The Clinical Laboratory Is an Integral Component to Health Care Delivery

An Expanded Representation of the Total Testing Process

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ABSTRACT

Objectives: Developing an expanded representation of the total testing process that includes contemporary elements of laboratory practice can be useful to understanding and optimizing testing workflows across clinical laboratory and patient care settings.

Methods: Published literature and meeting reports were used by the coauthors to inform the development of the expanded representation of the total testing process and relevant examples describing its uses.

Results: A visual representation of the total testing process was developed and contextualized to patient care scenarios using a number of examples covering the detection of blood culture contamination, use of next-generation sequencing, and pharmacogenetic testing.

Conclusions: The expanded representation of the total testing process can serve as a model and framework to document and improve the use of clinical testing within the broader context of health care delivery. This representation recognizes increased engagement among clinical laboratory professionals with patients and other health care providers as essential to making informed decisions. The increasing use of data is highlighted as important to ensuring quality, appropriate test utilization, and sustaining an efficient workflow across clinical laboratory and patient care settings. Maintaining a properly resourced and competent workforce is also featured as an essential component to the testing process.

INTRODUCTION

The initial conceptualization of the total testing process (TTP) as the "brain-to-brain" loop emphasized the complexity and vulnerability of the testing process.[1] Over time, the concept of the TTP advanced to include new paradigms in laboratory medicine as practitioners increasingly recognized the need for a systems approach in understanding and reacting to challenges in achieving accurate and timely test results of greatest benefit to patients.[2,3]

KEY POINTS

- This report provides an expanded representation and description of the total testing process useful for documenting and improving clinical test workflows across laboratory and patient care settings.
- Important attributes include engagement of laboratory professionals with patients and other health care providers, use of data to drive practice, and maintaining a competent workforce.
- Examples illustrate how the total testing process can be used to understand and optimize laboratory practices to support patient and health care provider informed decision-making.

KEY WORDS

Total testing process; Clinical laboratory; Laboratory medicine

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This approach includes the means to identify and classify errors across the testing workflow that can result in patient harm.[3] We present an expanded representation of the TTP that takes into consideration elements of the testing process less emphasized in earlier renditions but now recognized as significant elements of the testing process FIGURE 1. These additional elements include

- collaboration among laboratory professionals, health care professionals, and patients;
- the use of data that support various steps of the testing process;
- a competent workforce; and
- resources needed to operationalize and maintain testing services.

This expanded TTP representation has several applications. It could be adapted and used to describe testing services within a health care setting. Practitioners could also use the framework to develop a quality management plan, taking into consideration TTP vulnerabilities. The expanded representation may also inform evaluation of testing services to identify gaps and opportunities for improvement. For example, challenges can arise when new technologies are implemented into the clinical laboratory workflow that require new competencies and quality practices. Such challenges and potential solutions were discussed during past meetings of the Clinical Laboratory Improvement Advisory Committee (CLIAC), a federal advisory committee that provides scientific and technical recommendations

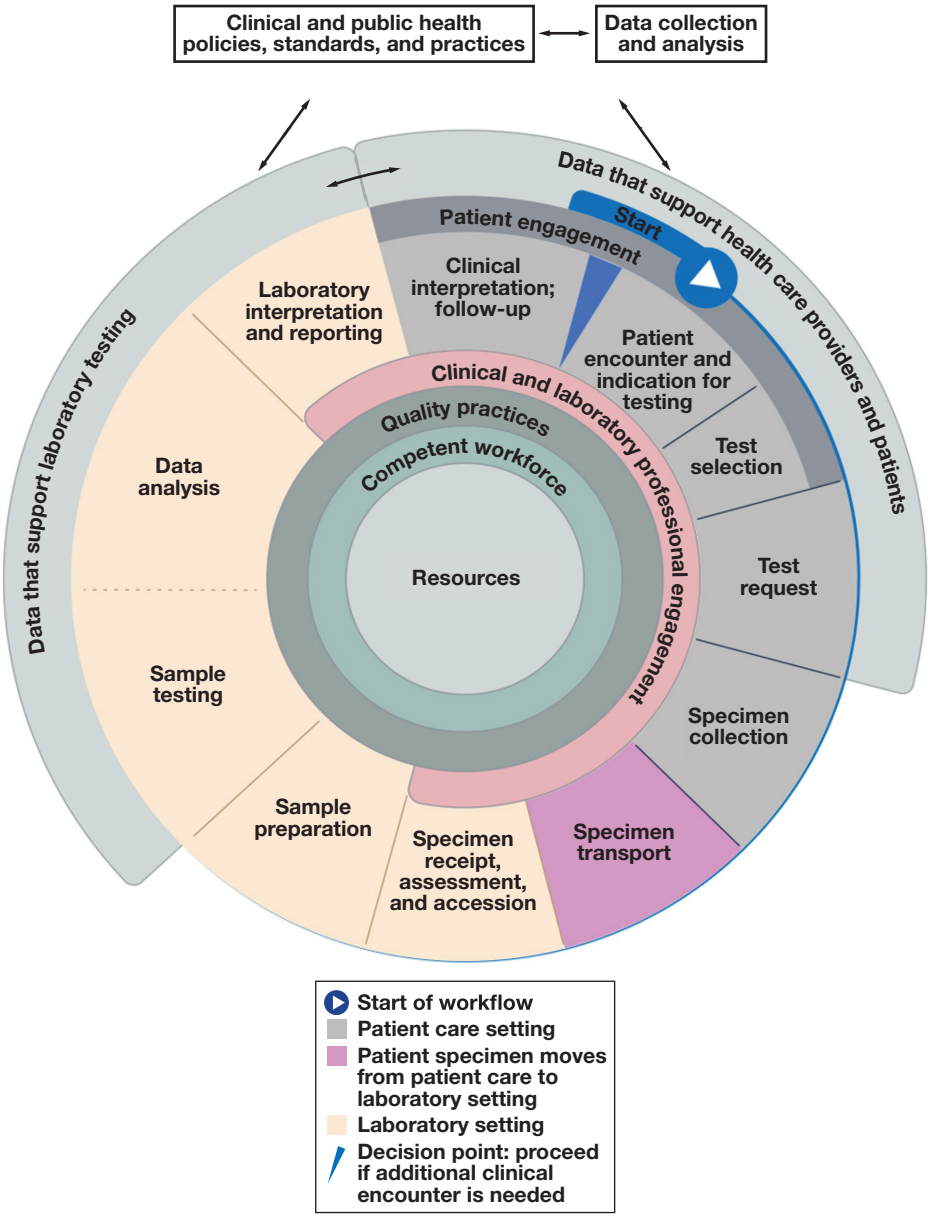

FIGURE 1 The expanded representation of the total testing process (TTP). This expanded representation of the TTP specifies 11 steps that are supported by the application of data, quality practices, a competent workforce, and engagement among the patient, laboratory, and health care professionals.

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to the Department of Health and Human Services (https://www.cdc.gov/cliac/docs/april-2022/CLIAC_RecommendationsTable_Apr2022.pdf).

AN EXPANDED REPRESENTATION OF THE TOTAL TESTING PROCESS

The expanded representation of the TTP illustrates the testing workflow, supportive elements, and interactions among patients, clinicians, and laboratory professionals FIGURE 1. Moving from inner to outer full circle, elements include the following:

- **Resources**
  - Physical infrastructure (eg, facility, equipment)
  - Business processes (eg, administrative, financial)
  - Data access and analytic capacity, including access to various data sources (eg, patient information, disease-specific databases, test performance indicators, algorithms to analyze test results and inform clinical assertions)
  - Practice resources (eg, guidelines/standards, regulatory requirements, educational/training resources, listservs of professional organizations)

- **Competent workforce.** Personnel inside and outside the laboratory involved in the development, implementation, validation, and use of clinical testing that meets accepted standards of practice.
- **Quality practices.** Activities implemented to ensure quality testing (eg, quality management systems, operationalizing policies and professional guidance, other quality practices).
- **Steps of the expanded representation of the total testing process.** Eleven steps specified in the full outer circle FIGURE 1; these steps were described previously.[1-3]

Other entries within the expanded representation of the TTP include the following:

- **Clinical and laboratory professional engagement.** Interactions primarily supporting "Laboratory Interpretation and Reporting," "Clinical Interpretation; Follow-up," and "Test Selection." These steps of the TTP provide opportunities for collaboration between clinician and laboratory professionals to ensure that the right test is ordered, and results are appropriately communicated, understood, and applied within the patient context.
- **Patient engagement.** Effective communication with the patient about the uses and limitations of tests and results that support informed decision-making.
- **Data and information that support health care providers, patients, and laboratory testing.** Data drive the testing process at several levels, informing
  - test selection,
  - specimen selection,
  - analysis of the results,
  - clinically meaningful decision-making, and
  - analytic and clinical performance and improvement.

- **Data collection and analysis, and clinical and public health policies, standards, and practices.** These two elements represent efforts to collect patient and laboratory data across practice settings to advance the development of evidence-based testing practices.

Sometimes, elements of clinical laboratory testing are performed outside the confines of a laboratory or medical facility. The expanded TTP can be adapted to these situations. Examples include the following:

- **Point-of-care testing.** Point-of-care testing (POCT) is performed at or near the site of patient care, not within a central laboratory, and is intended to provide more rapid return of test results that can lead to a change in medical management.[4,5] These tests can be offered bedside within a hospital, doctor's office, nursing home, and other settings. As such, POCT modifies the TTP workflow by eliminating the need to send the patient specimen to a clinical laboratory. In addition, POCT testing requires changes to the system by which test results are entered into the electronic health record since they are not generated by a central laboratory.[6] The person performing the test assumes responsibility for ensuring the quality of testing. In some instances, complying with the manufacturer's instructions is sufficient, whereas in other instances, additional guidance is needed. This is the case for POCT blood glucose monitoring, in which guidance has been developed that provides additional considerations for specimen collection, test performance, and interpretation.[7] In some hospital settings and health care systems, less so for independent physician offices, point-of-care managers are available to provide oversight, staff training, and ensure the quality of POCT.[8]
- **Telehealth.** Telehealth provides the opportunity for the patient to interact with medical professionals remotely using telecommunication technology.[9,10] When clinical testing is needed, patient specimens can be obtained at a local specimen collection site, by a health care worker who visits the patient, or by self-collection and shipment to the processing laboratory. While the TTP workflow essentially remains the same, access and use of telehealth services, which include associated testing, can be challenging, especially for patients who live in minority, rural, and medically underserved communities and where English proficiency, digital literacy, or health literacy is an issue.[11]
- **Direct-to-consumer testing.** Direct-to-consumer (DTC) tests are marketed and sold directly to customers typically without the involvement of a health care professional.[12,13] Results are returned to the client with or without a clinical interpretation that takes the patient's medical history into account. Customer access to health

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care professionals may or may not be offered or available from the company selling the test. Although DTC testing may eventually be combined with traditional modes of health care delivery, several challenges have been cited that can also be described in terms of the TTP workflow.[14] For example, there is a general absence of health professional engagement to help the customers understand the uses and limitations of the test and result, especially when other resources are limited. In addition, limitations exist to ensure quality practices associated with specimen collection, sample processing, shipping, and test performance, where applicable. Systematic means are also lacking to ensure appropriate test utilization and to monitor the use of DTC testing to determine their health impact for individual users and the broader population.

- **Nontraditional testing workflow.** Nontraditional testing workflow is a relatively new paradigm in laboratory practice that occurs when steps of the total testing process, normally performed within a single setting, are conducted at different locations, often under independent management. (See April 19 CLIAC summary, Appendices 8 and 8a, available at https://www.cdc.gov/cliac/docs/summary/CLIAC_SUMMARY_APRIL2019.pdf) Practitioners have expressed concern regarding the quality and continuity of this type of testing process. While the TTP workflow essentially remains unchanged, concerns were raised regarding who takes ownership for the overall quality and timely continuity of the testing process.

EXAMPLES THAT ILLUSTRATE THE USE OF THE EXPANDED TTP REPRESENTATION

Example 1: Laboratory Testing, Addressing Blood Culture Contamination

Blood cultures are the gold standard in the diagnosis of bacteremia and the timely and appropriate decision to initiate antimicrobial therapy that can save lives. Blood culture contamination, on the other hand, can cause a false positive that can result in a practitioner prescribing antibiotics for an infection that does not exist.[15] The risk of blood culture contamination is highest during specimen collection and blood culture bottle inoculation. The clinical laboratory is responsible for providing instructions regarding proper specimen collection procedures to those who draw and process the patient specimen and arrange for transport to the clinical laboratory. This example emphasizes several elements of the TTP that include specimen collection and preparation, testing, and engagement of laboratory and patient care professionals.

Procedures for specimen collection, detection, and reporting of blood culture contamination are codified in regulatory and accreditation processes and otherwise described in professional guidance.[16,17] Suboptimal collection volumes and blood culture contamination rates can be reported back to units where the samples were collected. This information can, in turn, be used to assess and modify blood culture collection practices to reduce blood culture contamination. Current guidance recommends these rates be no higher than 3%, and when best practices are followed, a target contamination rate of 1% is achievable.[16]

This example also illustrates the need for laboratory professionals to work with physicians, nurses, and others in the patient care setting to ensure proper specimen collection and bottle inoculation steps are followed. Blood culture collection and bottle inoculation can be optimized by working with an antimicrobial stewardship program that follows a team-based approach to ensure appropriate utilization of antimicrobials.[15] Antimicrobial stewardship teams are now required by the Centers for Medicare & Medicaid Services to be active in hospitals and other health care settings.[18] The team often includes infectious disease physicians, nursing managers, pharmacists, laboratory professionals, and infection control and prevention staff. These teams can foster quality improvement (QA) practices that minimize blood culture contamination and make sure that an adequate volume of blood is drawn to accurately diagnose bacteremia. Both of these QA practices can support appropriate antibiotic use. The expanded TTP offers these teams a framework for identifying steps of the testing process that can be subject to quality improvement efforts relevant to detecting and reporting blood culture contamination. These steps include test selection, specimen collection and transport, laboratory interpretation, and results reporting.

Example 2: Next-Generation Sequencing

An increasing number of clinical laboratories use next-generation sequencing (NGS), which poses novel challenges across the TTP.[19] This example focuses on elements of the TTP that cover engagement of clinical and laboratory professionals, including patient involvement, optimization of the test method, and data that support laboratory testing and the timeliness of decisions made by clinicians and patients.

The NGS analysis of a patient sample is typically a 2-step process.[19] The first step is the laboratory analysis of the patient sample to produce a set of sequence reads. The second step is entirely computational and is designed to produce contiguous nucleotide sequences from the set of sequence reads. Additional computational analysis is then used to identify and classify any clinically relevant features.

The decision to use NGS is often predicated on the need to interrogate multiple genes or discriminate among pathogens. This element of test selection and ordering optimally includes knowledge sharing among the patient, clinician, and laboratory professional. Knowledge sharing assists the patient in making an informed decision regarding whether to proceed with testing. Secondary findings of clinical relevance, independent of the indication for testing, may also be found using NGS, and how these findings are handled requires attention from the patient, clinician, and laboratory professional.[20] Similarly, when results are reported, correlating sequence findings with the needs of the patient often requires specialized expertise to place the uses and limitations of the test in the proper clinical context.[21]

As of 2022, many NGS tests were developed and operationalized as laboratory-developed tests within the clinical laboratory, not otherwise purchased or available as a test system. The design, validation, and use of NGS tests requires informatics expertise to ensure

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the computational phase of testing described above produces reliable results. Professional and regulatory guidance are available that support the quality and application of NGS clinical testing.[22-24]

Data external to those derived from the testing process are essential in deriving a clinically relevant test result.[25-27] For example, the ClinVar database provides information that supports clinical assertions as to whether variants are benign, pathologic, or of unknown significance.[28] This correlates to the outer partial rings of the expanded TTP that support both laboratory testing and decisions made by health care providers and patients. This also reinforces the need for a workforce competent to use data appropriately in deriving a clinically relevant test result and interpretation of that result.

Example 3: Precision Medicine and Pharmacogenetic Testing

Next-generation sequencing and other genetic tests are a primary driver for precision or "personalized" medicine, defined as "an innovative approach that uses information about an individual's genomic, environmental, and lifestyle to guide decisions related to their medical management" (see https://www.genome.gov/genetics-glossary/Precision-Medicine).

Pharmacogenetic tests inform drug selection and dosages appropriate for a given patient. The US Food and Drug Administration recognizes more than 60 pharmacogenetic associations for which data support therapeutic management recommendations (see https://www.fda.gov/medical-devices/precision-medicine/table-pharmacogenetic-associations). Examples include the tests that inform the use of clopidogrel to reduce the risk of blood clots following stent placement and warfarin to identify patients at high risk for major bleeds.[29] The pharmacogenetic repertoire of an individual is highly dependent on their ancestry. As of 2022, our knowledge of clinically relevant pharmacogenetic variants is greatest for persons of European descent because this population was the focus for most of published studies. In turn, available pharmacogenetic testing is most applicable to these patients. Because less data are available for persons of non-European ancestral backgrounds, it can be challenging to detect clinically important pharmacogenetic genotypes in these patients.[30]

Pharmacogenetic testing provides an example of the interplay among steps of the TTP, particularly test selection, sample testing, interpretation, and reporting. This is especially relevant to arriving at a test result that is analytically accurate and informative. For example, P450 2D6 is an enzyme, coded by the *CYP2D6* gene, that influences the metabolism of a variety of clinically important drugs.[31] The *CYP2D6* gene is highly polymorphic, with sequence variations accounting for differences in drug metabolizer status. Incorrect polymorphic *CYP2D6* assignments among several laboratories, documented through proficiency testing surveys offered by the College of American Pathologists, raised patient safety concerns related to drug choice and dosing based on test findings.[32] These errors have been attributed to differences in test design, particularly with respect to what genotypes are detectable by a given method. To address these shortcomings, international workgroups developed recommendations for advancing the uniformity of pharmacogenetic test methods and result reporting.[33,34] Collaboration between laboratory and patient care professionals is essential in applying these and future guidance to inform clinical decisions regarding pharmacogenetic testing.

CONCLUSIONS

The TTP provides a model for clinical testing that considers both laboratory and patient care processes. This expanded TTP model specifies testing processes that have evolved over time to include broader engagement with the health care system and the increasing use of data to inform evidence-based decisions. This model also recognizes the vital role of laboratory professionals in leveraging their expertise for developing tests applicable to target populations and sharing specialized knowledge with patients and other health care professionals to support informed clinical and personal health care decision-making.

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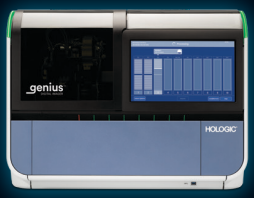

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