



# Value and Impact of Laboratory Medicine in Healthcare



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# Importance of lab medicine



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- *Single highest-volume medical activity*  
(Est 10-15 bn tests/year)
- Patient safety – *contributes to fast, accurate diagnosis*
- Essential to clinically cost-effective delivery of care  
*Often the principal basis for costly downstream care*
- Spans primary/secondary care
- Added value at pre- & post-analytical phases

*Global IVD market valued at \$49.2 bn in 2012, growing  
at a rate of 7% 2012-2017  
3-5% of healthcare costs*



# Healthcare Professionals Need to be Educated on the Critical Role of Laboratory Medicine



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## *Key reasons why we need laboratory medicine:*

- It is integral to many clinical decisions on prevention, diagnosis, treatment, managing disease of patients
- Supplies health care professionals with **OBJECTIVE DATA** necessary to provide high quality, safe, effective and appropriate care to patients

## *Value of Laboratory Tests and Services Across Patient Care Continuum*

Wolcott J, Schwartz A, Goodman C. Laboratory Medicine: A National Status Report. Prepared by: The Lewin Group.



# Laboratory medicine is *A hidden treasure in health care*



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94% objective data in medical records

60–70 clinical decisions influenced

37% of practice guidelines

23 % different disease areas & growing number of companion diagnostics

**Sources:** IMS Report 2003, [www.VDGH.de](http://www.VDGH.de) / Forsman, R.W. (2002) *Clin. Leadersh. Manag. Rev.*, **16**, 370 / Forsman, R.W. (2000) *Clin. Leadersh. Manag. Rev.*, **14**, 292 / Gibler et al. 1992, *Annals of Emergency Medicine*, 21, 504 / Herrmann et al., 2001 *Med. Klinik*, 144 / *Clinica* 19.7. + 13.9.2002, 11.04.2002

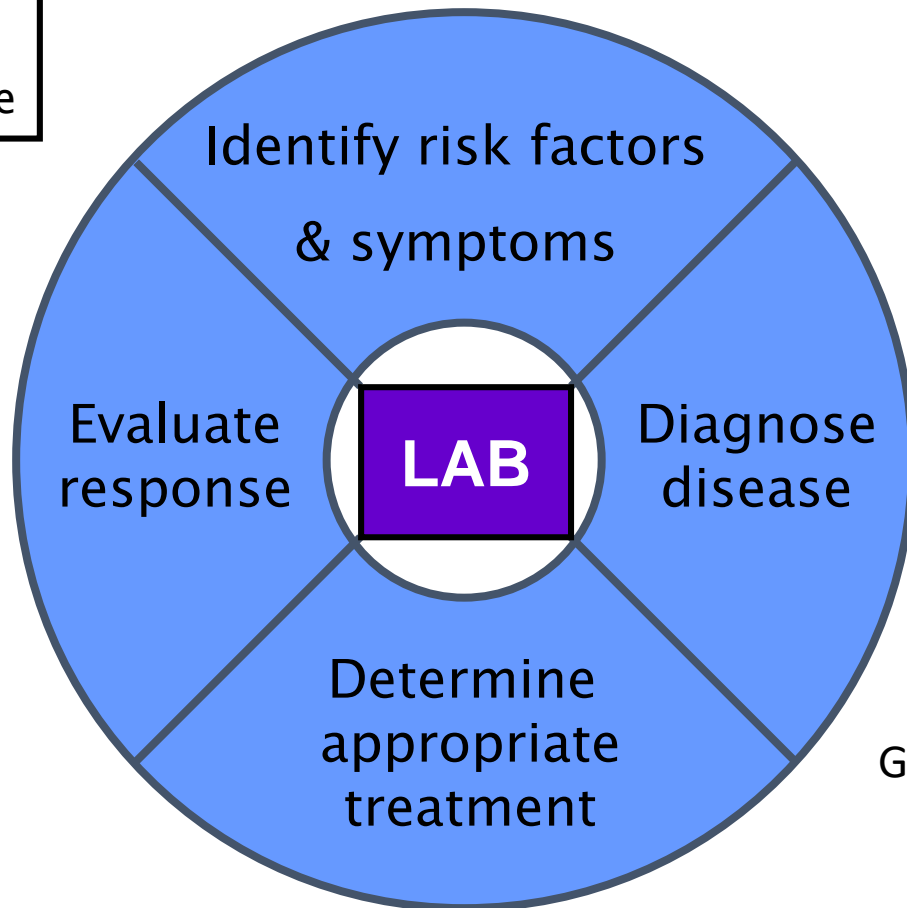


# Evidence Supports the Central Role of Laboratory Medicine



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Laboratory Medicine is part of the multi-disciplinary team at the centre of healthcare



G Beastall



# Despite Playing a Central Role, Lab Medicine Receives a Minor Proportion of the Global Hospital Budget

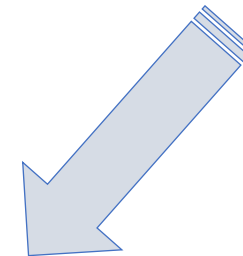


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**~70-80% of clinical decisions  
are informed by data from  
Laboratory Medicine  
(source UK  
Department of Health)**

**Major Cause:**

***Poor Visibility??***



**<5%  
spend**



# Laboratory Medicine:

*Poor Visibility as a Medical Discipline & as a Profession*



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*Laboratory Medicine  
as a Discipline*

*&*

*Laboratory  
Professionals*

*Profession without a Face*



Unknown and invisible  
profession in public

A BLACKBOX to most  
clinicians/nurses



# Recent Initiatives to Improve Our Visibility and Image



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- **IFCC Committee on Public Relations (C-PR)**
  - *Public Relation tools developed to promote both the field of lab medicine and the IFCC*
- **Lab Tests Online International**
- **Know Pathology, Know Healthcare Program in Australia**
- **Labs are Vital Program**
- **IFCC Taskforce on Impact of Laboratory Medicine on Clinical Management and Outcomes (TF-ICO) (2012-2015)**





# Laboratory Medicine:

*Poor Visibility as a Medical Discipline & as a Profession*



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**However, Enhancing Visibility of Our Profession is A Responsibility of Every Lab Professional**

***Promoting value and impact of the lab to hospital administrators within our own institutions, to clinical colleagues, to other healthcare professionals, to the general public, to our own families!***

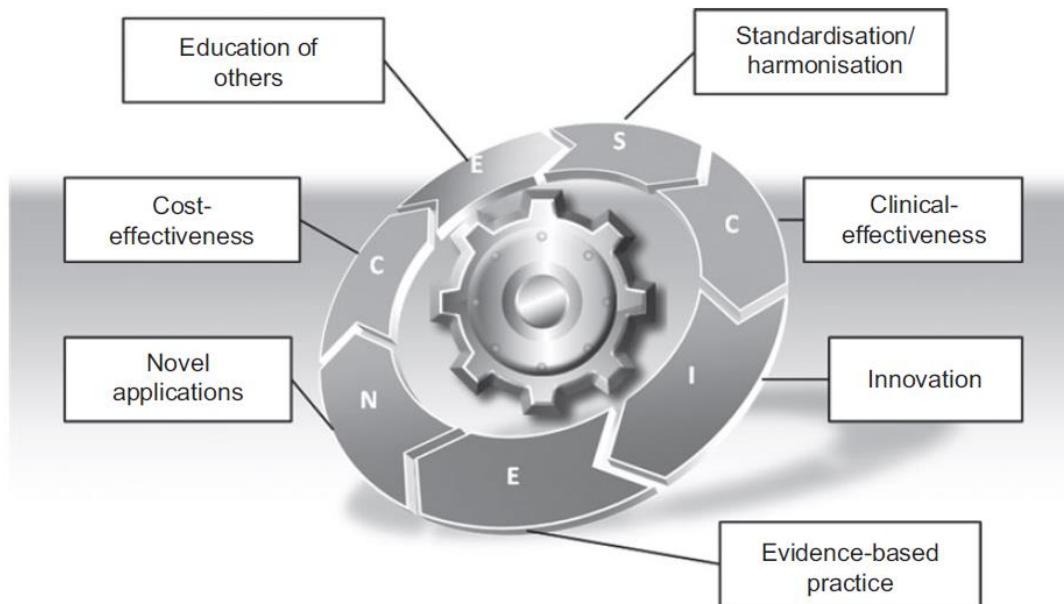


# Adding value to laboratory medicine: *a professional responsibility*



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The leadership of laboratory medicine at local, national and international level needs to 'add value' to ensure the optimal delivery, use, development and evaluation of the services provided for individuals and for groups of patients.



Clin Chem Lab Med  
2013; 51(1): 221–227

The importance and true impact of laboratory medicine can only be achieved by **adding value** to laboratory tests, represented by their effectiveness in influencing **the management of patients and related clinical outcomes**



# IFCC Taskforce - (TF-ICO) Terms of Reference



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1. **Evaluate the available evidence** supporting the impact of laboratory medicine in healthcare (a critical review of published literature) with a focus on data published 2007–2015.
2. **Develop the study design** for new retrospective and prospective studies to generate evidence-based data to support IFCC promotional activities to the healthcare community and the public

The taskforce also worked on refining the old and non-specific '70% claim' by defining some of the key decisions in the clinical process and looking at the role of lab medicine in each of these, either in specific care pathways (e.g using published guidelines for specific conditions) or in specific settings, e.g. ER – decision to admit, acute medical ward – decision to treat etc.



# Taskforce Recommendations Assessing the Value



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“In order to improve outcomes, a laboratory test must be *appropriately ordered, conducted, returned with results on a timely basis, correctly interpreted and affect a decision for further diagnosis and treatment*”

*Lewin Group report on The Value of  
Laboratory Screening and Diagnostic Tests  
for Prevention and Health Care  
Improvement, 2009*



# Taskforce Recommendations Assessing the Value



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The need for an outcomes research agenda *to determine value* for clinical laboratory testing

Lundberg G. JAMA 1998; 280: 565-6

*“clinicians and laboratorians should all be concerned about the effects of each laboratory test and whether the performance of it is useful for the patient or for the public’s health,”*



# Taskforce Recommendations Call to action



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Agree on *definition and validation of effectiveness measures* – a  
“common currency” for outcomes

*Benchmark existing and new biomarkers* in specified situations  
using commonly accepted effectiveness measures

*Improve utilization of new and existing biomarkers* –  
optimum testing strategies based on presenting complaint  
support of effective requesting  
timely and appropriate result transmission  
availability of consultation and interpretation  
audit of effectiveness in practice



# Taskforce Recommendations

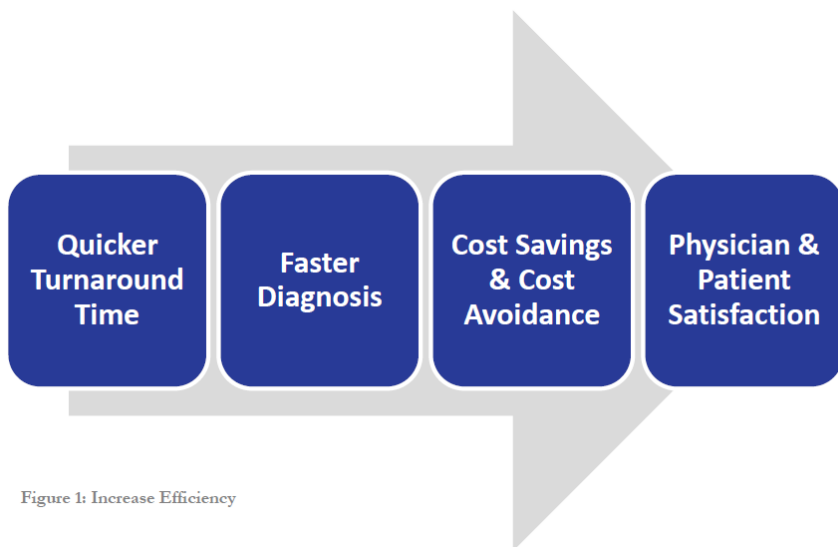
## Lab's Contribution to organizational efficiency



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Laboratories must begin to consider their contribution to the overall organization they represent. They can impact costs by:

- Increasing the speed and accuracy of diagnoses
- Monitoring patients to prevent disease
- Improving turnaround times that allow reduced hospital stays
- Promoting appropriate test selection to help avoid adverse events and point to the most appropriate treatment





# *Taskforce Recommendations:* Develop “best practice” ordering guidelines



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With their clinical knowledge and experience, laboratory professionals can advise clinicians about appropriate test orders and enhance test interpretations

## **CDC Identified Problems Associated with Incorrect Test Selection and Interpretation:**

- Large lab test compendium
- Inconsistency in test names
- Inconsistent guidelines for test usage
- Lack of training in lab medicine during medical school
- Limited knowledge of laboratory function
- Growth of molecular diagnostic testing





# Taskforce Recommendations

## Reduce and eliminate waste



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Reports from New England Health Institute and Dartmouth Medical School suggest that the cost of potentially avoidable clinical care is estimated as 30% of total healthcare spending. If this waste could be eliminated, over \$700 billion could be saved annually.

### Eliminate Waste To-do List

- Determine scenarios that justify expensive tests.
- Eliminate obsolete testing, such as bleeding times.
- Reduce non-value added testing. Providers waste time explaining why a patient's Chloride is 99.
- Create testing formularies.
- Develop algorithms, sequential protocols.
- Provide peer-to-peer data.

Figure 2: Eliminate Waste



# Taskforce Recommendations

## Ensuring appropriate test utilization



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*To be of use, a test must be applied appropriately*

**Epner et al. (2013)** have described the five basic ways in which the testing process can go wrong:

1. An inappropriate test is ordered
2. An appropriate test is not ordered
3. An appropriate test result is misinterpreted or misapplied
4. An appropriate test is ordered, but is delayed or misrouted within the testing process and is not available where it is needed at the time it is needed
5. The result of an appropriately ordered test is inaccurate



# Overdiagnosis: Harming the Healthy?



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# Lab Related Causes of Diagnostic Error



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- Inappropriate test ordered
- Appropriate test not ordered
- Appropriate test result not used properly
  - Knowledge deficit
  - Failure of synthesis
  - Misleading result
- Appropriate test result delayed/missed
- Appropriate test result wrong/inaccurate

(Epner & Astion, 2012)



# Analysis of malpractice claims – US

Ann Intern Med 2006; 145: 488-496



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## Faulty process leading to missed diagnosis:

- Failure to order diagnostic/lab test 55%
- Inappropriate/inadequate follow-up 45%
- Failure to obtain adequate history/exam 42%
- Incorrect interpretation of diag test 37%
- Failure to refer 26%
- Provider did not receive test results 13%
- Tests ordered but not done 9%
- Tests performed incorrectly 8%



# Landscape of Inappropriate Test Utilization



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A 15-Year Meta-Analysis  
(Zhi et al. 2013: PLoS One 8(11): e78962)

## 42 studies

- 38 investigated overutilization
- 8 investigated underutilization
- 4 both
- 31 objective/11 subjective criteria
- 20 looked at >1 test

Overall mean rate of inappropriate overutilization = **20.6%**  
(95% CI 16.2 – 24.9%, n=114)

Overall mean rate of underutilization = **44.8%**  
• (95% CI 33.8-55.8%, n= 18)



# IFCC Taskforce Report



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Published in an special issue of eJIFCC (2015)

[www.ifcc.org](http://www.ifcc.org)

IFCC Task Force report

“Current Evidence and Future Perspectives on the Effective Practice of Patient-Centered Laboratory Medicine”:

Hallworth MJ et al.

Clinical Chemistry – April 2015

*(doi:10.1373/clinchem.2014.232629)*



# Future Vision



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21st century lab medicine needs a flexible information resource:

- that facilitates **selection of the right test** on the right patients at the right time,
- with **results delivered in a timely fashion** to the right place
- accompanied by context-specific **interpretation**
- linked to **guidance on agreed action** to be taken (where appropriate)
- with **validated patient-oriented clinical and economic outcome measures**





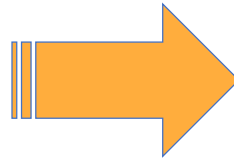
# Changing Role of Lab Medicine



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## From:

- Specimen-centred Clinical testing
- Lab. performance
- Provider of results

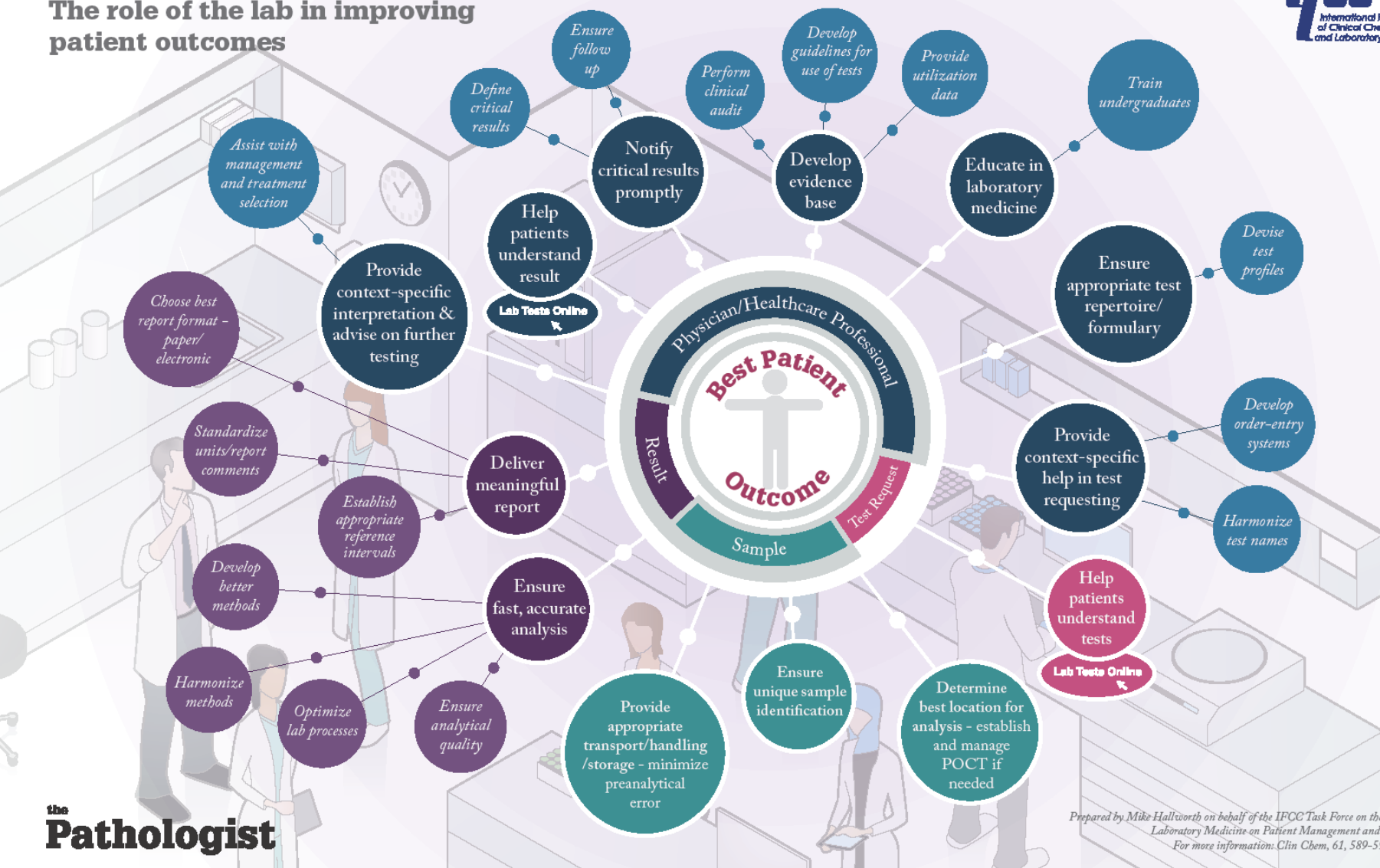


## To:

- Patient-centred Clinical decision-making
- Patient outcomes
- Partner in care

# Patient-Centered Laboratory Medicine

## The role of the lab in improving patient outcomes



спасибо  
danke 謝謝  
ngiyabonga  
teşekkür ederim  
dank je  
gracias  
tapadh leat  
bedankt  
hvala  
mauruuru  
thank you  
mochchakkeram  
dziękuje  
sagolun  
sukriya  
kop khun krap  
go raibh maith agat  
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takk  
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merci  
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terima kasih  
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