CDC Institutes on Critical Issues in Health Laboratory Practice (1984-1995)

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Introduction

During the 1980's and 1990's, CDC convened 5 meetings to build coalitions among stakeholders, to facilitate strategic planning, and to formulate recommendations on various laboratory-related issues. Proceedings of these meetings were subsequently published and disseminated to all participants and others interested in reviewing and implementing these recommendations. These meetings, all entitled "Institute on Critical Issues in Health Laboratory Practice," covered the following areas:

- impact of alternative reimbursement methods on laboratory practice, 1984;
- safety management in the public health laboratory, 1985;
- managing the quality of laboratory test results in a changing health care environment, 1986;
- improving the quality of health management through clinician and laboratorian teamwork, 1989;
- frontiers in laboratory practice research, 1995.

This paper summarizes major recommendations emanating from the deliberations in these meetings except for the one held in 1985. The 1985 meeting was composed of a series of presentations by noted experts in the specialized area of safety management in public health laboratories, and except for question-and-answer sessions, did not involve group techniques in making recommendations.

Methods

Participants were laboratorians, clinicians, diagnostic manufacturers, those involved in laboratory/health care accreditation and regulatory issues, administrators and policy makers, and health systems researchers and educators. The number of participants were as follows:

- 1984 Institute, 60;
- 1986 Institute, 120;
- 1989 Institute, 122;
- 1995 Institute, 227.

Recommendations resulted from presentations by invited experts, nominal group techniques, and break-out workshops involving all participants. The institutes took into account biases of specific groups by bringing together different entities involved in health care delivery systems.

Conclusions

Given the evolving nature of laboratory medicine, these institutes delineated thoughtful strategic directions, built coalitions among stakeholders, and made useful recommendations for future laboratory practice research and quality improvement efforts — some of which have begun to be implemented.

Institute Recommendations

1984 (Cost Containment)

- Revise quality assurance practices to improve cost-effectiveness while maintaining quality.
- Encourage certifying, regulatory and accrediting agencies to ensure that all providers of laboratory services … meet uniform standards of quality.
- Establish, improve and maintain educational programs for health laboratory professionals, clinicians, patients and regulators.
- Establish a coordinated national data bank on laboratory services and practices, and standardize systems for data collection.
- Expand and improve the consultative role of the laboratory to improve test selection, interpretation and utilization.
- Evaluate changing needs of laboratory organizations and settings.
- Encourage the development of innovative, cost-saving technologies and ways to assess their reliability.
- Explore alternative payment mechanisms for laboratory services and funding sources for research, development and education.
- Develop and implement studies to evaluate the cause and effect relationships of contemporary factors which impact health status. The studies should include preventive health testing, environmental health testing, long-term risk factors and causes of death studies.
- Improve communication and collaboration among laboratorians, health care administrators, clinicians, and policy makers.

1986 (Quality Management)

Total quality management
- Adapt an industrial/service model of total quality management (TQM) to the medical laboratory field.
- Design TQM systems for all types of health laboratories using new philosophy, management procedures and tools. Turn the emphasis from monitoring and correcting to prevention of errors and defects.

Interfaces within health laboratory practice
- Direct attention towards interfaces within health laboratory practice where most of the quality failures occur.
- Devise better approaches for improving communications between groups, and especially between laboratorians and clinicians, in the health laboratory.

Goal setting
- Determine what level of quality is needed in non-traditional, non-regulated testing sites and how these sites can be monitored.
- Define accuracy and precision necessary for clinical utility.

Testing methodology
- Define the responsibility of the laboratory industry to provide "foolproof" kits and devices for use by untrained personnel or the public.
- Apply more effective methods of technology assessment to new tests and procedures, equipment and reagent systems.

Quantitative data for non-analytical stages of testing
- Provide quantitative data for quality assurance schemes in non-analytical stages of the total testing process. Determine how cost-containment initiatives will affect the maintenance of laboratory quality assurance.

Standards and educational requirements
- Revise and coordinate laboratory regulatory standards and programs as well as educational requirements for personnel certification.

1989 (Quality Improvement)

Develop goals for each of the steps in the total testing process:

- Formulating the clinical question- Select a test or test system that has the discriminatory power to extract from the differential diagnoses the correct diagnosis of the patient's condition.
- Collecting the specimen and managing the sample- Provide for the proper collection, labeling, transportation, and storage of specimens.
- Selecting, implementing and integrating technology and methodology- Select and implement techniques and methodologies capable of providing test results with the quality required by the test user. Analyze the sample accurately.
- Validating and reporting the results- Generate a test report that accurately communicates the test results and all pertinent patient and test information for the correct interpretation by the test user.
- Interpreting and applying the results for the patient- Extract and accurately interpret from the laboratory report the test result, patient and test information, and assimilate and apply that knowledge for the benefit of the patient.

Ask the following questions before any test:

- What are the risks and benefits of testing?
- Whom and how should I test?
- Is the disease manageable?
- What are the likelihoods and consequences of false positive and false negative tests?
- Are there better (and more cost-effective) tests available that can provide the information the clinician needs?
- What information is needed to assess the best testing algorithms or methodologies for answering the clinical question?

1995 (Research Frontiers)

Proficiency testing
- Pursue multi-programmatic characterization of laboratory performance and reconstruct current proficiency testing models.

Personnel
- Include pre- and post-analytical factors in the assessment of personnel competencies.
- Determine personnel characteristics and behaviors contributing to value-added patient care.

Quality assurance
- Address the total testing process in research studies directed to quality improvement.
- Address the parts of the total testing process where a decrease in errors will produce the greatest impact on patient care.
- Link quality assurance activities to patient outcome.

Establishing analytical performance goals
- Develop methods for determining analytical goals for qualitative tests.
- Seek a consensus on how to design and conduct clinical trials.

Establishing medically relevant performance goals
- Reduce clinical judgement errors and enhance informational content of laboratory reports by re-designing them.
- Define laboratory goals by assessing if a change in laboratory performance is associated with a change in patient outcome.
- Better understand the impact of laboratory results on medical decision.
- Identify biases in test evaluations to prevent errors in decision making.

Detection of problems affecting patient outcome
- Focus research on medical conditions that require high volume testing, need expensive tests, and that are prevalent and have significant morbidity where interventions may have some impact.
- Work on uniform, standardized datasets that combine laboratory testing data, clinical information, and (prospectively collected) health care utilization measures.

Laboratory focused health systems research
- Develop data dictionaries to standardize data management so that information collected over space and time are comparable.
- Increase research in standardization of data codes, particularly a Universal Patient Identifier uniquely identifying a patient across all health care systems.

Impact of change on laboratory testing
- Collect data over time on the number and type of personnel, test locations, inventory of tests performed and their volumes, turnaround times, and tests referred from one laboratory to another.