What is the future of Laboratory Medicine?

Mauro Panteghini
EFLMpresident@efcclm.eu
Key reasons why we need Laboratory Medicine

- It is integral to many clinical decisions on prevention, diagnosis, treatment, managing disease of patients
- Supplies healthcare professionals with the data necessary to provide high quality, safe, effective and appropriate care to patients
The ‘70% claim’

• “70% of medical decisions depend on laboratory data”
• “70% of diagnoses depend on laboratory data”
• “70% of the information in physician’s notes is represented by laboratory data”
• ....but where does the evidence come from?
Laboratory Medicine
perceptions and the need for change

• Test repertoire increasing (to at least 3500 tests)
• Workload increasing
• Uncontrollable demand
• Unnecessary testing
• Utilisation is varied
• New evidence
• Limited role in outcomes
Technological Advances:

• Total laboratory automation
• Molecular diagnostic techniques,
  – including high-throughput microarrays,
  – next generation sequencing,
  – genome-wide association studies (GWAS).
• POCT

Economic Pressures (limited budgets)

[global IVD market valued at $49 billion in 2012, growing at a rate of 7% from 2012 to 2017 (3-5% of healthcare costs)]
• As a main consequence of the 2 driving processes (i.e., new technologies and economic pressures), cost savings is frequently realized by consolidation and, in some cases, regionalization of laboratory services with the creation of individual laboratories serving multiple healthcare facilities.

• This may undermine the influence of laboratory professionals and isolate them from clinical problems ("deprofessionalization").
Laboratory Medicine:
Poor Visibility as a Medical Discipline & as a Profession

Unknown and invisible profession in public

A BLACKBOX to most clinicians/nurses

“...laboratory scientists...are (often) perceived as managing machinery & equipment...(but) need to take a position of shared clinical leadership...”

What paths should we follow to ensure we become relevant to health care?
Fig. 1. Closing the loop of laboratory testing: A laboratory result should enable a decision to be made, which leads to an action being taken, yielding an improved outcome for the patient.
NHS Atlas of Diagnostic Variation

- Large variations in clinician requesting that cannot easily be explained by differences in disease prevalence
Annual rate of use for CA125

From 0.11 to 9.0 per 1000 practice population
→ 80-fold variation
or
(after excluding 5 outliers)
from 0.92 to 8.4
→ 9-fold variation

Suggested contributory factors?
• Differences in professional practice
• Differences in uptake of innovation post-NICE guidelines
What are the most common reasons for rejecting tumour marker requests in your laboratory?

- Panel of markers requested 41%
- CA125 in males 33%
- Timing – too soon 26%
**Clinical (health) outcomes**

- morbidity
- mortality
- quality of life

**Surrogate outcomes**

- Metric surrogates:
  - length of stay
  - readmission rate
  - complication rate
  - episode costs
  - treatment costs

- Medical surrogates:
  - number of clinic visits
  - therapeutic TAT
  - disease markers, e.g. HbA1c, LDL cholesterol

**Additional outcomes**

- emotional & cognitive effects (e.g. well-being)
- social effects (e.g. genetic)
- behavioural effects (e.g. adherence to treatment)
Demonstrating the value of lab tests on health outcomes is reliant on linking the test with processes that directly impact outcomes.
Problems in the performance of outcome studies of laboratory tests

- Remoteness of outcome from performance of test
- High cost of studies relative to potential financial profit to corporate funders
- Risk of loss of financial profits if favourable outcomes are not achieved
- Large required number of patients/volunteers (sample size)
- Reluctance to withhold accepted test to do comparative trial
- Limited ability to conceal identity of tested vs. not-tested participants

Adapted from DE Bruns & JC Boyd, *Scandinavian Journal Clinical & Laboratory Investigation* 2010;70(Suppl 242):85
Hierarchical Levels of Laboratory-Related Patient Outcomes

1. The performance of the test in actual practice (analytical validity)
2. The predictive value of the test (clinical validity)
3. The probability of a change in health status of the patient based on the test result (clinical utility)

Adapted from DM Eddy, 1997
Hierarchical Levels of Laboratory-Related Patient Outcomes

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Adapted from DM Eddy, 1997
The standardization issue: an absolute priority for public health

Our customers (i.e., clinicians and patients) expect laboratory results to be equivalent and interpreted in a reliable and consistent manner.
Decision threshold

Frequency

Non-diseased

Diseased

TN: True Negative
FN: False Negative
FP: False Positive
TP: True Positive

Measure
(e.g. single, multiple analytes or patterns)

Diagnostic Sensitivity = TP/(TP + FN)
Diagnostic Specificity = TN/(TN + FP)

Positive Predictive Value (PPV) = TP/(TP + FP)
Negative Predictive Value (NPV) = TN/(TN + FN)

Disease frequency ($\frac{AUC_{diseased}}{AUC_{non-diseased}}$) affects PPV and NPV

Impact of test accuracy (bias shifts and imprecision skews and broadens curves)
Economic impact

- $60M/yr wasted
- $199M/yr wasted

Source: NIST Planning Report 04-1, 2004
In short: the lack of standardization may become an ethical issue

“Standardization of laboratory tests has an ethical dimension as it aims to affect the way diagnostic tests are used in order to guarantee optimal care for patients in a global world.”

Analytical improvements are matter of patient safety and key to future

What did IVD-MD Directive 98/79/EC mean to Clinical Laboratory Professionals, Clinicians, Patients?

“To ensure that IVDs do not compromise the health and safety of patients, users and third parties and attain the performance levels attributed to them by their manufacturer."

"The IVD-MD Directive is a call to improve comparability of measurement results through more structured and understood approaches for standardization."
Future EU regulatory framework

• Supervision of Notified Bodies
• Post-market safety and surveillance activities, with enhanced involvement of healthcare professionals and patients
• Transparency
  – Summary of safety and performance data
  – Traceability of devices
• Access to external expertise (scientific experts, reference laboratories)
Basic requirements to establish traceability

- Establishment of a calibration hierarchy
- Establishment of the metrological traceability for the measurement results (understand the measurements)
- Elimination of measurement bias
- Adequate estimation of measurement uncertainties
Role of IVD manufacturers

IVD manufacturers should define a calibration hierarchy to assign traceable values to their system calibrators and to fulfil during this process uncertainty limits, which represent a proportion of the uncertainty budget allowed for clinical laboratory results.
Thus, clinical laboratories need to rely on the manufacturers who must ensure traceability of their analytical system to the highest available level.

[Adapted from Braga F & Panteghini M, Clin Chim Acta 2014;432:55]

[Adapted from Kallner A, Scand J Clin & Lab Invest 2010; 70(Suppl 242): 34]
Need to define criteria for manufacturers that can be achieved for their calibrators leaving enough uncertainty budget for the laboratories to produce clinically acceptable results.

**Measurand definition**

- System calibration (combined) uncertainty
- System imprecision
- Individual lab performance (IQC safety margin)

→ **Allowable limit for the combined uncertainty of manufacturer’s commercial calibrators @ 50% of the goals**

[Note that these are goals for random variability, as at the calibrator level the systematic error (bias), in agreement with the metrological traceability theory, must be corrected if present in a non negligible amount]

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**Measurement uncertainty budget**

**Patient result**

Opinion Paper

Clin Chem Lab Med 2013; 51:973

Renze Bais*, Dave Armbruster, Rob T. P. Jansen, George Klee, Mauro Panteghini, Joseph Passarelli and Ken A. Sikaris on behalf of the IFCC Working Group on Allowable Error for Traceable Results (WG-AETR)

Defining acceptable limits for the metrological traceability of specific measurands
Opinion Paper

Federica Braga*, Ilenia Infusino and Mauro Panteghini

Performance criteria for combined uncertainty budget in the implementation of metrological traceability

Table 2: The information that in vitro diagnostics manufacturers should provide to laboratory users about the implementation of metrological traceability of their commercial systems. Adapted from [7].

- a) An indication of higher order references (materials and/or procedures) used to assign traceable values to calibrators;
- b) Which internal calibration hierarchy has been applied by the manufacturer, and
- c) A detailed description of each step;
- d) The (expanded) combined uncertainty value of commercial calibrators, and
- e) Which, if any, acceptable limits for uncertainty of calibrators were applied in the validation of the analytical system.
Currently, the full information about calibration is usually not available.

Manufacturers only provide the name of higher order reference material or procedure to which the assay calibration is traceable, without any description of implementation steps and their corresponding uncertainty.
Verification of in vitro medical diagnostics (IVD) metrological traceability: Responsibilities and strategies

Federica Braga *, Mauro Panteghini
Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan, Milan, Italy

Table 1
Metrological traceability and uncertainty information derived from calibrator package inserts of commercial systems measuring blood glucose marketed by four IVD companies.

<table>
<thead>
<tr>
<th>Company</th>
<th>Platform</th>
<th>Principle of commercial method</th>
<th>Calibrator</th>
<th>Declared standard uncertainty</th>
<th>Higher-order reference employed</th>
<th>Type of traceability chain used</th>
<th>Combined standard uncertainty associated with the used chain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott</td>
<td>Architect</td>
<td>ND</td>
<td>Multiconstituent calibrator</td>
<td>2.70%</td>
<td>IDMS</td>
<td>NIST SRM 965</td>
<td>A</td>
</tr>
<tr>
<td>Beckman</td>
<td>AU</td>
<td>Hexokinase</td>
<td>System calibrator</td>
<td>ND</td>
<td>ND</td>
<td>NIST SRM 965</td>
<td>A</td>
</tr>
<tr>
<td>Siemens</td>
<td>Advia</td>
<td>GOD</td>
<td>Chemistry calibrator</td>
<td>1.30%</td>
<td>Hexokinase</td>
<td>NIST SRM 917a</td>
<td>C</td>
</tr>
</tbody>
</table>

a: Combined standard uncertainties calculated by triangular propagation of errors.
b: Type A (accuracy) for manufacturer's data; Type B (comparability) for methodological data.
c: Traceability chain includes all calibration levels up to the secondary standard.
n: Traceability chain includes all calibration levels up to the primary standard.
The role of the Laboratory Profession: “check”

• Availability and quality of information about IVD metrological traceability and uncertainty

• Daily surveillance of IVD system traceability
Analytical Quality Control in the Traceability Era

External Quality Assessment

Analytical quality of measurement

Qualify

Check alignment

Imprecision

Reliability of the analytical system

Internal Quality Control

### Requirements for the applicability of EQAS results in the evaluation of the performance of participating laboratories in terms of traceability of their measurements

<table>
<thead>
<tr>
<th>Feature</th>
<th>Aim</th>
</tr>
</thead>
<tbody>
<tr>
<td>EQAS materials value-assigned with reference procedures by an accredited ref. laboratory</td>
<td>To check traceability of commercial system to reference systems</td>
</tr>
<tr>
<td>Proved commutability of EQAS materials</td>
<td>To allow transferability of participating laboratory performance to the measurement of patient samples</td>
</tr>
<tr>
<td>Definition and use of the clinically allowable measurement error</td>
<td>To verify the suitability of laboratory measurements in clinical setting</td>
</tr>
</tbody>
</table>

Panteghini M, CCLM 2010;48:7
Infusino I et al., CCLM 2010;48:301
Braga F & Panteghini M. CCLM 2013;51:1719
What COPERNICUS did was take the existing ‘a priori’ concept of the world and pose an alternative ‘a priori’ concept.

The earth is flat and fixed in space

The earth is spherical and moves around the sun

What TRACEABILITY does is take the existing ‘a priori’ concept of the Quality Control and pose an alternative ‘a priori’ concept.

Equivalency-based grading

Trueness-based grading
Unique benefits of EQAS meeting metrological criteria

• Giving objective information about quality of individual laboratory performance
• Creating evidence about intrinsic standardization status/ equivalence of the examined assays
• Serving as management tool for the laboratory and IVD manufacturers, forcing them to investigate and eventually fix the identified problem
• Helping manufacturers that produce superior products and systems to demonstrate the superiority of those products
• Identifying analytes that need improved harmonization and stimulating and sustaining standardization initiatives that are needed to support clinical practice guidelines
• Abandonment by users (and consequently by industry) of nonspecific methods and/or of assays with demonstrated insufficient quality
Steps of the process and different responsibilities in implementing traceability of patient results and defining their uncertainty

Profession (e.g., JCTLM, IFCC, EFLM):

- Define analytical objectives: reference measurement systems (traceability chain) and associated clinically acceptable uncertainty (fitness for purpose)

Diagnostic manufacturers:

- Implement suitable analytical systems (platform, reagents, calibrators, controls) fulfilling the above established goals

End users (clinical laboratories):

- Survey assay and laboratory performance through IQC and EQA redesigned to meet metrological criteria

Sverre Sandberg*, Callum G. Fraser, Andrea Rita Horvath, Rob Jansen, Graham Jones, Wytze Oosterhuis, Per Hyltoft Petersen, Heinz Schimmel, Ken Sikaris and Mauro Panteghini

**Defining analytical performance specifications: Consensus Statement from the 1st Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine**

<table>
<thead>
<tr>
<th>Model 1: Based on the effect of analytical performance on clinical outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Done by direct outcome studies – investigating the impact of analytical performance of the test on clinical outcomes;</td>
</tr>
<tr>
<td>b. Done by indirect outcome studies – investigating the impact of analytical performance of the test on clinical classifications or decisions and thereby on the probability of patient outcomes, e.g., by simulation or decision analysis.</td>
</tr>
</tbody>
</table>

| Model 2: Based on components of biological variation of the measurand. |

| Model 3: Based on state of the art of the measurement (i.e., the highest level of analytical performance technically achievable). |
Hierarchical Levels of Laboratory-Related Patient Outcomes

1. The performance of the test in actual practice (analytical validity)
2. The predictive value of the test (clinical validity)
3. The probability of a change in health status of the patient based on the test result (clinical utility)

Adapted from DM Eddy, 1997
When is evaluating diagnostic accuracy (clinical validity) alone adequate?

- **Accuracy studies suffice if a new diagnostic test is safer (or cheaper) or more specific than, but of similar sensitivity to, an old test → less false positive**
- If a new test is more sensitive (where specificity, harms and costs are the same) than an old test, it leads to the detection of extra cases of disease. In this case, it needs to wait for results from randomized trials assessing treatment efficacy in cases detected by the new diagnostic test, unless that the new test detects the same spectrum and subtype of disease as the old test.

Serum human epididymis protein 4 vs carbohydrate antigen 125 for ovarian cancer diagnosis: a systematic review

Simone Fersano,1 Federica Baga,1 Monica Lanzoni,2,3 Patrizia Boracchi,2,3 Ella Mario Bignozzi,2,3 Mauro Panteghin1

Diagnostic or prognostic accuracy and classification of the condition are not ‘true’ health outcomes

Studies of diagnostic accuracy ask:
“Does the result of the test predict an outcome of interest (e.g. disease diagnosis)?”

Health outcome studies ask:
“Is the use of the test associated with improved patient outcomes?”

“The value of a diagnostic test is not only measured by its accuracy, but ultimately depends on how it affects patient health.”

Figure 1 Test-treatment pathway showing Accuracy, Impact on management and Treatment effectiveness as determinants of health outcomes. Adapted from Staub et al. [9]
Patients suspected of disease

Randomization

New test
- Positive: Treatment
- Negative: No treatment

Usual approach
- Treatment
- No treatment

Outcome measures: clinical events, LOS, costs, etc.

Do patients who undergo the new test fare better (in terms of health outcomes) than those who have the old test?
New millennium criteria for acute, evolving or recent MI

Ischemic symptoms

Ischemic changes on ECG

Q waves on ECG

Percutaneous coronary intervention

"Perhaps no other laboratory test has the authority to alter a patient’s clinical course and cost of care so broadly.”  

SW Sharkey

Troponin role in altering patient management and enabling earlier discharge from a UK district general hospital

<table>
<thead>
<tr>
<th></th>
<th>Median length of stay</th>
<th>Median cost</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Unstable angina pts</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test group</td>
<td>4 days</td>
<td>£ 910</td>
</tr>
<tr>
<td>Control group</td>
<td>5 days</td>
<td>£ 1125</td>
</tr>
</tbody>
</table>

| **Non-ischemic chest pain pts** |                       |              |
| Test group                     | 2 days                | £ 235        |
| Control group                  | 9 days                | £ 1125       |

“Control” indicates use of the traditional enzymatic approach.
“Test” indicates use of cardiac troponin protocol.
**Impact of troponin introduction on an US hospital resource utilization and costs**

<table>
<thead>
<tr>
<th></th>
<th>Length of stay</th>
<th>Charges</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Acute coronary syndrome pts</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Troponin group</td>
<td>3.7 days</td>
<td>$ 15,000</td>
</tr>
<tr>
<td>CK-MB control group</td>
<td>4.6 days</td>
<td>$ 19,200</td>
</tr>
<tr>
<td><strong>Non-ACS pts</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Troponin group</td>
<td>1.2 days</td>
<td>$ 4,487</td>
</tr>
<tr>
<td>CK-MB control group</td>
<td>1.6 days</td>
<td>$ 6,187</td>
</tr>
</tbody>
</table>

Impact of troponin on diagnostic classification of patients with suspected acute coronary syndrome

5% of all admissions, who were diagnosed as non-Q wave MI using WHO criteria, were found to have normal troponin values and to have been incorrectly classified as myocardial infarction.

“We would estimate the potential annual drug cost for treatment of these patients to be approximately £ 56,000. The 10-year estimated cost would therefore be close to £ 0.5 million in wasted resources.”

Removal from the test menu of obsolete and useless tests

• Removing tests that offer little incremental information would save money, avoid additional investigations arising from incidental and clinically irrelevant abnormalities, and improve the risk to benefit ratio.

• For instance, deleting myoglobin, total creatine kinase (CK) and CK MB isoenzyme determinations from laboratory order forms in patients admitted to ED leads to significant cost saving and reduces possible confusion in data interpretation and patient management → Overall testing costs were reduced by € 104,871 per annum.

Plebani M & Panteghini M, Clin Chim Acta 2014;432:15
Markers still used for the diagnosis of AMI in addition to troponin

The Cardiac Marker Guideline Uptake in Europe (CARMAGUE) Study of the EFLM WG Cardiac Markers
Clinical outcomes of patients with only hs troponin positive before and after the introduction of a sensitive troponin assay

3-months outcome

<table>
<thead>
<tr>
<th></th>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>16</td>
<td>20</td>
</tr>
<tr>
<td>MI</td>
<td>27</td>
<td>20</td>
</tr>
<tr>
<td>Death/MI</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

12-months outcome

<table>
<thead>
<tr>
<th></th>
<th>Before</th>
<th>After</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>21</td>
<td>29</td>
</tr>
<tr>
<td>MI</td>
<td>39</td>
<td>29</td>
</tr>
<tr>
<td>Death/MI</td>
<td>11</td>
<td>11</td>
</tr>
</tbody>
</table>

P<0.05

Mills NL et al, JAMA 2011;305:1210.
Cost-effectiveness of presentation versus delayed troponin testing for acute myocardial infarction

Praveen Thokala,1 Steve W Goodacre,1 Paul O Collinson,2 John W Stevens,1 Nicholas L Mills,3 David E Newby,3 Francis Morris,4 Jason Kendall,5 Matt D Stevenson1

<table>
<thead>
<tr>
<th>Test Type</th>
<th>Total costs (£)</th>
<th>Total quality-adjusted life years (QALYs)</th>
<th>Incremental cost-effectiveness ratio or cost per QALY gained</th>
</tr>
</thead>
<tbody>
<tr>
<td>No testing (hypothetical)</td>
<td>965,994</td>
<td>26,227</td>
<td>—</td>
</tr>
<tr>
<td>hs-TnT 3h testing</td>
<td>1,806,910</td>
<td>26,379</td>
<td>£ 7487/QALY</td>
</tr>
<tr>
<td>TnT 10h testing</td>
<td>2,016,540</td>
<td>26,386</td>
<td>£ 27,546/QALY</td>
</tr>
</tbody>
</table>
Biomarker measurement: issues to keep in mind when evaluating clinical studies

- Often the analytical characteristics of the assays are not adequately described.
- We need to know how the samples need to be collected and/or preserved for accurate measurements.
- We need to know the stability of the samples over time (use of archived samples).
- Populations studied are often convenience populations for initial studies (need of confirmation in unselected populations).
- Publication bias.

The advantages of including laboratorians early-on in studies and guidelines preparation are clear!
Crucial to application of biomarkers is laboratorians’ role in closely scrutinizing proposed assays and limiting their clinical use before the evidence for them is solid.
POCT: an issue of laboratory governance

• Any tensions that have existed between POCT programs and labs will ease in the future.

• We are much more realistic now that in certain situations POCT is a better way to go and in other cases it's better and cheaper to send the sample through the main lab. Laboratorians are better now at helping understand the balance of those two opposing forces.

• It’s quite clear that the trueness and precision of POCTs are probably not adequate for the some settings.

• More outcome-based research related to POCT is needed.
Lab-related causes of diagnostic error

- Inappropriate test ordered (20%)
- Appropriate test not ordered (45%)
- Appropriate test result inaccurate
- Appropriate test result not used properly
  - Knowledge deficit
  - Failure of synthesis (no results integration)
  - Misleading result (unaware of test limitations)
- Appropriate test result delayed/missed

The Report

The product that underpins the effectiveness of the laboratory product

A synthesis of:

• data
• knowledge
• information
Challenges reported by US primary care physicians when using lab test results

<table>
<thead>
<tr>
<th>Receiving results</th>
<th>% of respondents reporting factor is very or extremely problematic</th>
</tr>
</thead>
<tbody>
<tr>
<td>Results not received in a timely manner</td>
<td>34</td>
</tr>
<tr>
<td>Previous results are not easily available</td>
<td>32</td>
</tr>
<tr>
<td>Errors in results are suspected</td>
<td>25</td>
</tr>
<tr>
<td>Results are inconsistent with patient’s symptoms</td>
<td>24</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Report format</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Lab-to-lab variation in normal range</td>
<td>22</td>
</tr>
<tr>
<td>Lab-to-lab variation in report formats</td>
<td>21</td>
</tr>
<tr>
<td>Lab report format is difficult to understand</td>
<td>18</td>
</tr>
<tr>
<td>Not enough information in lab report</td>
<td>16</td>
</tr>
</tbody>
</table>

Potentially affecting 13 million pts/yr, raising significant concerns about the safety and efficient use of lab tests

To be interpreted results should be compared with:

- a population reference interval (transversal evaluation – biological level)
- a decision limit (transversal evaluation – nosological level)

Two fundamental issues drive improvement in defining and using reference intervals in clinical practice.

1) The ISO 15189:2012 clearly affirms that “biological reference intervals shall be periodically reviewed” and they should be verified every time a variation in analytical and/or pre-analytical procedures occurs.

2) There is the need to link the analytical standardization based on the principles of metrological traceability with the identification of appropriate reference intervals.
Lack of proper reference intervals may hamper the implementation of standardization

- The implementation of standardization can modify the analyte results
- Without adequate R.I. this situation can impair the interpretation of the results and, paradoxically, worsen the patient’s outcome
- The absence of reliable R.I. for the newly standardized commercial methods hampers their adoption
Until today

Method-dependent results
Method-dependent reference intervals

From today

Standardized methods that provide traceable results
Traceable reference intervals

Laboratory professionals can play a central role in improving clinical effectiveness

- Clinical optimization of operational efficiencies
- Survey performance through appropriately designed QC
- Improve testing appropriateness
- Improve patient outcomes
- Educate clinical users
- Improve decision-making strategies
- Improve cost-effectiveness

‘Hands on’ role @ laboratory-clinic interface
- Vetting
- Consultation
- Interpretation
- Clinical liaison and advice
Challenges for the future

- To become relevant in the healthcare environment, laboratory professionals have to change their attitude from one of being introspective and defensive to one that is outward looking and innovative.

- By combining the talent of performing quality laboratory assays with knowledge of the pathophysiologic rationale behind the tests, laboratory professionals have the unique opportunity to use their expertise to advise their clinical colleagues in regard to the appropriate test selection and interpretation of laboratory results, and to create opportunities to define the value and the pivotal role of laboratory medicine by focusing on its overall impact in healthcare delivery.
Laboratorians can be assured of two certainties: change is inevitable and lab tests will continue to play a role in medicine. The question is: do you want to be proactive in changing or simply suffer it?