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Utilization management in the core laboratory

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ABSTRACT

The need for appropriate utilization management of diagnostic testing is increasingly important. The majority of laboratory tests are performed in highly automated core laboratories that combine chemistry, immunoassays, hematology, coagulation and esoteric assays. These core laboratories are designed for high throughput leveraging economies of scale to produce large numbers of test results relatively inexpensively. Most core laboratory tests can be categorized based on whether they should or should not be ordered at all and, if so, by the frequency with which test ordering is reasonably appropriate (e.g. unrestricted, daily, weekly, monthly, yearly or once in a lifetime). Classifying tests by this approach facilitates electronic rule-based logic to detect which tests are appropriate for a given clinical indication.

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1. Introduction

Core laboratories are formed to take advantage of the ability to perform a large volume of tests at the lowest possible cost ("economies of scale" [1]). A core laboratory is a "mass production facility" whose raison d'être is to provide high throughput quality laboratory testing. Implicit in maintaining high throughput and high productivity is the expectation laboratory tests are ordered appropriately. The time needed to review individual test orders for clinical appropriateness reduces throughput, efficiency and thereby cost-effectiveness.

Yet we all know that laboratory tests are often not ordered appropriately. The near-instant gratification of rapid test results often encourages more testing as clinicians want earlier detection of biological changes for which timely treatment can be implemented.

As core laboratories continue to evolve and improve efficiency, there is less incentive for the core laboratory to reduce testing. The reward structure for a core laboratory is the exact opposite of that for controlling test utilization. Test utilization is rewarded by reducing unnecessary testing and associated costs. At some reduced level of testing, budgets are permanently reduced, staff positions may be eliminated and managerial positions reduced because of fewer staff to supervise. In contrast, increased core laboratory test volume maximizes cost effectiveness and justifies increased resources (personnel, instrumentation, reagents, etc.). Budgets are increased to match the increased test volumes, responsibilities for laboratory supervisors and managers are expanded, often with corresponding promotions and salary increases. These diametrically opposed reward systems create a natural tension between laboratory medicine principles of appropriate test utilization and laboratory management principles of cost-effectiveness [2].

2. How did core laboratories evolve?

Much of the literature on core laboratories is published in non-peer-reviewed laboratory management journals (examples in references [3–5]), likely because they originated from operational needs instead of scientific discovery.

3. What is the reason for core laboratories?

Core laboratories can trace their origins from the "make versus buy" analysis [6,7]. In brief, if a laboratory provides a certain test menu, the "fixed" cost of testing (e.g., instrumentation, quality control, personnel, rent, electricity, plumbing, and heating) has already been incurred. If the testing capacity is not maximized, there is "waste" related to idle instruments and personnel. Additional testing can be leveraged off the existing idle infrastructure (instrument, personnel) with each additional test adding only a marginal cost (i.e., reagent cost only). It is to the laboratory's financial advantage to best match the total test volume to total testing capacity to maximize cost-effectiveness.

4. How much time should testing take in a core laboratory?

Rapid test turnaround time is inferred from the core laboratory "economies of scale". Expectations for when a result should be available can be set by applying Lean methodology [8]. "Takt" time is the Lean term given to the expected rate at which a service (a test result) can be provided [8]. Through repeated observation and refinement of internal testing processes, waste is identified, "standard work" is developed

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and a standardized "cycle time" for the total test process determined [9]. For a core laboratory, a standardized "cycle time" sets the expectation that specific laboratory results will be available within a specific time after specimen receipt.

It is important to remember that takt time includes time needed for planned or unplanned non-productive matters — e.g., staff meetings, unanticipated instrument malfunctions, and information system "downtimes" [9]. In other words, the testing process itself is only a subset of total "takt time". A common practice is to set takt time at 80% productivity to accommodate equally important issues not measured by productivity. This is intentional to accommodate known critical non-testing tasks and unforeseen problems while maintaining a realistic and cost-effective level of productivity. Takt time is also useful for assessing current testing capacity and determining when new "fixed" costs must be incurred (i.e., new instrument and testing personnel needed because test volume exceeds existing capacity). All laboratories, including core laboratories, benefit from regular periodic takt time assessment and monitoring.

4.1. Technology

Technology has been pivotal for maximizing core laboratory effectiveness. The parallel emergence of total laboratory automation and autoverification encompassing the total test process (pre-analytical, analytical and post-analytical phases) have been major advances [10,11]. Automated instruments of different traditional Laboratory Medicine specialties (e.g., Chemistry, Hematology, Urinalysis, Immunology, Microbiology, and Blood Bank) are now co-located for efficient automated specimen receipt, processing and delivery to testing stations. Autoverification releases results as soon as available from the primary testing instrument if the results meet acceptable criteria.

These technology advances have reduced the need for highly specialized and skilled laboratory personnel to perform manual testing. This is fortunate given the growing concerns related to the "mature" Clinical Laboratory Scientist (CLS) workforce and predicted "wave" of impending retirements [12]. The short term needs of the clinical laboratory have shifted from CLSs technically skilled at performing tests to those facile with information systems and interfaces.

Some of the current core laboratory technologies have simply automated existing test methods. For example, many automated chemistry or immunology tests use the same underlying chemical reactions and endpoint detection as historical manual methods. In contrast, other automated tests have completely replaced prior test methodology. This transformation has been most marked in the Clinical Microbiology laboratory with the transformation of culture-based methods to "culture independent" test methods, many of which are based on molecular nucleic acid amplification methods (e.g., detection methicillin resistant *Staphylococcus aureus*, Group B *Streptococcus*, *Chlamydia trachomatis*, *Neisseria gonorrhea*, and Herpes simplex virus).

5. What tests are suitable for a core laboratory?

This depends on where the core laboratory is situated. If located within or contiguous to a clinical facility, a core laboratory will contain automation performing tests of high volume and requiring rapid turnaround time. Many laboratories have created internal "core" laboratories à la the Toyota Production "cell" concept [13] with breathtaking reductions in takt times and labor. The testing disciplines commonly included in these core laboratories are automated chemistry, hematology, coagulation and urinalysis.

5.1. Specimen transportation is important

If the core laboratory is located "remote" from the clinical laboratory, the major consideration becomes the clinically acceptable test turnaround time (TAT). "Remote" can be a few floors away from the main clinical laboratory or "stat" satellite laboratories, on the same campus but in a different building, city blocks or miles away. In large national healthcare systems, a "remote" core laboratory can be in a different state. Regardless of the distance, specimen transportation becomes very important because testing can begin only after the specimen has been received [14]. If rapid real-time transport is available to the core laboratory (e.g., pneumatic tube), the physical distance is not relevant and the "remote" core laboratory functions essentially the same as a core laboratory embedded within the Clinical Laboratory. In contrast, core laboratories relying on specimen transportation via courier usually means that only those tests for which a TAT $\geq$ 24 h for results is clinically acceptable can be considered to be moved from a local healthcare setting into a core laboratory.

Culture-based Clinical Microbiology testing is commonly considered as the typical turnaround time (TAT) for results is measured in days. Consolidating microbiology personnel from multiple disparate locations within a single core laboratory often has the advantage of placing sufficient personnel in the aggregate to reliably staff multiple shifts, often 24 h daily, with the added benefit of shorter takt times than would be possible in a single minimally staffed microbiology laboratory [15].

Esoteric testing for which a result TAT of >24 h is clinically acceptable is also commonly considered for relocation into a core laboratory. If a remote core laboratory serves multiple healthcare locations (e.g., hospital, clinic, physician offices) and each individual location has insufficient esoteric test volume to justify testing locally, economies of scale and shorter takt times can be achieved by relocating and consolidating the aggregate test volume within a core laboratory.

5.2. Laboratory Medicine and the core laboratory

The Laboratory Medicine subspecialist was historically intimately involved in the day to day oversight of subspecialty testing. When subspecialty testing was relocated to a core laboratory and if the core laboratory was in a different location than the subspecialty laboratory, this disconnected the subspecialist from the testing location. This did not diminish the need for subspecialty clinical expertise, however. It just created a different workflow for the subspecialist.

For example, consider the clinical microbiology laboratory and its current transformation to culture-independent molecular technology. If molecular testing is performed in a core laboratory, the clinical microbiologist is usually not involved in the details of day to day testing. Routine tasks of quality control, quality assurance, instrument maintenance, information system issues, etc. are typically managed by a core laboratory on-site technical specialist. Maintenance of these quality systems is expected, because the clinical subspecialist expects results to be accurate. As testing is completed, the clinical microbiologist located remotely may be referred unusual results for follow-up with the ordering clinician. Even if remote from the testing location, the clinical microbiologist remains central to the post-analytical process. Clinical Microbiology knowledge is required to discuss test performance with the ordering clinician (e.g., sensitivity, specificity – analytical and clinical, predictive values and likelihood ratios – positive and negative) and Laboratory Medicine knowledge is required to guide the clinician through applying and interpreting the test result for the individual patient ("personalized medicine"). The clinical microbiologist has to educate the clinician on the clinical utility of a result detecting only an organism's nucleic acid and not viability, often in the absence of pathogen or residual "normal flora" ("residual bacterial community" [16]) quantification. The clinical microbiologist has to maintain clinical information flow to public health agencies for epidemiological purposes. And the clinical microbiologist must help problem solve the evolving dilemma of assessing pathogen antimicrobial susceptibilities over time when viable organisms are no longer available [17,18].

The historical Laboratory Medicine subspecialist's clinical consultation role thus remains of utmost if not increased importance [2]. With core laboratories performing subspecialty testing remotely, interpersonal

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