Clinical Laboratory Integration into Healthcare Collaborative

"CLIHC™"

An Update on Activities

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Two major unmet needs of clinicians from the clinical laboratory

Consultation on :

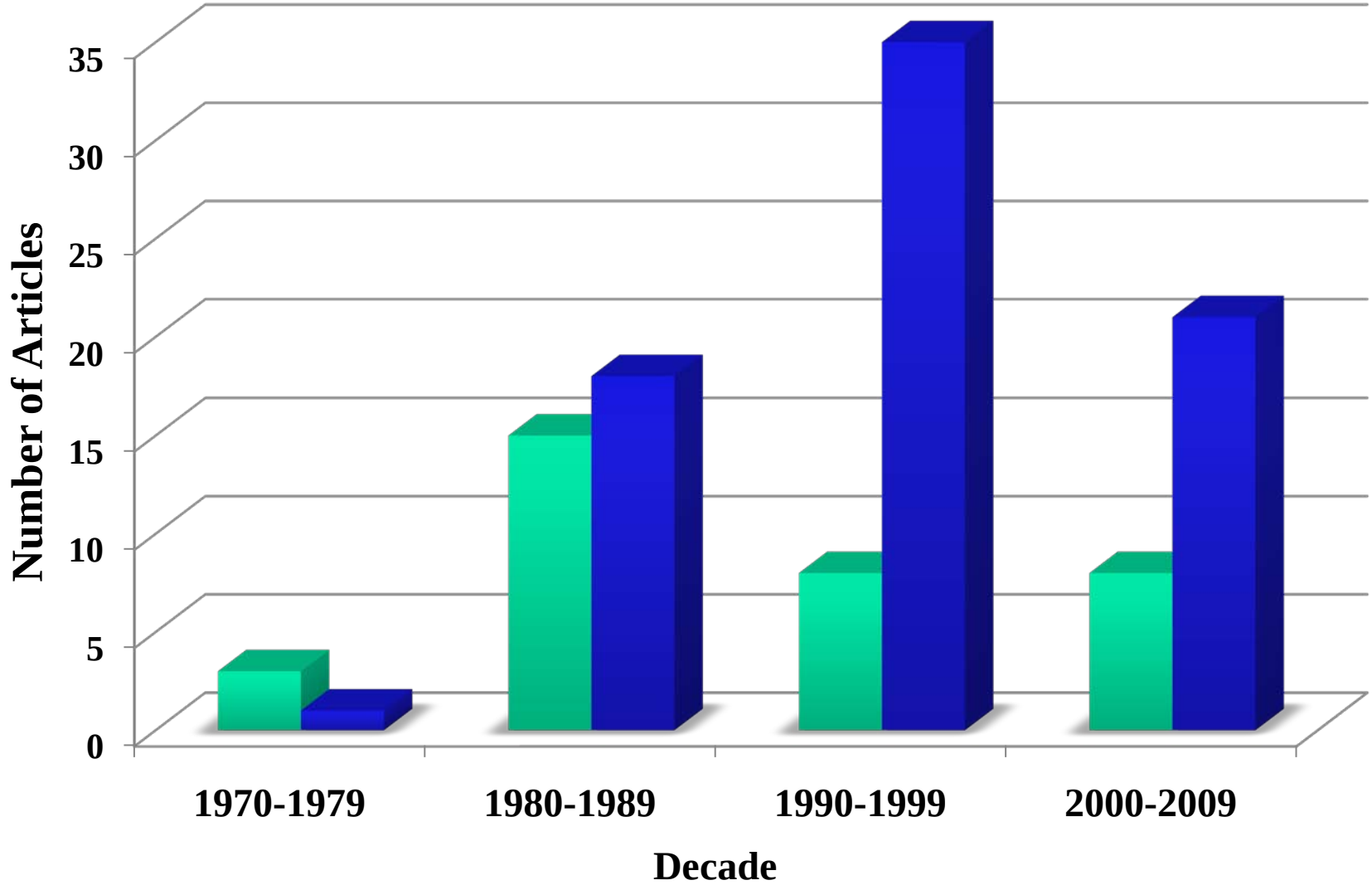
Appropriate test selection

Correct interpretation of test results

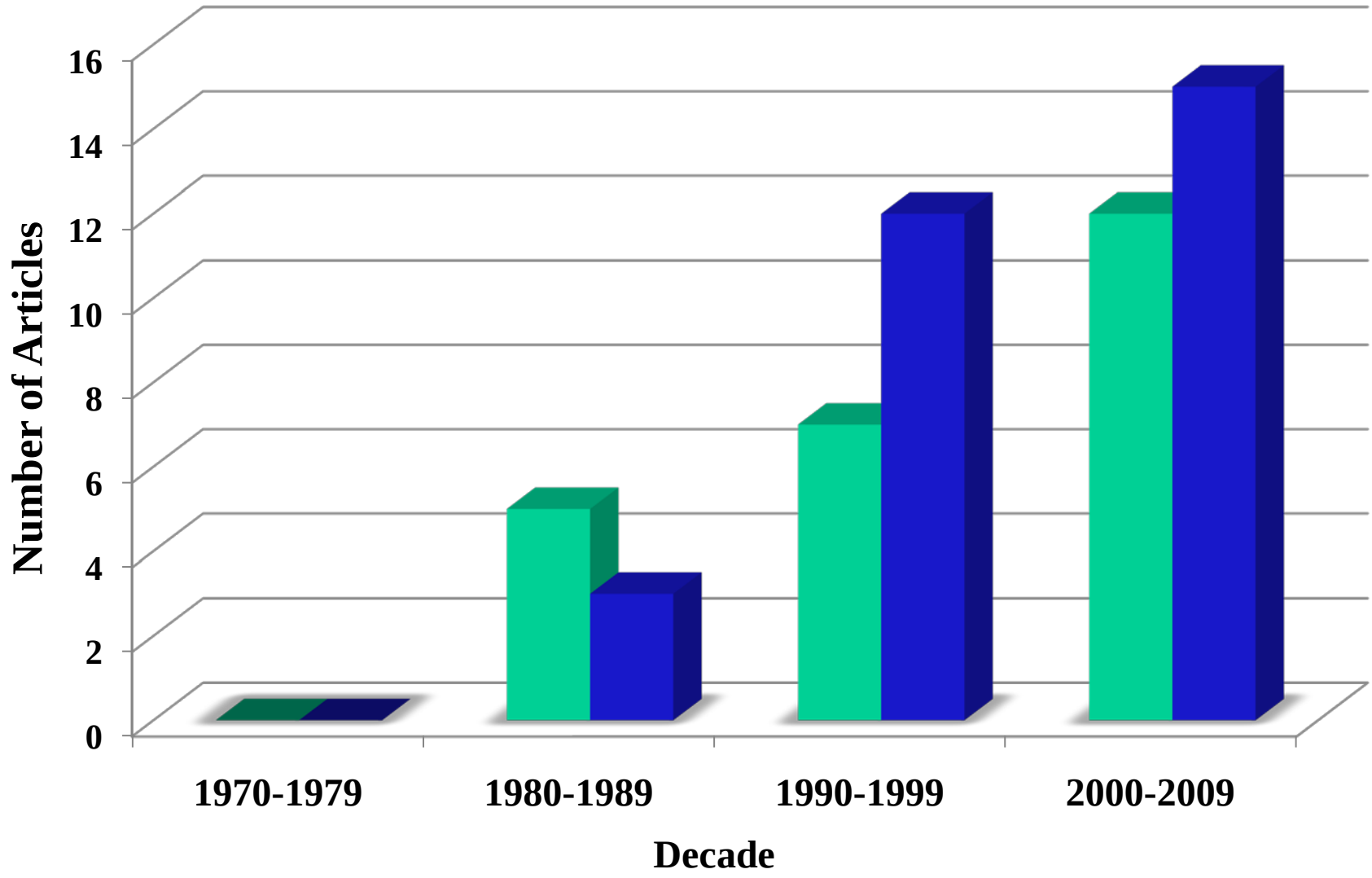
Patient safety errors associated with incorrect laboratory test selection and misinterpretation of test results have been largely unrecognized for 20 years:

A 40-year review of the literature

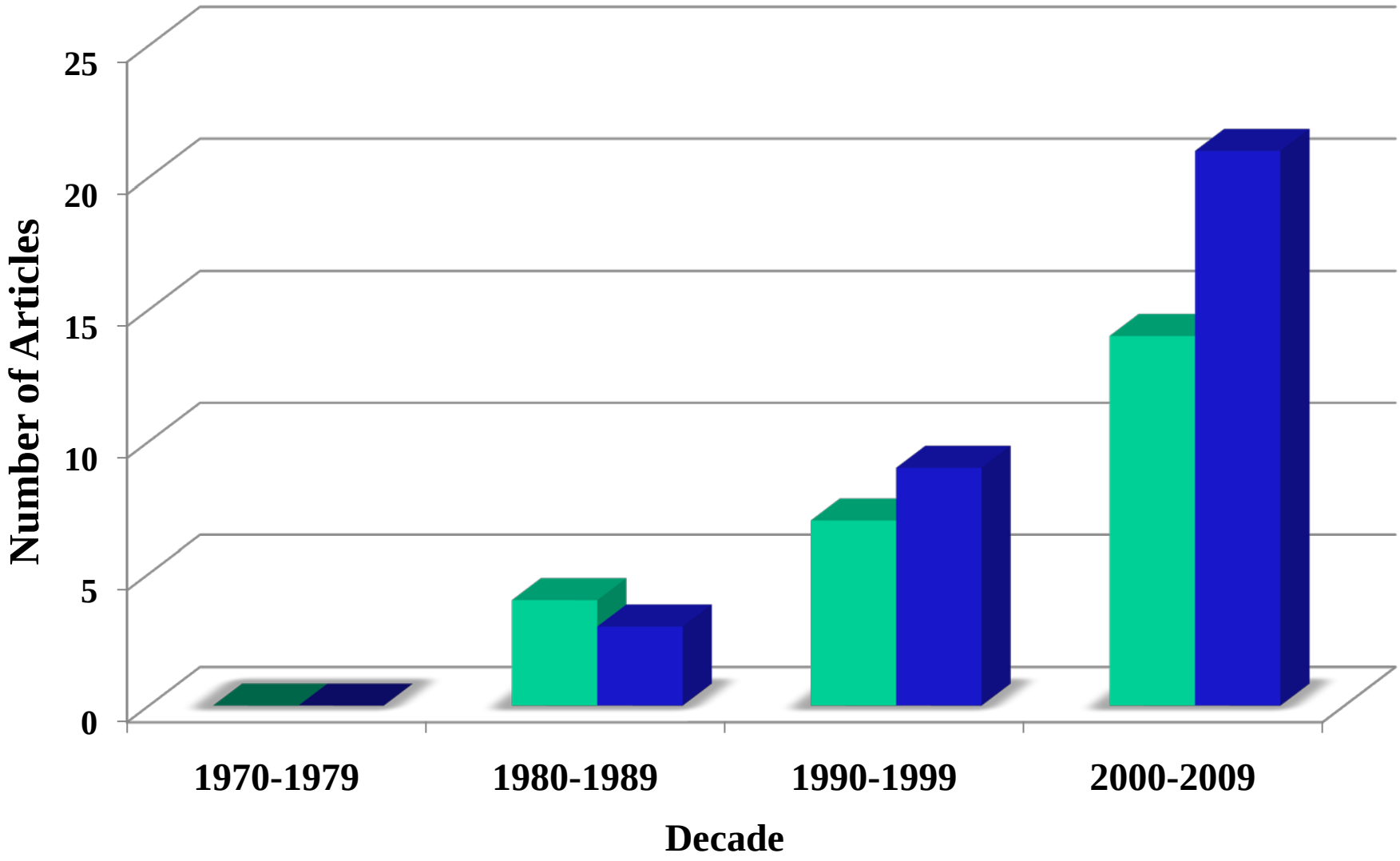
The number of articles written per decade since 1970 that discussed the problem of too many tests being ordered (left bar in pair) and the number of papers written offering a solution to the problem (right bar in pair)



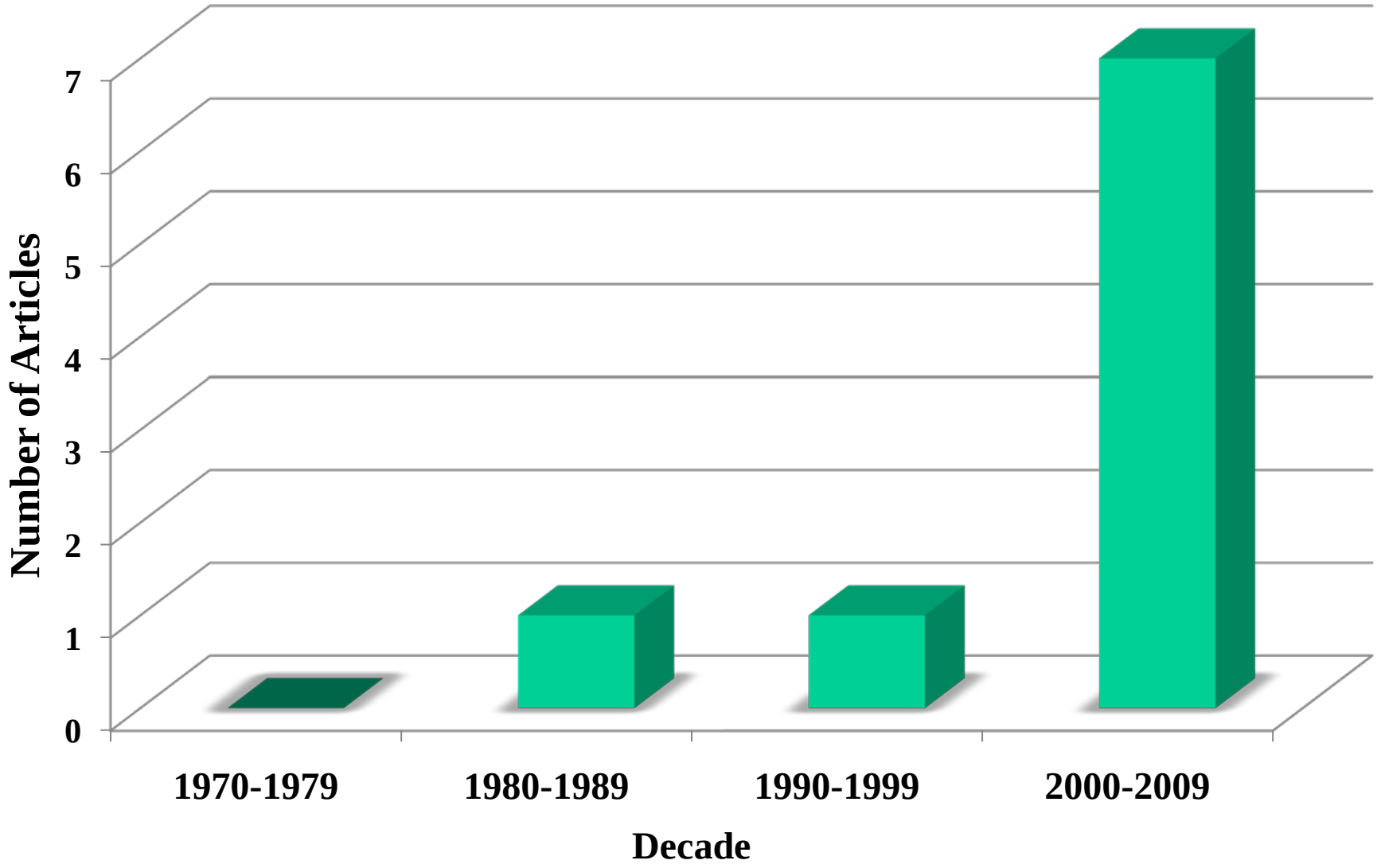
The number of articles written per decade since 1970 that discussed the problem of errors in test selection (left bar in pair) and the number of papers written offering a solution to the problem (right bar in pair)



The number of articles written per decade since 1970 that discussed the problem of errors in test result interpretation (left bar in pair) and the number of papers written offering a solution to the problem (right bar in pair)



Number of articles written per decade since 1970 regarding the adverse outcomes as a result of errors in test selection and result interpretation



For the last 15 years, we focused on the growing presence of the problem

It is now time to begin taking measures to reduce the problems associated with :

Appropriate test selection

Correct interpretation of test results

Nationally directed activities in the United States under the sponsorship of the

Centers for Disease Control and Prevention (CDC)

CDC sponsored activities to improve patient safety by reducing incorrect test selection and misinterpretation of test results

2005 Recognition by Institute for Quality in Laboratory Medicine/CDC of the importance of these problems

2007 Expert groups organized & convened by CDC to address the need for improved test selection & result interpretation

CDC sponsored activities to improve patient safety by reducing incorrect test selection and misinterpretation of test results

2008 An expert group is convened by the CDC entitled "The Clinical Laboratory Integration into Healthcare Collaborative" (CLIHC)™

CDC sponsored activities to improve patient safety by reducing incorrect test selection and misinterpretation of test results

The Clinical Laboratory Integration into Healthcare Collaborative™ is currently active

And

Each of its projects to improve the correct selection of laboratory tests and the interpretation of test results is briefly described in this presentation

The overall plan for the Clinical Laboratory Integration into Healthcare Collaborative (CLIHC)™

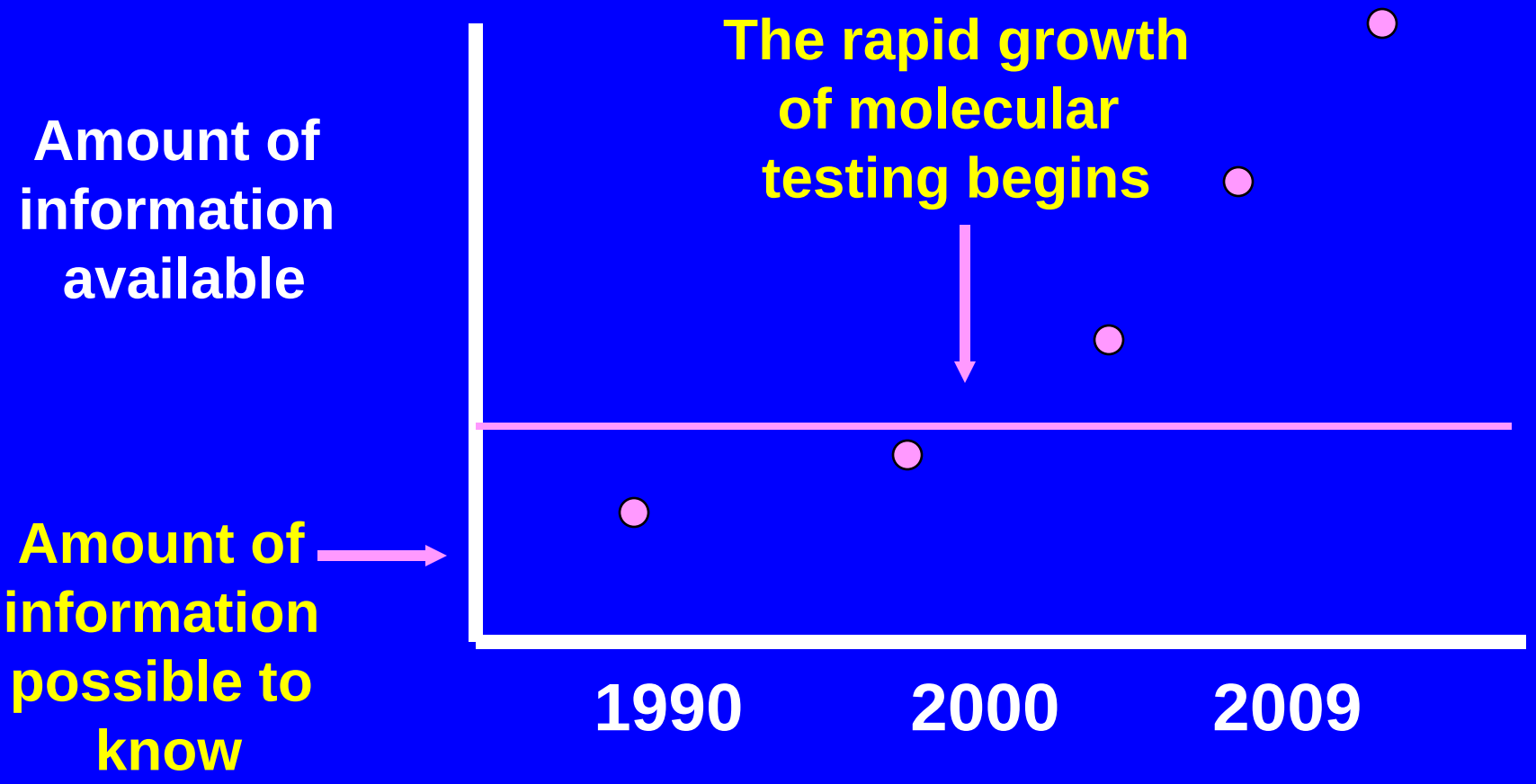
Identify the major problems associated with correct test selection and results interpretation

Create teams of expert laboratorians and clinicians to collect relevant data to illustrate the extent of each of the problems identified and provide possible solutions – with the publication of these data in peer reviewed manuscripts

The number of manuscripts expected to emerge from the effort of this committee in the next 2 years is 6-8

Major Problem 1:
Too many lab tests from which to select

In the last decade it has become virtually impossible to have enough facts in one's brain to provide optimum care



Modified from Dr. Bill Stead

What is the challenge introduced with the availability of molecular diagnostic testing ?

The example of cystic fibrosis

The Diagnosis of Cystic Fibrosis in the Mid-1980s

- Use of the sweat chloride test
- No genetic testing

The Diagnosis of Cystic Fibrosis in the Mid-1990s

- Use of the sweat chloride test
- Genetic testing for less than 50 mutations

The Diagnosis of Cystic Fibrosis in the Mid-2000s

- **Use of the sweat chloride test**

- **Genetic testing for hundreds of mutations would be informative because minor cystic fibrosis mutations have become associated with chronic sinusitis and chronic pancreatitis -**

  But testing for these indications is not often performed

The Diagnosis of Cystic Fibrosis in the Mid-2000s

- **Use of the sweat chloride test**

- **Genetic testing for hundreds of mutations would be informative because minor cystic fibrosis mutations have become associated with chronic sinusitis and chronic pancreatitis**

And now, it is realized that individual mutations are now classified into groups 1 to 5 and treatment for patients in these groups may be different !

Project 1
Diagnostic Algorithms

Marisa B. Marques

January 26 -27, 2011

Sheraton Airport Hotel

Acknowledgements

- Michael Laposata
- Oxana Tcherniantchouk
- Julie Taylor
- Pamela Thompson
- Diane Bosse
- Lindsay Morgan Burke
- Ondrea Simmons

Project to illustrate the challenge of correct test selection for clinicians

There are many tests in diagnostic coagulation – how difficult is correct test selection for evaluation of a patient with a prolonged PTT ?

Diagnostic Algorithms Study

Goals of the study

Demonstrate the high complexity of choosing appropriate laboratory tests when evaluating a patient with abnormal test results

Show how test selection in an apparently straight forward clinical setting may be highly complex, illustrating clinicians' challenges in appropriate test ordering

Methods

3 experts in clinical coagulation were asked to independently design algorithms for evaluation of a prolonged PTT

The hypothesis was that a simple algorithm could be used to help clinicians correctly select tests to effectively evaluate such patients

Is this the correct evaluation of a prolonged PTT for every patient?

Degrade heparin in sample and repeat PTT - if the PTT normalizes, heparin is the cause

↓

PTT mixing study (50:50 mix of patient & normal plasma)

↙ **PTT Normalizes**

↓

Factor deficiency- measure factors VIII, IX, XI, and XII

↘ **PTT remains prolonged**

↓

Inhibitor, most often a Lupus anti-coagulant; may be a Factor VIII inhibitor if PTT mixing study first normalizes and then becomes prolonged

Perform tests for specific inhibitor suggested by results of PTT mixing study

Conclusions

The experts concluded that one universal algorithm failed to suggest the correct tests to evaluate a prolonged PTT in a large percentage of cases-

**Clinical variables – limited in number –
also needed to be considered to order the correct tests**

Notably, whether the patient is bleeding, is an inpatient or outpatient, and if the patient is a neonate

Six different algorithms had to be designed to maximize the likelihood for correct test selection to evaluate a prolonged PTT

Major Problem 1:
Too many lab tests from which to select

Conclusion : Even in the absence of molecular testing in the evaluation of a prolonged PTT, selection of the correct tests to evaluate a prolonged PTT is a significant challenge for most clinicians –

Because there is not only a large number of tests to consider, but depending on the clinical circumstances, different large groups of tests may need to be considered –

Even for the simple evaluation of a prolonged PTT

Results

- **Manuscript submitted**

THE CHALLENGE OF CORRECT LABORATORY TEST SELECTION AND THE CONSEQUENCES OF ORDERING MISTAKES

Oxana Tcherniantchouk[1], Michael Laposata[2], and Marisa B. Marques[3]

Major Problem 2:
Inconsistent test nomenclature across laboratories for the same test

With the large number of names and abbreviations for the same test –

How can the clinician know with certainty if the test selected is the desired one ?

Project co-leaders : Elissa Passiment and James Meisel

Project 2: Nomenclature

Workgroup
January 26 -27, 2011
Sheraton Airport Hotel

Acknowledgements

- James Meisel
- Marisa Marques
- George Fritsma
- Samir Aleryani
- John Fontanesi
- Julie Taylor
- Pam Thompson
- Mike Laposata
- Anne Pollock

Existing nomenclature options for vitamin D and its multiple forms

Vitamin D2
Ergosterol
Vitamin D3
Cholecalciferol
25-0H vitamin D2
25-0H vitamin D3
25-0H vitamin D
25 hydroxy vitamin D2
25 hydroxy vitamin D3
25 hydroxy vitamin D
1,25 (OH)2 vitamin D2
1,25 (OH)2 vitamin D3
1,25 (OH)2 vitamin D
1,25 dihydroxy vitamin D2
1,25 dihydroxy vitamin D3
1,25 dihydroxy vitamin D
Vitamin D 25 Hydroxy D2 and D3
Vitamin D 1,25 Dihydroxy

In addition –

The number of abbreviations created for laboratory information systems for vitamin D and its multiple forms is almost limitless

Methods

- **Gathered multiple names and abbreviations or acronyms for commonly ordered tests and coagulation tests**
- **Sources were test directory of Vanderbilt University Medical Center Pathology Department, multiple medical centers in Boston and test directory at University of Alabama at Birmingham**

Results

- **Illustrated test name variation based on:**
  - **Disease association**
  - **Methods used to perform the test**
  - **Name of developer**
  - **Inappropriate names (i.e. no link between name and what is being tested)**
- **Illustrated multiple abbreviations**
  - **Many evolved from LIS implementation**

Next Steps

- Identify and work with an IS partner that may provide guidance for a solution
- Writing manuscript for peer-reviewed journal

Major problem 3
Significant variability in clinician use of laboratory tests

It is important to determine what practicing clinicians know about laboratory test selection and result interpretation

A project was initiated to survey clinicians to determine the opportunity for improved assistance on laboratory test selection and result interpretation

This would include laboratory consultation and enhanced decision support

Project leader : John Hickner

Focus Groups with Physicians on Laboratory Medicine Ordering and Interpretation Practices

CLIHC™ Meeting
January 27, 2011
Sheraton Airport Hotel

Acknowledgements

- Kim Bellis
- Beth Costello
- Paul Epner
- John Fontanesi
- John Hickner
- James Peterson
- Anne Pollock
- Megan Shaheen
- Julie Taylor
- Pamela Thompson
- Tom Wilkinson

Major problem 3
Significant variability in clinician use of laboratory tests

Establish from focus groups of physicians "behind the glass", key challenges physicians face in laboratory test ordering and result reporting / interpretation

Then

Use results of the national survey of primary care physicians to identify strategies that lessen those challenges

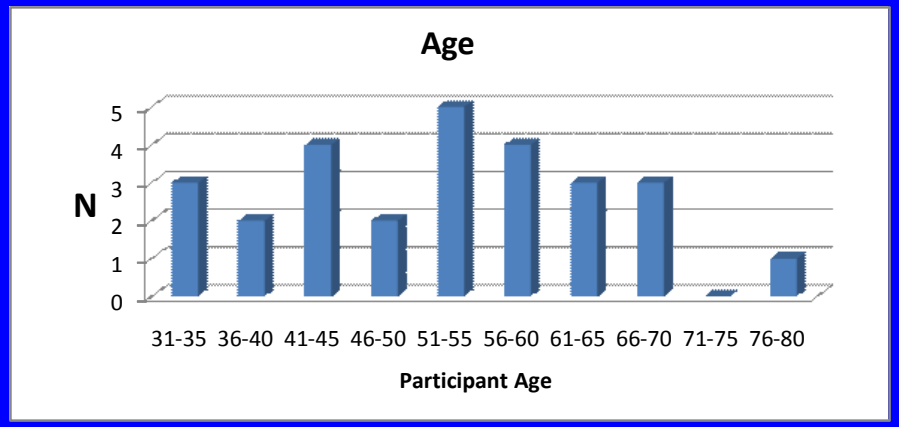
Methods

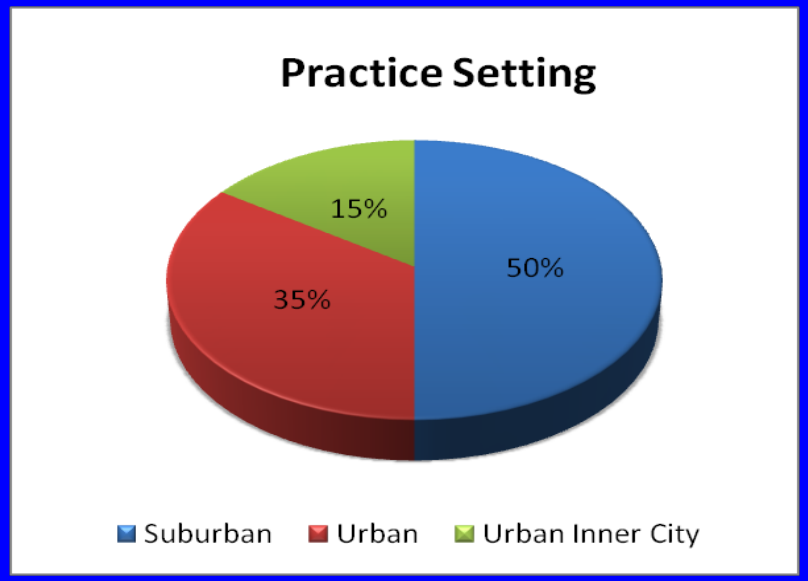
- **Sample frame**
  - **Samples of Family Practice & Internal Medicine Practitioners in four focus groups**
  - **Mailing lists of local physicians from several insurance companies databases**
- **Sites**
  - **Pilot test at Cleveland Clinic, Cleveland, OH**
  - **March 17, Atlanta, GA**
  - **April 12, San Antonio, TX**
  - **May 20, Ann Arbor, MI**

Methods (cont.)

- **Subject areas**
  - **Atlanta**
    - **Laboratory test ordering and result interpretation**
  - **San Antonio**
    - **Laboratory test ordering**
  - **Ann Arbor**
    - **Laboratory test interpretation**

Demographics





Major problem 3
Significant variability in clinician use of laboratory tests

Results from behind the glass interviews indicate that :

Physicians continue to use only routine tests for diagnosis and are confident with their knowledge about a limited number of test results

Physicians understand their lack of knowledge in test ordering and test interpretation but turn most frequently to resources, such as online resources and colleagues, for help

Physicians do not generally think of consulting with the laboratory but are very desirable of expert information from laboratory directors, if it were easily available.

Summary

- **Physicians are comfortable with selecting from a small working repertoire of common tests**
- **When uncertain, they first draw on informal contacts, followed by more formal outreach**
- **When test results did not fit their suspected diagnosis, physicians relied on combination of patient presentation and own diagnostic instincts more than the laboratory results**

Building on Focus Group Findings:

National Survey of Physician Practices in Laboratory Medicine Test Ordering and Result Interpretation

Questionnaire Design

- **Questionnaire items directly drawn from Domain Nodes identified in Focus Group**
  - **Ordering Uncertainty**
  - **Ordering Influences**
  - **Ordering Challenges**
  - **Interpretation Uncertainty**
  - **Interpretation Challenges**
  - **Test Utilization Enablers**
  - **Laboratory Consultation Practices**
  - **New Test Awareness**
  - **Diagnostic Evaluation Practices**
  - **Demographic and Practice Characteristics**

Questionnaire Development

- Questionnaire development by core Focus Group team
  - CDC representatives
  - Expert consultants
  - Survey research experts
- Development process included:
  - Iterative refinement of drafts by core team
  - Cognitive testing with primary care physicians
  - Expert review by national authorities

Survey Methods

- National sample of Family Practice and Internal Medicine physicians drawn from AMA Master File
- Target sample size of 1600 cases
- Survey delivered via Web
- Full OMB approval
- Robust statistical design to support analysis

Survey Timeline

- **Fall 2010: questionnaire development**
- **January 2011: cognitive testing, expert review, and questionnaire and sample design finalization**
- **February 2011: OMB submission (3–6 month process)**
- **Late Summer 2011: Full Field Pilot Test**
- **September – October 2011: Survey field operations**
- **Late Fall 2011: Data assembly and analysis**
- **Dec 2011: Analytical and Narrative Report**

Major problem 4
Lack of data on the impact of advice on test selection and result interpretation

The Prospective Generation of Data to Test Whether:

Failing to order necessary laboratory tests delays diagnosis, appropriate treatment and/or worsens patient outcomes

and if

Inappropriate utilization of laboratory test results delays diagnosis, appropriate treatment and/or worsens patient outcomes

IMPROVEMENTS IN TEST SELECTION AND RESULTS INTERPRETATION

CLIHC™ Meeting

Paul L Epner

January 26, 2011

Research on Improvements in Test Selection and Result Interpretation by Clinicians (ITSRI)

Do Errors in Test Selection and Result Interpretation Adversely Affect Patient Outcome ?

Project leader : Paul Epner

EXAMPLES OF IMPACT - ILLUSTRATION

Error	Classification	Likelihood of Occurrence	Potential Patient Impact
Missing label	Systematic	+++	0
Incorrect Pt ID	Systematic	++	+++
Pt incorrectly reports fasting	No-fault	+	++
Order unnecessary test	Cognitive	++	++
Failure to order necessary test	Cognitive	++	+++

WHAT WE DON'T KNOW – THE ITSRI TASK

- What is the prevalence of cognitive diagnostic errors triggered or impacted by the testing process?
  - Failure to order necessary tests
  - Ordering of unnecessary tests
  - Inappropriate utilization of test results

- What are effective interventions that reduce cognitive diagnostic errors and could be initiated by laboratory professionals?
  - What settings are appropriate for these interventions?
  - What limitations exist in the use of these interventions?
  - What new sources of errors are created by the interventions?

STATUS

- **Unfunded mini-studies**
  - **Vanderbilt**
  - **Emory**
  - **Mayo**
  - **Recruiting additional mini-study sites**

Major problem 5
Limited teaching of laboratory medicine in US medical schools

A project will be performed to collect data from medical schools in the US that reveal :

The amount of instruction on test selection and result interpretation

And

The courses in which such training exists

Project Co-leaders : Brian Smith and John Hickner

Status of Education in Laboratory Medicine in U.S. Medical Schools

Workgroup
January 26 -27, 2011
Sheraton Airport Hotel

Leadership Team

Brian R. Smith, M.D.	Professor & Chair, Laboratory Medicine, Professor of Internal Medicine & Pediatrics, Yale
John Hickner, M.D.	Professor & Chair, Family Medicine, Cleveland Clinic
M. Brownell Anderson, M.Ed.	Senior Director for Educational Affairs, Association of American Medical Colleges
Malek Kamoun, M.D., Ph.D.	Professor of Pathology and Laboratory Medicine, Univ of Pennsylvania
Matthew Stull, M.D.	Education and Research Fellow, American Medical Student Association (AMSA)

What is taught to students becoming physicians in the US?

The limited knowledge of clinicians about how the laboratory functions and how to interpret test results may have arisen because the pathology taught in medical school is predominantly anatomic pathology

To pass, most medical students must know what a heart looks like under the microscope after a heart attack – and not what blood tests are needed to diagnose a heart attack

But no one does a heart biopsy to diagnose a heart attack!

Methods

Goal: Survey all 133 allopathic and 26 osteopathic U.S medical schools

Letter to Deputy Dean for Education, Course Director for Laboratory Medicine & Pathology, accompanied by letter of support from CDC

Recruit one medical student (via AMSA) per school to help complete the survey. Incentive: lottery for 3 iPads for the students (not the faculty)

Analyze survey and subdivide by basic demographics

Methods

Example Questions:

Please indicate whether your medical students receive or may elect to receive Laboratory Medicine instruction in the pre-clinical and/or clinical portions of the curriculum and indicate for each part of the curriculum whether it is required or elective.

Please indicate what disciplines and individuals are involved in your REQUIRED Laboratory Medicine curriculum.

- **Family Medicine physicians**
- **Internal Medicine physicians**
- **Laboratory Medicine/Pathology Physicians**
- **PhD Laboratorians**
- **Pathology Residents/Fellows**
- **Medical Technologists**

Methods

Example Questions:

Does your school periodically have a formal review of the overall laboratory medicine curriculum by a Laboratory Medicine / Pathology physician? Yes/no

Is competency in Clinical Laboratory Medicine formally evaluated as a distinct curriculum component? yes/no

Do one or more of your major teaching hospitals have a Pathology and/or Laboratory Medicine Diagnostic Consult Service that provides verbal and/or written consultations as outlined above? yes/no

If a national standardized examination in clinical laboratory medicine designed for medical students were easily available, how likely is it that your school would use it? very unlikely somewhat unlikely somewhat likely very likely

Results

PENDING ...

Future Directions

Depending on results, consider:

1. **Establish a national resource for instruction**

   (? build on the ACLPS curriculum by refining in conjunction with primary care and specialty physician-educators

2. **Establish a national assessment that Schools can use (e.g., an on-line examination)**

3. **Extend the survey to other health professionals, especially PA's, APRN's**

Major problem 6
Lack of training on clinical consultation during laboratory medicine residency and clinical fellowships

Major goals of this project in the coming months for pathology residents

To collect from educators and residents perceptions about components of training that promote the trainees' ability to provide consultative service in laboratory medicine

To observe resident training activities identified by educators of residents as promoting the trainees' ability to provide consultative service

Project co-leaders : Robert Hoffman and Michael Laposata

Observational Study of Consultative Practice Training in Clinical Pathology Residency

Robert D. Hoffman, MD, PhD

CLIHC™ Face-to-Face

Atlanta, GA, Jan 27, 2011

Design:

- **Goals:**
  - **To study in multiple academic institutions, assess resident training activities identified by the progam as providing education in consultative practice in clinical pathology.**
- **Method:**
  - **Observational study:**
    - **Solicit participation from program directors**
    - **Observe practices identified**

Design:

- **Method:**
  - **14 accredited programs within 300 miles of Nashville, 8 States in Southeast and Midwest**
  - **Email to program directors soliciting participation**
    - **Project in support of a CDC-sponsored work group**
    - **IRB-approved**
    - **No “right” answers**
    - **Looking for practices and barriers to implementation**
    - **Participating sites not to be named in presentations**
  - **Follow-up emails if no response**
  - **Arrange visits to observe training activities**

Results:

- 14 programs contacted
  - 8 responses
    - 5 declined participation
    - 3 site visits
  - 6 non-responders even after follow-up

Some responses from decliners:

- **“You would be surprised to see how little consultation there is.”**
- **“Nothing to show.”**
- **“CP people are not interested in participating.”**
- **“After two requests to CP faculty, no interest in participation.”**
- **“Visit not feasible at this time per department leadership.”**

Conclusions:

- **Good news:**
  - **Some training programs have focal areas of consultative activity that could serve as a model for other programs, if there are committed pathologists to develop and maintain the consultative activity in the institution.**
- **Other news:**
  - **Most programs are not prepared to develop meaningful consultative roles for residents in laboratory medicine, and the limited number of doctoral level laboratory directors to teach the residents is a major contributing factor.**

Education & training in non-M.D. doctoral level laboratory programs

Major goal of this project in the coming year for clinically-based fellowships such as clinical chemistry and clinical microbiology, and clinical laboratory sciences (DCLS) doctoral degree programs

To determine whether training in these programs are focused on largely operational issues in the clinical laboratory or if there is a significant clinical consultative component in the training

Project co-leaders : Elissa Passiment and Michael Laposata

HOW HAS THE CLINICAL LABORATORY CHANGED IN THE PAST SEVERAL DECADES –

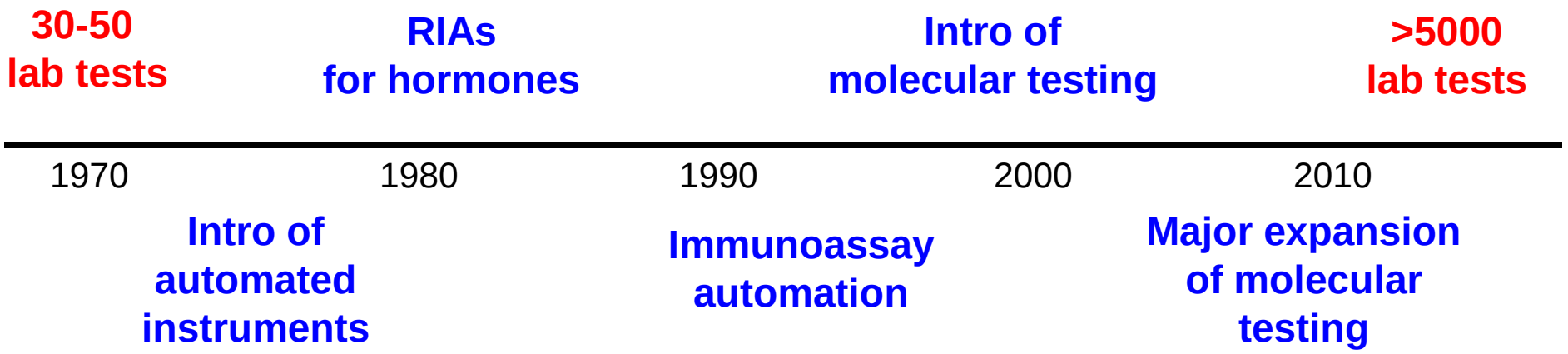
ESPECIALLY IN THE LAST 10 YEARS ?

Clinical Laboratory Testing - 1970

30-50
lab tests

1970 1980 1990 2000 2010

Clinical Laboratory Testing - Today



HOW HAVE THE ROLES OF THE CLINICAL LABORATORY DIRECTORS CHANGED IN THE PAST SEVERAL DECADES –

ESPECIALLY IN THE LAST 10 YEARS ?

Not as much as clinical medicine and the laboratory itself !

Doctors, patients, insurers and administrators understand the clinical value of consultative advice – and professional payment for this has precedence

Few understand the clinical value of laboratory test implementation and validation – and professional payment for this activity is therefore much more challenging

Clinical Laboratory Integration into Healthcare Collaborative™

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  Cleveland Clinic
- **Co-Lead: Michael Laposata, MD, PhD**
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- **Paul Epner, MEd, MBA**
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- **Brian Smith, MD**
  Yale School of Medicine

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  Michigan State University
- **Mitch Scott, PhD**
  Washington University
- **Katherine Kahn, MD**
  Rand Corporation and UCLA

Collaborative Group Support

Altarum

- Kim Bellis
- Beth Costello
- Fabian D'Souza
- Jim Lee
- Dana Loughrey
- Megan Shaheen
- Tom Wilkinson

CDC

Julie Taylor – Leader of CDC Team

- Diane Bosse
- MariBeth Gagnon
- James Peterson
- Anne Pollock
- Pam Thompson

For Additional Information

Please feel free to contact

Julie Taylor at JTaylor1@CDC.gov

for more information about CLIHC™

Specific Issues for Discussion

Directed by Elissa Passiment
and Julie Taylor

Questions for CLIAC

- Are the issues targeted in CLIHC™ projects still relevant for improving laboratory integration into healthcare? Are there other issues the workgroup should consider?
- Are there additional approaches CLIHC™ could consider to improve the clinician's ability to make more appropriate laboratory test selections and result interpretations?
- Are there suggestions for means to implement, disseminate and promote our ideas and solutions to improve patient care?
- Are other groups/organizations doing similar work that might be interested in collaborating with CLIHC™?