REDUCING DIAGNOSTIC ERROR IN MEDICINE

THROUGH A PROPOSED MODEL FOR PRESENTING LABORATORY RESULTS WITH POTENTIALLY CONFOUNDING ELEMENTS

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1. Describe how test result presentation may influence the diagnostic process. 2. Explain how, content, structure, and formatting are critical to patient safety. 3. Discuss the limitations imposed by two-dimensional presentation of results.

SITUATION

The number of different diagnoses, the number of different laboratory tests available to render a diagnosis, and the number of laboratory results generated during the diagnostic process have all risen dramatically over the last half-century. This has led to a significant increase in the volume and complexity of laboratory data presented to the clinician. Despite the capacity of the electronic health record to format laboratory data, it tends to hide **inherent technical limitations** regarding analytic reliability, the effect of **individual patient biologic variation**, as well as the **impact of medications**. The result; many elements impacting laboratory test results that should be presented to assure safe interpretation are hidden from view and excluded from clinical judgment.

PROBLEM

How can we

RISK	*Maximize patient safety* through effective presentation of laboratory test data
QUALITY	*Minimize* discomfort and the pain *suffered* by presenting inherent limitations of laboratory tests
UTILITY	*Minimize expenditure* of scarce resources through improved use of tests and interpretation of results

SOLUTION

A set of elements are proposed as potentially useful for presentation with laboratory test results informing clinicians during the interpretation phase of the diagnostic process. These could also be presented during test ordering as well to help inform as to value and reliability in clinical context.

The elements proposed are based on a literature search and review of presently available **eHR** test report formats.

A model two-dimensional schema is presented as a consideration in providing information about critical risk issues needed to protect the patient from an erroneous diagnosis.

IMPLEMENTATION

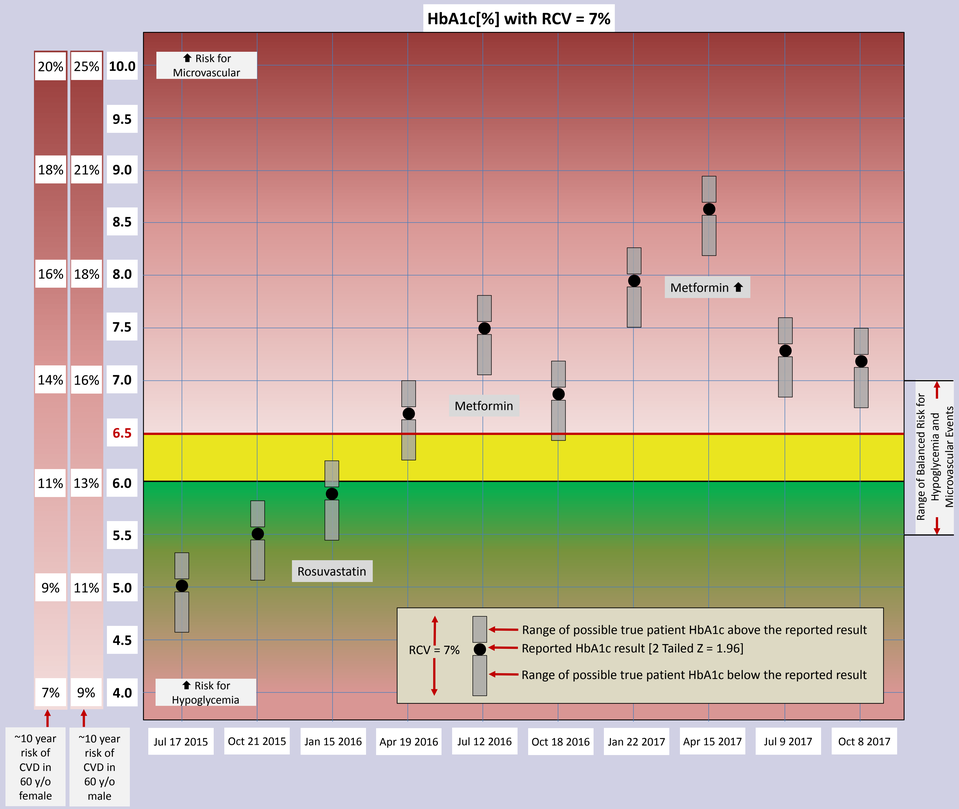
We found that, to a certain degree, a multidimensional set of laboratory test elements can be collapsed into a single two-dimensional format providing information about technical and biologic limitations affecting patient safety.

However, display of additional textual explanations and tabular information may be necessary to fully describe what risks are being taken when the clinician interprets test results in the presence of:

- ➡ Other Laboratory Results
- ➡ Multiple Medications
- ➡ Patient Centric Factors

EXAMPLE LABORATORY TEST PRESENTATION SCHEMA

PROPOSED PRESENTATION SCHEMA OF TEST RESULTS



POTENTIAL IMPACT OF MEDICATIONS		
MEDICATION	**DATE START**	**IMPACT ON HBA1c**
Metformin	7/12/16	DECREASES
Rosuvastatin	1/15/16	UNKNOWN
Albuterol	5/25/14	HYPERGLYCEMIA
Diltiazem	8/1/15	HYPOGLYCEMIA
RECOMMENDED: Interpret in context of medications		

POTENTIAL IMPACT OF LABORATORY TESTS			
ANALYTE	**TEST DATE**	**IMPACT ON HBA1c**	
Hemoglobin	6/29/17	9.0 mg/dl	DECREASES
RBC Morphology	6/29/17	Microspherocytes	DECREASES
RECOMMENDED: Interpret these results in context of other laboratory results			

ESTABLISHING TREND	
% CHANGE IN HBA1c	**CLINICALLY RELEVANT CHANGE**
0.1 TO 0.5%	NO CHANGE
0.6 TO 1.0%	INDETERMINATE
1.1 TO 1.5%	POSSIBLE
≥ 1.6%	DEFINITE
RECOMMENDED: 3+ test values to establish trend	

THE MEANING OF THE RCV BAR

The range of possible true patient test values for an analyte is plotted within a range that is calculated based on the concept of the **Reference Change Value** [**RCV**]. This takes into account analytic **Coefficient of Variation** [CV_A], **Within Subject Biologic Variation** [CV_I], and **Skewing of the Distribution** of possible results that indicate the degree of uncertainty as to reliability of the reported result.

$$RCV = 2^{1/2} * Z * (CV_A^2 + CV_I^2)^{½}$$

FOR A 2 TAILED DISTRIBUTION

For Z = 1.96 then a change in any direction the RCV is called *"Significant"* at 95% probability in the literature
For Z = 2.58 then a change in any direction the RCV is called *"Highly Significant"* at 99% probability in the literature

FOR A 1 TAILED DISTRIBUTION

For Z = 1.65 then a unidirectional change the RCV is called *"Significant"* at 95% probability in the literature
For Z = 2.35 then a unidirectional change the RCV is called *"Highly Significant"* at 99% probability in the literature

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COST BENEFIT ANALYSIS

Presentation of the most significant risk issues associated with the use and interpretation of one or more laboratory tests will allow the clinician to better balance risks of over or under diagnosis against benefits of over or under treatment reducing:

- ➡ Risk for an adverse event
- ➡ Patient suffering
- ➡ Unnecessary utilization of a test thereby lowering costs
- ➡ Diagnostic error leading to significant additional cost savings

EXAMPLE

In this poster a number of possible confounding elements are presented. The first is a two-dimensional plot of **HbA1c** test results showing an abbreviated **RCV** bar with a dot indicating the laboratory test result. Listed next to each whole **HbA1c** value is the percent risk for a clinically important outcome as **HbA1c** rises, stratified by sex. What is not shown is the projected time to occurrence which would require extensive epidemiologic research.

In addition, the impact of medications and laboratory results are displayed in tables to provide additional information that might affect the reported test value of an analyte and influence its interpretation. The potential effect of imprecision on trending results is also included.

Below this is a brief overview of what the **RCV** means. It should be noted that:

Whereas the instrument **Coefficient of Variation** [CV_A] is specific for the facility, and so globally applicable to all patient test results, the **Within Subject Biologic Variation** [CV_I] is an average value based on published data and so may not be specific to the individual patient. Confounding issues to consider when applying the **RCV** concept are patient specific:

- ➡ Genetic profile/Ethnic Background
- ➡ Comorbidities
- ➡ Medications effecting analyte as well as medication interactions
- ➡ Acute clinical state including physiologic and biochemical status

CONCLUSION

Laboratory test results reported without indication of imprecision are not safe for diagnostic purposes.

Multiple elements, both technical and biologic that could impact a test result need to be included to assure appropriate interpretation.

A two-dimensional grid with integrated technical information appears to fulfill most but not all of this need to:

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