REDUCING DIAGNOSTIC ERROR

THROUGH A SYNOPTIC ANATOMIC PATHOLOGY REPORTING SYSTEM

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1. Describe how organization of pathology data with predefined Synoptic Headings clarifies diagnostic elements facilitating diagnosis 2. Recognize theoretical basis for a synoptically based reporting system that organizes Pathology Data Elements in support of differential diagnosis engines
3. Explain how a configurable set of automated Pathology Data Elements in the synoptic system captures clinical data safely and efficiently

SITUATION

Diagnostic accuracy in Anatomic Pathology is greatly dependent on the effective collection, correlation, and synthesis of pathologic and clinical information utilizing accepted diagnostic criteria to facilitate interpretation. Unfortunately, today's Anatomic Pathology Reporting Systems recapitulate conventional paper-based systems that limit the capacity of the Pathologist to render reliable diagnoses and effectively communicate them to the clinician while adding additional administrative overhead. In addition, true validation of diagnostic criteria as well as monitoring of pathologist accuracy is greatly hindered because the structure and contents of the underlying database are not standardized nor do they explicitly state what diagnostic criteria were used to make a specific diagnosis.

PROBLEM

How do we integrate pathologic diagnostic criteria with laboratory and clinical data to most effectively to:

RISK: → **Maintain patient safety**
QUALITY: → **Minimize pain and discomfort**
UTILITY: → **Maximize efficiency and minimize cost**

Through accurate, timely, and clearly communicated diagnosis

SOLUTION

If properly designed and automated, the capabilities provided by advanced **Relational Database Management Systems** [**RDMS**] will allow the pathologist to avoid many diagnostic and reporting errors related to:

- ➡ Incomplete clinical information to correlate with pathologic findings
- ➡ Disorganized pathologic findings that hinder the diagnostic process
- ➡ Obscuring reporting structure and format that lead to incomplete understanding
- ➡ Lack of standardized terminology that lead to misinterpretation
- ➡ Absence of criteria utilized to arrive at the diagnosis for prospective validation

All of which can lead to compromise of patient safety.

IMPLEMENTATION

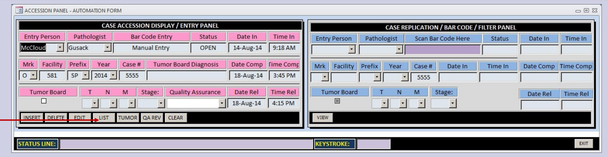
I have developed an **Anatomic Pathology Reporting System** utilizing a synoptic approach to structure all pathological and clinical data. This offers an effective means of organizing a report as a set of predefined **Synoptic Report Headings** [**SRH**] and **Synoptic Pathology Elements** [**SPE**] that optimize and fully automate data entry, retrieval, and presentation while providing an optimal means for the application of diagnostic criteria to reduce errors in diagnosis as well as errors in interpretation by the clinician. Displayed on the right is an exploded view of key parts of the user interface to illustrate this concept.

Approximately 5000 accessions with over 12000 specimens have been successfully accessioned, grossed, diagnosed, and reported using this synoptic approach. In development is software to analyze data across reports to allow for validation.

EXAMPLE DATA STRUCTURE AND INTERFACE WITH TEXTUAL REPORT

Accession Panel

NOTE: An accession list panel is available to the user to bring up groups of cases for batch actions.

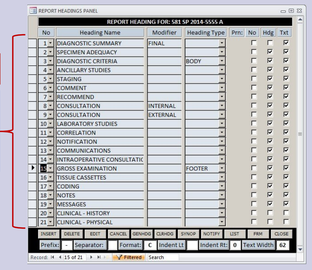


Specimen Panel

NOTE: For presentation, only one specimen is shown. An unlimited number can be added to each accession.

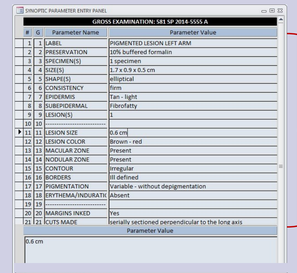
Report Headings

NOTE: Each Report Heading can have an unlimited number of Synoptic Pathology Elements linked to it to fully characterize gross, histologic, and immunohistochemical results to name just a few.



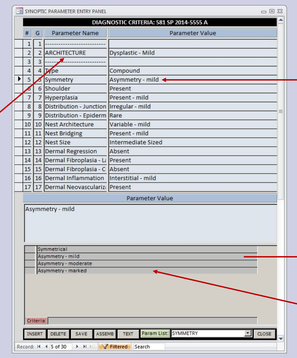
Gross Synoptics

NOTE: All synoptic elements are stored in their own record with predefined but configurable Parameter [Element] Name and Parameter [Element] Value. In addition, not shown is a Parameter [Element] Type to define how an analytical application should treat the data stored in each record.

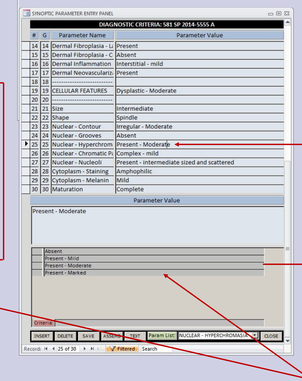


Diagnostic Synoptics [Architectural]

NOTE: As shown here we can even organize diagnostic criteria into hierarchical subsets of Elements for application of logical mappings to the correct diagnosis and staging.



Diagnostic Synoptics [Cellular]



Query Panel

NOTE: Rapid query form is available at all times for ease of retrieval.

NOTE: Predefined context sensitive Elements shown in a pick list linked to the specific Element highlighted for data entry.

If the appropriate Element is not present in the list the user can dictate or type in any free text they wish.

Then, if appropriate, this new entry can be included in the list for future use.

Report: Gross

```
==========S81 SP 2014-5555==========
Submitted in 1 container labeled with patient name.

A. - LABEL:                  PIGMENTED LESION LEFT ARM
   - PRESERVATION:           10% buffered formalin
   - SPECIMEN(S):            1 specimen
   - SIZE(S):                1.7 x 0.9 x 0.5 cm
   - SHAPE(S):               elliptical
   - CONSISTENCY:            firm
   - EPIDERMIS:              Tan - light
   - SUBEPIDERMAL:           Fibrofatty
   - LESION(S):              1
   ----------                ----------
   - LESION SIZE:            0.6 cm
   - LESION COLOR:           Brown - red
   - MACULAR ZONE:           Present
   - NODULAR ZONE:           Present
   - CONTOUR:                Irregular
   - BORDER2:                Ill defined
   - PIGMENTATION:           Variable - without depigmentation
   - ERYTHEMA/INDURATION:    Absent
   ----------                ----------
   - MARGINS INKED:          Yes
   - CUTS MADE:              Serially sectioned perpendicular to
                             the long axis
   - SUBMITTED:              Multiple pieces [A1 Tips [A2]
                             Central portion
   - CASSETTE(S):            2
   - RETAINED:               Entirely submitted
```

NOTE: The synoptically stored data can be extracted and formatted into a well organized text based report for transmission to any word processor or third party reporting application.

Formatting of headings and Elements can be done through XML and HTML methodologies. XML allows inclusion of data base structure providing a means of applying HL7 standards to this model.

Report: Microscopic

```
==========S81 SP 2014-5555==========

A. LESION - PIGMENTED, ARM - LT, BIOPSY - EXCISIONAL: FINAL [88305]

   - Melanocytic nevus - dysplastic, moderate
   - Short surgical margin POSITIVE for nevus

SPECIMEN ADEQUACY

   - Satisfactory

DIAGNOSTIC CRITERIA

   ----------                          ----------
   - ARCHITECTURE:                     Dysplastic - Mild
   ----------                          ----------
   - Type:                             Compound
   - Symmetry:                         Asymmetry - mild
   - Shoulder:                         Present
   - Hyperplasia:                      Present - mild
   - Distribution - Junctional:        Irregular - mild
   - Distribution - Epidermal:         Rare
   - Nest Architecture:                Variable - mild
   - Nest Bridging:                    Present - mild
   - Nest Size:                        Intermediate Sized
   - Dermal Regression:                Absent
   - Dermal Fibroplasia - Lamellar:    Present
   - Dermal Fibroplasia - Concentric:  Absent
   - Dermal Inflammation:              Interstitial - mild
   - Dermal Neovascularization:        Present
   ----------                          ----------
   - CELLULAR FEATURES:                Dysplastic - Moderate
   ----------                          ----------
   - Size:                             Intermediate
   - Shape:                            Spindle
   - Nuclear - Contour:                Irregular - Moderate
   - Nuclear - Grooves:                Absent
   - Nuclear - Hyperchromasia:         Present - Moderate
   - Nuclear - Chromatic Pattern:      Complex - mild
   - Nuclear - Nucleoli:               Present - intermediate
                                       sized and scattered
   - Cytoplasm - Staining:             Amphophilic
   - Cytoplasm - Melanin:              Mild
   - Maturation:                       Complete

ANCILLARY STUDIES

   - MART-1: EXAMINED [88342]

RECOMMEND

   Re-excision with adequate surgical margins as clinically
   indicated.

CONSULTATION - INTERNAL

   This case was reviewed by William Triest, M.D. who
   concurs with the above diagnosis as written.

NOTIFICATION

   The diagnosis was called to Dr. Robert Blades by Dr.
   Gusack at 04:52 PM on 02 Sep 14 and read back.

CPT Codes: 88305 x 1, 88342 x 1
```

REFERENCES – SELECTED:
1.Cottier H, Sobin L; **A Proposal for a Standardized System of Reporting Human Lymph Node Morphology in Relation to Immunologic Function**; J Clin Path Vol 26 p 317-331 1973.
2. O'Connor M, Smith J; **A Computer-Assisted Information system for Anatomic Pathology**; AJCP Vol 59 p 357-364 Mar 1973.
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4. Aller R; Editorial: **Surgical Pathology Computer Systems Have Come of Age**; Arch Pathol Lab med Vol 112 p 1186-1187 Dec 1988.
5. Taubman S; **A Surgical Pathology Reporting and Encoding System Using Industry-Standard Hardware and Software**; Arch Pathol Lab med Vol 112 p 1195-1199 Dec 1988
6. Varma V, Lau S; **Electronic Pathology System May Improve Accuracy and Efficiency**; ASCP Annual Meeting Abstract 48 Medscape Medical News November 15 2010.

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COST BENEFIT ANALYSIS

The system has been tested for over four years. By integrating voice recognition with configurable predefined point and shoot Synoptic Pathology Elements [**SPE**'s] I have completely eliminated transcription, reduced content error to virtually zero from over 5%, standardized report organization as well as presentation of pathologic and clinical data within the report, while reducing clinician confusion. There is enhanced task completion and documentation while the process management structure drives the diagnostic efforts. This has reduced error increasing patient safety, improved quality and reduced operational costs. A triple play!

An added bonus is the integration of CPT codes and the potential for integrating both ICD10 and SNOMED codes without requiring labor intensive efforts through comprehensive pre-configuration of the most common specimens and diagnoses.

EXAMPLE

This particular operational model for a Synoptic Anatomic Reporting System [**SARS**] follows the **eHR** model closely replacing the Synoptic Section with a Specimen Section. So we have:

- ➡ Table of **CASE ACCESSIONS** that link to the **SPECIMENS**
- ➡ Table of **SPECIMENS** that link to a set of **SYNOPTIC HEADINGS**
- ➡ Table of **SYNOPTIC HEADINGS** linked to a set of **SYNOPTIC PATHOLOGY ELEMENTS**
- ➡ Table of **DIAGNOSES** is eliminated and a **SYNOPTIC HEADING** is used instead

This hierarchical organization can be easily queried using **SQL** to allow **SPE**'s to be displayed as required for diagnostic interpretation regardless of heading they fall under. This can be extended to collate across multiple accessions and/or diagnoses for the purpose of quality assurance and validation of diagnostic criteria.

To provide automation in data entry and standardization in data retrieval and diagnostic analysis there are three tables of predefined data elements including:

- ➡ Table of predefined **SPECIMENS** that generate a set of **SYNOPTIC HEADINGS**
- ➡ Table of predefined **SYNOPTIC HEADINGS** linked to a set of predefined **SYNOPTIC PATHOLOGY ELEMENTS** that act as a pick list for completing each **HEADING** entry
- ➡ Table of **SPECIAL STUDIES** integrated into the **SYNOPTIC HEADINGS** that can be linked to any of the above table entries for diagnostic and classification purposes.

As shown, the predefined **SYNOPTIC PATHOLOGY ELEMENTS** allow for automation of the completion of gross description, microscopic diagnostic criteria, staging elements, as well as quality assurance, notification, and consultative elements using standardized terminology that allows for reliable querying and meta-analysis.

CONCLUSION

The utilization of synoptic database structure throughout the surgical and cytopathology application creates a highly organized system that allows for:

- ➡ Predefining data to be captured
- ➡ Predefining data entry results for automatic entry while still allowing free text
- ➡ Providing a reliable means of analyzing results across reports
- ➡ Directing the diagnostic process to greatest advantage

This provides the means of establishing a rigorous process by which diagnostic criteria can be validated in actual clinical practice on any and all specimens as well as allowing for determining concordance across multiple pathologists and even institutions if they use the same application.