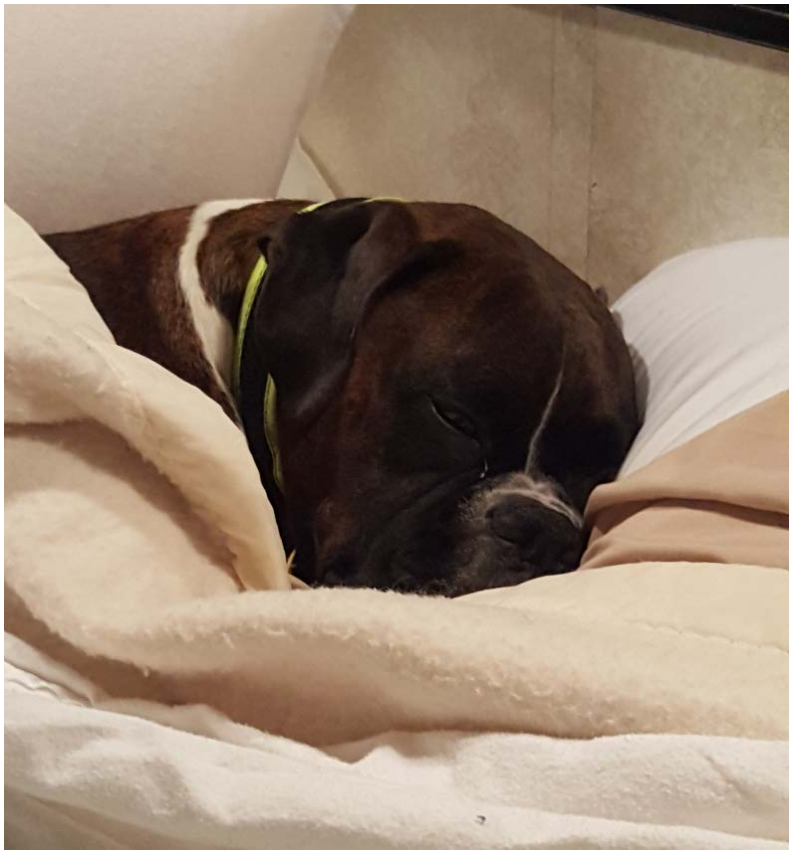
NPCR-AERRO: Electronic Pathology (ePath) and Biomarker Synoptic Reporting Activities

Sandy Jones, Public Health Advisor
Cancer Surveillance Branch
Division of Cancer Prevention and Control
Centers for Disease Control and Prevention (CDC)

Good Morning.



Background and Purpose

- U.S. Laboratories still produce narrative reports
- Non-standard across labs
- Time-consuming
- Enhance data completeness, timeliness, and quality using the CAP Cancer Protocols and electronic Cancer Checklists (eCC)

[+] Show Report
Legend

Path Final Diagnosis

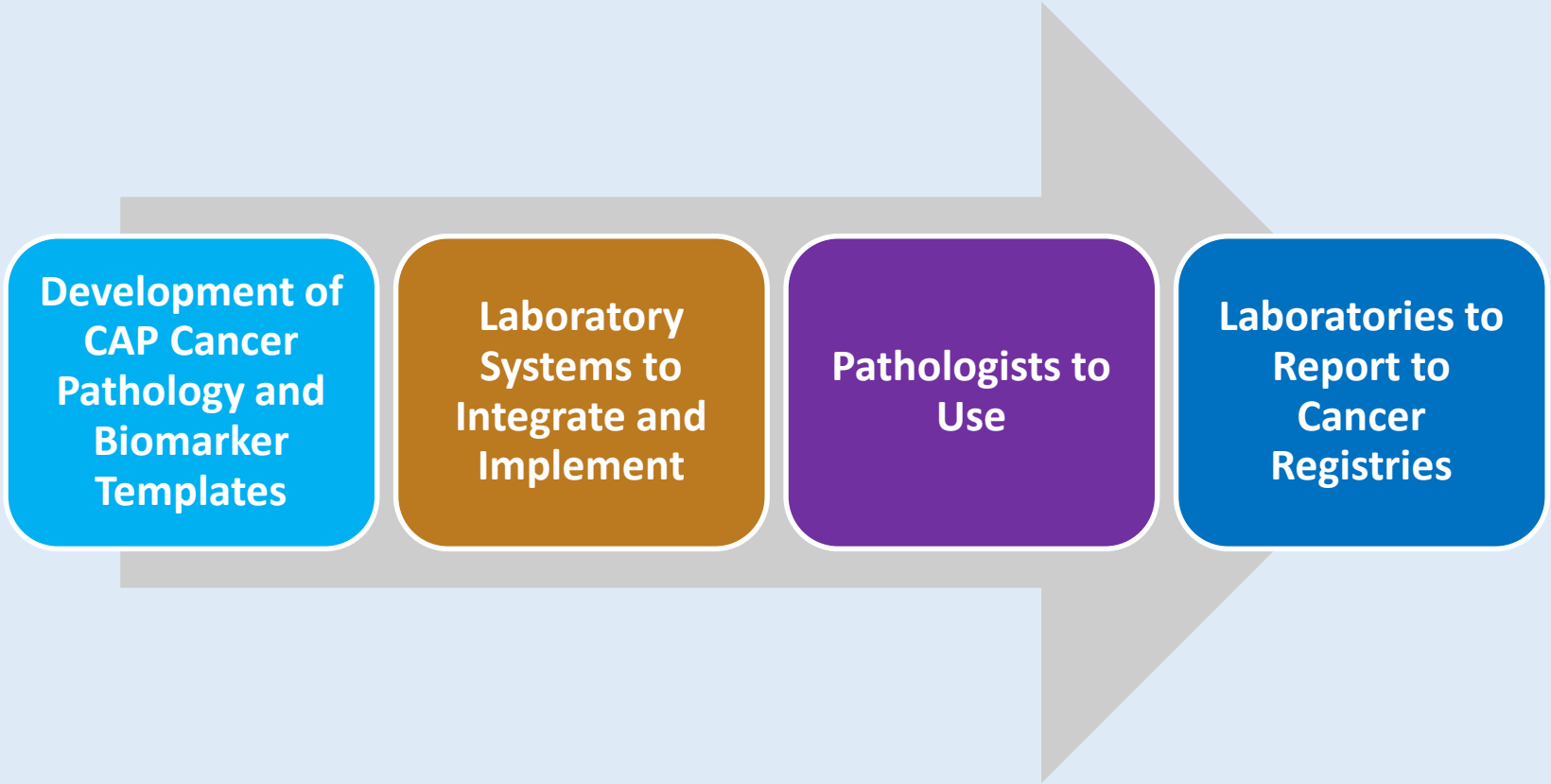
Test Breast Diagnosis CANCER CHECKLIST: CLINICAL Clinical History : Palpable mass, ,, Prior neoadjuvant treatment for this diagnosis of DCIS Specify Type: Test specific Type Radiologic Finding: Mass or architectural distortion SPECIMEN Procedure : Total Mastectomy (including Nipple and skin) Lymph node Sampling : Lymph nodes present within the Breast specimen (i.e., intramammary Lymph nodes) Specimen Laterality: Right Tumor Site: Upper inner quadrant Specify Clock Position of Tumor Site: 6 o'clock Size (Extent) of DCIS Estimated Size (extent) of DCIS (greatest dimension using gross and microscopic evaluation) is at Least (mm): 8mmmm Additional Dimension (mm): 2mmmm Number of Blocks with DCIS: 3 Number of Blocks Examined: 8 Histologic Type : DUCTAL CARCINOMA IN SITU. Classified as Tis (DCIS) or Tis (Paget) Architectural Patterns : PAGET DISEASE (DCIS involving Nipple skin), Cribriform, Papillary MARGINS MARGINS (Note H): Margins uninvolved by DCIS Distance of DCIS from Closest Margin (mm): Distance is < 1 mm Closest Uninvolved Margin: Anterior, Superior Specify Which Margin(s) and Extent of Involvement: Anterior, Posterior, Superior, Inferior, Medial, Lateral Extent of Anterior Margin Involvement: Extensive Extent of Posterior Margin Involvement for DCIS: Minimal / moderate Extent of Superior Margin Involvement: Minimal / moderate Extent of Inferior Margin Involvement: Extensive Extent of Medial Margin Involvement: Extensive Extent of Lateral Margin Involvement: Minimal / moderate ACCESSORY FINDINGS Treatment Effect: Response to Presurgical (Neoadjuvant) Therapy : No definite response to presurgical therapy Microcalcifications : Present in DCIS, Present in both DCIS and nonneoplastic tissue Sentinel and Non-Sentinel Nodes Total Number of Lymph nodes Examined (sentinel and nonsentinel): Number cannot be determined (explain), test explanation Micro / Macro Metastases: Present Number of Lymph nodes with Isolated Tumor Cells (<= 0.2 mm and <= 200 cells): Number cannot be determined (explain) Number of Lymph nodes with Macrometastases (> 2 mm): Specify, 8mm Number of Lymph nodes with Micrometastases (> 0.2 mm to 2 mm and / or > 200 cells): Specify Sentinel Nodes Number of Sentinel Lymph nodes Examined: Specify Method of Evaluation of Sentinel Lymph nodes : Hematoxylin and eosin (H and E), one level, H and E, multiple levels, Immunohistochemistry STAGE (pTNM) TNM Descriptors: r (recurrent) Primary Tumor (pT): pTis (Paget): PAGET DISEASE of the Nipple NOT associated with INVASIVE CARCINOMA and / or CARCINOMA IN SITU (DCIS and / or LCIS) in the underlying Breast parenchyma. Modifier: (sn): Only sentinel node(s) evaluated. If 6 or more nodes (sentinel or nonsentinel) are removed, this modifier should not be used. Category (pN): pN2a: Metastases in 4 to 9 axillary Lymph nodes (at least one tumor deposit greater than 2.0 mm)## Distant Metastasis (pM): pM1: Distant detectable metastasis as histologically proven larger than 0.2 mm (Deprecated Items) (Deprecated Answers): cM0 (i!~): No clinical or radiographic evidence of distant metastasis, but deposits of molecularly or microscopically detected tumor cells in circulating Blood, Bone marrow, or other nonregional nodal tissue that are no larger than 0.2 mm in a patient without symptoms or signs of metastasis Specimen : Total Breast (including Nipple and skin) Estrogen Receptor (results of special studies performed on this specimen or a prior core needle biopsy) : Immunoreactive tumor cells present Progesterone Receptor (results of special studies performed on this specimen or a prior core needle biopsy) : Immun
and Interpretation: Positive %
Receptor (PgR): Performed o
Positivity: 20% Average Intens

Path Text Diagnosis

CAP eCC
1.003.001.1000043
Number cannot be determine
Specify
Specify

Path Clinical History

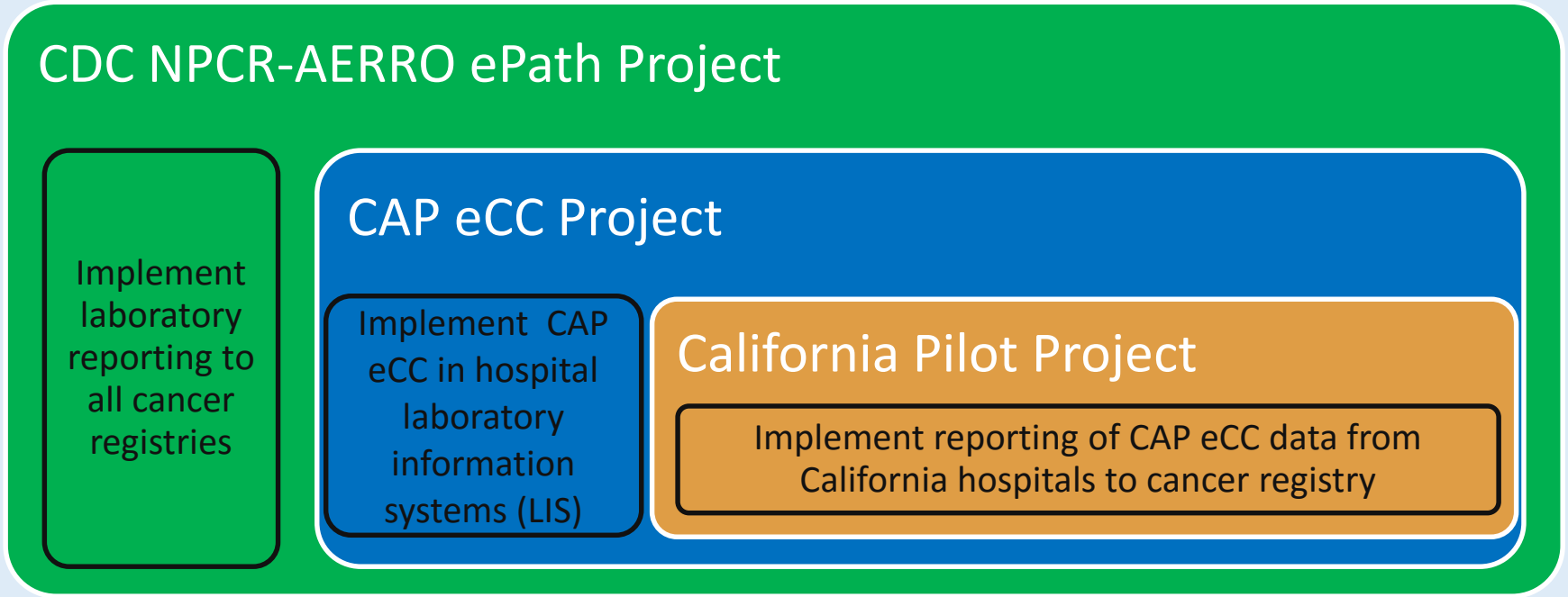
Overview of Necessary Components



The Stars are aligning…

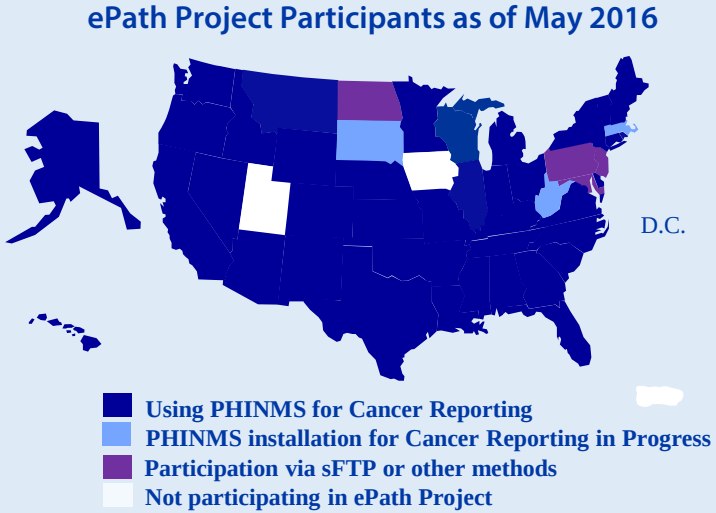
- NPCR-AERRO ePath Project began working with national laboratories to transmit narrative reports using NAACCR Volume V in 2006
- CAP eCCs first published in 2007
  - CAP Cancer Protocols cancer reporting gold–standard since 1984
- Cancer Care Ontario (CCO) implemented a CCO-developed checklist in 2008 and implemented the CAP eCCs from 2010-2012
- PathGroup implemented CAP eCCs in 2012
- CA pilot project with St. Joseph's Health, CAP, and mTuitive began in January 2014

Project Collaboration for Greater Impact

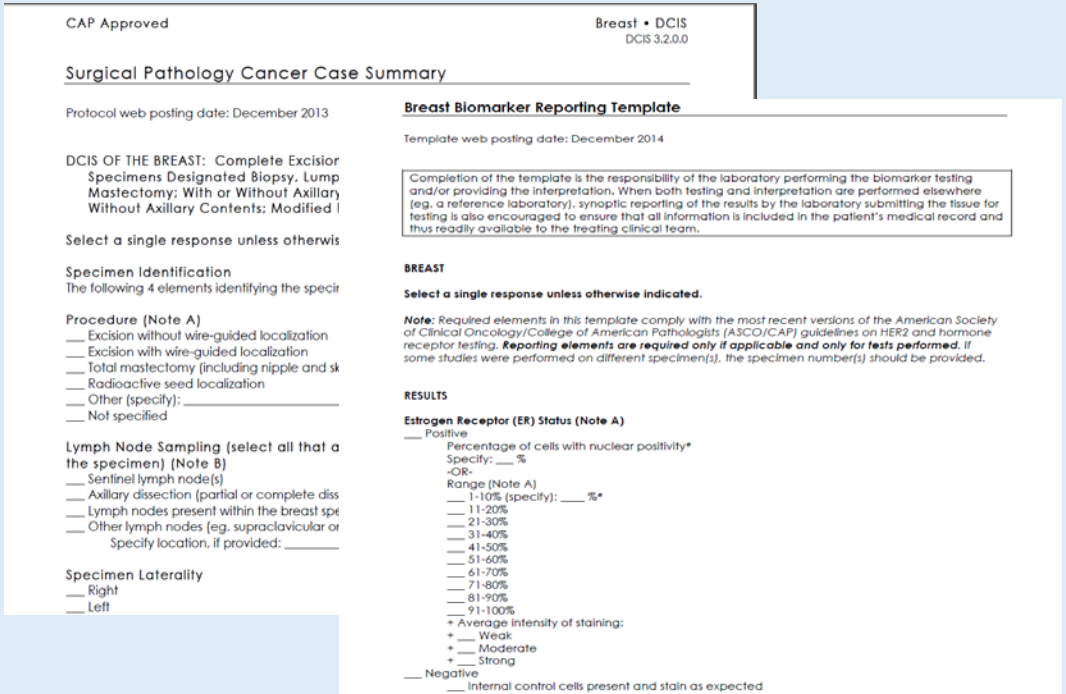


Update on CDC NPCR-AERRO ePath Project

- Use NAACCR Volume V
  - HL7 2.3.1 or 2.5.1 ORU message for narrative reports
- Established ICD-10-CM filter to identify cancer cases for reporting
  - Core vs. Expanded
- Use Public Health Information Network Messaging System (PHINMS) for secure message transport
- Currently implemented ePath reporting from 25 national/regional labs to over 40 registries



CAP Cancer Pathology and Biomarker Templates



CAP Approved

Breast • DCIS
DCIS 3.2.0.0

Surgical Pathology Cancer Case Summary

Protocol web posting date: December 2013

DCIS OF THE BREAST: Complete Excisior
Specimens Designated Biopsy, Lump
Mastectomy; With or Without Axillary
Without Axillary Contents; Modified

Select a single response unless otherwis

Specimen Identification
The following 4 elements identifying the specir

Procedure (Note A)
___ Excision without wire-guided localization
___ Excision with wire-guided localization
___ Total mastectomy (including nipple and sk
___ Radioactive seed localization
___ Other (specify): _____
___ Not specified

Lymph Node Sampling (select all that a
the specimen) (Note B)
___ Sentinel lymph node(s)
___ Axillary dissection (partial or complete diss
___ Lymph nodes present within the breast spe
___ Other lymph nodes (eg, supraclavicular or
Specify location, if provided: _____

Specimen Laterality
___ Right
___ Left

Breast Biomarker Reporting Template

Template web posting date: December 2014

Completion of the template is the responsibility of the laboratory performing the biomarker testing and/or providing the interpretation. When both testing and interpretation are performed elsewhere (eg, a reference laboratory), synoptic reporting of the results by the laboratory submitting the tissue for testing is also encouraged to ensure that all information is included in the patient's medical record and thus readily available to the treating clinical team.

BREAST

Select a single response unless otherwise indicated.

Note: *Required elements in this template comply with the most recent versions of the American Society of Clinical Oncology/College of American Pathologists (ASCO/CAP) guidelines on HER2 and hormone receptor testing.* ***Reporting elements are required only if applicable and only for tests performed.*** *If some studies were performed on different specimen(s), the specimen number(s) should be provided.*

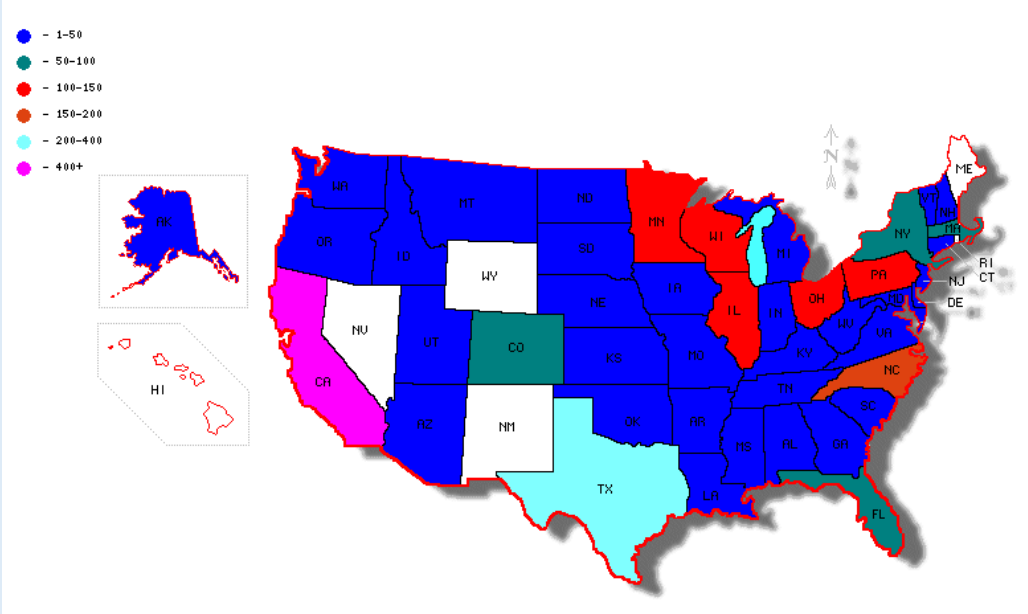
RESULTS

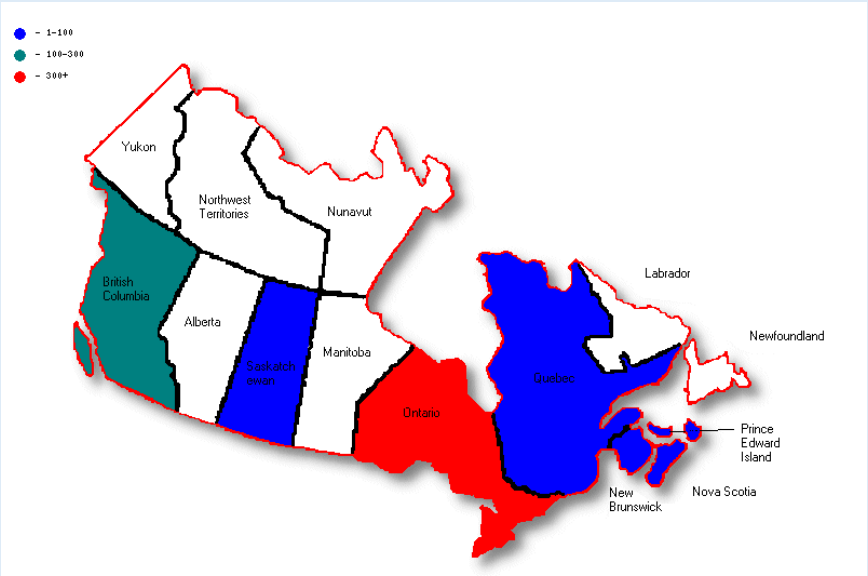
Estrogen Receptor (ER) Status (Note A)
___ Positive
Percentage of cells with nuclear positivity*
Specify: ___ %
-OR-
Range (Note A)
___ 1-10% (specify): ___ %*
___ 11-20%
___ 21-30%
___ 31-40%
___ 41-50%
___ 51-60%
___ 61-70%
___ 71-80%
___ 81-90%
___ 91-100%
+ Average intensity of staining:
+ ___ Weak
+ ___ Moderate
+ ___ Strong
___ Negative
___ Internal control cells present and stain as expected

- **3,162 pathologists using checklists**
- **96 CAP Cancer eCCs, including 13 Biomarker Templates**
  - Breast Biomarkers
  - Stomach: Gastric HER2 Biomarkers
  - Lung Biomarkers, Non-Small Cell Carcinoma
  - Colorectal Biomarkers
  - CNS Biomarkers
  - GIST Biomarkers
  - MPN Biomarkers
  - CLL Biomarkers
  - CML Biomarkers
  - Melanoma Biomarkers
  - DLBCL Biomarkers
  - Thyroid Biomarkers
  - Endometrium Biomarkers

Source: Cancer Protocols on www.cap.org

Pathologists Licensed to Use CAP eCC in U.S. and Canada





Pathology Reporting in Cancer Care Ontario (CCO)

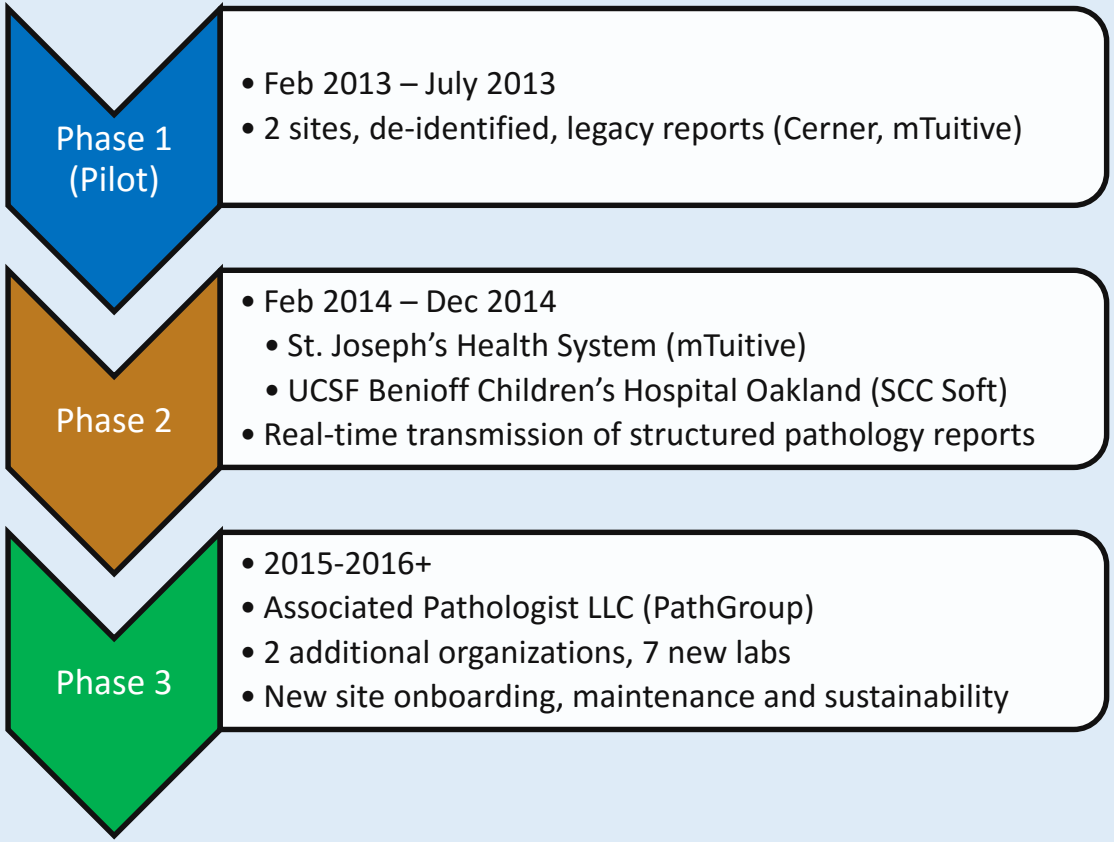
Proportion of Ontario hospitals reporting cancer pathology to CCO, by level of standardization, from narrative to synoptic format

Reporting Level	Level 1	Level 2	Level 3	Level 4	Level 5	Level 6
Description	• Narrative • No CAP content • Single text field data	• Narrative • CAP content • Single text field data	• Level 2 + • Synoptic-like structured format	• Level 3 + • Electronic reporting tools using drop-down menus	• Level 4 + • Standardized reporting language • Data elements stored in discrete data fields	• Level 5 + • Common data and messaging standards with ckeys, SNOMED CT or other encoding
% Ontario Hospitals 2004-05	5%	40%	50%	5%	0%	0%
% Ontario Hospitals 2006-07	0%	5%	70%	25%	0%	0%
% Ontario Hospitals 2008-09	0%	0%	65%	17%	18%	0%
% Ontario Hospitals 2009-10	0%	0%	20%	2%	78%	0%
% Ontario Hospitals January 2012	0%	0%	8%	0%	0%	92%
% Ontario Hospitals May 2012	0%	0%	3%	0%	0%	97%
% Ontario Hospitals October 2015	0%	0%	0%	0%	0%	100%

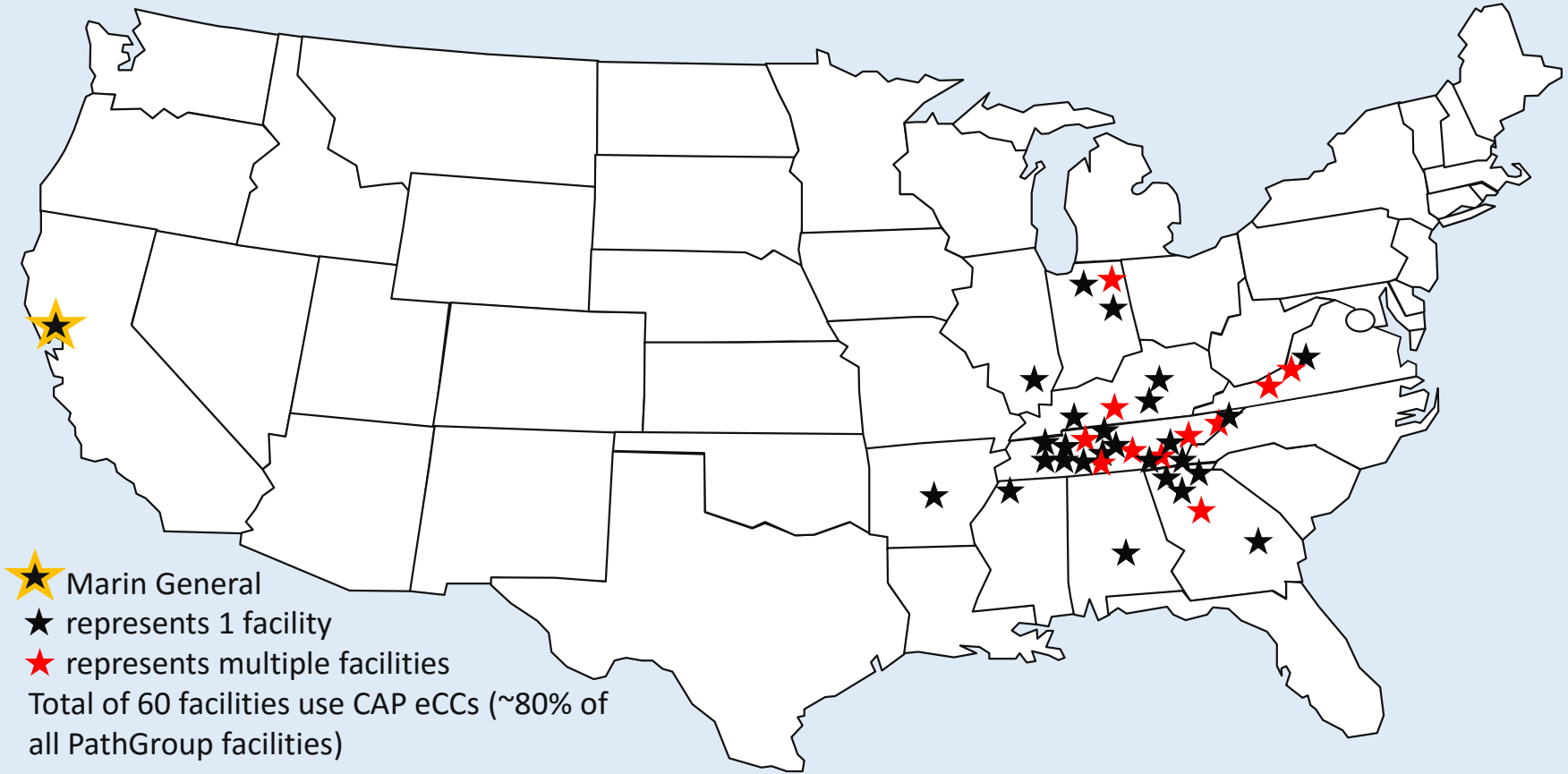
Data Source: CCO ePath, as of October 2015

Ontario hospitals includes 119 acute care facilities – primary and secondary. Primary sites submit cancer pathology reports directly to CCO Ontario Cancer Registry via CCO ePath system. Primary sites may also report cancer pathology for secondary hospitals. Private labs and Paediatric facilities are not included

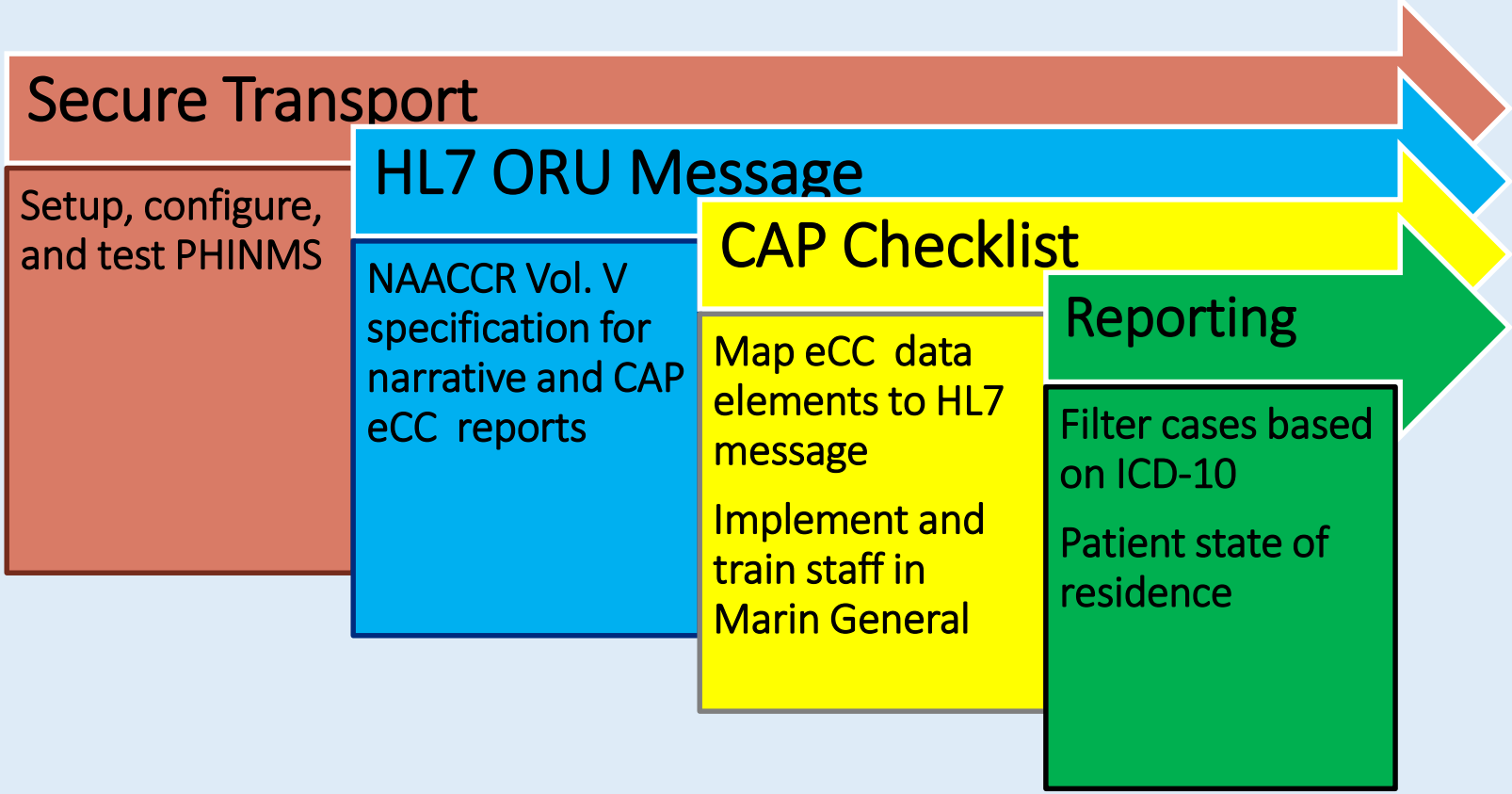
CCR Structured Reporting Initiative – to date



PathGroup facilities using CAP eCCs



PathGroup Implementation Activities



Sample PathGroup HL7 Message

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MSH|^~\&|PathSys|Associated Pathologists, LLC d/b/a PathGroup^44D0934312^CLIA|Eureka|CCR|20160607141304||ORU^R01^ORU_R01|201606071413040001|P|2.5.1|||||||VOL_V_40_C
PID|1||N00150471^^^^MR^999990&Test PathGroup Systems University&PG~^^^USSSA^SS^~N00150471^^^PathGroup^PI^||Testauto^CCPat1^^^^^L||19420901|M|||2420 Sunnyview Lane^^BR
PV1|1|N
ORC|RE|||||||||||||||||||Test PathGroup Systems University^L|5301 Virginia Way^Suite 300 room 1^Brentwood^TN^37027|^PRN^PH^^1^615^5629350|CMC^^Nashville^TN^37076
OBR|1||16-11-000988^PathSys^44D0934312^CLIA|11529-5^SURGICAL PATH REPORT^LN||20160607000000|||||||20160607000000|&Esophagus, Biopsy|1234567890^Test^Doc
OBX|1|TX|22637-3^Path report.final diagnosis^LN||Esophagus, mid, biopsy:\X0D\\X0A\     ADENOCARCINOMA, poorly differentiated, signet ring cell type, wit
Extension:  Tumor invades through the muscularis propria into\X0D\\X0A\ the periesophageal soft tissue (adventitia)\X0D\\X0A\ MARGINS\X0D\\X0A\   Uninvo
(pTNM)\X0D\\X0A\   TNM Descriptors:  Not applicable\X0D\\X0A\   Primary Tumor (pT):  pT3: Tumor invades adventitia\X0D\\X0A\   Regional Lymph Nodes (pN)
OBX|2|TX|22638-1^Path report.comments^LN||\X0D\\X0A\ Comments - Results communicated by phone. An immunohistochemical stain for Her-2 is\X0D\\X0A\ order
OBX|3|TX|22633-2^Path report.site of origin^LN||Mid esophagus biopsies|||||F|||201606071334|44D0934312^Associated Pathologists, LLC d/b/a PathGroup^CLI
OBX|4|TX|22634-0^Path report.gross description^LN||Received in formalin labeled "CCPat1 Testauto, esophagus" are multiple white,\X0D\\X0A\ irregular tis
OBX|5|TX|22635-7^Path report.microscopic examination^LN||Microscopic examination is performed.||||||F|||201606071334|44D0934312^Associated Pathologists,
OBX|6|TX|22636-5^Path report.relevant Hx^LN||History - PEG tube||||||F|||201606071334|44D0934312^Associated Pathologists, LLC d/b/a PathGroup^CLIA
OBR|2||16-11-000988^PathSys^44D0934312^CLIA|60568-3^SYNOPTIC REPORT^LN||20160607000000|||||||20160607000000|&Esophagus, Biopsy|1234567890^Test^Doctor^^
OBX|1|ST|60573-3^Report template source^LN||CAP eCC||||||F|||201606071334
OBX|2|CWE|60572-5^Report template ID^LN||21.100004300^ESOPHAGUS: Endoscopic Resection, Esophagectomy, or Esophagogastrectomy (Note A)^CAPECC||||||F|||2
OBX|3|ST|60574-1^Report template version ID^LN||2.004.001.100004||||||F|||201606071334
OBX|4|CWE|18497.100004300^Specimen^CAPECC||18561.100004300^Esophagus^CAPECC|||||F|||201606071334
OBX|5|CWE|4158.100004300^Procedure^CAPECC||4160.100004300^Esophagogastrectomy^CAPECC||||||F|||201606071334
OBX|6|CWE|6369.100004300^Primary Tumor Site^CAPECC||16171.100004300^Esophagogastric junction (EGJ)^CAPECC||||||F|||201606071334
OBX|7|CWE|18562.100004300^Relationship of Tumor to Esophagogastric Junction^CAPECC||18578.100004300^Tumor midpoint is located at the esophagogastric jun
OBX|8|CWE|4172.100004300^Histologic Type^CAPECC||4174.100004300^Adenocarcinoma^CAPECC||||||F|||201606071334
OBX|9|CWE|4180.100004300^Histologic Grade^CAPECC||4185.100004300^G3:  Poorly differentiated^CAPECC||||||F|||201606071334
```

Strategies to increase use of CAP eCCs

- Describe benefits to laboratories
- Demonstrate ease of use for pathologists
- Introduce use of eCCs at academic level
- Market to standard setters at national level
- Market to labs, pathologists and lab system vendors
- Market to oncologists and other physician specialists

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Questions?

For more information please contact Centers for Disease Control and Prevention

1600 Clifton Road NE, Atlanta, GA 30333
Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
Visit: www.cdc.gov | Contact CDC at: 1-800-CDC-INFO or www.cdc.gov/info

National Center for Chronic Disease Prevention and Health Promotion
Division of Cancer Prevention and Control