

Structured Reporting:

Successes and Needed Solutions

Rodney Schmidt MD, PhD
University of Washington

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Rodney Schmidt, MD, PhD
Cortex Medical Management Systems
Consultant
Consultant Fees

Efficient Pathology, LLC
Owner
Consultant Fees

Outline

- Structured data and successes
- Value of extended structured data collection
- Needed enabling technology

Types of Structure

- Synoptic summaries
 - Paper- or text-based (passive)
 - Electronic GUI- or Voice-driven (active)
 - Structured (discrete) data
- Entire reports
 - Named report sections
- Discrete results (IHC, molecular, etc)

Successes

- Standard content
 - CAP cancer protocols
- Complete reporting
 - Enforced via data entry forms
- Accurate reporting
 - Standard criteria
 - Pick lists
- Standard concepts
 - SNOMED, Ckey
- Use data to drive improvements in health care
 - Dr. Divari's presentation, Wed. morning

Extended Uses

~17,000 completed worksheets; PowerPath

- Reflex testing
- Prospective internal second opinions
- Cross-case correlations
- Pre-selection of blocks for ancillary testing
- Cytotech correlations (non-GYN)
- Prognostic markers
- Documentation for billing

Competing requirements with current CAP protocols!

Reflex Testing

- Problem: How to ensure that appropriate reflex tests are done?
- Example: Mismatch repair testing for Lynch syndrome in endometrial carcinoma.
 - Society of GYN Oncologists
 - New endometrial carcinoma diagnosis
 - Age \leq 60
 - Order IHC for MLH1, MSH2, MSH6, PMS2

Usual process

Historical process	IHC Order time (relative to report signout)			n
	At/before S/O	1d later	>1d later	
No reflex testing	32%	17%	51%	72 cases
Reflex testing (no prompts)	65%	12%	23%	26 cases

MSI Testing

◆ Patient age ≤ 60?

- No
 Yes

Get MSI IHC on all patients age ≤ 60.

If tested on previous biopsy, list result below. If now ordered and pending, say so and prepare to issue addendum with results.

◆ MSI testing status

- Done previously
 Ordered with addendum report to follow.
 Results included in this report
 Not applicable
 Not ordered/performed

Explain why below

MSI testing comment

Mandatory Worksheet Prompt

Historical process	Order time (relative to report signout)			n
	At/before S/O	1d later	>1d later	
No reflex testing	32%	17%	51%	72 cases
Reflex testing (no prompts)	65%	12%	23%	26 cases
Worksheet prompt	87%	11%	2%	46 cases

Dramatically improved success rate in timely ordering!

Reasons for Success

- Part of standard case workflow
 - Required cancer worksheet
 - Required element of worksheet
 - Minimal extra work
- Closely coupled to case (easily accessed)
- Extensible worksheet design

Residual Issues

- Why next day IHC ordering?
 - People lie on the worksheet
 - MMR IHC actually not ordered
 - “Age” question answered incorrectly
- What would be better?
 - Tighter integration with LIS
 - Age auto-entered or prompt only presented for young patients
 - Enable ordering of ancillary tests directly from worksheet

Reflex p16 Resulting

Oropharyngeal primary

Yes

p16 status

If preformed on a previous biopsy/sample, give result and accession number
If tested on this case, give result.
If ordered and pending, say so.

No

Required for oropharyngeal cancers only

Characteristics and extent of tumor

Histologic type: **Squamous cell carcinoma (80703)**
Tumor site (epicenter): **Pharynx, oropharynx**
Tumor laterality: **Right**
Tumor focality: **Multifocal**
Histologic grade: **G 1: Well differentiated**
Tumor size: **0.9cm**
Tumor thickness: **0.3cm**
Local extension: **Confined to superficial mucosa/submucosa**
p16 status: Positive (see below).
Lymph-vascular invasion: **Not identified**
Perineural invasion: **Not identified**

Prompting and result summary

Prognostic Marker Results

◆ Estrogen receptor

Allred score is defined as the sum of Proportion score + Intensity score

Proportion score

1=0-1%

2=1-10%

3=11-33%

4=34-66%

5=67-100%

Intensity score

0=negative

1=weak

2=intermediate

3=strong

Negative with positive internal controls (Allred score = 0 of 8)

Negative with positive internal controls (Allred score = 2 of 8)

Negative with positive internal controls

Negative with negative internal controls (Allred score = 0 of 8)

Negative with negative internal controls (Allred score = 2 of 8)

Negative with negative internal controls

Negative with no internal control (Allred score = 0 of 8)

Negative with no internal control (Allred score = 2 of 8)

Negative with no internal controls

Negative

Weakly positive (Allred score = 3 of 8)

Positive (Allred score = 4 of 8)

Positive (Allred score = 5 of 8)

Positive (Allred score = 6 of 8)

Positive (Allred score = 7 of 8)

Positive (Allred score = 8 of 8)

Positive

See comment

Not performed/reported

◆ Progesterone receptor

(no answer)

◆ c-erb-B2 (Her-2/neu) by IHC

(no answer)

Ki-67 proliferative index

%

◆ Her-2/neu by FISH

(no answer)

- Interpretation criteria
- Required entry

Duplicate data entry for inside cases (IHC results primarily entered in separate tool)

Structured Data Reporting

Ancillary Studies

Source: **Previous UW Medicine biopsy**

Accession number: **SU-14-19074**

Outside pathology laboratory (by report only)

Estrogen receptor: **Positive (Allred score = 8 of 8)**

Progesterone receptor: **Positive (Allred score = 7 of 8)**

c-erb-B2 (Her-2/neu) by IHC: **Equivocal for Her-2/neu overexpression by IHC**

Ki-67 proliferative index: **30%**

Her-2/neu by FISH: **Negative for Her-2/neu gene amplification by FISH**

```
OBX|14|CWE|^^^^^^^^^Source of ancillary studies:|1|^^^^^^^^^Outside pathology laboratory (by report only)|^^ISO+|||
OBX|15|CWE|^^^^^^^^^Estrogen receptor:|1|^^^^^^^^^Positive (Allred score = 8 of 8)|^^ISO+||||F|||201409191254
OBX|16|CWE|^^^^^^^^^Progesterone receptor:|1|^^^^^^^^^Positive (Allred score = 7 of 8)|^^ISO+||||F|||201409191254
OBX|17|CWE|^^^^^^^^^c-erb-B2 (Her-2/neu) by IHC:|1|^^^^^^^^^Equivocal for Her-2/neu overexpression by IHC|^IS
OBX|18|NM|^^^^^^^^^Ancillary Studies:Ki-67 proliferative index|1|30|^percent^ISO+||||F|||201409191254
OBX|19|CWE|^^^^^^^^^Her-2/neu by FISH:|1|^^^^^^^^^Negative for Her-2/neu gene amplification by FISH|^ISO+||||F
```

Reported synoptically in text

Interfaced discretely to enterprise repository
via HL7

Detailed Grading

Gleason score can be determined

**If 3 patterns are present, record all three. If only one pattern, record it as both predominant and secondary.
If any pattern 5 is present, include it as predominant or secondary when computing Gleason score (PubMed 16096414).**

Gleason grade ♦ Primary ♦ Secondary Tertiary ♦ Score

♦ Grade Comment(s)

Type of pattern 4, if present

Gleason score not applicable

♦ Reason Gleason score not applicable

Gleason score cannot be determined

Gleason score cannot and should not be assigned if there has been prior systemic therapy.

Reason Gleason score cannot be determined

Collects detailed grade parameters

Used for biopsies and radical prostatectomies

Analogous grade detail collected for other tumors

Cross-Case Correlation

Print Date: 9/27/14

HMC ANATOMIC PATHOLOGY
 QUALITY ASSURANCE PROGRAM
 GU CORRELATION REVIEW
 FROM 8/1/14 TO 9/1/14

Reviewing Fellow

Reviewing Pathol

Resection#	Diagnosis	Resect Comm	Agree with Diagnosis	Attending	Biopsy#	Diagnosis	Bx Comm	Agree with Diagnosis	Attend
SH-14-05241	4+3+5=7		Yes / No	Tretiakova	SH-14-04654	3+4+5=8		Yes / No	Tretiak
SH-14-05443	4+3=7		Yes / No	Vakar-Lopez	SH-14-03375	3+3=6		Yes / No	Vakar-L

RP Grade not PNB Grade

- QA report automatically identifies Patients where biopsy grade differs from radical prostatectomy (RP) grade
- Analogous reports for pap/Cx and thyroid

Thyroid FNA

Cytotechnologist 1

Screened by cytotech (No Answer)

Final Diagnoses

◆ Include specimen A Yes

Specimen A ◆ Designation Procedure

◆ Pathologist's part A Dx **NONDIAGNOSTIC**

◆ Specific Nondiagnostic Dx (none)

BENIGN

◆ Specific Benign Dx (none)

Per the 2009 Bethesda System for Reporting Thyroid Cytopathology, the Benign diagnostic category is associated with a 0-3% risk of malignancy.

ATYPICAL

◆ Specific Atypia Dx (none)

Per the 2009 Bethesda System for Reporting Thyroid Cytopathology, the diagnostic categories of AUS/FLUS carry an overall 5-15% risk of malignancy.

SUSPICIOUS FOR FOLLICULAR NEOPLASM

◆ Specific Follicular Dx (none)

- Captures cytotech interpretations
- Diagnoses as discrete choices
- Enables Cytotech/Pathologist correlation
- Automatic inclusion of Bethesda significance

Previous Case Info

Pre-treatment tumor characteristics	
Pre-treatment size and comment will not be printed on the pathology report	
Pre-treatment tumor size	<input type="text"/> cm
Pre-treatment tumor size comment	<input type="text"/>
Enter accession number and/or date of previous biopsy below	
Source of pre-treatment data	<input type="text"/>
Comment about pre-treatment source	<input type="text"/>
◆ Pre-treatment Nottingham grade	<input type="text" value="(no answer)"/>
◆ Pre-treatment ER	<input type="text" value="(no answer)"/>
◆ Pre-treatment PR	<input type="text" value="(no answer)"/>
◆ Pre-treatment Her-2/neu by IHC	<input type="text" value="(no answer)"/>
Pre-treatment Her-2/neu by FISH	<input checked="" type="radio"/> (No Answer)
Pre-treatment Ki-67	<input type="text"/> %
Other pre-treatment studies	<input type="text"/>
Pre-treatment characteristics comment	<input type="text"/>

- Used on breast cancers after neoadjuvant Rx.
- For clinician convenience.

Tedious and error-prone.
Need better solution.

Other Solutions

Capture internal reviews (slide reviews)

Internal Review
Internally reviewed by: <input type="text" value="(none)"/>
Include details of any review by Pathologists at another institution in Comment
Review comment: <input type="text"/>

Prospectively identify blocks for future testing

Future Studies
Identify block(s) with the most invasive cancer and least in situ, atypical, or normal tissue. Avoid blocks with abundant normal tissue.
Do NOT pick blocks that show seminal vesicle involvement, positive margins, or other critical features.
♦ Best block(s) from the present case to use for future additional studies <input type="text"/>
Best block comment(s) <input type="text"/>

More Uses

- Billing documentation



A screenshot of a billing form. The form has a light blue background. On the left, there is a text field containing the text "Pleura assessed by Movat pentachrome stain" with a small red asterisk icon to its left. To the right of this text field is a vertical column of three radio buttons. The top radio button is selected and is labeled "Yes". The middle radio button is labeled "No". The bottom radio button is labeled "Not applicable".

- Data repository for clinical trial (Dr. Mark Routbort, MDACC)
- Compelling needs to add local content to the equivalents of CAP cancer protocols!

Issues

- Formatting
- Maintenance

- Need cooperative development involving CAP (eCC), vendors, users, and third party developers.

Formatting/Layout

“Illegal” report outputs (*CoC commendation denied*)

Histologic type: **Adenocarcinoma, NOS (81403)**

Histologic (Gleason) Grade: Primary: **4** + Secondary: **3** = Total: **7**

Lymph Node Status

Node summary: Nodes with carcinoma: **1** / Total nodes examined: **17**

From CAP synoptic report definition

Two data element names may not be listed on the same line, with the following exceptions.

- o Anatomic site or specimen, laterality, and procedure
- o Negative margins. Example: for colorectal carcinoma resection specimens, negative proximal, distal, and radial margins may be listed on one line
- o Pathologic staging: pT, pN, and pM categories may be listed on one line. It is not necessary to include definitions of the pT, pN, and pM categories in the report.

Formatting proposal

- Use formatting appropriate to the recipient
 - Printed reports (human readability)
 - More exceptions to “single line” reporting rule for items like grade, size, node counts
 - Or, relaxed formatting restrictions if data are captured and transmitted discretely
 - Electronic interfaces to data repositories
 - Key/Value pairs, preferably with accompanying identifiers (e.g. Ckey or SNOMED)
 - Specs available

Maintenance

- Independently update CAP and local content
 - CAP updates cannot break local content
- (Semi-) automated incremental updates
 - Local approval
 - Version control
- Requires enhanced functionality by LIS vendors or service providers
- Probably based on Ckey

Ckey

```
<fixed-list-note note-id="16080.100004300" sort-order="400">
  <title>The current clinical / radiologic breast findings for which this surgery is performed include:</title>
</fixed-list-note>
<fixed-list-item answer-id="21534.100004300" sort-order="500">
  <title>Palpable mass</title>
</fixed-list-item>
<fixed-list-item answer-id="21535.100004300" sort-order="600">
  <title>Nipple discharge</title>
```

- Unique identifiers for checklist items
- Format: ID.assigning_authority
- Enables selective updating of CAP content
- Weakness: Answers don't explicitly reference the parent Question

Ideal Synoptic Tool(s)

- Flexible formatting for output
- Locally extensible (keys, values, order, instructions)
- Maintainable
 - Version control
 - Upgradable by individual elements
- Real integration with LIS
 - Pull in data; avoid redundant entry
 - Data storage within LIS
 - Interface out as discrete data
- Dictation solution
- Calculations (stage, grade, etc)
- Reflexive logic
- Linkouts for instructions, etc

Thanks to:

- Pathologists, Residents, Cytologists, Computer Support Staff at UW
- Mike Riben
- Mark Routbort
- Samantha Spencer
- Janice Caputo
- John Murphy