REDUCING DIAGNOSTIC ERROR IN MEDICINE

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

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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 limits 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

Make use of tests and interpretation of results

Maximize patient safety through effective presentation of laboratory test data

Minimize discomfort and the pain suffered by presenting inherent limits of laboratory tests

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. This 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

HbA1c[%] with RCV = 7%

Potential Impact of Medications

Potential Impact of Laboratory Tests

Establishing Trends

The range of possible true patient HbA1c 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), Within Subject Biologic Variation (WSBV), and the Distribution of possible results that indicate the degree of uncertainty as to reliability of the reported result.

RCV = CV\textsuperscript{2} + Z\textsuperscript{2} (CV\textsuperscript{2} + CV\textsuperscript{2})

FOR A 2 TAILORED DISTRIBUTION

For Z = 1.96 then a change in any direction the RCV is called “Significant” at 95% probability in the literature

FOR A 1 TAILORED DISTRIBUTION

For Z = 1.65 then a unidirectional change the RCV is called “Significant” at 95% probability in the literature

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: REDUCE DIAGNOSTIC ERROR IN MEDICINE