REDUCING DIAGNOSTIC ERROR

Through Integration of Synoptic Based Diagnostic Criteria and Images to Anatomic Pathology

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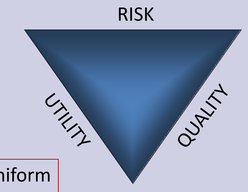


1. Describe how a growing number of specimens harboring earlier lesions that are diagnostically indeterminate leads to diagnostic error 2. Explain how introducing standardized configurable synoptically based criteria facilitates and assures uniform application of criteria to all cases. 3. Discuss how linking in medical literature and images assures prospectively avoiding diagnostic error.

SITUATION

Safe health care requires accurate and timely diagnoses to avoid, prevent, or mitigate the adverse affects of disease.

Rapid advancements in diagnostic screening tests have led to earlier and earlier intervention to achieve this goal. Unfortunately, this trend has yielded a growing number of specimens harboring earlier lesions that are diagnostically indeterminate. The tendency has been to over or under call these depending on a variety of external pressures and bias's leading to inappropriate management.

There is a significant cost to the patient and to society not fully addressed by present methods of Anatomic Pathology. Despite advanced computing capabilities, diagnosis still relies mostly on the unsupported and uncalibrated memory of each pathologist.

PROBLEM

How can we redesign the diagnostic system and processes so that diagnostic criteria are:

- Established Scientifically instead of through force of personality
- Effectively taught to pathologists using objective methods
- Integrated into the daily diagnostic activity using automation
- Validated Prospectively on future biopsies so as to:

RISK: Maximize the patient's safety with correct timely diagnosis.

QUALITY: Minimize discomfort and the pain suffered due to a wrong diagnosis.

UTILITY: Minimize unnecessary expenditure of scarce resources.

SOLUTION

If properly designed and automated, the capabilities provided by advanced Relational Database Management Systems [**RDMS**] allows for the incorporation of a synoptically based set of diagnostic criteria that are descriptive and visual to effectively:

- Train assuring within-pathologist calibration on diagnostic criteria
- Assure diagnostic concordance between-pathologists
- Prospectively validate diagnostic criteria established in the literature
- Link in critical journal references underpinning the diagnostic criteria
- Mine across facilities on standardized terminology applied in a standardized way

All of this will lead to improvement in diagnostic accuracy and thereby improvement of patient care.

IMPLEMENTATION

A working application implementing a Synoptic Anatomic Pathology Reporting System has been developed and presented previously at the 2014 Diagnostic Error in Medicine Conference.

The present model extends this synoptic approach by allowing the inclusion of fully configurable diagnostic, grading, and classification criteria into the application. These are made available automatically with each type of specimen as it is accessioned.

Note that the criteria can be linked to supporting medical literature and images for use in teaching and training to attain greater diagnostic accuracy. This provides a means of automating ongoing validation of criteria through a standardized terminology stored in a highly structured and searchable synoptic data structure.

DATA STRUCTURE WITH EXAMPLE OF APPLICATION OF SYNOPTIC CRITERIA

SYNOPTIC OF MICROSCOPIC DIAGNOSTIC FINDINGS

#	CHARACTERISTIC	OBSERVED FINDING	RANK	#
1	Characteristic 1	Finding 11	Absent	0
2	Characteristic 2	Finding 25	Moderate	3
3	Characteristic 3	Finding 32	Marked	5
4	*	*	*	*
5	*	*	*	*
6	*	*	*	*
7	Characteristic m	Finding mn	Mild-Mod	2

FILTER: DIAGNOSIS\GRADE\STAGE

#	DIAGNOSIS	PROBABILITY
1	Diagnosis 1	P 1
2	Diagnosis 2	P 2
3	Diagnosis 3	P 3
4	*	*
5	*	*
6	*	*
7	Diagnosis p	P p

LIST OF FINDINGS FOR EACH CHARACTERISTIC: 1

#	FINDING 1	DESCRIPTION OF MICROSCOPIC CRITERIA
1	Finding 11	Microscopic Description 11
2	Finding 12	Microscopic Description 12
3	Finding 13	Microscopic Description 13
4	*	*
5	*	*
6	*	*
7	Finding 1n	Microscopic Description 1n

RANK

#	RANK	#	CRITERIA
1	Absent	0	Criteria 0
2	Mild	1	Criteria 1
3	Mild-Mod	2	Criteria 2
4	Moderate	3	Criteria 3
5	Mod-Mrk	4	Criteria 4
6	Marked	5	Criteria 5
7	Other	-	Criteria 6

KNOWN CHARACTERISTIC:FINDINGN PAIRS FOR EACH

#	CHARACTERISTIC	FINDING	PROBABILITY
1	Characteristic 1	Finding 1	P 11
2	Characteristic 1	Finding 2	P 12
3	Characteristic 2	Finding 3	P 13
4	*	*	*
5	*	*	*
6	*	*	*
7	Characteristic 1	Finding q	P 1q

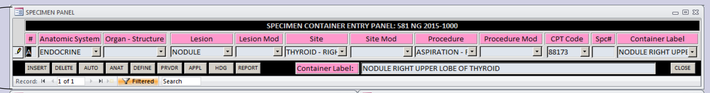
LIST OF IMAGES AND REFERENCES FOR DIAGNOSTIC CRITERIA

#	NAME	TYPE	LOCATION: PATH/URL
1	File 1	Image	Z:\Microscopic\Image001.jpg
2	File 2	Ref	Z:\References\Article001.jpg
3	File 3	Image	Z:\Microscopic\Image002.jpg
4	*	*	*
5	*	*	*
6	*	*	*
7	File o	Image	Z:\Microscopic\Image00o.jpg

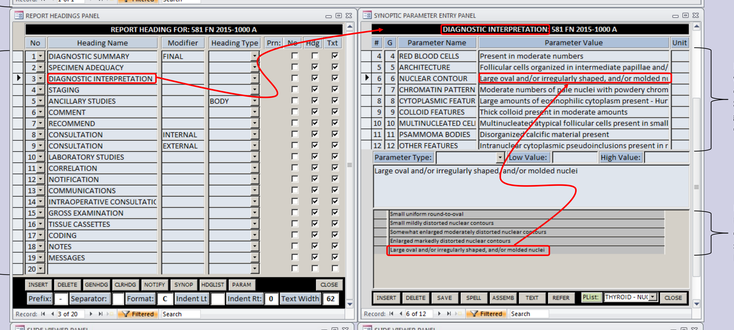
SYSTEM PROCESSES

- A standardized synoptic list of **CHARACTERISTICS** is developed for each diagnosis
- A standardized synoptic list of **FINDINGS** is developed for each CHARACTERISTIC
- The user populates the **SYNOPTIC OF DIAGNOSTIC MICROSCOPIC FINDINGS** from the lists
- **REFERENCES** and **IMAGES** can be linked in as **CALIBRATORS**
- Case images can be captured for direct comparison with visual calibrators
- A **DIFFERENTIAL DIAGNOSIS ENGINE** can be added and predefined logic/probabilities utilized to generate a list of potential diagnoses

Each Specimen will have a standard set of ICD10 and SNOMED descriptors assigned either manually or via a configurable automated accessioning table [Not shown]



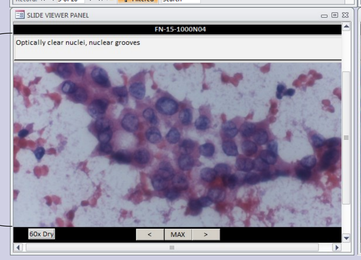
Each Specimen will have a standard set of configurable **REPORT HEADINGS** generated when accessioned.



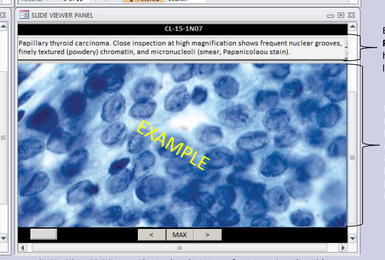
Each **REPORT HEADING** will have a standard set of configurable **SYNOPTIC PARAMETERS** generated when created during accessioning.

Each **SYNOPTIC PARAMETER** has a configurable set of standardized results linked into a pick list.

Each Specimen will have a standard set of configurable **REPORT HEADINGS** generated when accessioned.



Each **SYNOPTIC PARAMETER** result chosen can be supported by the user adding images from the slide used to make the diagnosis.



Each **SYNOPTIC PARAMETER** result can have diagnostic criteria linked to it.

Each **SYNOPTIC PARAMETER** result can have agreed upon diagnostic images linked to it. These can be from linked in references. [Shown beneath this image]

Ali, SZ, Cibas ES Editors; **The Bethesda System for Reporting Thyroid Cytopathology: Definitions, Criteria, and Explanatory Notes** ; Springer

REFERENCES – SELECTED:
1. Nakhleh RE; **Has Diagnostic (analytic) Accuracy Improved in Anatomic Pathology?**; Archives of Pathology and Laboratory Medicine; 2015 Vol 139 716 – 718.
2. Lind AC, et al.; **Prospective Peer Review in Surgical Pathology**; American Journal of Clinical Pathology; 1995 Vol 104 560 – 566.
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4. Calhoun BC, Livasy CA; **Mitigating Overdiagnosis and Overtreatment in Breast Cancer**; Archives of Pathology and Laboratory Medicine 2014 Vol 138 1428 – 1431.
5. Brito JP, Morris JC, Montori VM; **Thyroid Cancer: Zealous Imaging has Increased Detection and Treatment of Low Risk Tumors**; British Medical Journal 2013 Vol 347 1 – 6.
6.. Grin A, Streutker CJ; **Esophagitis: Old Histologic Concepts and New Thoughts**; Archives of Pathology and Laboratory Medicine 2015 Vol 139 723 – 741.
ACKNOWLEDGEMENTS: Jamie Stratton and Della McCloud for their ongoing support for this project.

COST BENEFIT ANALYSIS

What has been achieved:

- A configurable set of diagnostic criteria for any gross or histologic diagnosis.
- A configurable set of linked medical literature supporting diagnostic criteria.
- A configurable set of linked images for teaching, validation, and calibration.
- A configurable set of predefined standardized values or states in a pick list.

All of these resources can be linked in a context sensitive manner to each individual Synoptic Pathology Element [**SPE**] providing an extremely efficient and open ended means of applying diagnostic, classification, and grading criteria using standardized terminology for use in follow on analytical tasks. The only cost is the investment of time in collecting the literature and images and entering the configuration data.

EXAMPLE

Before the use of Fine Needle Aspiration [**FNA**] of small thyroid nodules, only 13% were found to be clinically significant on surgical removal. After implementation of **FNA** there was a considerable improvement to approximately 50%. However, this still leaves 50% of patients having major surgery with risk for morbidity and mortality:

Over time it has become apparent that there are considerable problems in both within-pathologist and between-pathologist concordance on diagnoses of thyroid **FNA's**. This has been multiplied by the increase in discovery of incidental small nodules by CT scans and Ultrasound studies done for other clinical purposes.

This provides an ideal test for incorporating:

- Literature based criteria.
- Literature based images.
- Specimen specific images for comparison to literature based images.
- Case specific application of criteria.
- Introduction of standardized terminology and rankings.

The graphics in the upper left show a brief overview of some of the data structure used to achieve this end. The graphics in the lower left illustrate several example screen shots of a case of papillary carcinoma of the thyroid diagnosed on **FNA** with accompanying synoptic diagnostic criteria, case specific microscopic image and literature based microscopic image for comparison.

The follow on would be to add into this data structure the outcome of surgical intervention correlating the tissue diagnosis as well as the outcome of not removing the nodule to study the natural history of lesions that are called negative or indeterminate and use this to determine more accurate diagnostic criteria.

CONCLUSION

First, the inclusion of applicable and useful criteria based on standardized terminology is critical in **REDUCING DIAGNOSTIC ERROR IN MEDICINE**.

Second, use of standardized configurable synoptically based criteria facilitates and assures their uniform application to all cases.

Third, the capacity to link in supporting medical literature and images assures proper application through real time prospective teaching, validation, and calibration.

Fourth, the generation and storage of standardized diagnostic data across multiple institutions provides a very powerful tool for exploring the usefulness of both old and new diagnostic/grading/staging criteria.