How to evaluate and implement new technologies in an era of managed care and cost containment

DAVID D. KOCH

New technologies often enable clinical laboratorians to overcome the challenges we face. These technologies sometimes become available with amazing punctuality, addressing recent problems and keeping the physician-customer satisfied for another day. Traditionally, developments such as a new cancer marker have been implemented into routine use with little circumspection because the benefits diagnostically and financially were perceived to far outweigh the risk that the new test or technology was not as effective as described. The notion of subsequently removing older tests inferior to the new one has hardly been considered. The challenges confronting clinical laboratorians today, however, are affecting that typical pattern dramatically. Four of the most pervasive challenges are comprehensively examined in the 1995 Clinical Chemistry Forum. One of these key areas—the proper implementation of modern technology in the form of new tests or new approaches to producing clinical laboratory results—is the main topic of this review.

INDEXING TERMS: laboratory management • diagnostic performance • technology assessment • method evaluation

Nearly everyone in the clinical laboratory profession has at one time or another solved a problem by developing and (or) using new technology. The history of clinical laboratory science is replete with examples of problems being conquered through new technologies [1-4]. Implementing these service improvements was a fairly simple matter in years past. All it took was the perception that the benefits outweighed the risks. Often this perception was correct: A new test provided more accurate diagnoses, a new instrument enhanced productivity, a marker for rejection improved transplant survival, more tests led to increased reimbursement, and so on.

The unique mix of challenges confronting clinical laboratorians today causes wonder about whether advancing technolo-

gies will continue to provide similar benefits as before. Implementation of new technology in today’s marketplace is significantly influenced by two other topics of the Forum:

1) Regulatory pressures affect the development of new technology as never before. Statutes such as the complexity level designation described in the 1988 Clinical Laboratory Improvement Amendments (CLIA) [5] steer diagnostics manufacturers to design features into their products that ensure a “moderate complexity” or “waived” classification and the personnel flexibility for their customer that results [6]. A backlog in the Food and Drug Administration (FDA) in vitro diagnostic device approval process affects the diagnostics industry in the US with uncustomed delays, meaning new developments are not able to reach the US market in the same timely manner as in the past [7]. Some of these companies have therefore decided to launch their new products in other countries [8].

2) Financial pressures exacerbate the burden on manufacturers and make it tougher for the end-user to take advantage of the new technologies. Fierce economic constraints on all of healthcare apply equally to laboratories [9]. These fiscal factors cannot be escaped and are generating various trends in response that affect healthcare in general [10] and laboratories in particular [11].

Other significant challenges, such as ever-increasing physician expectations and the need to enhance the information content of laboratory data, intensify pressure on clinical laboratories. Will new technology continue to provide solutions to today’s problems? It is a fair question. The goal of this paper is to pull together current thinking about how new clinical laboratory technologies can and should be chosen, evaluated, and implemented in an era of cost containment. First, three issues will be explored to build a foundation for this goal: (a) What tasks are expected of clinical laboratories today? (b) What do physicians require of the laboratory, and have these requirements changed because of regulatory and financial pressures? (c) What resources are available to clinical laboratories to meet these demands? Then two questions pertinent to the goal will be addressed: (d) What steps are needed in choosing and evaluating a new technology? (e) How can new technologies be justified and implemented today in the face of regulatory burdens and economic constraints? By equipping ourselves with answers to these five questions, we as clinical laboratorians will underscore our value

Department of Pathology & Laboratory Medicine, Clinical Chemistry Laboratory, University Hospital & Clinics, University of Wisconsin, Madison, WI. Fax 608-263-0910; e-mail dd.koch@uwmsg.hosp.wisc.edu.

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Table 1. Expectations of clinical laboratories.

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<th>Task</th>
<th>From physicians (&quot;providers&quot;)</th>
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<tr>
<td>Respond to all requests for service as quickly as possible</td>
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<tr>
<td>Never make a mistake</td>
<td></td>
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<tr>
<td>From administrators and payors</td>
<td>Ensure that reimbursements exceed expenses</td>
</tr>
<tr>
<td>Provide an excellent product at a low cost</td>
<td></td>
</tr>
<tr>
<td>From regulators</td>
<td>Fulfill all federal and state regulations</td>
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Table 2. What physicians need from the clinical laboratory.

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<th>Trustworthiness</th>
<th>Precision</th>
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<tr>
<td>Timeliness</td>
<td>Guidance about proper utilization</td>
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<td>Analytical accuracy</td>
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Table 1 catalogs some of the main customers of clinical laboratories and a simplified list of their expectations. Physicians and other providers are our primary clients. The reasons why they order our services haven't changed very much over the years and include case-finding in individuals, monitoring a patient's condition, establishing a prognosis, and following therapy. Other less justifiable but real explanations include their own innate curiosity, defensiveness, and habit, along with a "placebo effect" whereby the patient may feel better if testing is done. Whatever the reason, and almost no matter what the test, providers want the result quickly. The laboratory industry has, of course, fueled this aspiration by providing rapid turnaround for many procedures, which physicians then come to expect from most laboratory services. Physicians also count on laboratories to never make mistakes, at least not ones that affect the medical usefulness of the result. Laboratory professionals need not be troubled over this daunting challenge, however, as long as they remember that perfect laboratory tests do not exist. We should strive to satisfy these provider expectations, but also be vigilant in our educational efforts concerning such subjects as the reality of overlap between healthy and diseased populations and the effect of prevalence of disease on the predictive value of a positive test result in case-finding and screening situations.

Because of the paramount position of healthcare providers to laboratories, it is worthwhile to stop at this point and review just what they require from the clinical laboratory. A feasible list appears in Table 2. Perhaps foremost, laboratories must provide trustworthiness. If trust between the laboratory and physician breaks down, a great deal of effort will need to be expended. Maintaining trust from your provider-customers is a lot cheaper than trying to regain or establish it. Physicians will convey lack of trust to patients, their families, and hospital administrators. Patient care may suffer, costs may rise because of additional testing being requested simply to check previous work, administrators may become concerned with higher costs; consequently, the laboratory places itself at risk of losing its function in the healthcare provided by its institution. Second on the list is timeliness, already discussed above. Physicians articulate this need to laboratories more vigorously than other necessities, especially in the mid-1990s. Next come accuracy and precision, which have been important traditionally and must be preserved. With the resources available today, there are no excuses for not providing state-of-the-art accuracy and precision for all of the ordinary analytes. Accuracy—to be sure there are no doubts about what is meant—is best defined as agreement with the true value. The clinically important mark of accuracy is how a method performs vs the reference method or the agreed-upon "gold standard" for that analyte, with fresh human samples.

Are the precision demands of physician-users of the laboratory unjustified in this era of cost-containment? Significant discussion has occurred over the past few years that questions the importance of making further improvement in precision for common analytes, most notably at the 1992 Forum[12]. Some argue that precision goals should be defined by medical relevance. Surely medical relevance should govern issues such as proficiency testing grading requirements; for example, a deviation of 0.2 mmol/L from the group mean for potassium should not give the laboratory a failing grade if a clinically important deviation (with today's technology) is >0.4 mmol/L. A person's perception of "medically relevant" or "clinically important" is, however, clouded by what technology allows. Fraser and Hyltoft Peterson [13], among others, argue that quality standards for laboratory tests should be based on within-subject biological variation. They also point out the advantages of having the lowest possible imprecision, even if biological variation goals have been met. Westgard et al. [14] further demonstrate that generally accepted standards for an analyte as familiar as cholesterol are not adequate to meet the quality goals we think we are meeting. Koenig reinforced the importance to the physician of consistent results [15].

Taylor stressed this idea that analytical precision has a profound impact on the usefulness of chemical measurements in his landmark book [16]. Fig. 1 illustrates how the precision of an assay affects its utility. A precise method has a far better chance of being accurate than an imprecise method; even somewhat biased methods will still be accurate most of the time if they are precise. Finally, physicians need guidance about utilization of laboratory services, particularly now as primary care physicians emerge in the influential role of gatekeeper to the rest of the healthcare system. Clinical laboratorians ought to be sure they possess quantitative understanding about the interpretation of test results, and then appropriately but persistently convey that information to the clinical staff to enhance cost-effective use of the laboratory by these individuals.

Other customers of the laboratory include healthcare institution administrators, whose main expectation of the laboratory in the current climate is that reimbursements will exceed expenses, and third-party payors, who want excellent laboratory service at the lowest possible cost. Meeting these rival demands is increasingly tough. Capitated healthcare plans and competitive market forces are reducing reimbursement, increasing the pressure upon laboratories to contain or even decrease their...
costs. A third group placing demands upon laboratories is the regulators in all forms, who expect total compliance with each federal and state regulation. Laboratories need to pass inspections and thus should document fulfillment of requirements for activities such as quality assurance, proficiency testing, and method evaluation. Section 1213, subpart K of the CLIA regulations [5] covers establishment of method performance in detail. The bottom line is that these rules simply give legitimacy to good laboratory practices that clinical laboratory professionals should satisfy without regulatory incentive, to give both ourselves and our customers confidence that we work in and manage high-quality laboratories.

HAS WHAT PHYSICIANS REQUIRE OF CLINICAL LABORATORIES CHANGED BECAUSE OF REGULATORY AND FINANCIAL PRESSURES?
If anything, provider expectations have intensified because of the current situation. Physicians must make diagnostic and treatment decisions more quickly than in the past. Patient stays are shortening, or many procedures formerly done while patients were in the hospital are now accomplished on an outpatient basis. Financial considerations limit what services a clinician will utilize, and how many. Patients also apply pressure; they are better informed than ever and are no longer content to wait for action from the clinician (who often used laboratory delays as the excuse for tarrying). These time, cost, and patient pressures mean that physicians increasingly rely on single laboratory results, whereas in the past, multilist profiles, follow-up testing, and confirmatory investigation were common. Hence, the methods laboratorians use today to produce these valuable pieces of data must be exquisitely valid to fit the manner in which physicians are depending on the data. This realization increases the importance of objective and accurate selection, evaluation, and implementation of laboratory methods.

WHAT RESOURCES DO CLINICAL LABORATORIES POSSESS TO MEET THESE DEMANDS?
Today's world is increasingly complex. Everyone is told to "do more with less." People's expectations are very high; patients with difficult conditions anticipate being discharged faster by institutions that use state-of-the-art technology, all at reduced prices. The situation seems grim. Clinical laboratorians need not give up; at least three commonly available resources exist to assist in meeting these challenges:

First, we have the good laboratory practices referred to above briefly in regard to CLIA. Working in laboratory medicine with professionalism, high ethics, and a sense of duty and respect for the customer is essential. Note that conducting procedures the same old way does not constitute good laboratory practices; now it is not the time to follow old, tried-and-true procedures if they no longer make sense. But we must know who our customers are and interact with them as never before to understand their needs more exactly.

Second, we have technology in the form of instruments, reagents, methods, automation, and modern information technology, all of which must be appropriately deployed. Innovative technology will continue to be essential as clinical laboratories strive to meet our goals.

The third resource—people—is our most valuable asset. Individuals working diligently in clinical laboratories provide the wherewithal to accomplish whatever success we have in meeting our demands. All technological applications require people to appropriately utilize, monitor, and through skillful observation modulate them as needed to produce information of value. Laboratory staff must receive adequate training so that they will fulfill their responsibilities with knowledge and enthusiasm.

STEPS IN CHOOSING AND EVALUATING NEW CLINICAL LABORATORY TECHNOLOGY
As clinical laboratories remain competitive and select strategies that maintain their role in healthcare, they will find that they are increasingly dependent upon new technologies supplied by diagnostics companies. These tests, devices, and instrument systems must be selected, evaluated, and implemented in such a way as to ensure satisfaction from all the customers of the laboratory. The variety of four-, five-, and six-part schemes for conducting these evaluations described in recent years [17–19] gives us a place to start. Perhaps the summary by Fraser [19] of

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<th>Table 3. Steps in assessment and assimilation of new technology into the clinical laboratory.</th>
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<tr>
<td>1. Analytical investigation</td>
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<td>2. Determination of the reference range</td>
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<td>3. Clinical investigation</td>
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<td>4. Outcome investigation</td>
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<td>5. Utility investigation</td>
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the recommendations from Robertson et al. [20] is the most
cogent. These five steps are listed as a guide in Table 3.

All of the proposals begin with an analytical investigation,
whereby the technical efficacy is studied in detail. Plenty of
written instruction about analytical method evaluation exists,
including two commonly available clinical chemistry texts
[21, 22] and documents from the National Committee for
Clinical Laboratory Standards (NCCLS) [23].

Despite the wealth of material accessible on this subject,
several key blunders are committed far too often when analytical
evaluations are conducted. These misjudgments can be plainly
summarized as the following five statements:

1) **Analytical method evaluation can be accomplished cheaply.** Of
course, these days everyone hopes to accomplish everything
cheaply, and performing our tasks as inexpensively as possible
is a worthy goal, so what makes method evaluation any different?
The mistaken assumption is that a new device can be unpacked,
originated, operated according to the manufacturer's directions,
and can turn out patient-reportable data all on the same day,
and that is the end of method evaluation. Administrators may love
us—for a while, at least—but we deceive them and belittle
ourselves. We should not succumb to the notion that we are in
a commodity business, which is the image we project if we utilize
laboratory tests "right out of the box" as if they were packets of
ketchup at a fast food restaurant or motor oil from an auto
supply shop. As important as these commoditites are, we must
realize that we are in the information business, providing
information about patients that will affect their lives. As stated
above, accurate evaluation and implementation of methods is
more crucial than ever. We must reach our conclusions about
implementing methods on the basis of the facts, collected in a
series of method evaluation experiments. These experiments
take some time and use up some reagents and (or) other
resources, but this expenditure is a necessary and valuable part
of our responsibility.

2) **A new method will be acceptable for use once the experiments are
done and the data are collected.** If the device is working in
accordance with manufacturer's guidelines, creditable-looking
data are being produced, the sales representative continues to be
friendly and helpful, and we selected the method to begin with,
it must be acceptable, right? Nothing is further from the truth!
**What** makes the data creditable? **How** do we decide that a
method/device/instrument is acceptable? The place to start is by
establishing a goal or analytical target before commencing any
experiments. Then actual data are collected, and these data are
used to estimate the analytical errors, which are then compared
with the allowable error goal. If the actual errors are smaller
than the target or allowable error, they are acceptable and the
method is acceptable; if the errors are equal to or larger than the
target, they are unacceptable and the method must be improved
or rejected. This approach is simple and logical, but it is
distressing how often the fundamental step of establishing a goal
is bypassed in evaluating methods because of the misguided
assumption that collecting experimental data is the most impor-
tant task, and quickly getting on with conducting experiments is
the most cost-effective way to complete a method evaluation
task. Unfortunately, collecting data without knowing what you
are going to compare the observed errors with leads to an
unnecessarily complicated, subjective, and cost-inefficient
decision-making process.

3) **A few experiments to estimate precision and accuracy are
adequate.** Most laboratorians realize that experimental data must
be collected and have a sense that measuring imprecision and
inaccuracy are meaningful. But conducting the right experi-
m ents in a comprehensive manner so these errors are estimated
correctly is essential. Given all of the literature resources on this
aspect of method evaluation (for example, refs. 21–23) and our
general propensity for experimental data collection, laboratori-
ans don't have as much difficulty with this common mistake as
the other four. Perhaps the most troublesome error noticeable
from published work, manufacturers' literature, and posters
displayed at scientific meetings comes in comparison-of-meth-
ods experiments, where far more samples are assayed than is
obligatory (40–50 samples will do), and most of them are
bunched within the reference range (even 30 samples are
adequate if the concentrations are distributed uniformly
throughout the analytical range of the method being tested).

4) **Statistics such as the correlation coefficient and the t-value are
most useful to estimate inaccuracy.** Once the experiments are
finished and the data are organized, reducing the volume of data
and obtaining valid estimates of the errors from statistics help
the evaluator to manage what would otherwise be an over-
whelming task. Most laboratorians recognize this situation and
have no hesitation in using statistics from an evaluation exper-
iment. The problem is not reluctance to use statistics but which
statistics to use, when to use them, and what they tell us.
Commonly published work again gives us a portrait of reality:
Comparison-of-methods experiments are often summarized
only with the correlation coefficient of the data, where a high
(i.e., close to 1.00) value is used to imply equivalency between
the two methods (i.e., accuracy). In actual fact, the correlation
coefficient does not relay any information about whether one
method agrees with another method, only the degree to which
the data from the two methods are associated with each other.
Careful thinking about this situation should make one realize
that two methods measuring the same analyte should be highly
associated (or "correlated") with each other. That fact is almost
given before the experiments are begun; what is desired is to
know how **accurate** the new method is compared with the old
method. A high correlation coefficient is not informative about
the question we need to answer; for that inquiry, the slope and
y-intercept from regression of the data are necessary. In reality,
the correlation coefficient is primarily a function of the range of
the data [24]; widening the range will cause the correlation
coefficient to approach 1.0 regardless of whether the new
method is accurate compared with the old method, which will
confuse both the investigator and the reader.

A similar mistake is made in regard to the t-value. A t-value
indicating a statistically insignificant bias does not prove accu-
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So—use statistics in analytical method evaluation, but use the right ones and know what information these statistics provide.

5) Conclusions about the acceptability of a method being evaluated are easy—just accept the method giving the "most bang for the buck." Clearly, clinical laboratorians must join the rest of healthcare in efforts to reduce cost. But accepting methods should not be based solely on the financial picture; they are not easy decisions to simply accept the low bid. Rather, these conclusions must be made objectively, on the basis of data and other information collected during the method selection and evaluation process. A recent study [25] gives an example of following the key steps to analytical evaluation correctly.

If these five common mistakes of analytical method evaluation are avoided, correct assessment of the technical efficacy of a test can be assured. If a method is shown to provide reproducible and valid analytical results, other steps in the assessment of the test can proceed.

The second phase of new test evaluation is determination of the reference range. Again, several resources are available to guide this process, including a guideline from the NCCLS [26]. Fraser [19] terms this Phase 2 trial the "overlap investigation" because he includes the additional step of comparing the values found in healthy individuals with those found in samples from diseased individuals.

That experiment is actually more a part of the third phase of evaluation, which is clinical investigation or measure of the diagnostic accuracy of the new procedure. The degree of overlap between the distribution of values relating to the population with a given disease and the values from the healthy or reference population is essential data to assess the quality of information produced by measuring the analyte. The smaller the overlapping area, the greater the diagnostic accuracy available from the test. This clinical investigation is measurable by determining the diagnostic sensitivity and specificity of the test, although reporting only one value for these quantities is deceptive since an analyte can have different values of diagnostic sensitivity and specificity simply by changing the cutoff or discriminant value. A more complete, graphical alternative to presenting this information is the use of receiver-operating characteristic (ROC) curves. ROC curve analysis is a powerful tool in this phase of the evaluation of a laboratory procedure whenever the test is applied to discriminate between two alternative states of health. A review [27] and several examples of their application [28, 29] provide assistance in the use of ROC curves. The NCCLS also has a guideline [30] in this aspect of laboratory test evaluation. ROC curve analysis is only as good as the patient population studied, however, and the skill with which clinical judgments used to classify these patients have been made.

As an analyte becomes established and is applied by more than just the initial investigators, estimates of its diagnostic accuracy and clinical value may differ among various studies. Decisions about the implementation of such a test then depend upon the fourth phase in evaluation, the outcome investigation. This phase tries to answer the question of whether individuals subject to the procedure or test gain an advantage vs if they had not undergone the procedure. One way to make sense out of the various potentially conflicting studies is to statistically combine the results of previous research through metaanalysis. General guidelines for this approach [31] and an application of meta-analysis to clinical chemistry [32] have been provided. This fourth phase of the evaluation may also be said to address the impact of the test in the care and management of patients by physicians. If the result of the test does not add to or measurably influence the outcome of the patient, don't do the test.

The final phase in the evaluation of a test is utility investigation or cost–benefit analysis. These studies are difficult but bear more importance in this era of cost containment. The cost to the individual patient relative to the outcome, and the cost to society at large vs the cost if the test wasn't performed, need to be assessed. This analysis can also be valuable for long-standing assays as clinical laboratory professionals serve as consultants on utilization of laboratory services.

The first three phases of these trials should ideally be performed before a new procedure is introduced into routine use. In fact, the FDA approval process has incorporated many of these steps into the application for marketing authorization, which will ensure that at least some data pertinent to each aspect will be available from the inception. Phases 4 and 5 should occur early during the establishment of the test as laboratory professionals (ideally different from those who originated the test) assess the test's efficacy in the marketplace. These studies must be published in some fashion and made widely available so all may benefit and little work will be needlessly repeated.

Who should perform these trials? Clinical laboratorians in all branches of the profession will continue to produce a large amount of the data and experience that will answer the questions asked in these trials. Indeed, the Graylyn Conference defined competency characteristics for clinical pathologists [33], in which "select, evaluate, and apply laboratory instruments and procedures..." is the second of five on the list. McDonald and Smith [10] quite correctly extended this skill requirement to clinical laboratory Ph.D. scientists, as well. Appropriate clinical laboratories must shoulder an increasing share of the development load, which includes performance of these evaluative exercises. The same is true of the diagnostics manufacturers who stand to benefit financially from new technologies. Perhaps the best scenario will see manufacturers and clinical laboratorians working more closely together to conduct the required experiments. Manufacturers can supply some of the resources that are now in short supply, while clinical laboratorians of hospitals and other healthcare institutions can supply practical expertise, samples from patients, and professional oversight of the evaluative protocols, data, and the conclusions. Beyond working with each other, these two groups can also benefit from the cooperation of motivated clinicians, especially in regards to phases 3, 4, and 5.

HOW TO JUSTIFY AND IMPLEMENT NEW TECHNOLOGIES
WHEN CONFRONTED WITH TODAY'S REGULATORY BURDENS
AND ECONOMIC CONSTRAINTS

Decisions to implement new technologies are more complex than in the past, but can be made with confidence if they are justified with appropriate data and based on these data rather than on some extraneous, impulsive, prejudiced motive. Interested clinicians can be used effectively to assist in correctly assessing the new technol-
ogy, particularly in phases 3–5 of the evaluation. These and other healthcare colleagues can also be of help to justify whatever purchase is necessary to administration. Scarce resources must be spent wisely, and support from clinical staff adds credence to what laboratorians request. Often a few dollars spent in the laboratory can save hundreds elsewhere in the institution.

Justifying and implementing new technology these days demands that the clinical laboratory develop trust. With a dogged determination to continuously improve in the effort to meet the customer’s needs, laboratories will project the image of not being technology driven, but rather using technology to better satisfy the customer. This perspective should characterize the entire institution; perhaps the laboratory can be the place where this approach is championed. The entire laboratory staff will ideally contribute to this attitude; one way to foster that outcome is through empowerment of the personnel. Empowerment energizes the people closest to patient care delivery; these staff can thus best improve processes and enhance cost-effective delivery of services. A dynamic, straightforward book [34] makes this point in a most enjoyable way. This book should be required reading for anyone engaged in patient care today.

Some comments at the 1995 Forum made in reaction to this presentation indicated that it was too idealistic. Perhaps they are right. But each of us cannot change the situation we are in or alter the challenges we face very much, in spite of how hard we might try. The only factor over which we can exercise some choice is our attitude or response to these situations. With a positive attitude and a clear focus regarding our objectives, we can continue choosing, evaluating, and implementing new technologies to our satisfaction and to the betterment of our contributions to healthcare.

References