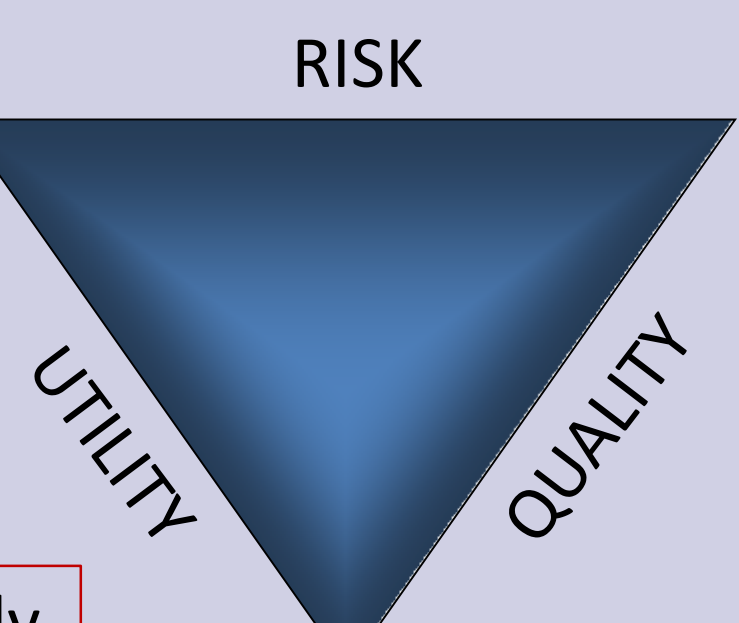


REDUCING DIAGNOSTIC ERROR

Utilizing a Model Electronic Compendium of Clinical Laboratory Tests

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1. Describe how rapid advancements in laboratory testing capabilities and effective therapeutics have led to greater numbers of significant errors in diagnosis 2. Recognize how a well-designed electronic laboratory test compendium can effectively address this problem 3. Explain how configurability with the capability to link in medical references provides a means of continued improvement

SITUATION

The number and value of today's clinical laboratory tests place a very powerful diagnostic tool in the clinician's hands. However, paradoxically, this power has led to the discovery that single diseases of the past actually consist of numerous previously unrecognized diseases many of which can now be effectively treated by new therapeutic modalities made possible through scientific research and clinical trials.

The intersection of these two trends has greatly amplified the significance of diagnostic errors. Now, the expectation of patients and society is for a virtually perfect outcome. Perception of error is heightened and **Acceptable Risk** is greatly reduced. Complicating this trend is the absence of up to date, centrally accessible libraries that provide a comprehensive compendium of knowledge and information pertaining to laboratory tests, their use, and interpretation.

PROBLEM

How can we redirect the utilization of laboratory testing so as to:

RISK: Maximize our patient's safety by reducing misdiagnosis and thereby inappropriate therapy.

QUALITY: Minimize delay in diagnosis and so patient suffering.

UTILITY: Minimize wrong or unnecessary tests reducing costs.

SOLUTION

THE eCOMPENDIUM SHOULD ANSWER THE CRITICAL QUESTIONS THAT ASSURE PROPER USE AND INTERPRETATION

Applicability	Screening / Diagnosis / Staging / Prognosis / Monitoring / etc.
Clinical Appropriateness	Where the test is most useful for each application
When to Order/Obtain	Both clinically and technically when to obtain a specimen & test
When Not to Order	Interferences or mitigating circumstances invalidating results
How to Obtain the Specimen	Assuring optimal specimen to maximize the reliability of results
How to Preserve the Specimen	Assuring optimal specimen state for the same reason as above
How to Interpret Results	Integrating one or more test results to address each application
Test Reliability	Sensitivity / Specificity / Analytic Reliability / Biologic Variation

The eCompendium [eCMP] should provide the clinician with information helpful in establishing **Acceptable Risk** in using each test in most clinical situations.

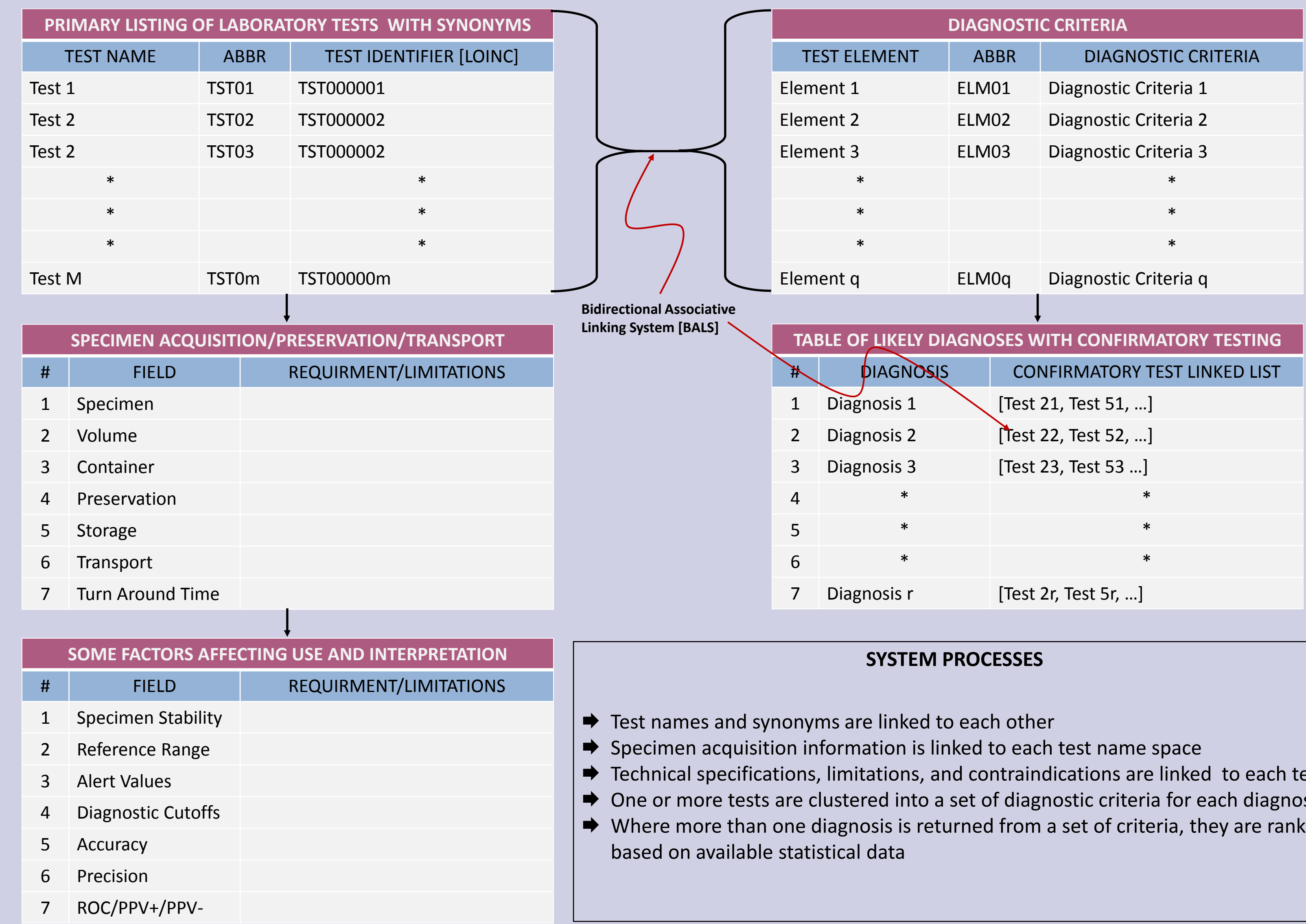
IMPLEMENTATION

I have developed two interrelated models:

First, a simple measure of analytical reliability for Hemoglobin A1c based on control data. This is reported with A1c results that includes a link to a PDF file containing additional information regarding reliability, use, and interpretation of this analyte.

Second, a highly configurable user friendly electronic compendium [eCMP] based on a Relational Database Management System [RDMS] that provides information regarding proper selection, acquisition, preservation, submission, and interpretation of laboratory tests. Furthermore, the eCMP provides the means of configuring multiple optional diagnostic protocols linked to and based on criteria established in medical literature that can be stored locally, or accessed via the internet.

ABBREVIATED OVERVIEW OF THE DATA STRUCTURE OF THE eCMP



eHR Laboratory Test Report Including Reliability Information

Report Released Date/Time: Feb 31, 2025@25:09
 Provider: DOCTOR NOTLIMDOC
 Accession #: XXX-XX-XXX-XXXXX
 Specimen Collection Date: Feb 20, 2025@16:16

Test name	Result	units	Reference range
HGBA1c(HPLC)	6.6 H	%	4.2 - 5.8

COMMENT: The patient's actual A1c may fall between -0.3 and +0.1% of that reported above.
 Changes in A1c <0.3% may not be clinically significant due to inherent limitations of the test methodology.
 See A1c Resources on Tools>Pathology/Laboratory Menu

eHR Interface Showing Menu Item Linked to PDF File

RELIABILITY OF A1c TEST RESULTS AND ADDITIONAL RESOURCES

HEMOGLOBIN A1c - A GUIDE TO SAFE USE IN DIAGNOSIS AND MANAGEMENT OF YOUR PATIENTS

TECHNICAL CONSIDERATIONS WHEN INTERPRETING YOUR PATIENT'S A1c

- TOTAL VARIABILITY: Your Patient's actual A1c may fall as much as 0.3% below and 0.3% above the A1c reported.
- TWO A1c RESULTS: A difference <0.3% between any two A1c test results may not be clinically significant.
- SKEWING: Your Patient's actual A1c will often be below and rarely above the reported value as shown below.

ADDITIONAL RESOURCES FOR THE DIAGNOSIS AND MANAGEMENT OF TYPE II DIABETES

MANAGEMENT OF CAREFUL RESULTS LEVEL, CONTROLLED DIABETES

MANUAL DIABETES INFORMATION (GLUCOSE AND HEMOGLOBIN A1c)

DIABETES AND CATIONIC DRUGS

MANAGEMENT OF THE HYPOTENSIVE PATIENT (COMPLETED MANUAL)

NEXT: LIMITATIONS, WARNINGS, RECOMMENDATIONS

A1c TEST LIMITATIONS, WARNINGS, AND RECOMMENDATIONS

TEST LIMITATIONS

- A1c is an average of the patient's glycemic state over periods greater than 2 - 3 months.
- A1c does not measure wide swings in glycemia over this time period nor can it fully predict risk for hypoglycemia.

WARNINGS

- Aggressive treatment of a single A1c result may result in an increase in clinically significant hypoglycemic events.
- A1c prediction value for microvascular complications of chronic hyperglycemia improves at higher values.
- A1c is best used in combination with calibrated glucose meter test results, clinical status, and patient goals.

RECOMMENDATIONS

- A1c testing is best suited to long term trending of at least two test results over a 3 to 12 month period.
- A1c prediction value for microvascular complications of chronic hyperglycemia improves at higher values.
- A1c is best used in combination with calibrated glucose meter test results, clinical status, and patient goals.

BIOLOGIC CONSIDERATIONS WHEN INTERPRETING YOUR PATIENT'S A1c

Biologic variation specific to each Veteran can affect A1c test results. This is especially true of anemia which can reduce A1c levels and lead to chronic under treatment of their glycemia. Therefore, if your Patient has a low hemoglobin and/or elevated reticulocyte count at the time of A1c testing, you should consider modifying treatment at lower A1c levels.

NEXT: INTERPRETATION GUIDELINES

GUIDELINES FOR TYPE II DIABETES SCREENING AND MANAGEMENT

RECOMMENDED VA/DoD GUIDELINES FOR INTERPRETING A1c RESULTS

A1c	RISK	FOLLOW UP CONSIDERATION
<5.7%	LOW RISK FOR DIABETES	Fasting glucose <100 mg/dL
5.7-6.4%	RISK FOR DIABETES	Fasting glucose >100 mg/dL
≥6.5%	PROBABLE DIABETES	Fasting glucose ≥126 mg/dL
>7.0%	PROBABLE DIABETES	Second value > 7.0%

MANAGEMENT DECISION POINTS (Target A1c Levels)

COMBINED CHIEF'S LIFE EXPECTANCY	ABSENT - MILD	MODERATE	ADVANCED
ABSENT > 10 YEARS	<7%	7-8%	8-9%
PRESENT	7-8%	7-8%	8-9%
5-10 YEARS	7-8%	7-8%	8-9%
MARKED <5 YEARS	8-9%	8-9%	8-9%

NEXT: THE EFFECT OF PRECISION ON RELIABILITY OF A SINGLE A1c RESULT

REFERENCES - SELECTED:
 1. Smellie, WSA et al.; **Best Practice in Primary Care Pathology**: Review 11; Journal of Clinical Pathology 2008 Vol 61 410 - 418.
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 6. HL7 Version 2.5.1 Implementation Guide: S81 Framework Laboratory Test Compendium Framework R2, DSTU Release 1.1 - US Realm (Electronic Directory of Service - EDOS); Health Level Seven International Draft Standard for Trial Use March 2014.
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COST BENEFIT ANALYSIS

The model compendium:

- ➔ Allows searchable synonyms to avoid duplicate or wrong test ordering.
- ➔ Provides acquisition, preservation, and submission instructions to assure reliability.
- ➔ Provides utility of one or more tests in the diagnostic workup of specified states.
- ➔ Delineates technical issues complicating or invalidating test results.
- ➔ Provides capacity to establish diagnostic protocols utilizing test data.
- ➔ Provides capacity to establish information regarding use of confirmatory tests

The data structure allows for flexible configuration and the inclusion of additional useful features all of which are known to reduce patient risk, increase quality of care while limiting over utilization.

EXAMPLE

The images in the upper left show an abbreviated and simplified schema of the data structures upon which the model eCompendium is built. There are five basic tables that include some but not all of the critical data fields defined into the eCompendium:

- ➔ A primary listing of test names and their synonyms associatively linked together.
- ➔ Specimen acquisition, preservation, and transport information to assure reliability.
- ➔ Factors that affect the use and interpretation of the test in question.
- ➔ A table listing diagnostic criteria linked bi-directionally to the tests
- ➔ A table of diagnoses based on diagnostic criteria that can include probabilities.

The images in the lower left show the active model system running on an eHR:

- ➔ Standard comment regarding reliability of A1c test result in the eHR
- ➔ Instruction to find additional information on the Tools Tab of eHR
- ➔ Three images of the PDF file contents that is linked to this menu item

The file pointed to in the her can be anything meaning that an RDMS database application utilizing the structure shown above left could be substituted and include links within its data to:

- ➔ References located on a local server
- ➔ Images located on a local server
- ➔ Audiovisual resources located on a local server
- ➔ References located over the Internet
- ➔ Images located over the Internet
- ➔ Audiovisual resources located over the Internet

CONCLUSION

The availability of an easy to access and use compendium of clinical laboratory tests provides a prospective means of assuring that:

- ➔ The correct test(s) are ordered reducing both diagnostic error and delay.
- ➔ The incorrect or unnecessary test(s) are not ordered reducing over utilization and spurious results that might initiate unnecessary workups.
- ➔ Assure proper collection, preservation, and transport to reduce analytic error
- ➔ Provide information regarding the proper interpretation of test results.

This combination simultaneously increases patient safety, improves quality of care while reducing costs in **REDUCING DIAGNOSTIC ERROR IN MEDICINE.**