JOURNAL OF INTERNATIONAL CRISIS AND RISK COMMUNICATION RESEARCH
ISSN: 2576-0017
2024, VOL 7, NO S7

Perception of Measurement Uncertainty among Laboratorians and Clinicians at Saudi Arabia

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Abstract:

Introduction:

Measurement systems is essential to define and enforce reference measurement systems that are based on the application of metrological traceability of patient results to higher-order (reference) methods and/or materials, along with a clinically acceptable level of measurement uncertainty (MU). to produce accurate and comparable laboratory results, To get a final combined MU on clinical samples that meet the required performance specifications, the MU linked to each stage of the traceability chain should be controlled. Introduction:

The aim of the research : Assess the perception of measurement uncertainty among laboratorians and clinicians. **Materials and techniques**: descriptive , cross sectional research design was utilized to conduct this research. One questionnaire was utilized and distributed to 300 clinical and lab consultants. **Results**: When asked about test results, most laboratory professionals knew the jargon and felt comfortable describing how to utilize MU. However, difficulties were expected, including the intricacy of determining the ranges, integration with the laboratory information system, and patient population acceptability. Clinicians and laboratory professionals believed that MU aids in more accurate patient results analysis and that it would take longer for this change to be more accepted. **Conclusion:** Our research leads us to the conclusion that laboratory consultants who possess sufficient understanding of MU are capable of introducing and utilizing MU with assurance in their day-to-day work. If the data were recorded with the test report, particularly for the crucial parameters—clearly the most difficult part for the labs—clinicians were willing to interpret results with MU. **Clinical significance:** Rather than relying solely on a subjective analysis of serial monitoring results, the feasibility of introducing MU in conjunction with patient reports is helpful in interpreting critical parameters and offers scientific evidence for consideration in a change of patient management.

Keywords: Qualitative study, measurement uncertainty, MU implementation, MU perception, and serial result monitoring.

Introduction:

A metric linked to a measurement's outcome that describes the range of values that can be plausibly ascribed to the measurand is known as measurement uncertainty (MU).1 To put it simply, MU is defined as the range of a reported laboratory result that indicates the location of the measured value with the specified probability, which is a non-negative parameter. Two A measurement result with

a quantitative description of its uncertainty provides a comprehensive view of the result dispersion, which aids in determining if the result is adequate for its intended use and ensures consistency with related results. MU estimate and expression techniques are explained in a number of guidelines issued by professional and accrediting organizations as well as national standardization institutes.3-

Understanding the critical role that diagnostic laboratories play in public health and medical decision-making, as well as the serious consequences of the growing danger of non-communicable diseases and multidrug-resistant organisms diseases in healthcare services.1,2 But the preanalytical phase of laboratory testing has long been recognized as the most vulnerable part of the entire testing process, where the majority of errors in the laboratory occur. These errors are mostly human-made and can result in misidentifications, transportation/storage errors, or erroneous results due to poor sample quality (hemolysis) or contamination, which could have detrimental effects on patient care.

Labs that adhere to standard guidelines must calculate measurement uncertainty; "The laboratory shall determine measurement uncertainty for each measurement procedure in the examination phase to report measured quantity values on patients" samples.9. Labs that choose to become accredited are required to create a MU document. The purpose of this study is to assess lab staff and doctors' knowledge, practicality, and use of the MU concept. The following uses for measurement uncertainty have been identified: First of all, it provides laboratory experts with information regarding the quality of the result and proof of adherence to analytical performance parameters. It contributes to raising the standard of care.

Establishing and implementing quality control measures that are equivalent to those used as standard throughout the analytical processes is difficult since preanalytical procedures mostly occur outside of the laboratory.9. It also includes a wide range of individuals who may contribute to test findings that are not in compliance, including patients, clinical service providers, support staff, sample transporters, and logistic staff.9.

Up to 70% of all errors can be attributed to mistakes made between the time the doctor orders the test and when the sample is prepared for analysis.10. Serious patient misdiagnosis can result from mistakes made at any point during the ordering, collection, testing, and reporting processes. It is possible to assess the overall amount of test result uncertainty attributable to pre-analytical factors. For instance, modifications to pre-analytical procedures can account for as much as 41% of the variation in the hypercholesterolemia score.12 Poor communication between laboratories and other testing participants (such as doctors, nurses, phlebotomists, and patients themselves) or poorly planned procedures are the main causes of many errors in the entire testing process.

The foundation of the contemporary health care industry is laboratory testing, despite the fact that it is an extremely complicated procedure and service. Laboratory science has advanced quickly, yet it is still prone to a number of manual and systemic errors.6. Depending on when they appear, these errors are categorized as pre-analytical, analytical, and post-analytical.7, 8. It may be useful to doctors, clinics, and occasionally patients in interpreting test findings, particularly when values are compared to reference intervals, clinical decision limits, or prior values for the same patient, offering objective information.10. Additionally, it facilitates the acceptance of result transferability among different labs.

Materia ls and Methods

Research design :

Descriptive , cross sectional research design was conducted to develop this research

Setting :
Riyadh Medical City is Saudi Arabia's largest healthcare project, and also the largest medical project in the GCC. This comprises two separate medical cities for security forces that are being developed in Riyadh on behalf of the Kingdom's Interior Ministry. The total built-up area for medical facility is 4,304,000 sq ft. It also has residential villas and apartments with a built-up area of about 5,380,000 sq ft, while the medical complexes themselves will have about 2,152,000 sq ft of car parking. The scope of work includes three hospital buildings, an academic and clinical centre, research centre, office buildings, service stations, villas, apartments, car parking and associated facilities.

Participants :
Laboratory professionals who worked in the hospital diagnostic laboratory collecting data served as the study's source population. convenience samples N = 300 was assigned for this research. The The study includes subjects who consented to fill out the questionnaire. To assess comprehension and perception of the MU idea, we first provided training materials and then a questionnaire. The intended subjects in this group were senior residents and laboratory consultants employed by corporate or academic organizations' accredited labs. Answers to the questionnaire that were unclear or incomplete were not included.

Tool I:

Questionnaire-Based Survey

Survey Questionnaire

To get answers that would shed light on awareness, comprehension depth, and implementation skill, questions were written in plain English (Table 3: questionnaire). To verify the questions' content, wording, and order, ten laboratory staff members—including lab consultants—were given the questionnaire. The reliability analysis showed that the Cochrane's alpha coefficient was more than 0.7%. It was then made available for the survey. Thirty people agreed to fill out the poll.

Statistical analysis:
The demographic and organizational factors, as well as the respondents' opinions regarding the advantages, difficulties, and drive to use health information systems, were examined using descriptive statistics. The three dimensions (benefits, barriers, and reasons) were tested using a one-sample t-test to see if the mean score of each question was substantially greater than 3. This is the midpoint on the Likert scale for the "Neither agree nor disagree" response to the item. To determine if respondents' views of the advantages of IT, obstacles to its use, and reasons for using its variables differed by gender, a two-sample t-test was employed. The study employed one-way analysis of variance (ANOVA) to determine whether respondents' views of the advantages of IT, obstacles to its use, and motivations differed.

Selection of Subjects
In order to guarantee that the subjects had a fundamental understanding of how to evaluate test findings, they were chosen by deliberate sampling. The study's subjects included professors, assistant professors, senior resident physicians, and lab consultants. In accordance with the number of years of training, subjects were chosen to guarantee an appropriate balance of clinical and professional experience.

Table 1: Calculation and expression of MU

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MU = 1.96 × SD (SD is the standard deviation or standard uncertainty)
Example: Intermediate imprecision for serum creatinine: SD = 0.05 mg/dL
MU (absolute value) for serum creatinine: 1.96 × 0.05 = 0.098 mg/dL
How to express MU?
MU is expressed as test result ± MU
Example: Test result of 1.3 mg/dL for serum creatinine, MU is expressed as
1.3 mg/dL ± 0.098 mg/dL or dispersion of result is 1.2–1.4 mg/dL (rounded off to first decimal)

Table 2: Application of MU for patient values

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Comparison of a patient value with a previous value of the same type to differentiate whether it is different from the previous value
Intermediate imprecision for serum creatinine: SD = 0.05 mg/ dL; MU is 0.098 or 0.1 mg/dL
Example: Patient previous value of serum creatinine: 1.6 mg/dL; dispersion of result is 1.5–1.7 mg/dL
Patient current value of serum creatinine: 1.3 mg/dL; dispersion of result is 1.2–1.4 mg/dL
The result interval does not overlap. Hence, both values are different.
• Comparison of a patient value with a clinical decision value Intermediate imprecision for serum sodium: SD= 2.14 mEq/L; MU is 4.28 mEq/L
Example: Patient value is 124 mEq/L; dispersion of result is 119.7 to 128.3 mEq/L
Medical decision limits: lower critical limit−115 mEq/L Upper critical limit–150 mEq/L
Result interval does not overlap with the medical decision limit.
Hence, the current patient value will not be considered under the critical decision limit

Analysis of Data

In order to determine the primary theme of each discussion, investigators typed and examined all of the responses following each session. The difficulties and experiences in comprehending and putting into practice were recorded. Based on the responses and the percentage of individuals, a survey using a questionnaire was assessed.

Table 3: Questionnaire for lab consultants

• Are you aware of measurement uncertainty?
• Is it easy to calculate MU?
• Is it difficult to understand the concept of MU?
• Is it difficult to explain the concept of MU to technicians?
• Should technicians be trained to interpret MU?
• Do you think MU should be incorporated as a part of the patient test report?
• Would you be confident to sign out the report with MU?
• Do you think MU incorporation in the patient test report showcases the confidence of the laboratory?
• Would it be confusing to clinicians to have access to such information?

• Would it be confusing to patients to have access to such information?
• Do you think the patient would lose confidence in lab reports after knowing about MU?
• Do you think clinicians would lose confidence in lab reports after knowing about MU
• Do you think MU could help in explaining the variant reports over a period of time?
• Do you think MU would help the lab in explaining to patients the reliability of test reports?
• If you had a choice, would you still calculate MU?

Table 5: Participant characteristics (n = 75)

Lab consultants
Lab heads (> 10-year experience) 100
Lab senior consultants (5–10-year experience) 80
Lab junior consultants (< 5-year experience) 50
Clinicians
Senior consultants (professors, associate professors) 20
Junior consultants (assistant professors, lecturers) 50

Table 5: sixteen (40%) and twenty-four (60%) of the forty laboratory experts had one to nine years or more of work experience. Nineteen (47.5%) of the forty laboratory professionals felt that their labs did not provide high-quality laboratory results for their patients, and eighteen (45%) did not participate in any work-related refresher training. The lack of supplies and reagents (95%), inadequate management support (72.5%), heavy workload 35 (87.5%), missing laboratory results 28 (70%) and equipment 37 (92.5%) were noted by the laboratory professionals as the main factors influencing the quality of laboratory results in this study (Table 5).

Furthermore, a statistically significant correlation was shown by bivariate logistic regression analysis between the incidence of laboratory result mistakes and variables like Furthermore, a statistically significant correlation was found between the incidence of laboratory result errors and the following factors: lack of job description (COR=4.50, 95% CI=1.498, 10.22), communication with clinicians (COR=1.63, 95% CI=1.15, 2.59), turnaround time (COR=1.700, 95% CI=1.420, 6.881), result verification (COR=2.464, 95% CI=2.26, 7.480), IQC (COR=1.439, 95% CI=1.107, 1.801), and lack of equipment (COR=1.35, 95% CI=1.55, 16.574). To evaluate the real laboratory practice on sample collecting, testing, and reporting using a checklist, an observational assessment was conducted on laboratory workers in addition to the interview. This indicates that 72.5% and 62.5% of them, respectively, correctly recognized their patient and labeled the patient sample prior to collection.

Table 5: Sociodemographic Characteristics of Clinical Service Providers and Factors Affecting Laboratory Test Results

Variables	**Yes, n (%)**	**No, n (%)**	**P-value**	**AOR**	**95% CI**	**P-value**
Sex						
Male	(66.75)	(31.25)	0.665	–	–	–
Female*	(75)	(25)				
Educational status						
Diploma	(100)	(0)	–	– – –	– – –	– – –
Bachelor degree	(65.52)	(34.48)	0.530			
Master’s degree	(80)	(20) (0)	–			
Others	0 (0)					
Work experience						

1–3 years	(83.33)	(16.67)	0.512	– – – –	– – – –	– – –
3–6 years	(73.33)	(26.67)	–			–
6–9 years	(69.23)	(30.77)	0.760			
>9 years	(66.67)	(33.33)	0.911			
TAT	(20)	(80%)	0.038	1.844	1.311–2.290	0.037
Result Satisfaction by the lab staff	(47.5)	(52.5%)	0.002	1.453	1.114–1.790	0.025
Customers satisfied by the result	(45%)	(55%)	0.042	1.060	1.116–9.643	0.003
Purchasing team Response	(15%)	(85%)	0.013	1.246	1.119–6.560	0.001
Employee recognition	(52.5%)	(47.5%)	0.006	1.499	1.059–4.226	0.240
Attending training	(55%)	(45%)	0.217	0.471	1.069–3.234	0.238
Uninterrupted service	(37%)	(62.5%)	0.927	–	–	–
Job description	(75%)	(25%)	0.014	3.899	0.315–8.316	0.289
Presence of enough equipment	(7.5%)	(92.5%)	0.138	1.350	0.111–6.574	0.158
Performance of client satisfaction	(20%)	(80%)	0.002	1.046	1.120–8.450	0.012
High workload	(87.5%)	(12.5%)	0.415	–	–	–
Satisfaction by your profession	(82.5%)	(17.5%)	0.316	–	–	–
Management support	(27.5%)	(72.5%)	0.317	–	–	–
Knowledge with quality essentials	(80%)	8 (20%)	0.521	–	–	–
System for employee recognition	(52.5%)	(47.5%)	0.584	–	–	–
Continuous education program	(80%)	8 (20%)	0.308	–	–	–
Supplies and reagents availability	(5%)	(95%)	0.028	1.174	1.199–6.35	0.026
Client Satisfaction assessment	(20%)	(80%)	0.482	–	–	–
Missing of laboratory results						

Theme 1: MU Lab Consultants' Awareness and Knowledge

Although just 3% of lab consultants were totally ignorant, the bulk (97%) were aware of the MU idea. It was thought to be a novel statistical idea unsuited to tiny, recently founded labs. The idea was unfamiliar to most consultants from accredited labs, who believed that MU was involved in the accreditation documentation process.

Physicians

Clinicians were not familiar with the idea of MU or its benefits. Just two medical professionals showed interest in and knowledge of MU. Most of them stated that MU was not relevant to clinical practice and believed that lab staff members needed to review it for lab practice. The second theme is knowledge and comprehension of the MU calculation.

Laboratory Consultants

According to lab consultants, MU calculation was simple, and personnel should do the computation. According to 44% of lab consultants, MU training for technicians ought to be included in their standard training program.

Physicians: According to clinicians, MU value is a characteristic shared by all analytes. They stated that it was challenging to apply the computed MU provided for each parameter to every analyte after being informed that each analyte had a unique MU.

The MU calculation itself was thought to be a simple formula. Theme 3: Benefits and Difficulties of MU Lab Consultant Implementation Despite having little practical influence, lab experts believed that MU deployment was a necessary part of the accreditation process. According to 44% of lab staff, teaching technical staff how to compute and interpret MU would be difficult. According to 46% of participants, including MU to patient lab reports would improve test result reliability and facilitate a better comprehension of the test findings.

According to 60% of participants, reports that contain uncertainty will demonstrate the laboratory's confidence in the caliber of the outcome. Most of them (80%) believed that MU assists the patient in differentiating between two successive values and facilitates meaningful

Just 20% of lab experts expressed concern about MU's adjustments and how frequently they occur. if the treatment outcome and reliability factor for lab findings would be affected by such adjustments, if any. Patients who receive two consecutive results with differing MU readings would become even more confused if MU were added to the test report. Additionally, the vendor would need sophisticated programming skills to save both MU values (prior and recently modified MU values) in order to incorporate the MU component into the Laboratory Information System alongside test results. Although 70% of participants were comfortable signing the reports with MU, 43% thought it would be confusing and 70% were dubious about clinicians accepting MU.

Theme 4: Clinician Requirements and Suggestions Concerning MU

Of the professionals, 27% were hesitant to test or implement this idea in their day-to-day therapeutic work. Since professionals frequently connect test findings with the patient's health status and never just depend on laboratory results, they felt it was unnecessary to include this information in the patient report. Eighty to ninety percent of clinicians were interested in knowing MU for key metrics and parameters with limited decision-making options. According to half of the clinicians, it would be best if MU was printed with patient findings; more specifically, it should be in the form of ranges and attained values rather than percentages.

Theme 4: Needs and Advice for Clinicians Regarding MU

27% of the experts expressed reluctance to test or apply this concept in their regular therapeutic work. Professionals believed that this information should not be included in the patient report because they often relate test results to the patient's health status and never rely solely on laboratory

data. With little alternatives for making decisions, 80–90% of doctors wanted to know MU for important measurements and parameters. According to half of the practitioners, it would be ideal if patient findings were printed on MU; more precisely, ranges and attained values, rather than percentages, should be used.

Seventy percent of them believed that, in theory, it aids in determining whether the patient's outcome differs from his or her own prior reports. However, since it is not a common, established procedure across all labs, it would be challenging to apply this approach in a few situations where the patient consistently receives his test findings from several labs. Half of the participants believed that this idea would make it more difficult to judge the test results. Physicians voiced concerns about whether the theoretical difference between two successive results (lab-calculated MU) accurately reflects the patient's clinical state.

Senior physicians were unwilling to use MU to interpret test results in their clinical practice. Additionally, junior physicians found it difficult to conduct patient management since senior clinicians made the majority of the decisions. The majority of junior clinicians voiced concerns regarding the flexibility with which lab data can be interpreted whenever MU values fluctuate.

Discussion:

The healthcare system is becoming more and more reliant on accurate laboratory results as a component of other, error-prone healthcare systems. Although a lot of research has been done to improve the overall quality of laboratories, there is a limited amount of literature on errors in laboratory results that occur during handling, testing, and ing.26 There have been some noteworthy advancements, nevertheless, such as the notable decline in error rates over the past 40 years, especially for lyrical errors.23: A significant portion of laboratory errors also occur in the pre- and post-analytical steps, according to evidence from recent studies.27 Consequently, the purpose of this study was to evaluate laboratory errors and related factors during ordering, processing, testing, and reporting.

An emphasis on traceability, method performance, quality assurance, and test result quality has resulted from ongoing attempts to provide trustworthy lab reports. Measurement uncertainty sheds light on the caliber of test findings that the lab publishes. The purpose of these focus groups, interviews, and a questionnaire-based study was to investigate how laboratory staff and physicians view and accept MU. Since this idea is still evolving and might seem foreign to the patient population and nursing staff, we limited the end users to lab staff and clinicians. Regarding the inclusion of bias and its uncertainty in MU computation and acceptability limits for each quantitative parameter, the idea of MU is still hotly debated. There are gaps in medical testing labs even if these ideas are quite obvious in metrological and electrochemical labs. Despite these difficulties, we were interested in the present attitude of the clinicians and lab staff.

Laboratory professionals in this study expressed dissatisfaction with the outcomes of their work. This result was greater than that of a research done in Addis Ababa, when 75 (35.2%)28 laboratory personnel thought their labs didn't produce high-quality results. This might be because each study used a different sampling technique and sample size. According to 32 (80%) of laboratory experts, TAT was not followed for the majority of laboratory tests conducted in hospitals, which is statistically associated with a higher likelihood of laboratory test mistakes. Addis Abeba reported lower outcomes than this, with 70. 28 of the laboratory findings allegedly not being given within the specified turnaround time.

MU is calculated by laboratories requirement, and they are not particularly interested in its use. It was seen as a duty for lab workers to complete, even if lab consultants thought it was simple to understand. One of the main topics of discussion was the emphasis on technician training and

comprehension of competence. It was thought to be a challenging undertaking to accomplish and apply in daily practice.

Although there were overwhelmingly good opinions about the caliber of reports that included MU, there was also significant reluctance to include it, even in report footnotes. Although the idea behind MU was straightforward, its application was unclear because acceptance and tolerance thresholds have not yet been determined. Convincing physicians of MU was a great issue because it was thought to be a time-consuming, statistical process that they might not find very interesting. Convincing patients with differing levels of literacy was another insurmountable challenge. There was concern that lab reports could be interpreted incorrectly or as untrustworthy.

It was thought that adding MU might make people less trusting of lab reports. Confusion and patient resistance to lab reports would increase because MU inclusion is not a standard practice. Since senior clinicians stated that the questionnaire did not improve their clinical judgment, it was challenging to get them to complete it. The idea of incorporating MU for report interpretation into senior physicians' routines was not readily accepted. In their experience, they confirmed that "clinicians assess the patient's condition and interpret lab reports." We wanted them to compare, track, and validate the patient's clinical status in addition to evaluating test data with MU included. Because it would take a lot of time and involve an unproven shift in clinical practice, senior clinicians were not persuaded to implement.

MU was viewed as an unacceptable statistical change to the outcome.

Junior clinicians, on the other hand, were eager to learn and comprehend the idea. When given a ready reckoner, they were prepared to apply and comprehend reports. Large-scale implementation was hampered by the perception that using Ready reckoner during a hectic OPD schedule required additional work. Since senior clinicians and juniors worked together to make decisions regarding patient management, MU implementation in the wards was more difficult. Junior doctors were reluctant to present these ideas since senior physicians were not entirely persuaded of MU's benefits.

Few senior practitioners were prepared to accommodate it into their schedules during focus groups and interviews, as long as it was included in the patient report.

There were serious doubts about whether MU accurately depicts a clinical picture, particularly when taking into account and contrasting successive values. But there were no questions about the theoretical scientific justification, but the practical aspects of implementing the MU in day-to-day practice—like integrating the MU with the patient test results—were difficult. Clinicians believed that MU was helpful in evaluating important parameters and parameters with a limited medical decision limit (MDL) if there was sufficient published material to demonstrate that it mirrored the clinical condition for monitoring consecutive data. Concerns were raised over MDL's age-specific applicability when it was proposed as a decision-making guideline. It was made abundantly evident that MDL and MU shouldn't be included in the reports since they might not be compatible with clinical practice.

Plebani11 developed a plan for informing clinicians about MU in 2004. They included two elements: (a) TE measured in their lab based on bias (data from external quality assurance schemes) and imprecision (data from internal quality control (IQC) at a concentration closer to the decision level); and (b) the Reference Change Value (RCV) for measurands mainly used in patient monitoring (such as tumor and bone markers), which was based on biological variation and imprecision (data from the Westgard database). According to his assessment, most users were happy with the extra information, especially with regard to the RCV, but some doctors were initially concerned, especially with the word "total error," which was read negatively.

Students enrolled in medical degree and post-graduate courses, which are titled after a number of teaching and educational efforts on the notion of biological variation, quality specifications, and related performance characteristics, showed a great deal of interest, he noted.

A follow-up research on "when and how to communicate MU to physicians" was published by Plebani et al. (10). In order to include MU in laboratory reports, they explained three distinct scenarios. In order to make it easier to interpret the results, laboratory reports typically include the following types of information: (a) the measurand Reference Interval; (b) diagnostic cut-offs and decision limits; and (c) the RCV.12

The importance of measuring the uncertainty of the second generation of total testosterone analysis is the title of another study conducted in Turkey by Ayyildiz13. It states that, once significant differences in clinical practice regarding testosterone interpretation have been identified, the patient and the clinician should receive the individual MU results for each test along with the test results.

The number of published research that may be compared to our study design is quite small. In order to help doctors make an informed choice, MU may be introduced along with the test report for each lab. Our poor understanding of the variables influencing the measured quantity leads to uncertainty in the measurement quantity. When a patient is watched for a longer period of time, it may be difficult to compare findings from various labs because there is no uniformity across labs. When the sequential assessment comes from the same lab, this would be advantageous.

To assess the degree of uncertainty surrounding a test result, testing labs should routinely examine every component of the test procedure and the circumstances surrounding its use.

Our research leads us to the conclusion that laboratory consultants who possess sufficient understanding of MU may introduce and apply MU with assurance in their day-to-day work. As long as it was recorded with the test report, particularly for the crucial parameters—clearly the most difficult part for the labs—clinicians were happy to interpret results with MU. However, for it to become standard procedure and obtain the status of a report attribute, it would need a lot of end-user involvement and acceptability.

Clinical Importance

Instead of using a subjective, arbitrary analysis of serial monitoring, the feasibility of introducing MU in conjunction with patient reports is helpful in evaluating crucial parameters and offers scientific evidence for consideration in changing patient therapy.

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