1,487	96.81%
Corpus Uteri	300	2	298	99.33%
Prostate	575	23	552	96.00%
<b>Total</b>	<b>4,907</b>	<b>151</b>	<b>4,756</b>	<b>96.92%</b>

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## 2013 DQE RESULTS

- ✦ **Overall Accuracy Rate = 96.9% - Commendation**
- ✦ **Visual Editing Accuracy Rate = 96.0% - Commendation**
- ✦ **Reconsolidation Accuracy Rate = 96.0% - Commendation**
- ✦ FCDS is encouraged to continue conducting visual editing to maintain data quality in the State, in addition to reviewing basic abstracting principles with staff and data reporters and emphasizing to all reporting facilities that text documentation to support data element code selection is required.
- ✦ Text documentation should support all coding decisions.
- ✦ Text documentation should support all consolidation decisions.

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## CONGRATULATIONS AND THANK YOU



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## NPCR DQE RECOMMENDATIONS

1. Provide an overview of abstracting principles to staff and data reporters.
2. State training should include a focus on the following data items:
  - *CS Extension and CS Metastasis at Diagnosis*
  - *CS Tumor Size, CS Extension, and CS Lymph Nodes when neoadjuvant treatment is administered*
  - *RX Summary Surgery Primary Site and RX Summary Scope Regional Lymph Node Surgery* particularly as they apply to breast cancer and sentinel lymph nodes
  - *Date of Diagnosis Review diagnostic language, including ambiguous terminology*
  - *Rules for coding Site-Specific Factors including training regarding text documentation*

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## NPCR DQE RECOMMENDATIONS

2. State training should include a focus on the following data items:
  - *Grade Conversion Tables, particularly as it applies to Gleason Grade for prostate cancer – discussion tomorrow morning*
  - *Date of Initial RX – SEER rules and providing training on the importance of including dates with text documentation*
  - *Rules for coding Radiation Regional RX Modality, including training regarding text documentation of modality and energy*
3. Visual Editing Review and Consolidation:
  - *Educating all reporting facilities that text documentation, with dates, is required for all data elements, preferably using hands-on training*

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## FCDS FOLLOW-UP PLAN

- ✦ Share NPCR Audit Results with Reporters
- ✦ Introduce Clinical Edit Checks to Registrars
- ✦ Reinforce Text Documentation Requirements
- ✦ Reinforce FCDS QC Review/Visual Editing Rationale
- ✦ Incorporate Recommendations into 2013 FCDS Webcast Series
- ✦ Reinforce FCDS QC Review/Visual Editing Feedback Procedures
- ✦ Standardize Format for FCDS Policy and Procedures Manual
- ✦ Annual Review of FCDS Policy and Procedures Manual

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## NPCR CLINICAL EDIT CHECKS

FCDS Annual Meeting  
 July 26, 2013  
 Sunrise, Florida



Steven Peace, CTR  
 FCDS Data Quality Staff




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## PURPOSE OF CLINICAL EDIT CHECKS

- The primary purpose of the Clinical Check edits is to evaluate reported prognostic and treatment items for cancer cases with specific tumor characteristics.
  - Missing/Incomplete Tumor Characteristics (site/type/stage)
  - Missing/Incomplete Site-Specific Factors (prognostic factors)
  - Missing/Incomplete First Course Treatment
- Clinical Checks are based on consensus measures for quality of cancer care developed by CoC and NPCR for specified cancers.
- Endorsed by National Quality Forum, CoC, ASCO, and NCCN.
- If the reported treatment does not appear to be consistent with widely recognized standards of care or cases fail to contain known prognostic characteristics, a warning is generated.

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## Florida Tracking Program Overview

- Environmental Public Health Tracking (Tracking) focuses on surveillance of environmental factors and related health outcomes
  - Examples of environmental factors: drinking water contaminants, ozone, particulate matter, community design
  - Examples of health outcomes: asthma, birth defects, cancer, cardiovascular disease, heat-related illness, birth outcomes
- Funded through a cooperative agreement with CDC since 2003

## Tracking Web Portal – [www.floridatracking.com](http://www.floridatracking.com)

The screenshot shows the Florida Environmental Public Health Tracking website. The header includes the Florida state logo and navigation links: home | about us | contact us | mobile | researchers. A search bar is located in the top right. The main content area is divided into several sections:
 

- Environment:** Air Quality/Outdoor, Drinking Water, Indoor Air.
- Health:** Birth Defects, Cancer, Cardiac Myocardial, Childhood Lead, Child, Clinical, Heart Attacks, Heat-Related Events, Occupational, Pesticide Exposure, Reproductive Outcomes.
- My Community:** Community Data, Community Fair Safety, County Profiles, Public Acid Awareness, PRCE-EN.
- Tools You Can Use:** Exposure Map, EPHT Discovery, EPHT User Guide, Graphs.

 The central content area features a map of Florida with a highlighted region, a text box stating: "The Florida Poison Information Center Network has released dynamic maps showing calls to their centers reporting exposure to high levels of action monoxide. CO Poisoning is entirely preventable. Learn more." Below this is a "What is Environmental Public Health Tracking?" section with a brief description of the program and a "Learn more" link. There is also a "What's new?" section with a "Updated asthma and heart" link and a small image of a person's face. Social media icons for Facebook, Twitter, and YouTube are visible. The Florida Health logo is also present.

## Cancer – Core Indicators

- Nationally Consistent Data Measures (NCDMs) – indicators displayed by all Tracking grantees
  - Bladder
  - Brain & other Nervous Systems
  - Breast
  - Leukemia (Acute Lymphocytic, Acute Myeloid, Chronic Lymphocytic)
  - Lung & Bronchus
  - Non-Hodgkin's Lymphoma
  - Thyroid



## Florida's System for Cancer Research & Collaboration

Robert Hood, Ph.D.  
Manager, Florida System of Cancer Research and Collaboration  
robert\_hood@doh.state.fl.us (850) 245-4585



*Protect, promote and improve the health of all people in Florida.*

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### FL System for Cancer Research & Collaboration

- o Use existing state structures
  - C-CRAB, BRAC, registry
  - Bankhead-Coley, King
- o Establish state cancer research agenda
- o Enhance collaborations between researchers and develop research networks
- o Develop metrics to evaluate health impact of research



*Protect, promote and improve the health of all people in Florida.*

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### Cancer Center of Excellence Award

- o Establishes a Cancer Center of Excellence Award (381.925 F.S.)
  - Encourage excellence in patient-centered, coordinated cancer care
  - Attract and retain the best care providers
  - Help Florida providers to be recognized nationally as a preferred destination for quality cancer care
- o After January 1, 2014 DOH will conduct two application cycles annually



*Protect, promote and improve the health of all people in Florida.*

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Florida Department of Health  
Division of Community Health Promotion  
Bureau of Chronic Disease Prevention

Sue Higgins, MPH  
Director, Comprehensive Cancer Control Program

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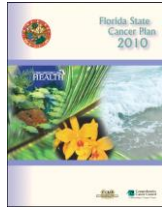
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- Goal I: Infrastructure
- Goal II: Prevention
- Goal III: Treatment/Access to Care
- **Goal IV: Survivorship**  
"Floridians affected by cancer are aware of and have access to quality, appropriate services for quality of life, palliative care, and survivorship"



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American College of Surgeons  
Commission on Cancer

**Standard 3.3 Survivorship Care Plan**

The cancer committee develops and implements a process to disseminate a comprehensive care summary and follow-up plan to patients with cancer who are completing cancer treatment. The process is monitored, evaluated, and presented at least annually to the cancer committee and documented in minutes.

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**Cancer Control and Research Advisory Council (CCRAB)**

**Goal 4: Survivorship Committee**

Created a brochure to help explain what cancer treatment summaries and survivorship care plans are and why are they important



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**SUCCESS THROUGH COLLABORATION: ENHANCING SURVEILLANCE DATA WITH INSURANCE CLAIMS**

**Brad Wohler**  
Florida Cancer Data System  
FCDS Annual Meeting 2013



*Protect, promote and improve the health of all people in Florida.*

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**PHYSICIAN OFFICE REPORTING  
WHAT THIS MEANS TO YOU**

Dr. Jill A. MacKinnon  
FCDS Project Director

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## Pro-Active Reporting of Physician Medical Claims Data: Capturing Complete and Missed Treatment Data

MONIQUE HERNANDEZ, PHD  
FLORIDA CANCER DATA SYSTEM

ANNUAL MEETING  
SUNRISE, FL  
JULY 25-26, 2013

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## The Model is Changing

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- **The management of cancer has evolved and no longer fits the model implemented in the late 1970's when FCDS was designed**
  - Diagnosis and treatment of many cancers shift from the hospital to the private practitioner's office
- **As more and more cancer patients become cancer survivors, more information is needed by the medical community to improve the quality of life for our cancer survivors**
- **Survival is no longer the only salient endpoint**

Florida Cancer Data System

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## Ramifications of old Model on Cancer Surveillance and Data on the Cancer Patient

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- **Underestimates of incidence of certain cancers**
  - Dx/Tx taking outside of hospital
- **Treatment incomplete**
  - Not capturing full course of treatment, especially chemo
- **Data used by policy makers**
  - Misallocation of funds and services
  - Unable to identify areas/subgroups in need
- **Data Used by Researchers**
  - Sampling frame for patient studies
  - Data for hypothesis driven research
  - Trends over time

Florida Cancer Data System

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New Model

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# Physician reporting via medical claims data

Florida Cancer Data System

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## Incorporate/Operationalize Medical Claim Form Electronic Data

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- National standard record layout currently used by every private practitioner in the nation
  - 837 Record, Version 5010
  
- Using existing insurance industry standard record layout (837 record)
  - Patient demographics
  - Patient diagnosis codes
  - Procedure codes -- Cancer directed treatment
  - Date of last contact

Florida Cancer Data System

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## HICFA 1500 -- Demographics

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1500 HEALTH INSURANCE CLAIM FORM											
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE 1983											
1. TYPE		2. MEDICARE		3. SOCIAL SECURITY		4. CHAMPVA		5. OTHER		6. INSURED'S ID NUMBER	
Medicare #		Social Security #		Champion #		Other #		ID #		ID #	
7. PATIENT'S NAME (Last Name, First Name, Middle Initial)				8. INSURED'S NAME (Last Name, First Name, Middle Initial)				9. PATIENT RELATIONSHIP TO INSURED			
Address (incl. Street)				Address (incl. Street)				Relationship (e.g., Self, Spouse, Child, Other)			
City				City				Relationship			
State				State				Relationship			
ZIP Code				ZIP Code				Relationship			
Telephone (Include Area Code)				Telephone (Include Area Code)				Relationship			
10. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)				11. INSURED'S POLICY OR PLAN NUMBER				12. INSURED'S DATE OF BIRTH			
Name				Policy/Plan #				MM / DD / YY			
13. EMPLOYER'S NAME OR SCHOOL NAME				14. AUTO ACCIDENT?				15. OTHER ACCIDENT?			
Employer/School Name				Yes/No				Yes/No			
16. EMPLOYER'S NAME OR SCHOOL NAME				17. INSURANCE PLAN NAME OR PROGRAM NAME				18. IS THERE ANOTHER HEALTH BENEFIT PLAN?			
Employer/School Name				Insurance Plan Name				Yes/No			

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## Broad Learning Objectives

73

- How effective are claims data in augmenting registry records?
- How use of this new data source can assist the hospital based registrar?
- Is there potential for creating a 'virtual abstract' from disparate data streams?

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## Data Capture and Evaluation a Florida Pilot Project

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## Data Capture

75

### Data capture via multiple methods

- CER -- Comparative Effectiveness Research Project
  - Expanded treatment captured by CTR from Florida Cancer Specialists' electronic medical record system
- Florida Cancer Specialist Data submitted via 837 claim feed since July of 2012. Goes back to 2011.
- Routine capture using consolidated hospital abstracts – Registry Core Record

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### General Descriptive Analysis

76

#### Objectives:

- To compare summary chemo treatment information from claims records against core treatment records using CER as a gold standard.
- This will help us answer two main questions...

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### Answer Two Questions

77

1. Can the claims data produce incident Tx data according to NAACCR standards (first course chemo)?

Chemo given yes/no

2. Can the claims data augment the existing NAACCR standard treatment data?

Chemo single/multiple agents

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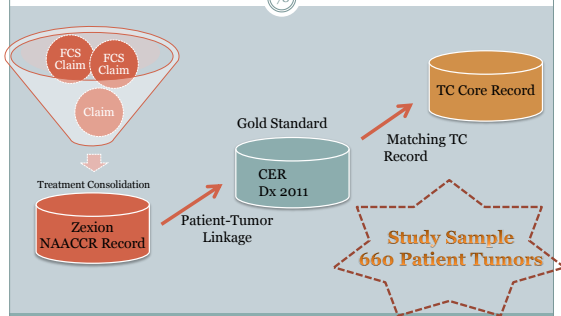
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### Methods for Identifying Study Sample

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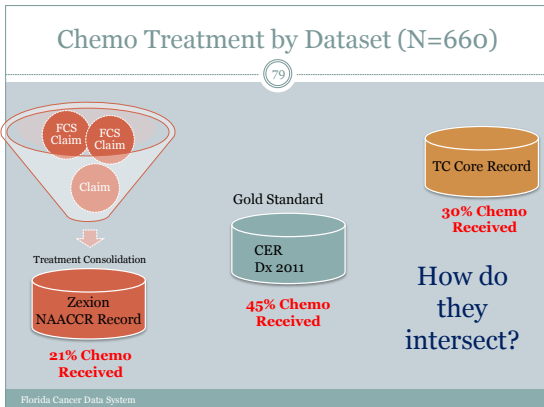
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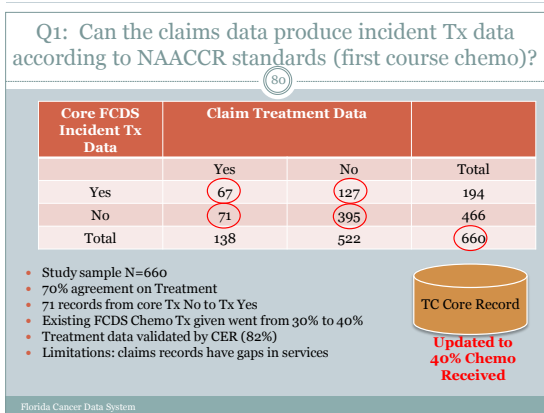
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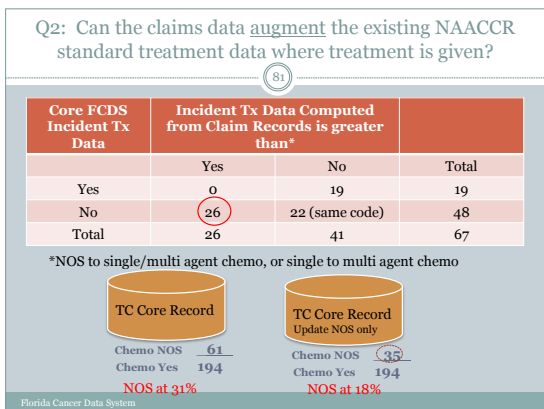
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## Data Enhancement

82

- **Date of Last Contact**
  - 94% of matched records updated
- **Treatment**
  - Chemo treatment changed by 37%
  - Treatment NOS went down from 31% to 18%
- **21% Granular Tx detail (chemo agents)**

Florida Cancer Data System

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## Two Questions

83

1. Can the claims data produce incident Tx data according to NAACCR standards (first course chemo)?  
**YES!**
2. Can the claims data augment the existing NAACCR standard treatment data?  
**YES!**

Florida Cancer Data System

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## What Does This Mean to You?

84

- **Once fully operational**
  - FCDS can and will provide you with
    - Detailed treatment and dates
    - Dates of last contact
    - Patient status

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## 2011 ICD-O-3 UPDATES SUMMARY

- > 29 non-CNS benign and borderline entities
- > 8 new reportable terms
- > 31 hematopoietic and lymphoid terms – approved 2010
- > 18 new histology/behavior including word “dysplasia” behavior = 2.
- > The term “in-situ” is no longer used in to describe neoplasms arising in the GI tract – now called “glandular dysplasia high grade,” “high grade dysplasia” or “intraepithelial neoplasia, high grade”
- > Carcinoid of Appendix changes to a Reportable Malignancy
- > Clarification/Explanation of two confusing heme codes
- > 5 new preferred terms replace outdated ICD-O-3 terms
- > Many related terms and synonyms added to existing codes

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## ICD-O-3 WORK GROUP – SCOPE OF WORK

1. Review WHO ICD-O-3 Update list
2. Heme/Lymph New Codes already accepted
3. Determine possible impact of new terms/codes
4. Canada has already implemented WHO ICD-O-3 Update
5. Utilize Guest Experts in Pathology and WHO Classification of Diseases for Oncology
6. Identify associated files, lists, programs, and documents that will be affected by changes
7. **The ICD-O-3 Work Group recommends implementation of the non-controversial terms and the few completely new codes as soon as possible.**

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## WHO CLASSIFICATION OF DISEASES

- > Completed Fourth Edition Updates Include:
- > 2007 – Tumors of Central Nervous System
- > 2008 – Tumors of Hematopoietic and Lymphoid Tissues
- > 2010 – Tumors of Digestive System
- > 2011 – Tumors of Breast
- > 2012 – Tumors of Soft Tissue and Bone

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## WHO CLASSIFICATION OF DISEASES

- > **PENDING** Fourth Edition **Updates** Include:
- > Tumors of Head and Neck
- > Tumors of Urinary System
- > Tumors of Skin
- > Tumors of Lung, Pleura, Thymus, Heart
- > Tumors of Female Genital System
- > Tumors of Male Genital System

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## ICD-0-3 WORK GROUP – NOT IN SCOPE

1. **New terminology and behavior for bronchioloalveolar carcinoma.**  
Note: Terms are already in use by pathologists around the US and Canada.
2. **Reportability guidelines for GIST tumors.** Note: This has been partially addressed in a sentence added to FORDS 2013 and the SEER 2013 Coding Manual, which indicate that GIST and thymoma are reportable when there is evidence of multiple foci, lymph node involvement, or metastasis.
3. **WHO Classifications of Soft Tissue and Bone** as well as Breast **have been published since 2011, and more updated volumes of the WHO Classification are planned.**
4. **NAACCR needs to be proactive** in deciding how to handle new codes, obsolete codes, and other changes published in these volumes.

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## HGD/IEN/CIS AND IMC OF GI TRACT

- > IEN/HGD/CIS of Genital Sites - Squamous Epithelium
- > IEN/HGD/CIS of GI Tract – Glandular Epithelium
  
- > IEN – Intra-Epithelial Neoplasia
- > HGD – High Grade Dysplasia
- > CIS – Carcinoma In Situ
  
- > IMC of GI Tract – Intramucosal Carcinoma
  - Invades lamina propria with no involvement of muscularis mucosa
  
- > Non-Invasive (in-situ) Neoplasms DO NOT Metastasize
- > Retire “polyp” in-situ codes (8210/2, 8261/2, 8263/2)

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## GI TRACT TOPGRAPHY CODES

- C15.\* - Esophagus
- C16.\* - Stomach
- C17.\* - Small Intestine
- C18.\* - Colon (includes appendix)
- C19.\* - Rectosigmoid Colon
- C20.\* - Rectum
- C23.\* - Gall Bladder
- C24.\* - Bile Ducts
- C25.\* - Pancreas
- Excludes: Anus (C21.\*) and Liver (C22.\*)

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## ICD-O-3 WORK GROUP RECOMMENDATIONS

- **Reportability Changes**
  - 8240/3 – Carcinoid Tumor, NOS of Appendix (C18.1)
- **Accept All Heme/Lymph Changes in Heme DB**
- **Correct a few Heme/Lymph Terms or Codes in Heme DB**
  - 9960/3 – Myeloproliferative Neoplasm, NOS
  - 9971/1 – Post Transplant Lymphoproliferative Disorder, NOS
  - 9571/3 – Polymorphic Post Transplant Lymphoproliferative Disorder

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## ICD-O-3 WORK GROUP RECOMMENDATIONS

**DO NOT USE [OBS] or (obs) Codes**

Obsolete ICD-O Codes Neoplasms of Hematopoietic and Lymphoid Tissue		
9654	9675	9753
9661	9684	9754
9662	9728	9760
9664	9835	9764
9665	9836	9805
9667	9729	9960
9670	9733	9984
	9750	9987

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## ICD-O-3 WORK GROUP RECOMMENDATIONS

- **NO ACTION AT THIS TIME** - The ICD-O-3 Update Implementation Work Group recommends NO ACTION for the following codes and terms in the WHO Update until the impact of a reportability change for terminology that includes “dysplasia” can be further assessed.
- **Current reportability legislation affects these codes/terms**
  - All new codes/terms w/reference to high grade intraepithelial neoplasia or dysplasia of GI Tract (esophagus, colon, pancreas, biliary, other GI Tract)
    - Squamous Neoplasms
    - Glandular (adeno) Neoplasms
    - Mucinous cystic neoplasms
    - Papillary neoplasms

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## ICD-O-3 WORK GROUP RECOMMENDATIONS

- **NO ACTION AT THIS TIME** - continued

8077/2	Squamous intraepithelial neoplasia, high grade
8077/2	Esophageal squamous intraepithelial neoplasia (dysplasia), high grade (C15. .)
8148/2	Glandular intraepithelial neoplasia, high grade
8148/2	Flat intraepithelial glandular neoplasia, high grade (C24.1)
8148/2	Biliary intraepithelial neoplasia, high grade
8148/2	Esophageal glandular dysplasia (intraepithelial neoplasia), high grade (C16. .)
8163/2	Papillary neoplasm, pancreatobiliary-type, with high grade intraepithelial neoplasia (
8453/2	Intraductal papillary mucinous neoplasm with high grade dysplasia
8453/3	Intraductal papillary mucinous neoplasm with an associated invasive carcinoma
8470/2	Mucinous cystic tumor with high-grade dysplasia (C25. .)
8470/2	Mucinous cystic neoplasm with high-grade intraepithelial neoplasia (C22. .)
8470/2	Mucinous cystic neoplasm with high-grade dysplasia (C25. .)
8470/3	Mucinous cystic tumor with an associated invasive carcinoma (C25. .)
8470/3	Mucinous cystic neoplasm with an associated invasive carcinoma (C25. .)
8503/2	Intraductal papillary neoplasm with high grade intraepithelial neoplasia
8503/2	Intraductal tubular-papillary neoplasm, high grade
8503/3	Intraductal papillary neoplasm with associated invasive carcinoma

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## IMPACT ON CANCER REGISTRARS?

- Adoption Delay will create confusion pathology/cancer registry
- Many proposed Update Codes/Terms and pending 4<sup>th</sup> edition Blue Books reflect current terminology already in use by pathologists
  - 8148/2 - Glandular intraepithelial neoplasia (dysplasia), high grade when the term in-situ is not used in conjunction with the diagnosis
  - 8453/2 - Intraductal papillary mucinous neoplasm with high grade intraepithelial neoplasia/high grade dysplasia (no invasive tumor)
  - No New ICD-O-Codes Yet Proposed by WHO to reflect Changes in Bronchoalveolar Lung Adenocarcinoma using Travis Classification
    - All BAC now called something else
    - Adenocarcinoma in situ (formerly BAC)
    - Mucinous Adenocarcinoma with Lepidic Pattern (formerly mucinous BAC)
    - Adenocarcinoma Lepidic Predominant (formerly non-mucinous BAC)
    - Colloid Adenocarcinoma (formerly mucinous cyst-adenocarcinoma)
    - Enteric Adenocarcinoma (similar to colorectal adenocarcinoma)
- All proposed changes in turn effect CS, TNM, Tx, etc

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## GRADE CLARIFICATIONS

### 2 Grade System

Code	Terminology	Histologic Grade
2	Low grade	1/2
4	High grade	2/2

### 3 Grade System

Code	Terminology	Histologic Grade
2	Low grade, well to moderately differentiated	I/III or 1/3
3	Medium grade, moderately undifferentiated, relatively undifferentiated	I/III or 2/3
4	High grade, poorly differentiated to undifferentiated	II/III or 3/3

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## GRADE CLARIFICATIONS

Description	CS Code	Grade Code	AJCC 7th	SEER 2003-2013	AJCC 6th	SEER prior to 2003
Gleason Score						
2	002	1	G1	G1	G1	G1
3	003	1	G1	G1	G1	G1
4	004	1	G1	G1	G1	G1
5	005	1	G1	G2	G2	G2
6	006	1	G1	G2	G2	G2
7	007	2	G2	G3	G3	G2
8	008	3	G3	G3	G3	G3
9	009	3	G3	G3	G3	G3
10	010	3	G3	G3	G3	G3

Analyses of prostate grade before 2014 based solely on the grade field is not recommended

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## GRADE CLARIFICATIONS

### Current Conversion FCDS DAM Update

Code	Gleason's score	Terminology	Histologic Grade
1	2, 3, 4	Well Differentiated	I
2	5, 6	Moderately Differentiated	II
3	7, 8, 9, 10	Poorly Differentiated	III

### AJCC 7<sup>th</sup> edition 2014 Proposed Conversion

Code	Gleason's score	Terminology	Histologic Grade
1	2, 3, 4, 5, 6	Well Differentiated	I
2	7	Moderately Differentiated	II
3	8, 9, 10	Poorly Differentiated	III

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## CLOSING REMARKS

- FCDS has already begin utilizing edits for [OBS] codes
- FCDS will not allow any facility to use proposed ICD-O Codes
- DO NOT USE GRADE CODING GUIDELINES UNTIL APPROVED
  
- > 20 critical cancer registry reference manuals, tables, algorithms, and coding instruction documents to be updated – IMPACT ???
  
- How to schedule and coordinate updates to multiple references
  
- All Staff Must Use - current manuals, versions, updates, etc.
- Please Do Not Use Outdated Materials – put them away
  
- MANAGERS/FAA: Please share QC feedback and QC Review Findings and any other Field Coordinator and Quality Review corrections and comments with their staff – especially when new rules and tools and manuals or manual updates are introduced.

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**FCDS** Florida Cancer Data System  
A PART OF THE UNIVERSITY COMPREHENSIVE CANCER CENTER AND THE FLORIDA DEPARTMENT OF HEALTH

# 2013 SEER Rx and Heme/Lymph Database Updates

Background  
Rules and Instructions  
Tips and Tools

Gema G. Midence, MBA, CTR  
Steven Peace, CTR

Florida Cancer Data System Annual Meeting  
Friday, July 26, 2013  
Sunrise, Florida



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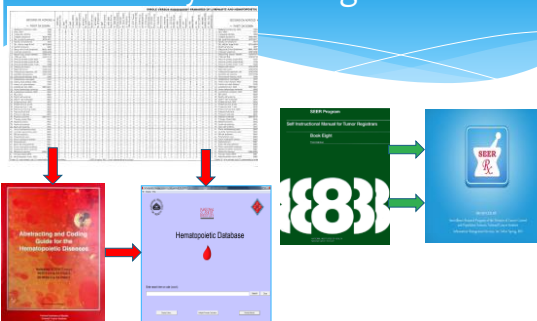
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## History and Background



The diagram illustrates the development of the Hematopoietic Database. It starts with a table of codes, which leads to the 'Assigning and Coding Codes for the Hematopoietic Database' book. This book is used to populate the 'Hematopoietic Database' interface. The interface is linked to the 'SEER Manual' and the SEER logo.

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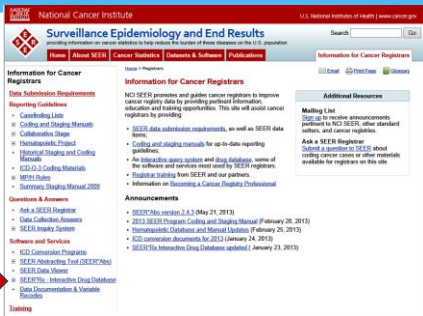
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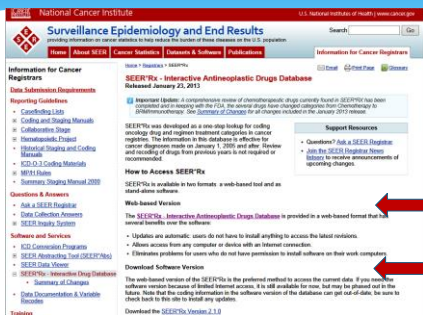
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# Information for Cancer Registrars



# SEER\*Rx



# Summary of Changes in 2013

- Total number of drugs listed in SEER\*RX: **1825**
- Total number of Regimens listed in SEER\*RX: **853**
- Number of drugs added: **12**
- Number of drugs modified: **71**
- Number of regimens added: **3**
- Number of regimens deleted: **1 (duplicate)**
- Number of regimens modified: **255**



## Summary of Changes in 2013

Prior to 2013, targeted therapies that invoke an immune response, such as Herceptin, had been coded as chemotherapy.

Effective with cases diagnosed January 1, 2013 and forward these therapies are classified as biological response modifiers.

Coding instructions for these changes have been added to the remarks field for the applicable drugs in the SEER\*RX Interactive Drug Database

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## Summary of Changes in 2013

Drug Name(s)	Previous Category	New Category	Effective Date
Alemtuzumab/Campath	Chemotherapy	BRM/Immuno	1/1/2013
Bevacizumab/Avastin	Chemotherapy	BRM/Immuno	1/1/2013
Rituximab	Chemotherapy	BRM/Immuno	1/1/2013
Trastuzumab/Herceptin	Chemotherapy	BRM/Immuno	1/1/2013
Pertuzumab/Perjeta	Chemotherapy	BRM/Immuno	1/1/2013
Cetuximab/Erbitux	Chemotherapy	BRM/Immuno	1/1/2013

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**National Cancer Institute** U.S. National Institutes of Health | www.cancer.gov

**SEER\*Rx Interactive Antineoplastic Drugs Database**  
Data last updated: January 23, 2013

Fluorouracil

**Drug Information**

**Generic Name**  
Fluorouracil

**Brand Name**  
5-Fluorouracil  
5-FUracil  
Adrucil  
Efudex  
Fluoroplex  
Fluracil  
Fluril  
Oncoil  
Ro 2-9757  
W-56950

**Abbreviation**  
5-FU  
5FU  
FU

**Category**  
Chemotherapy

**Subcategory**  
Antimetabolite

**NDC Number**  
19893, 919893

**Primary Site**  
Breast - adjuvant setting and advanced disease  
colorectal - adjuvant setting and advanced disease  
GI malignancies: anal, esophageal, gastric and pancreatic  
Head and Neck cancer  
Hepatoma  
Ovarian cancer

**Remarks**  
Fluorinated pyrimidine; antimetabolite. FDA approved uses on basal cell carcinoma, breast cancer, colorectal cancer, gastric cancer, and pancreatic cancer.

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## CANCER SCREENING GUIDELINES - LUNG

- ✦ August 2011 - National Lung Screening Trial (NLST) Results
- ✦ Screening with low-dose spiral CT compared to CXR reduced lung cancer deaths among older heavy smokers by 20%.
- ✦ Improved detection of lung cancer at earlier stages is key to increased survival and improved mortality due to lung cancer.
- ✦ Weigh Benefits/Risk of lung cancer screening using CT scan
- ✦ Recommend Screening in High Risk Population:
  - + Current/Former Smoker
  - + Age 55-74 Years
  - + Smoking History of at least 20-30 pack-years (varies by organization)
  - + No personal history of lung cancer
- ✦ Frequency of Screening not included in All Recommendations
  - + Annual
  - + Once Every 3 Years
  - + Other

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## CANCER SCREENING GUIDELINES - LUNG

- ✦ Endorsement/Adoption of Guideline
  - + American Cancer Society (ACS)
  - + American Lung Association (ALA)
  - + American College of Chest Physicians (ACCP)
  - + American Association for Thoracic Surgery (AATS)
  - + ASCO/NCCN Clinical Practice Guidelines (ASCO/NCCN)
- ✦ Pending Endorsement
  - + United States Preventative Services Task Force
    - ✦ 2004 - Last update to USPS TF Lung Cancer Screening

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## CANCER SCREENING GUIDELINES - LUNG

**American Lung Association Recommendations**

- The best way to prevent lung cancer caused by tobacco use is to never start smoking or to quit smoking.
- Low-dose CT screening should be recommended for those people who meet NLST criteria:
  - Current or former smokers aged 55 to 74 years
  - A smoking history of at least 30 pack-years
  - No history of lung cancer
- Individuals should not receive a chest X-ray for lung cancer screening
- Low-dose CT screening should NOT be recommended for everyone
- Patients should be referred to a facility that uses "best practices" for CT screening

The complete report can be found at [www.Lung.org](http://www.Lung.org).

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## CANCER SCREENING GUIDELINES - LUNG

- ✦ ALA Developing an **Educational Portfolio for Patients** to Explain:
  - + **The difference between a screening process and a diagnostic test**
    - ✦ **Cancer Screening is testing for cancer *before* there are any symptoms**
  - + **The benefits, risks and costs (emotional, physical and economic)**
  - + **That not all lung cancers will be detected through use of low dose CT scanning**
- ✦ ALA issued a **Call to Action for Hospitals and Screening Centers** to:
  - + **Establish ethical policies for advertising / promoting lung cancer screening svcs**
  - + **Develop educational materials to assist patients in having thoughtful discussions between patients and physicians regarding lung cancer screening**
  - + **Provide lung cancer screening services with access to multidisciplinary teams that can deliver the needed follow-up for evaluation of nodules.**

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## CANCER SCREENING GUIDELINES - PROSTATE

- ✦ PSA screening in **men under age 40 years is not recommended.**
- ✦ **Routine screening in men between ages 40 to 54 years at average risk is not recommended.**
- ✦ **For men ages 55 to 69 years,** the decision to undergo PSA screening involves weighing the benefits of preventing prostate cancer mortality in 1 man for every 1,000 men screened over a decade against the known potential harms associated with screening and treatment. For this reason, **shared decision-making is recommended for men age 55 to 69 years that are considering PSA screening, and proceeding based on patients' values and preferences.**
- ✦ **To reduce the harms of screening, a routine screening interval of two years or more may be preferred over annual screening** in those men who have participated in shared decision-making and decided on screening. As compared to annual screening, it is expected that screening intervals of two years preserve the majority of the benefits and reduce over diagnosis and false positives.
- ✦ **Routine PSA screening is not recommended in men over age 70 or any man with less than a 10-15 year life expectancy.**

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## CANCER SCREENING GUIDELINES - PROSTATE

- ✦ **What do the guidelines actually mean?**
- ✦ **Men of any age should not be routinely screened using PSA until evidence demonstrates mortality benefit of screening**
- ✦ **Men ages 55 to 69 are urged to talk with their doctors about benefits and harms of testing and treatment**
- ✦ **The best available evidence suggests that following these guidelines will lead to an improved benefit-to-harm ratio.**
- ✦ **What will this mean for cancer registry programs?**
- ✦ **What will this mean for cancer treatment centers?**

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## CANCER SCREENING GUIDELINES - PROSTATE

- ✦ Endorsement/Adoption of Guideline
  - + American Cancer Society (ACS)
  - + American College of Physicians (ACP)
  - + American Urological Association (AUA)
  - + American Society for Radiation Oncology (ASTRO)
  - + ASCO/NCCN Clinical Practice Guidelines (ASCO/NCCN)
  - + United States Preventative Services Task Force (USPSTF)

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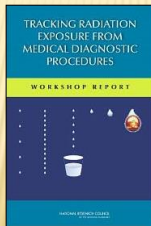
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## NEW CANCER SCREENING METHODS

- ✦ Need to Track Radiation Exposures from Screening
- ✦ Need to Track Radiation Exposure from non-screen CTs
- ✦ Screening Risk from Radiation Exposure Hypothesis Testing



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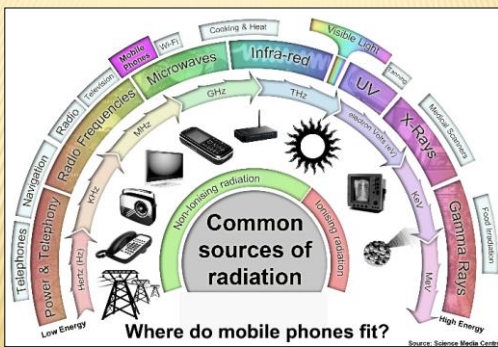
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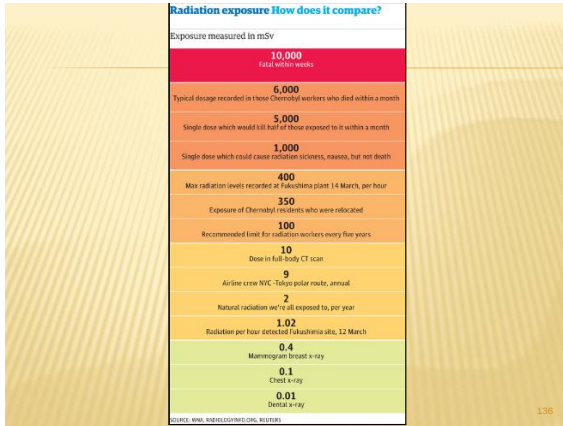
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## NEW TREATMENT DELIVERY METHODS

- ✦ Transition from infusion chemotherapy to oral administration
- ✦ New Inhalable chemotherapeutic agents using "nanostructured lipid nanocarriers" can transport antineoplastic agents at full strength directly into lungs or other organs – highly efficient.
- ✦ Nanoparticles also carry small interfering RNA (siRNA) molecules which helps control and repress certain genes to eliminate "pump" resistance (when tumor cells actively expel chemo agent(s) before the chemo can work) and "non-pump" resistance, which keeps cancer cell from dying.
- ✦ MRI-Guided Focused/Concentrated Ultrasound Therapy

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## NEW TREATMENT DELIVERY METHODS

- ✦ Photo-Dynamic Therapy (PDT)
  - + Approved for airway malignancy, Barrett's esophagus with high grade dysplasia and non-melanoma skin cancers
  - + Investigational for high-grade glioma, oral and laryngeal neoplasms, inoperable cholangiocarcinoma, and mesothelioma
- ✦ New Embolization Techniques
  - + Code as Chemo or Radiation plus Other Therapy
  - + Trans-Arterial Chemo Embolization (TACE) – direct administration of chemo into liver or other organ then embolization of artery
  - + Drug Eluting Bead Therapy – administration of beads impregnated with chemo agent(s) through catheter with timed release of agent(s)
  - + Yttrium-90 Microsphere Therapy – administration of spheres with low levels of radio-isotope Yttrium-90 attached – direct radiation to liver
    - ✦ Code as brachytherapy not radio-isotope per CoC

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## NEW TREATMENT DELIVERY METHODS

- ✦ HIPEC Chemotherapy – Heated Intra-peritoneal Chemotherapy
  - + Chemotherapy solution heated to 107.6 degrees before administration
  - + Chemotherapy solution kept at 107.6 degrees and recirculated throughout peritoneal cavity for at least two hours by going through a heating chamber
- ✦ Proton Therapy Increases Precision and Reduces Side Effects
- ✦ Focusing not only on direct treatment to tumor burden but also reducing side effects from treatment and collateral tissue damage
- ✦ Also focusing on long-term /secondary effects from treatment(s)

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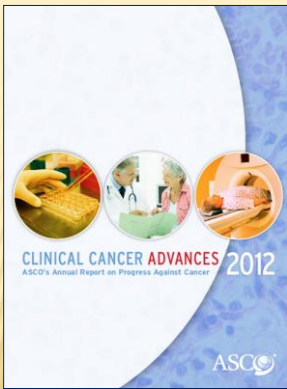
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## FOCUS AREAS IN CANCER RESEARCH

- ✦ Cancer Screening Risks and Benefits
- ✦ No Two Tumors Are Alike
- ✦ Precision Medicine – Personalized Medicine
- ✦ Targeting Molecular Pathways
- ✦ Targeting Genetic Alterations
- ✦ FDA and New Drug Approvals
- ✦ Management of Clinical Trials
- ✦ Overcoming Treatment Resistance
- ✦ Quality of Life and Survivorship Issues
- ✦ End of Life Care



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## FDA APPROVALS OF ANTICANCER AGENTS

Newly Approved Agents			
Generic Name	Trade Name	Indications	Date of Approval
Axitinib	inlyta	For treatment patients with advanced kidney cancer (renal cell carcinoma) who have not responded to other treatments for this type of cancer.	January 27, 2012
Vismodegib	Erivedge	For use in patients with locally advanced basal cell cancer who are not candidates for surgery or radiation and for patients whose cancer has metastasized.	January 30, 2012
Pertuzumab	Perjeta	For use in combination with trastuzumab and docetaxel as a first-line treatment for patients with HER2-positive metastatic breast cancer.	June 8, 2012
Carfilzomib	Kyprolis	For treatment of patients with multiple myeloma whose disease progressed despite at least two prior therapies, including bortezomib and an immunomodulatory agent.	July 20, 2012
Ziv-Aflibercept	Zaltrap	For use in combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI) for the treatment of patients with metastatic colorectal cancer that is resistant to or has progressed following an oxaliplatin containing regimen.	August 3, 2012
Enzalutamide	Xtandi	For treatment of patients with metastatic castration-resistant prostate cancer who have previously received docetaxel.	August 31, 2012
Regorafenib	Stivarga	For treatment of patients with metastatic colorectal cancer that has progressed despite standard treatments.	September 27, 2012

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## FDA APPROVALS OF ANTICANCER AGENTS

Expanded Indications for Existing Agents			
Generic Name	Trade Name	Indications	Date of Approval
Imatinib mesylate	Gleevec	For the adjuvant treatment of adult patients following complete gross resection of KIT (CD117) positive gastrointestinal stromal tumors (GIST).	January 31, 2012
Pazopanib	Votrient	For treatment of patients with advanced soft tissue sarcoma who have received prior chemotherapy.	April 26, 2012
Cetuximab	Erlbitux	For use in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) chemotherapy for first-line treatment of patients with KRAS mutation-negative, epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer.	July 6, 2012
Everolimus	Afinitor	For use in combination with exemestane to treat certain postmenopausal women with advanced hormone-receptor positive, HER2-negative breast cancer.	July 20, 2012
Vincristine sulfate liposome injection	Marqibo	For treatment of adult patients with Ph+ acute lymphocytic leukemia in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies.	August 9, 2012

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## MAJOR CLINICAL ADVANCES IN YEAR 2012

- ✦ Breast Cancer
  - + Chemo - Everolimus (Afinitor) for hormone-receptor + breast
  - + Chemo - Trastuzumab-DM1 for HER2-positive metastatic breast
  - + BRM - Pertuzumab (Perjeta) for HER2-positive metastatic breast
- ✦ Lung Cancer
  - + Combination Chemo - Carboplatin and Pemetrexed for non-small cell lung cancer



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## MAJOR CLINICAL ADVANCES IN YEAR 2012

### ✦ Prostate Cancer

- + Hormone - Enzalutamide (Xtandi) for late stage prostate cancer

### ✦ Esophageal Cancer

- + Neoadjuvant chemo plus XRT then surgery for esophagus and gastroesophageal junction tumors



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## MAJOR CLINICAL ADVANCES IN YEAR 2012

### ✦ Multiple Myeloma

- + BRM - Lenalidomide (Revlimid) maintenance delays relapse after stem cell transplant
- + BRM Agents for MM - Thalidomide, Velcade, Kyprolis, Pomalyst

### ✦ Soft Tissue Sarcoma

- + Chemo - Pazopanib (Votrient) for soft tissue sarcoma – 1<sup>st</sup> new drug in decades for soft tissue sarcoma



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## MAJOR CLINICAL ADVANCES IN YEAR 2012

### ✦ Thyroid Cancer

- + Chemo - Cabozantinib (Cometriq) in medullary thyroid cancer

### ✦ Colorectal Cancer

- + Chemo - Regorafenib (Stivarga) in metastatic colorectal cancer

### ✦ Ovarian Cancer

- + BRM - Bevacizumab (Avastin) in recurrent ovarian cancer



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## MAJOR CLINICAL ADVANCES IN YEAR 2012

### \* Colorectal Cancer Screening

- + Flexible sigmoidoscopy reduces colorectal cancer incidence and deaths - where does it fit into screening paradigm?
- + Flexible sigmoidoscopy results are comparable to colonoscopy



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## MAJOR CLINICAL ADVANCES IN YEAR 2012

### \* Factors increase risk of death in elderly chemo population

- + Geriatric assessment for patients > 70 yrs of age
- + Advanced disease
- + Low nutritional assessment score
- + Poor mobility

### \* Chemo-induced Nausea and Vomiting

- + Ancillary - Olanzapine (Zyprexa) for breakthrough nausea/vomiting



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## MAJOR CLINICAL ADVANCES IN YEAR 2012

### \* Predicting risk for adverse effects of chemo in elderly

- + New model introduced scoring system and risk-stratification
- + Low-Risk / Intermediate-Risk / High-Risk

### \* Chemo-induced Peripheral Neuropathy

- + Ancillary - Duloxetine (Cymbalta) for alleviating pain from chemo-induced neuropathy



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# QUESTIONS



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