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Clinical Laboratory Management: Basic Principles and Practices

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OBJECTIVES

To familiarize the reader with the concepts of leadership, management, and administration

To define how leadership, management, and administration are similar, are different, and overlap

To place modern management ideas in their historical context

To review the four management functions: planning, organizing, directing, and controlling

To discuss how laboratory models are evolving

To review in general terms the variety of financial management concepts and philosophy

To learn in general terms the process of decision making and how a decision-making style reflects one's leadership style

To define relevant economic issues that influence the delivery of healthcare services and their significance to the practice of laboratory medicine

Management is the art of getting things done through people.

Mary Parker Follett

Management, Leadership, and Administration

Leadership and management are terms that are often considered synonymous. It is essential to understand that leadership is a critical part of effective management. Managers are in constant action. Almost every study of managers in action has found that they switch frequently from task to task, changing their focus of attention to respond to issues as they arise, and engaging in a large volume of tasks of short duration.

As a crucial component of management, leadership behavior stresses building an environment in which each employee develops and excels. Leadership is defined as the potential to influence and drive the group's efforts towards the accomplishment of goals. A manager must have the traits of a leader. Leaders develop and begin strategies that build and sustain competitive advantage. Organizations require robust leadership and robust management for optimal organizational efficiency (Appendix 1.1).

Leadership differs from management; while managers lay down the structure and delegate authority and responsibility, leaders provide direction by developing the organizational vision, communicating it to the employees, and inspiring them to achieve it. Management includes focus on planning, organizing, staffing, directing, and controlling activity; leadership is mainly a part of directing the function of management. Leaders focus on listening, building relationships, teamwork, inspiring, motivating, and persuading the followers. A leader gets his/her authority from his/her followers; a manager gets his/her authority by virtue of his/her position in the organization. Managers follow the organization's policies and procedures; leaders follow their own instincts. Management is more of a science, as managers are exact, planned, standard, and logical. Leadership is an art.

In an organization, if managers are required, then leaders are essential. Management deals with the technical dimension of an organization or the job content; leadership deals with the "people" aspect in an organization. Management measures/evaluates people by their individual actions, past records, and present performance; leadership sees and evaluates individuals as having potential for things that cannot be measured, i.e., it deals with future and the performance of people if their potential is fully extracted. Management is reactive, leadership is proactive. Management is based more on written communication, while leadership is based more on verbal communication (Appendix 1.1).

Organizations that are over-managed and under-led do not perform up to their potential. Leadership, accompanied by management, sets a new direction and makes efficient use of resources to achieve their goals. Both leadership and management are essential for individual as well as organizational success.

With leadership and management defined, "administration" will be discussed. Is this something different from the above or merely a different word for what managers and leaders do? Defined by Merriam-Webster, *administer* lists first, "to manage or supervise . . ." and later, "to furnish a benefit" (1). Based on that second definition, it is possible to think of administration as an action apart from leadership and management, focusing effort on assistance and service, as opposed to the specific acts that a manager or leader might undertake. A manager and/or leader may have as his charge the requirement to serve others. But that becomes a task specific to that individual rather than a general charge to managers at large.

One of the primary definitions of *administrator* refers to government and public sector affairs (1). Administration, by that definition, becomes a public service job, much like one would see in academia or healthcare. Thus, administrators might, in fact, do different things than managers. This is to say, administration is a subset of management. Administrators do all those things that make one a manager. Administrators have a public service requirement and commitment that would not necessarily be found in the portfolio of all working managers.

We have quickly covered some of the basics of leadership and management and touched briefly on administration. More information on leadership can be found in chapter 5 of this volume.

A Brief History of Management Concepts

The history of management can be categorized into four periods: classical theory, behavioral theory, quantitative theory, and integrated theory.

Classical Theory

The earliest perspective on management and management theory was described by a group called classical theorists. Most notably, this group includes Frederick Taylor and his work on scientific management theory. Additionally, this group includes Henri Fayol and his work, referred to as administrative management, and Max Weber and his research into the nature of bureaucracy. This group and others laid the foundation for management theory, in part by identifying the key managerial processes and the skills a manager needs to succeed. Perhaps most importantly, their work made management a valid subject for academic inquiry.

Taylor was one of the first people to create a science of management (2). He is best known for his attempts to systematically analyze human behavior at work. His model was a machine made of cheap interchangeable parts. Taylor attempted to do to complex organizations what engineers had done to machines. This involved breaking down each task into the smallest identifiable unit and then figuring out the best way to do that part of the job. He felt that productivity would improve if each aspect of work was carefully studied and the alternatives facing each worker were restricted. He was correct but has been criticized for dehumanizing the workplace and reducing human beings to little more than machine cogs in the production process. But, the principles of scientific management had been well defined:

1. Describe and break down each task into its smallest component and study that task until the best way to do that task is fully defined.
2. Remove uncertainty and alternatives facing each employee and reward productivity with incentives.
3. Use experts—for example, industrial engineers—to define optimal work outputs and plan for optimal results.

Fayol identified the four basic management functions: planning, organizing, leading, and controlling. His work

focused on management more than tasks and production. He identified 14 principles of management, universal truths he thought could be taught (reference 3, p. 20–41), namely, division of work, authority, discipline, unity of command, unity of direction, subordination of individual interest, remuneration, centralization, chain of command, order, equity, stability, initiative, and esprit de corps.

We will not discuss each principle individually, leaving that for the reader to explore. These are still taught as the basics of management, and Fayol's work remains as pertinent today as it did early in the 20th century.

Max Weber embellished the scientific management theories with his views on bureaucracy and organizational theory (4). He focused on dividing organizations into hierarchies and establishing lines of authority and control. He suggested that organizations develop comprehensive and detailed standard operating procedures for all routine tasks. Where Fayol, before him, had laid out his principles of management, Weber identified the core elements of the new organization, i.e., the bureaucracy: formal rules and behavior defined by those rules, uniformity of operations despite changes in personnel, division of labor based on functional specialization, rational allocation of tasks, impersonal orientation, membership that constitutes a career, promotion based on technical competence, employment based on merit, tested qualifications, legally defined and prescribed lines of authority, limited discretion of senior management and officers, specific spheres of competence, and legally based organizational tenure (4).

Weber believed that emphasizing order, rationality, and uniformity would lead to more equitable treatment of the workers. He is faulted in some circles for his authoritarian views and the concept that authority is position-based and not focused on the individual. Clearly, however, his work moved beyond that of Taylor and Fayol and laid the groundwork for the next generation of management thought.

Behavioral Theory

The second category of management concepts is behavioral theory. Despite the economic progress brought about by the implementation of scientific management, as noted above, many critics were pointing to the dehumanization of the workplace. Labor and management conflict ensued, and worker apathy and boredom were believed to be widespread. These concerns, along with developments in the field of psychology and economics, brought to the forefront challenges to the assumptions of the scientific management school.

The Hawthorne studies at a Western Electric plant in Illinois were a straightforward attempt to determine if there was a relationship between the work environment and productivity (5). In one famous experiment, the illumination in one work area was adjusted and another area acted as a control. The productivity between the two groups was compared. Curiously, the productivity of each group increased, challenging the assumption that mere physical environmental changes were the key. Elton Mayo and his associates, who performed the experiments, believed the increase in productivity was a result of the increased attention paid to both sets of workers. Other studies performed by Mayo illustrated that workers will perform at a level informally set by the work group and that external management often will have little impact on those decisions. Thus, Mayo concluded that social processes play a major role in determining worker attitudes and behavior, far from the previously accepted notions that workers and tasks could be parsed out like parts of a machine (5). This led to the development of the human relations movement, which is based on the idea that a manager's concern for his workers will lead to increased worker satisfaction and improved performance.

Shifting the focus from strictly organizational needs, the human relations movement sought to bring the wants and needs of the individual worker into the discussion. American psychologist Abraham Maslow devised his six-level hierarchy of needs that, according to his theory, determines human behavior (6). He ranked them as follows: physiological, security and safety, love and feelings of belonging, prestige and esteem, self-fulfillment, and curiosity and the need to understand.

As one level of needs is met, we can work toward meeting the next level. If management wants solid, productive employees, motivated to work at their best, then every individual must be compensated and supported to the point where their basic needs are fulfilled and no longer seem to be a concern. Crucial, of course, is the understanding that what would fulfill one person may not address another's perceived needs. Hence, individual attention to each worker is a requirement for management to succeed.

Douglas McGregor developed his own theory of motivation and management, which is referred to as **theory X and theory Y** (7). In short, behind every management decision and action are assumptions about human nature and human behavior. Theory X ascribes to the more negative and perhaps Taylorist concept that people need direction and control and are incapable of taking responsibility. Individuals all need financial inducements and threats to make them work. Theory Y, on the other hand, presumes that people want their work to be fulfilling and that they seek self-respect and self-development. Theory Y suggests that work is a natural human enterprise and that the average person does not dislike work. Effort on the job need not come as a result of threats, but rather results if the individual is committed to the organization and its objectives. Satisfaction on the job and self-actualization can be directed toward the objectives of the organization. Additionally, theory Y proponents accept that imagination, ingenuity,

and creativity are not restricted to a narrow group within the organization but are widespread and only need to be tapped.

Both behaviorist models emerged because previous management theory was far too simplistic and did not address the needs of the individual. Maslow and McGregor tried to address individual needs and their relation to the needs of the organization (6, 7). This gives us some insights into group process and interpersonal relationships among the workers, and it focuses management on the needs of employees as people, not just as part of the production process. But there are also some limitations of this view. People are complex beings, and it is never easy to predict what anyone will want at any given moment. Managers themselves often find it easier to focus on processes than on people. Organizational goals and objectives are frequently stated in other than human relations terms. Nonetheless, these theories remain at the core of modern human resource management and are still robust today in their insights and perspectives.

Quantitative Theory

Quantitative theory emerged as the world moved out of World War II and industrial production shifted its focus from military hardware and support of national causes to consumer goods and services. Corporations moved from "cost is no object" to a cost-containment, profit-driven mindset. The legions of industrial engineers, previously focused on industrial efficiency to support the war effort, were now charged with improving corporate efficiency. The origin of the statement is unknown, but the adage "if it can be measured it can be managed" took hold, and strong quantitative approaches were adopted.

Management science focused very specifically on the development of mathematical models (reference 8, p. 49–52). Early computer applications in this direction centered on helping managers find the best way to do things and save money. Linear programming models and inventory management and control—difficult mathematical concepts, often beyond the ability of a person to compute within rational time limits—became trivial questions when the power of even the simplest of computers was employed. But this also looked very much like the pendulum was swinging back into Taylorism and the dehumanization of the organization. Much of senior management in the post-WWII period was made up of former officers and military veterans who placed their focus on the accomplishment of the task at hand, often at the expense of the welfare of their employees. Employee work groups could not readily convert to a mathematical problem; hence, a new concept of management needed to be developed to bring together the needs of the corporation and the needs of the individual.

Operations Management and the Integrated Theory

Operations management was the attempt to develop a set of tools, applied mathematics, and human resource management to develop techniques to produce products and services more efficiently (reference 8, p. 49–52). Operations management often includes substantial measurement and analysis of internal processes. Ultimately, the nature of how this is accomplished depends very much on the nature of products or services in the organization, for example, retail, manufacturing, or wholesale. As with management science, though, the focus moved away from the individual and related more to the organization at large and how it interacted within the larger business environment (9).

Management by objectives (MBO) tried to integrate the concept of managing what can be measured while simultaneously bringing the individual into focus (reference 10, p. 126–127). At its simplest, in MBO every employee has a set of objectives to achieve, which together with all other employees in the organization will pull the enterprise toward its overall objectives. All targets are quantifiable and easily recognizable for their value to the company. Realistically, though, performance management is difficult, and inevitably the biases and personal agenda of the rater may come into play. Key points here are that objectives must be clearly defined, plans for achieving the objective must be detailed and clear, and there must be ongoing monitoring to see if the plans are moving forward (reference 10, p. 126–127).

Thus, the quantitative perspective accelerates the development of mathematical techniques for decision making and the setting of objectives. This modeling methodology dramatically increased the awareness of organizational processes and assisted greatly in organizational planning. As with the previous theories, however, human behavior is unpredictable, and following the dictate "garbage in/garbage out," mathematical models based on faulty information or assumptions will not lead to better management.

With the failure of mathematical modeling to fully address management problems, integrated theory—a new, more holistic view of the organization—emerged (reference 8, p. 56–57). Speaking generally, the integrated systems approach to management tried to incorporate the best of all that came before it while trying to maintain a human focus (11). **Systems theory** represents the merger of many ideas from scientific management and the human relations movement. It is project based and strives toward organizational synergy. There are those who would nest systems theory under the heading of quantitative management. Such an approach misses the point that systems theory is all-encompassing, whereas the basics of quantitative management are pure mathematics.

A system, in this context, is defined as an organized unit composed of two or more interdependent parts, subsystems perhaps, where the whole can be identified as

something separate and apart from its surrounding environment (reference 8, p. 58). Consider an organization to be a system. It will experience problems, and issues will need to be addressed. The systems-oriented manager, rather than merely trying to manage the problem away, will look at the opportunities a problem might bring and will try to bring all available resources from his organization to bear on the situation.

Much of systems theory resembles the scientific method: you see a problem to be examined, you hypothesize a solution, you design a controlled experiment to test that hypothesis, you collect and analyze the data. The key here is to maintain your focus and attention on the entire organization (11). You cannot change one part of the system without affecting all the others. Systems theory might seem quite basic, yet it is extremely difficult to examine the whole of an entity. We are familiar with many approaches to break down problems into identifiable and workable parts. It should be noted that information system tools to allow a real-time focus on an entire organization have only recently become available.

Into this mix, and possibly in part because of the difficulty of trying to manage the whole, a **contingency theory** of management emerged. Contingency theory asserts that when managers make decisions, they must consider all aspects of the current situation and then act on only those aspects that are most crucial (12). You keep the entire entity in mind but only focus on that which seems most important. While you will be impacting the entire system, you must also keep your attention directed at that which seems most pressing at that moment. Thus, there is no one "best way" to manage an organization. The contingency perspective would say that universal theories do not apply to every organization, because every organization is unique. This falls under the subheading of an integrated theory, because it presupposes that the decision maker involved will keep in mind that even though his concern might be on a subsystem of the larger organization, it is still nested in that larger system.

As powerful as the above integrated approaches might be, they soon were dwarfed by the emergence of the various **total quality management** and **continuous quality improvement** models.

W. Edwards Deming is often referred to as the founder of the modern quality movement (reference 8, p. 622; https://deming.org). An American whose ideas were developed based on Western management theory, he gained wide prominence through the acceptance of his theories by the Japanese. The Japanese themselves will say that the application of his ideas led in great measure to their postwar economic success. Deming's theories by themselves are very basic and deceptively simple to implement. To start, he believed that **total quality management** (TQM) begins at the corporate level. The entire enterprise must have a deep and wide-ranging commitment to the continuing improvement of products and services (13). The enterprise must always move forward and keep innovating toward the next improvements. Quality needs to be a part of every stage of production, where there is continuous inspection and review. The quality check should not be saved until postproduction. True quality requires quality that can be measured and must be willing to pay the price for that result. Managers should not rely on low-cost bidding by suppliers just to save money while sacrificing quality. Finally, managers should initiate training programs and leadership models to help people do a better job and to empower them to speak out and respond when problems are detected (reference 14, p. 129). Deming says that if you do this you will produce a better product.

More than 40 years after their adoption, these concepts seem obvious and basic to modern industrial management. At the time, however, they were revolutionary, and their adoption by the Japanese changed the meaning of the phrase "made in Japan" from cheap and poorly made to solid and reliably built (reference 14, p. 98–99).

Total quality management (TQM), one of the first so-named theories of the quality movement, is a structured system for satisfying internal and external customers by integrating the business environment, continuous improvement, and technological and production breakthroughs (reference 15, p. 15–37). "Structured" means it is strategy driven by the identification of customer wants and needs that have been determined through ongoing interaction with those customers. TQM is a description of the culture, attitudes, and organization of a company that aims to provide, and to continue to provide, its customers with products and services that satisfy their identified needs. It is a corporate culture that requires quality in all aspects of the company's operation, with things done right the first time, while defects and waste are removed from operations. The products are designed to be quality output, and the manufacturing and product systems follow through to meet that goal.

There are differences in approach that are important to compare. As an example, Ford Motor Company strove to become the number one producer of automobiles by determining first what price the consumer would accept and then working toward making a car that could be produced for that price. The challenge was not quality. The challenge was production efficiency and unit cost (reference 8, p. 130–131). The production of Ford cars can be seen as a "Taylorism" experiment: divide the work into its smallest parts, make each part as efficiently as possible, and ramp up production to get quantity pricing. On the other hand, consider the production of a Toyota in 1975. Via marketing research, the focus was on what level of quality the customer expected for every unit of cost (13). Toyota's approach was to design the product to meet the quality demands of the customer. They focused on producing a

quality product at each step, not throughput. They acknowledged that the customer does not want the cheapest car, but rather the best value for the selling price. The attitude shift was from car production at whatever the market will bear, to getting the best-quality product onto the market as the best value to be found.

Many organizations have trouble integrating a TQM model into their operations. Fewer than half of those who have adopted a TQM approach report any improvement in quality, productivity, competitiveness, or financial return (reference 15, p. 6). But that percentage may be deceiving. The focus should be on successful operations, where many more than 50% rely upon TQM to maintain their success.

A subset of the TQM movement is often referred to as **continuous quality improvement** (CQI). What separates CQI from TQM is the focus on the employee (16). A CQI approach forces the organization to look at its employees and their work as part of a continuous process. CQI is thought to have a more human face than TQM; this distinction is not always clear.

Whatever acronym you choose to use, the quality management approach to production changed the way manufacturers looked at their world. The focus on cost reduction and profit improvement has been replaced forever by a focus on the customer and the production of a quality product that meets the customer's needs at a reasonable price.

Management theory and thought continue to move forward, with ongoing work in the behavioral and individual employee world, as well as focusing on the organization and production processes.

Above, it was noted that management by objectives was one of the most widespread approaches to working with individual employees. Taking a step farther, the approach has led to the popularity of interest in lifelong learning, also known as **continuous lifelong learning** (reference 17, p. 332–336). The continuous lifelong learning process starts by identifying where a person is at that moment and where they would like to be in the future in their career. Assessment of the individual is an essential part of this self-identification, so that person can move to the next phase of the process. The next phase of the process has individuals taking initiative, to strive to achieve their goals.

There are several key factors for this process to be successful:

1. First, the employer recognizes that crucial to lifelong learning is the concept that no one individual will necessarily stay in that job or with that employer forever. As people learn and grow, they move on to new jobs and experiences.
2. Second, individuals can take charge of their lives to reach their full potential. Self-empowerment is both a result and an employee need.
3. Third, everyone is accountable for and responsible for his or her individual progress. Some people might choose a mentor for assistance, but the mentor is not responsible for the individual's growth.

The connection to the employer and management is that learning-inspired/driven employees do better work and absorb the total quality management message much more effectively (reference 17, p. 332–336). TQM and CQI require employees to think and to consider the options available to them to work better and more efficiently. Dialogue between management and worker is enhanced when employees think in terms of their jobs as part of a lifelong journey, and they are learning and working toward better lives. This is almost a utopian vision but nonetheless is the direction in which much of the industrial world is heading.

Similarly, while on an individual basis the organization actively develops its employees to evolve and grow, on a product and process basis modern corporations are starting to work toward a **total product life cycle management** concept. This theory suggests that more than merely focusing on a product as a unit at a point in time, the organization needs to consider whether that product is in the ascendancy or is fading and adjust the product to their customer needs accordingly (18, 19). The marketplace is always moving forward, and the organization must move forward with it. Product design and production must think through the issues of product introduction and placement in the marketplace, ultimately the disposal and replacement of that product, and planning for the next generation of product to meet the customer's demands and needs. Similar in many ways to TQM, in which a product design defines its quality and use, the life cycle management theory goes a step farther to plan for product demise and redefinition as customers change their focus to something new. At some point the organization will decide to stop making or doing one thing and to move on to another. Life cycle management forces an enterprise, early in a product's life, to plan for its replacement (18). Thus, engineering is always thinking ahead, and employee education always works toward preparing the workforce for the future.

Similarly, **process reengineering** forces the organization to rethink how it does its work and how it can be done better (reference 20, p. 103–129). Again, this is an extrapolation on TQM and CQI. The difference is that with TQM and CQI you are always trying to improve what you already do. Process reengineering suggests that you entirely abandon what you are doing now in favor of something entirely new and different (reference 20, p. 174–192). In the extreme, process reengineering assumes the current process to be irrelevant. Thus, start over with a clean slate and see what you can do. Those subscribing to this theory think in terms of vision and the future (21). What must we

look like at some future point to meet the needs of our customers? What technological changes have taken place that we should incorporate to make us better and more responsive? What will our customers expect of us in the future that we must plan and build toward now?

A reengineering tenet is that technological change has negated all that we do now. Thus, this is not merely a desire on our part to change what we do to improve ourselves. As technology advances, it then moves forward to invalidate what is currently the "best." As a result, in order to implement the newest technologies, rebuilding occurs starting from the beginning. Competition in the marketplace demonstrates that new organizations that do not use outdated methods are likely to surpass you. Thus, finding new ways to do things, redesigning processes around new technology, is central to organizational survival.

Finally, many believe that the customer base we work with now is much more quality sensitive and driven, with only the best surviving. Defining what is the best is always a challenge, with **Six Sigma** as one approach. A thorough coverage of Six Sigma can be found at the Six Sigma website, which covers in depth all aspects of Six Sigma. That site defines Six Sigma as a highly disciplined process to focus on developing and delivering near-perfect products and services (http://www.isixsigma.com/new-to-six-sigma/; accessed July 2022). "Sigma" is a statistical term that measures how far a given process deviates from perfection. Knowing that deviation, one can predict how many errors and defects there will be in a process; thus, one can systematically try to find and remove them.

The Six Sigma website states the following: "Six-Sigma by definition is not more than 3.4 defects per million events." A Six Sigma defect is further defined as anything outside of customer specifications (reference 22, p. 184–202). Thus, it is not merely an operational or production defect. A process can function perfectly, but if the end result is outside of what the customer wants, it is a product defect.

Six Sigma incorporates product and process improvement. It integrates many of the features of TQM and CQI and process reengineering. Those who apply the theory refer to two acronyms: DMAIC (define, measure, analyze, improve, control) and DMADV (define, measure, analyze, design, verify) (reference 22, p. 329). Six Sigma process implementation staff are often referred to as Green Belts and Black Belts, suggesting a special trained status and the aggressive nature by which the measurement and improvement processes are implemented (reference 22, p. 125–145).

Six Sigma is another in the many process and product review methodologies, all with the aim of giving the customers what they want. Six Sigma has "raised the bar" on the definition of product and process quality. Like all management techniques, commitment at all levels of the organization is required, and this becomes the primary message carried in all of the above-described modern and new theories.

Table 1.1 Emergence of management theories

Emergence	Theory
1940s	Operations management
1950s	Systems theory
	Management by objectives
	Total quality management
	Continuous quality improvement
1980s	Six Sigma
	Lean
1990s	Process reengineering
2000s	Lean Six Sigma

Lean Six Sigma adds additional layers by including a measure of time efficiency to the already established efficient production process. As stated on the Six Sigma website, "Lean production is aimed at the elimination of waste in every area of production including customer relations, product design, supplier networks and factory management. Its goal is to incorporate less human effort, less inventory, less time to develop products, and less space to become highly responsive to customer demand while producing top quality products in the most efficient and economical manner possible" (http://www.isixsigma.com/new-lean-six-sigma/; accessed July 2022). For more information on quality management, see chapter 18 of this volume, "Quality Management." Table 1.1 summarizes the emergence of various management theories over the past 80 years.

Decision Making and Problem Solving

Decision making is the process of making choices by identifying a decision, gathering information, and assessing alternative resolutions. Decision making is an integral part of modern management, with rational or sound decision making a primary function of management. A decision can be defined as a course of action purposely chosen from a set of alternatives to achieve organizational or managerial objectives or goals. Most everyone makes many decisions every day. Granted, many decisions are small and made almost unconsciously, while other decisions are more significant, requiring a more conscious effort, time to study, and consideration of the potential consequences. Regardless of the nature of the decision, every decision encompasses elements of a basic decision-making process (23).

Decision making by leaders and managers exhibits significant differences (see Table 1.2). Including staff in collecting data, analyzing data, and decision making, though, can also affect efficiency and effectiveness in an organization.

Table 1.2 Decision-making differences between leaders and managers[a]

Characteristic	Leader	Manager
Vision	Search for long-term opportunities	Maximize current opportunities
Communication	Tell people why we are doing something	Tell people what to do; listen to have an effect; listen for understanding
Question(s) asked:	Why?	How? What?
Planning	An opportunity to excite, educate, prepare for future	A path to follow
Power	Something to share and use for the goal of the group	Something to have and use
Approach to problem solving	Something to learn from, opportunity for growth	Something to solve, to fix
Perceived role	Integrator; maker of decision makers	Controller or decision maker

[a] Adapted from reference 34.

A common rule of thumb is that decisions should be made at the lowest possible level in an organization. The closer one is to the information and effects of a decision, the higher the quality of that decision, so the manager is not always the best person to make the final decision (23).

Decision making is the complex process of choosing one alternative from among a set of alternatives. Inherent in this definition is an awareness that a decision needs to be made, that alternatives need to be developed and considered, and that one "best" alternative is chosen and implemented.

What Is Decision Making?

The science of decision making, as described in the literature, applies models based on deductive, inductive, analytical, and simulation approaches. These models describe decision making as a deliberate process, differentiating managerial decisions from habit and reflex. Decision making also has an artistic side, drawing on the decision maker's creativity and judgment. In addition, managers often base their decisions on personal or organizational value systems and philosophies.

Since the closer one is to the information and effects of a decision, the higher the quality of the decision, the greater is the empowerment of individuals in an organization. This makes them better able to participate in decision making, which is an essential skill. Pickett notes that empowerment requires "stretching, coaching, training, giving authority, and implying permission to make mistakes (obviously, this must be judiciously applied)" (24). When people in an organization are empowered decision makers, they think differently, act differently, and are more energetic. Table 1.3 outlines multiple concerns in decision making.

Table 1.3 Concerns in decision making

Parameter	Rules	Question(s)
Quality	1. Leader information rule	Does the problem possess a quality requirement?
		Do I have sufficient information to make a high-quality decision?
	2. Unstructured problem rule	Is the problem structured?
Acceptance	3. Acceptance rule	Is acceptance of the decision by subordinates important for effective implementation?
	4. Acceptance priority rule	If I were to make the decision by myself, am I reasonably certain that it would be accepted by my subordinates?
Quality and acceptance	5. Goal congruence rule	Do subordinates share the organizational goals to be attained in solving the problem?
	6. Conflict rule	Is conflict among subordinates likely in a preferred solution?
	7. Fairness rule	

[a] See reference 28.

Types of Decisions

There are various types of decisions. Decisions can be studied and classified from various perspectives (25). Some decisions are strategic or tactical, with the former focusing on the means to reach a goal, and the latter focusing on steps or objectives to be accomplished. Some decisions are administrative, requiring substantial resource commitment; other decisions are operational, dealing with day-to-day activities. Some decisions are programmed because they are routine and repetitive in nature. Other decisions are termed nonprogrammed because they are novel and unstructured. Still other decisions are individual or group, differentiated by who makes the decision (26).

Strategic decisions are concerned with an organization's relationships with the external environment, the choice of a competitive posture, and the formulation of major policies. The goal is to arrive at the best plan for the organization, given operational, economic, logistical, and political constraints. Examples include mergers, expansions into new markets, and off-site testing facilities.

Tactical decisions are, as the name implies, tactics or steps for implementing the organizational strategy. These can be categorized further as administrative decisions or operational decisions. Administrative decisions deal with authority, responsibility, and accountability relationships. Operational decisions handle the routine, day-to-day problems in accomplishing work.

Decisions may also be classified as programmed or nonprogrammed. **Programmed decisions** are structured and recur with some frequency (25). For example, the decision to reorder supplies and reagents for the laboratory is a programmed decision. Structure exists in terms of

quantity to order, purchase requisition process, etc. This decision is made on a recurring basis. Programmed decisions are guided by rules, policies, and procedures.

By contrast, **nonprogrammed decisions** are relatively unstructured, in part because they occur infrequently (25). Situations that have never arisen exactly like the present or are very complex usually do not have procedures to guide the decision-making process. Some years ago, when the concept of core laboratories was introduced, the decisions necessary to plan these high-volume, cross-specialty facilities were unstructured, hence nonprogrammed. A decision today to purchase experimental equipment is a nonprogrammed decision. Nonprogrammed decisions require intuition, creativity, and a tolerance for ambiguity.

A manager's natural tendency toward decision making prompts two more decision types: **intuitive decisions** and **judgmental decisions**. Intuitive decisions are made using hunches, subjective values, and personal or emotional factors. A manager who becomes impatient with the time it takes to gather information and sort through details may make an intuitive decision. The manager's decision cannot be readily explained by looking for details but is more likely rationalized by a perception of the "big picture," a holistic view of the situation. Individuals who tend to make intuitive decisions believe creativity comes from inspiration rather than perspiration.

Because of the education and experience in clinical laboratory science, most laboratory managers tend to make **judgmental decisions**. These decisions are reached after data are gathered, facts analyzed, and concrete examples explored. Judgmental decisions rely on objective analysis and rational procedures. For those decision makers who tend to make judgmental decisions predominantly, creativity is very challenging. The potential danger of "analysis paralysis" is a real threat (25).

Individual versus Group Decision Making

Individual versus group decision making needs to be strongly considered. The involvement of groups in decision making adds both benefits and liabilities. Groups tend to make more accurate decisions compared to individual decisions, although reaching a group decision is slower. Social interaction in group decision making tends to foster competition among members for respect, provide social support, and self-correct errors that might occur when an individual is making the decision alone. Group decision-making dynamics sometimes are counterproductive, however. When not constrained by a mandate to reach a group decision, individuals tend to produce more ideas, more unique ideas, and better ideas. Generally, people accept better decisions reached by a group versus an individual if they feel their participation in the decision was considered and valued. Obviously, acceptance of a decision is key to commitment and implementation.

Vroom and Jago (27) have shared their insight into the question of whether a decision should be made by the individual manager or with involvement of the affected group of employees. Originally researched by Vroom and Yetton, these insights consider three criteria: (i) quality or rationality of the decision, (ii) acceptance or commitment of subordinates to implement the decision, and (iii) time required to decide.

The Problem-Solving/Decision-Making Process

While it is true that decisions are choices, decision making and problem solving is a process of steps. Many decisions can be made quickly with little attention to the steps along the process. The more complex the problem, and the more mission-critical the objectives, the more important each step is to reach a successful, high-quality decision. The problem-solving/decision-making process described below and illustrated in Fig. 1.1 is a continuous circle of events (23). The steps overlap in practice, and the connection of all steps leading back to solving the identified problem or meeting the intended objectives is important to "closing the loop."

Step 1: Identify the problem or determine the objectives. Identifying the problem requires a manager to first diagnose the situation. Too often a symptom of the problem is misidentified as the root cause. For example, a manager who identifies poor morale in the laboratory has misdiagnosed the situation. Poor morale is a symptom of an underlying problem. The range of root causes could be low pay, unappreciative supervisors, or lack of respect from coworkers, among other causes. Failure to define the problem in step 1 will negate all subsequent steps to solve the problem. Similarly, clear definition of objectives for a decision provides a constant point of reference when subsequently gathering information and developing alternatives.

Step 2: Gather facts and evaluate information. At this step, the manager will learn whether he is dealing with a programmed or nonprogrammed decision. Are there rules, policies, and procedures that need to be followed? Has someone already solved this problem, and if so, how similar are those characteristics to this situation? Is there a need to get group input, and if so, individually or collectively, and from whom? Figure 1.1 shows the influence of the manager's perceptions of information gathered as data are evaluated. The natural tendencies to either rely on the five senses to identify factual details (sensing) or to use hunches and a more holistic view (intuition) will be part of this step.

Step 3: Develop and evaluate alternative solutions and options. Some possible solutions will be obvious; other solutions will be more creative. The tendency to

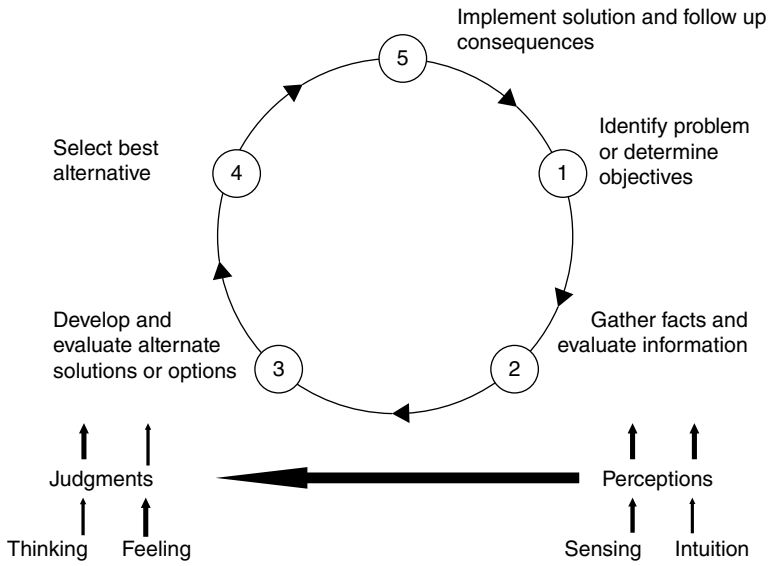

Figure 1.1 Problem-solving/decision-making process.

quickly adopt the first viable solution may be time-efficient but lead to a lower-quality decision or solution. In general, the more important the decision, the more alternatives should be developed. At this step, as shown in Fig. 1.1, the evaluation of options will be influenced by the judgments of the decision maker. The use of both subjective values and objective analysis will lead to a better sorting of potential options.

Step 4: Select the best alternative. After considering each option in light of the situation or objectives to be achieved, the manager chooses the one most likely to be the highest quality with the greatest acceptance within the time available for decision making.

Step 5: Implement solution and follow up consequences. The chosen alternative is implemented, and over time the manager determines whether the problem has been solved or the objectives met. The potential pitfall here is to ensure that once the chosen alternative is implemented, the process is complete. Two key questions need to be answered: (i) Did the chosen alternative work? and (ii) Are there unintended consequences to the decision that now must be addressed?

All decisions involve some element of risk. Risk is based on uncertainty. The greater the outcome uncertainty of the alternative chosen, the greater the risk. A manager's decisions can be influenced significantly by both his own and his organization's propensity for risk. A manager with a high propensity for taking risks with decisions, in an organizational culture with a low propensity for risk, will likely experience problems. Good decision making relies on knowledge of both the importance and components of the process. It requires an awareness of personal skills to determine the best way to reach the highest-quality decision with the greatest acceptance in the amount of time available. Good decision making requires experience and learning from one's mistakes (reference 17, p. 66–68). Good decision making requires the ability to reflect on information, then decide (28, 29). Table 1.1 summarizes the emergence of various management theories over the past 80 years.

Management Functions

The study of management is typically broken out into four primary areas: planning, organizing, directing, and controlling. This section provides an overview of those management functions, presented in basic, practical language.

Planning

Planning is the process of formulating objectives and determining the steps which will be employed in obtaining them. No modern healthcare organization can be effective without an overall plan of action (reference 18, p. 30). **Strategic planning** is a methodical process whereby an organization defines its mission, identifies directions, develops a unified approach, prioritizes long- and short-term goals, assigns accountabilities, and allocates financial resources. If done properly, strategic planning involves supervisors and staff, and it requires the use of time and resources. Therefore, a manager must plan to plan. Before any planning is initiated, a number of important questions must be answered, including the readiness of the organization to engage in such a process, whether the culture of the organization generally supports a planning process, how committed the organization is to a time- and energy-consuming process, who

should be involved in the planning group, how and when the process should be initiated, how others in the organization who are not directly involved in the planning process will be informed about the process, and the time frames for the process (reference 30, p. 6).

The objective of planning is to set an achievable course of action by establishing long- and short-term goals, monitoring progress, and establishing an environment where day-to-day activities are well controlled, measurable, and thoroughly understood. The plan helps the organization develop an action-oriented approach and identify the pieces needed to build a successful operation. Good strategic planning is a structured process. "Structured" means that the plans of individual laboratory sections must fit into an overall plan that covers the entire laboratory operation. It is a "process," because good plans are not produced in isolation according to some predefined formula.

Strategic planning presents challenges. The more far-reaching the laboratory's mission is defined, the greater the challenge. One constant, whenever the paramount resource of an organization is the experience of its people, is the absolute necessity to include the input of the staff (17). Points to be considered when planning include:

- Involve staff at every level in developing a strategic plan. Solicit feedback from individuals who really know what's going on and who will be responsible for executing the plan. You will get great ideas and critical buy-in by getting staff at the bench level to offer input during the process.
- Be flexible in developing a plan by circulating drafts and allowing people to provide feedback.
- Ensure that everyone knows their responsibility for deployment of the plan and that feedback mechanisms are implemented. The most carefully written plan will fail if those responsible for its execution do not know their roles, deadlines, and resource allocations. A defined feedback mechanism will ensure that the plan does not get lost in daily crises.

An important tool of planning is assessing the laboratory's strengths, weaknesses, opportunities, and threats, through what is called a **SWOT analysis**. A SWOT analysis is a tool that can help to analyze what your company does best right now, and to devise a successful strategy for the future.

If one does not already exist, at the beginning of the planning process a **vision statement** should be written to articulate what the organization seeks to become. A vision statement is an internal document, by design. It is intended to inspire those within the organization to maximize their potential, and by so doing, to maximize the potential of the organization. A vision statement need not be wordy; some of the best vision statements are brief and succinct. A vision statement should be lofty in its ideals. It should state a common purpose, and it should express the long-term goal of the organization. An example of a vision statement, from the Virginia Commonwealth University (VCU) Department of Pathology, states, "Our vision is to become a preeminent Department of Pathology in the United States, which is recognized for excellence in biomedical research, the education of health care professionals, and the innovative application of science and technology to the diagnosis and management of human disease" (https://pathology.vcu.edu/about-us/, accessed 12 September 2023).

A **mission statement** for the laboratory should also be developed at the beginning of the planning process. A mission statement answers certain fundamental questions about the organization, such as What is our purpose? In what activities will we be engaged to accomplish that purpose? and What are our basic values and shared beliefs? Having a clearly articulated mission statement benefits the planning process by defining the organization's purpose, but it also benefits the organization by reminding everyone, staff and clients alike, about the organization's purpose. An example of a mission statement, also from the VCU Department of Pathology, states, "Our Mission is to provide high quality, cost effective molecular pathology services in a manner that supports the patient care, education, and research missions of the Virginia Commonwealth University Health System and School of Medicine" (https://pathology.vcu.edu/about-us/). Note that this statement clearly defines what the organization is and the clientele that it serves. As planning progresses, people should look to the mission statement for guiding principles in the decision-making process.

The mission statement should be credible and closely aligned with the organization's actual purpose. Credibility is lost when the mission goes beyond the stakeholders' ability to believe in it (reference 30, p. 67).

Planning is done to produce a list of goals and strategies that will guide laboratory management decisions for a period of time. Through discussion, the planning group produces a written document that lists specific goals and strategies. A goal is an end or an outcome that one hopes to attain. An example of a goal is "to enhance laboratory revenue by increasing referral testing from external sources." This is a clear statement of something that the laboratory will try to achieve.

Once goals and strategies are established, they must be prioritized between "must do" and "want to do" decisions. Action items are assigned to specific people to be responsible for delivering results. Attach specific names to specific action items, because if everybody is accountable for a certain task, then they will take proprietary ownership to make certain that the task is done correctly and in a timely way.

Finally, a reporting mechanism must be established to review progress, reevaluate priorities, and make updates based on a constantly changing operating environment. The ideal venue for reviewing metrics is a regularly scheduled meeting attended by everyone who has assigned

accountabilities. At this meeting, accountable people are asked to report upon the progress made on their assignments. A regular reporting forum helps to maintain momentum by removing the human inclination to procrastinate. Monthly, or perhaps even weekly, meetings should be scheduled to discuss progress toward stated goals and objectives.

A strategic planning process includes the following steps (see Appendix 1.2):

1. Select a knowledgeable planning group.
2. Perform an environmental analysis.
3. Identify strengths, weaknesses, opportunities, and threats (SWOTs).
4. Make a manageable and realistically achievable list of goals.
5. Prioritize goals.
6. Develop strategies to accomplish goals.
7. Assign accountabilities and timelines.
8. Measure progress with metrics.
9. Review progress and make updates on a regular basis.

For more information on strategic planning, see chapter 28 of this volume, "Strategic Planning."

Organizing

Organizing is the process of structuring activities, materials, and personnel for accomplishing predetermined objectives (reference 18, p. 136).

One of the most important functions of a manager is to organize the activities of the laboratory in such a way that use of time is carefully considered, so that effort is minimized while output is maximized. Profitability, efficiency, and quality are often determined by how well resources and workflows are organized.

An essential management tool is the **organizational chart** (see Appendix 1.3). An organizational chart shows hierarchical relationships between functional areas. It is a visual depiction of the organization, which helps to clarify workflow, reporting lines, and areas of responsibility by explicitly listing delineated work areas, be it by division, laboratory, or medical specialty.

To be well organized is to develop a structured approach to time management. A time management system allows a manager to:

- Minimize time wasted on nonproductive issues
- Be prepared for meetings
- Be aware of existing commitments
- Understand the capacity to take on new assignments and when to say "no"
- Plan each day's work efficiently and effectively
- Make certain that no project (large or small) is neglected

Simply stated, the conscious use of a time management system allows a manager to be well organized and well prepared. Failure to use a system ensures disorganization and lack of preparedness.

An effective organization has policies and procedures. **Policies** express behavioral expectations within the workplace. All policies have seven basic characteristics: they must be (i) well thought out; (ii) flexible enough to be applied to both normal and unusual situations; (iii) acceptable to those who apply them; (iv) consistent; (v) objective; (vi) clear and communicated to those individuals to whom they apply; and (vii) continuously reevaluated and changed when necessary (28). **Procedures** are formal steps to guide an employee through a specific job task. A procedure is a written, sequential course of action to be taken to achieve a desired outcome. A laboratory manager must maintain current, concise procedure manuals for all processes that are performed in the laboratory. As with policies, the book of laboratory procedures should be continuously reviewed and revised by a team of experts to ensure that they are up to date and in compliance with the most current regulations and standards of care. Accreditation of the laboratory will be judged in part on the accuracy and thoroughness of the procedures, so maintaining them should be among the highest priorities of all laboratory managers.

A laboratory manager must be a master of all the interconnected processes within the laboratory. These processes are logically sequential, and they are accomplished in such a way that one process or step must be completed before the next can begin. This is known as **workflow,** or organizing tasks in a way to accomplish a specified result. An important tool for analyzing workflow is the **flowchart.** Process design flowcharting is a fact-gathering technique used to make the effort of a task visible by writing down what is done. A flowchart graphically illustrates the relationships between necessary tasks.

Clinical laboratories have unique staffing needs. Each laboratory has an ideal number of employees based upon throughput and automation. A manager must ensure that efficient staffing is always maintained. Accurate staffing must align to the organizational chart, taking into consideration how each laboratory component serves the ultimate mission of the laboratory. Staffing should be a topic of discussion in the strategic planning process. A well-thought-out strategic plan considers staffing, enabling a manager to make long-term predictions about future staffing needs.

Directing

Managers direct people and activities. Staff members require and expect direction in their activities. Directing is the process of influencing people to attain predetermined objectives (reference 18, p. 30).

Communication is among the most important components of directing/management. Clear written and verbal communication—from manager to employee, from employee to manager, between managers, and between peers—influences action. Without it, there is no effective way of articulating expectations, expressing concerns, providing feedback, and ensuring that policies are implemented. Communication must flow in all directions. It must be concise, clear, consistent, and continuous. Employees rely upon regular feedback from their supervisors. Supervisors rely upon their employees to inform them of their needs. People at all levels of authority within the laboratory rely upon communication with their peers to remain aware of changes in policy.

In every organization, there are four basic communication flows through which messages can be passed: **downward, upward, lateral,** and **diagonal.** Downward communications travel from the superior to the immediate subordinate. Downward communications are used to transmit information and instruct employees in the performance of their jobs. Upward communication travels from the subordinate to the immediate supervisor, and it is used to provide feedback on how things are going. Lateral communication takes place between people on the same level of authority within an organization, and it is used for promoting coordination and teamwork. Diagonal communication occurs between people who are neither in the same department nor on the same level of authority within the organization. Diagonal communication is used for cutting across organizational boundaries to save time (reference 18, p. 211–214).

The basic attributes of good-quality communication are attention, acceptance, and empathy. **Attention** is the thoughtful consideration of others. When speaking to someone, be considerate of his or her concerns, needs, and experiences. It requires active listening to what people are saying. Ask questions to clarify concerns. Affirm your understanding by paraphrasing and restating their concerns until there is no ambiguity and no room for misunderstanding. Active listening should always be incorporated when communicating with staff members.

Acceptance is the act of favorably receiving someone's thoughts and opinions. This does not necessarily imply agreement but conveys that you understand the concerns being expressed and that you will keep an open mind. Successful listening is an active, dynamic process. Alertness at every point of the communication encounter is a prerequisite for the supervisor, as well as for the subordinate (reference 31, p. 86).

Empathy is a very important aspect of communication. It is the ability to share in another's emotions or feelings. It is the identification of another's thoughts and attitudes as they might apply to a situation. When placed in identical circumstances, every person has his or her own interpretation based on personal experience and bias. Therefore, to truly connect with an employee, one must make every effort to understand his or her perspective in each situation (reference 31, p. 87).

Finally, it may seem obvious, but it bears mentioning that a manager must establish trust and maintain credibility with the staff. Trust is earned through honest communication and consistent follow-through on promises made. Trust is the foundation of good working relationships. Credibility cuts both ways in the manager-employee dynamic. Each party must take responsibility in establishing trust and maintaining credibility.

Controlling

Controlling is the process of determining that everything is going according to plan (reference 18, p. 30). Every employee should have a **job description,** which is a written agreement concerning the responsibilities of the position. The job description should include a job title, a compensation classification or range, the name of the supervisor who will review performance, a specific and detailed listing of responsibilities, and a performance evaluation schedule. Then a regularly scheduled, structured evaluation is a necessary expectation of employees. People deserve to know how they're doing in relation to a written set of expectations about performance. Regardless of the purpose or format of an appraisal, there are a few critical elements that must be included: standards and criteria of performance, communication of these standards and criteria to the subordinate, adequate frequency of appraisal, and a clear communication of appraisal results.

A **performance appraisal** provides an employee with valuable written feedback about progress made toward specific employment objectives. It serves the employee's need for objective evaluation about how he or she is doing. It also serves the manager's obligation to assess performance and provide constructive feedback. It is the manager's opportunity to put into writing an employee's level of competence measured against the stated requirements of the position. An appraisal also provides a forum for discussion about the employee's training needs, salary expectations, professional development, and career progress. A properly conducted performance appraisal is a two-way conversation, with the manager actively listening to the employee's feedback.

Summary

A laboratory manager has unique skills and a high level of daily responsibility spanning all areas of the organization. Because the technical aspects of running a laboratory are tightly regulated, when technical problems arise there is very often a written set of guidelines that dictate a solution. However, when it comes to managing the human side of the laboratory, there are daily challenges for which there

are no rulebooks and no obvious solutions. But there is a set of time-tested management tools for use by laboratory managers to address these daily challenges. A laboratory manager must become familiar with these tools and use them daily to gain confidence and experience in managing the human side of the laboratory.

The Evolving Models of Clinical Laboratories

In recent years the trend in healthcare delivery has been movement away from separate, independent healthcare entities to larger organizations through the process of consolidation. As part of this trend, many believe the clinical laboratory landscape will similarily evolve, with movement towards large regional laboratory networks that will be formed as a result of laboratory consolidation. The number of laboratories will reduce, driven by outsourcing of laboratory services, competition between laboratories for hospital work, and the commoditization of laboratory tests. Laboratory staff will be expected to deal with demand management and will be responsible for providing additional consultative services related to laboratory testing. The future role of laboratories will be more geared toward quality control, reducing laboratory errors, and eliminating unnecessary testing. Laboratory staffing shortages will continue to be a source of concern, leading to further automation of laboratory services. Also, the future of laboratory medicine will be towards more point-of-care testing. It will involve the integration of point-of-care testing into patient management strategies and pathways of care and more testing at home.

Centralized Testing

Laboratory testing is performed in many different settings, ranging from large, centralized reference labs such as Quest and LabCorp, which perform many complex tests, to one's own home, where one might take a pregnancy test or monitor blood glucose levels. All labs are not the same for the simple reason that not all tests are the same. Just as tests vary, labs also vary in complexity, the volume of tests performed, the technology utilized, and the number and type of professionals who perform the testing. Testing is performed in hospital laboratories, independent reference laboratories, or public health laboratories, at the point of care, or by direct-access testing or home testing.

All hospitals have a laboratory, which is usually proportionate in size to the population it serves. Busy hospitals may process hundreds of samples in just one shift. Tests that are performed include those needed in emergency situations, such as markers for heart attack like troponin, tests where results are needed rapidly for patient care like STAT testing, and other tests done in high volume, such as electrolytes. Hospital laboratories are generally used by all of the hospital's inpatients and outpatients, as well as outpatients who are being seen by hospital-affiliated physicians, such as at hospital-affiliated clinics and physician offices.

Independent reference labs are usually private, commercial facilities that do high-volume routine and specialty testing. Most of the tests performed are referred from physician's offices, hospitals, and other healthcare facilities like nursing homes. While most hospitals try to do as many tests as possible in-house, reference labs are used for specialized tests that are ordered only occasionally or that require specialized equipment.

Public health laboratories are run by state and local health departments to diagnose disease and protect the public from health threats, such as outbreaks of infectious diseases and environmental hazards. These laboratories perform tests to monitor, for example, the prevalence of certain diseases in the community, such as sexually transmitted diseases (STDs); to investigate outbreaks of foodborne illness or water pollution; and to screen newborns for various genetic and metabolic conditions at birth. They also perform rare or unusual testing that clinical laboratories do not offer, like specialized molecular tests to characterize a unique strain of *Escherichia coli* causing infection.

Laboratory tests may also be performed at the point of care—wherever a patient is receiving medical care, rather than in a laboratory. While results from clinical laboratories remain a crucial component of healthcare, they are now complemented by tests performed outside of the laboratory. Point-of-care tests (POCTs) span many areas of medicine and are performed in a wide variety of locations: in the home, at a doctor's office, in the emergency department, and increasingly on hospital units. Technology has caught up to the demand for convenient, rapid test results by enabling testing devices that are smaller, more portable, and easy to operate. Examples of POCTs are blood glucose monitoring, pregnancy tests, and hemoglobin, fecal occult blood, and rapid strep testing, to name a few. Tests included in POC programs must comply with quality standards comparable to tests performed in central laboratories. Point-of-care testing will continue to grow as new devices become available, in part because they provide immediate information to patients and their healthcare providers, allowing for more timely medical treatment.

Decentralized Testing

Direct-access testing (DAT) and home testing allow consumers to order their own laboratory tests without consultation with their healthcare practitioner. As with POCT, DAT has been growing over the past several years. DAT reflects a focus on health and preventive medicine, offering individuals the opportunity to take more active roles in their healthcare. Most states in the U.S. permit some degree of DAT. Over-the-counter home tests are an example of DAT since they do not require a prescription and can be bought and used at the consumer's discretion. It has

expanded to include laboratories offering clinical tests at the individual's request, without consultation with their healthcare provider. In some retail centers, people can walk into a laboratory and request certain tests; wellness centers offer health screens and other laboratory tests; and free-standing and mobile testing facilities such as those in grocery stores and pharmacies offer screening tests to the public. Most DATs limit the availability of tests to simple, general health tests such as cholesterol levels, urine cultures, diabetes screening, and pregnancy tests; however, increasingly sophisticated genetic testing is now offered using self-collection and mail-in of appropriate samples. As with POCT and home testing, DAT may benefit individuals by reducing the expense of office visits, providing vital information to individuals who are concerned with a health problem or who may otherwise avoid testing due to inconvenience or concerns over privacy. However, most insurance companies do not cover tests that are not ordered by a healthcare practitioner, so consumers should expect to pay out of pocket for these services. Laboratories providing DAT services must provide consumers with reference ranges and some assistance in interpreting the results.

The Basics of Financial Management

Departments and functional work areas can be grouped into two groups: revenue centers and cost centers. Revenue departments receive revenue for the organization for services rendered. A **revenue center** is an area of the organization which is responsible for generating a portion of the total revenues expected by the organization. Costs are expenditures incurred by the organization in the course of providing a service. A **cost center** is a unit within the organization whose primary purpose is to provide a service at the lowest possible cost. Examples of cost centers in the hospital setting include the departments of maintenance, dietary service, and medical records. The laboratory may be viewed as either a revenue center or a cost center, depending on how the organization is structured. In smaller institutions, the laboratory may be categorized as a single cost center, whereas in larger organizations, individual sections such as hematology and cytology are assigned as separate cost centers. However, the laboratory does produce revenue in the form of the billable test. In this case, the laboratory (or sections of the laboratory) could be thought of as a revenue center. There are other such departments in the hospital such as radiology and pharmacy.

Costs

Costs are expenditures and are classified as either **direct** (variable) or **indirect** (fixed). Direct costs are those that are specifically associated with a service or process. In the laboratory setting, examples of direct costs include instruments, reagents, and technical personnel. Indirect costs cannot be specifically associated with a certain service or process and must be paid even when a service is discontinued. Examples of indirect costs include clerical staff, inspection costs, and hospital overhead. These costs are shared among several departments or units and thus are allocated accordingly. An example could be hospital utility costs, which may be allocated as indirect costs to departments based on the square footage of the unit.

Direct costs change proportionately with a given change in volume. If the workload for a test or service increases by 10%, the direct costs of performing this test would be expected to increase proportionally. Indirect costs, on the other hand, do not vary as volume changes. As the workload for the test increased by 10%, the cost of the department manager's salary would remain constant.

There are costs having elements of both fixed and variable costs. They vary with volume, but not in direct proportion. These costs are called semivariable. Testing volume could continue to increase without additional supervisory staff, but there could be a breaking point where the test volume increase would necessitate another supervisory position, which forces an increase in the semivariable cost.

Revenue

Hospital laboratory revenues have continued to be reduced over the past few decades. Traditionally, laboratory revenue is paid as percent of charge (gross versus net revenue) or from a prospective payment system that reimburses hospitals based on diagnosis-related groups (DRGs) for hospital inpatient services (Medicare Part A). There is also an ambulatory payment classification (APC) (https://www.acep.org/administration/reimbursement/reimbursement-faqs/apc-ambulatory-payment-classifications-faq, accessed 12 September 2023) (31). Both the DRG and APC systems have shifted the financial risk from the payor to the provider. Another payment method involves laboratories accepting capitated payments based on an insurance carrier's membership, a per-member-per-month fee (PMPM). Laboratories agree to perform all required tests for an entire panel of patients for a monthly fee for all the members regardless of test volume. The emergence of large commercial laboratories has created market forces which drive down the fees laboratories charge and the amounts of PMPM rates. The economies of scale and the ability to have loss leaders for these larger laboratories have continued to put a strain on the viability and contribution margin in the laboratory industry. Laboratories will continue to need to think of new ways to grow revenue, such as supporting quality outcomes measures and developing new proprietary testing.

Gross versus Net Revenue

The bill a medical facility sends a patient or a patient's insurance company lists what is termed the "gross billing"

charges. Rarely are these gross billing charges paid in full. There are adjustments that are made (discounts) from the original charges based on the contractual payment agreements set up with various insurance payors. The original patient charge represents the gross revenue that is billed. The adjustments lower the gross revenue and determine the amount the medical facility should receive. This is the net revenue or expected dollars received. The difference between the gross revenue and the net revenue can be as much as 50 to 60%. A medical facility could bill a total of $100,000,000 for patient services but receive only $40,000,000 to $50,000,000.

Medicare

The Medicare program provides healthcare for the elderly and people with certain chronic diseases. Initially hospitals were paid based on their actual expenses for inpatient care for Medicare patients. In 1983 this all changed when the government instituted the prospective payment system, which reimburses hospitals based on DRGs for hospital inpatient services (Medicare Part A) (18). This system was based on reimbursing hospitals after Medicare patients were discharged and paying a set amount based on the discharge diagnosis. A major revision of the DRG system in 2007 resulted in more than 700 medical severity DRGs (MS-DRGs). If a hospital can treat a patient with a specific MS-DRG for less than it is reimbursed, then it makes money; if it costs more than the MS-DRG reimbursement, the hospital loses money. The government has instituted a similar program for outpatients with ambulatory payment classification (APC) (https://www.acep.org/administration/reimbursement/reimbursement-faqs/apc-ambulatory-payment-classifications-faq, accessed 12 September 2023) (31). Both the MS-DRG and APC systems have shifted the financial risk from the government to the provider.

Physician services and most non-physician outpatient services are paid by the Medicare Part B program based on a fee schedule. Over the years the Medicare Part B fee schedule for laboratory services has not kept pace with the medical price index, so the reimbursement for laboratory services by Medicare Part B has been decreasing in constant dollars.

Managed Care

Managed-care organizations are constantly negotiating with healthcare providers regarding reimbursement. They may pay a set fee for each day a patient is in the hospital (per diem). They may pay on a per-case basis, like Medicare DRGs. They may pay a set fee per month per member for any healthcare needed (capitated payment).

The net effect of the prospective payment system is a significant decrease in reimbursement and cash flow for providers. It does not appear that this trend will change soon. The payment for laboratory services reflects this trend, and reimbursements are usually less than half of the gross laboratory charges. As a result, the overall profit margin for laboratory services is decreasing.

Budgeting

The budget is a financial plan of operations. It is used to forecast anticipated revenues and expenditures over a period, typically 1 year. It provides a reference for the evaluation of financial performance of a department or the organization, and helps control costs. The budget is also a measuring stick for financial accountability. Supervisors or managers are generally held responsible for operating within their approved budgets. It is important to remember that the budget should be driven by the organization's strategic plan. It is for this reason that developing the budget should be a coordinated process between top organizational management and the department-level manager.

Operating Budget

An operating budget is a detailed projection of what an entity expects its revenue and expenses will be over a period. Operating budgets are usually completed annually. Companies complete an operating budget near the end of their budget year to plan for activity during the following year. There are various budgeting processes, with two of the most common types being incremental budgeting and activity-based or zero-based budgeting. Incremental budgeting is the traditional budgeting method where the budget is prepared by taking the current period's budget or actual performance as a base, with incremental amounts then being added for the new budget period. Activity-based (zero-based) budgeting is a system that records, researches, and analyzes activities for each cost the company incurs. Every activity in an organization that incurs a cost is scrutinized for potential ways to create efficiencies. Budgets are then developed based on these results.

Capital Budget

Capital budgeting is a process to determine which fixed asset purchases should be accepted. It involves identifying cash inflows and cash outflows rather than accounting revenues and expenses flowing from the investment. The process is used to create a quantitative view of each proposed fixed asset investment, thereby giving a rational basis for making a judgment. The prevalent methods include net present value analysis and payback period and replacement analysis. Present value is the current value of a future sum of money or stream of cash flows given a specified rate of return. Future cash flows are discounted at the discount rate, and the higher the discount rate, the lower the present value of the future cash flows. The payback period is the length of time it takes to recover the cost of an

investment or to reach a break-even point. Replacement analysis is the method used to decide whether the existing assets need to be replaced or not.

Revenue Cycle: Billing and Collecting

The revenue cycle starts with the office appointment, hospital visit, or other medical service provided and ends when the provider or hospital gets paid fully for the service. The seven steps of revenue cycle include preregistration, registration, charge capture, claim submission, remittance processing, accounts receivable (AR) follow-up, and patient collections. Preregistration is the first step before a patient visits a healthcare institution or healthcare provider. It is the process of obtaining each patient's demographic, health, and insurance information. Registration is finalizing the preregistration process once the patient arrives for service, to ensure all the required information is correct and complete. Charge capture is a process used to get paid for services provided. It is the process where healthcare providers record information for their services and then send it out to different payors and insurance companies for reimbursement. Claim submission is the process of determining the amount of reimbursement that the healthcare provider will receive from the insurance firm or grantor. Remittance processing is when a sum of money is sent from the insurance company or grantor back to the healthcare institution electronically. AR follow-up and patient collections ensure that healthcare organizations have a way to recover overdue payments. Most AR follow-up responsibilities include looking after denied claims, exploring partial payments, and reopening claims to receive maximum reimbursement.

More information on financial management, billing, coding, and reimbursement can be found in sections V, VI, and VII of this volume.

A Brief History of Clinical Laboratory Finances

After decades of profitability created by low direct costs, favorable inpatient reimbursement, hospital-based outpatient reimbursement, and physician utilization, the clinical laboratory industry suffered severe setbacks beginning in the 1990s and continuing into present times. Increased regulatory requirements and the expansion of managed care were the change drivers for many trends in the healthcare and clinical laboratory industries, as listed in Table 1.4 (16). Faced with possible loss of market share, commercial laboratories engaged in fierce competitive bidding for managed-care contracts, further decreasing laboratory reimbursement. At the same time, hospital laboratories faced excess testing capacity created by shifting STAT testing to point-of-care testing (POCT) and decreased inpatient lengths of stay. Laboratory managers have had to expand their focus to evaluating technical proficiency along with analyzing and controlling costs. Managers have strengthened their skills in human resource management, financial management, process improvement, and the creation of business plans. The industry has continued to observe record numbers of laboratory consolidations, mergers, acquisitions, and joint ventures during the past decades. Laboratory restructuring often followed hospital or healthcare system reorganization. Laboratory regionalization, first developed in the 1980s, focused on standardizing policies and procedures and providing improved continuity of care across multiple facilities and sites of care. This enhanced income by expanding the geographic market and lowered costs through economies of scale. This became a primary strategy in maximizing efficiency, thus reducing cost. Additionally, technological developments continue to improve productivity in the clinical laboratory. Laboratory services information is accessible globally, and laboratories are faced with international competition and greater pressures to reduce costs, increasing the commoditization of the clinical laboratory industry (32).

Table 1.4 Change drivers in healthcare and clinical laboratories[a]

Driver	Change
Tighter quality and documentation requirements (CLIA '88)[b]	Reduced test volume Increased cost of production
Increased coding and claims requirements	Reduced collections Increased denials
Reduced Medicare fee schedule	Reduced reimbursements
Managed-care enrollments more than doubled	Shift from fee for service to capitated reimbursement models
Fierce competitive bidding among commercial laboratories	Prices and reimbursements reached plateau, then decreased in 1990s

[a] See reference 21.
[b] Clinical Laboratory Improvement Amendments of 1988.

Managed care, pricing pressure, and capitated payment models, along with advances in medicine and technology, have created a constant state of change. Table 1.5 shows the typical paradigm shifts encountered by the laboratory industry over the past decade. A growing Baby Boomer population, more uninsured (or underinsured) patients, employees exiting the work force earlier, and employers balking at continuing to pay escalating premiums for healthcare coverage will cause many healthcare institutions to accept lower reimbursements. The downward trends in reimbursement will continue with even greater controls and limitations on utilization, forcing further reductions in the unit cost of medical services (reference 33, p. 170).

Management Ethics

Ethics is a very relevant issue in modern management. Every organization should espouse and live a clearly understood set of moral values and maintain the highest

Table 1.5 Industry trends during the past decades

Old paradigm	New paradigm
Centralized laboratory testing	Point-of-care testing (POCT)
	Near-patient and bedside testing
Physician office testing	Home testing kits
	Direct-access testing (DAT)
Laboratory-supervised phlebotomy	Patient-care technician at nursing stations
Inpatient procedures	Outpatient invasive procedures
Fee-for-service reimbursement (FFS)	Global payment systems Diagnosis-related groups (DRGs) Ambulatory payment classification (APCs)
Skilled hospital beds	Skilled-nursing facility (SNF) beds
Prospective payment system (PPS) for skilled-nursing facilities	Consolidated billing: services reimbursed under resource utilization groups (RUGs)
Standing orders	Patient care plans
Preventive healthcare screening and diagnosis V-codes	Medically necessary testing Local medical review policies (LMRP) Advanced beneficiary notices (ABNs)
Routine testing	Specialized esoteric testing
Top-down hierarchy	Bottom-up customer focus
Exceptional service	Creating value

possible standards. The *Complete Guide to Ethics*, an internet guide, provides an excellent resource for all matters relating to business and managerial ethics (http://www.managementhelp.org/businessethics/ethics-guide.htm; accessed July 2022). Ethics, speaking simply, involves knowing what is right and wrong, lessons presumably learned at an early age from parents and other guides (reference 8, p. 86).

Generally, business ethics problems center on two main themes: managerial mischief and "moral mazes" (reference 17, p. 255). Managerial mischief refers to illegal or questionable practices of individual managers or organizations, as well as the causes of those behaviors. A moral maze refers to the numerous and unclear ethical issues a manager faces in everyday work life (reference 34, p. 347–348). Examples here might be real conflicts of interest, wrongful use of resources, or mismanagement of contracts. What is right and what is wrong are not always clear in a competitive work environment.

Organizational vision and ethics come from the top (reference 17, p. 255). The organization's chief executive must support and underwrite an ethics program. Failure on the part of top management to actively and enthusiastically support an ethics program will be noted by the rank and file. The executive officer should champion the program's development and foster a climate that encourages ethical behavior. From the start, the senior officers must espouse honesty and integrity as primary operational traits. The most important step management must take regarding an ethics program is to fully promote it and never waver from the tenets accepted as organizational guidelines (reference 17, p. 255). A strong ethical framework must be one of the guiding tenets for the modern organization. The benefits of developing such a framework are many, whereas the downside can be severe. From the top to the bottom, all employees must accept and live the positive values their organization espouses, thus removing any uncertainty of where they stand with any moral dilemma.

SUMMARY

Leadership, management, and administration are not one and the same. At any moment, any one person may fill any of those roles. Learning what style fits you is a process of self-discovery and is shaped by the situation. The body of research and literature on management theory is broad, from a historical context as well as in terms of the number of those interested in the topic. There is no consensus on what theories present the best and most accurate picture of how to manage groups of people. As society moves forward and technology advances, management theory likewise expands and adapts to the new workplace. The ability to make good decisions often separates the best leaders and managers. Knowing how to work through to a good decision, keeping in mind the elements of time and risk, provides one of the solid bases for managerial success. A manager must develop a system to organize the workflow, policies, and staffing of the laboratory. They must also provide direction to the laboratory by communicating, delegating, motivating, and coaching. A manager must control the activities of the laboratory, constantly reviewing the current situation to ensure that there are no unattended details. There is no substitute for engaged leadership.

KEY POINTS

- Management and leadership are distinct and each serve essential functions. Leadership is an essential part of management. Managers lay down the structure and delegate authority and responsibility; leaders provide direction by developing the organizational vision.
- Management theory has evolved over time. Various models exist which can be applied to situations after consideration of the environment.
- Decision making is the process of making choices by identifying a decision, gathering information, and assessing alternative resolutions. Decision making is an integral part of modern management, with rational and sound decision making a primary function of management.

- Management is typically broken out into four primary areas: planning, organizing, directing, and controlling. Clinical laboratory models have continued to evolve. The balance between centralized and decentralized testing has shifted by institution based on financial considerations, speed of testing, accuracy of results needed, personnel resources, and scope of services.
- Financial management models have changed as revenue streams have evolved and testing models have changed, leading to cost variations.
- Laboratory processes have continued to change, and using proven management and leadership skills, along with qualitative financial analysis grounded in ethical practices, is needed for continued success.

GLOSSARY

Accountability An individual's obligation to be responsible for his or her own actions within the work environment.

Activity-based costing A method used by organizations that assigns a cost to every activity throughout the organization.

Administration Managerial work with a service orientation.

Behavioral theory Management theory based on shifting the focus from strictly organizational needs to the wants and needs of the individual worker.

Business ethics Learning and doing the right thing in the workplace, directly relating to products, services, and stakeholders.

Capital budgeting Process to determine which fixed asset purchases should be accepted.

Classical theory Management theory described by a group called classical theorists. Their work laid the foundation for management theory, in part by identifying the key managerial processes and the skills a manager needs to succeed.

Communication The exchange of information, flowing in all directions within the organization. It can be written or spoken, verbal or nonverbal, formal or informal.

Conflict of interest A situation in which a person has a private or personal interest sufficient to appear to influence the objective exercise of his/her duties.

Continuous/lifelong learning A self-empowering theory, that the employee will throughout his/her life learn and strive to improve and move on to new things.

Continuous quality improvement A more human-focused quality management theory, relying heavily on worker involvement in the product improvement process.

Core laboratory This term may refer to a main (central) laboratory within a multiple-laboratory system, or it may refer to a dedicated section within a single laboratory that does the majority of routine and STAT testing.

Cost center Unit within an organization whose primary purpose is to provide a service at the least possible cost.

Decision theory The study of how decisions are made and what guides a manager to a good decision.

Diagnosis-related groups (DRGs) Based on the discharge diagnosis, DRGs are a system developed by the federal government for prospective payment of Medicare inpatient services to providers.

Directing Planning a specific action and actively overseeing the execution of a plan.

Gross revenue The actual billed charges or fees for products and services before applying any adjustment for contractual arrangements for volume discounts, third-party limits of allowance, or direct and indirect expenses. Gross revenue is derived by multiplying the volume or quantity of services used by the unit price for the service.

Hierarchy of needs Defined by Maslow, from the most basic to the highest level, needs that must be addressed to motivate the employee.

Human relations movement An approach to management that focuses on the worker and his individual needs.

Intuitive decisions Utilization of hunches, subjective values, and personal or emotional factors in deciding what actions to take.

Judgmental decisions Conclusions reached after data are gathered, facts are analyzed, and concrete examples are explored.

Laboratory network A system (formal or informal) of clinical laboratories spread over a geographical area to provide laboratory services in a coordinated, integrated manner.

Leadership Influencing others to attain group, organizational, and societal goals.

Lean Management technique used to increase customer value while minimizing waste and using fewer resources.

Lean Six Sigma Combining Lean and Six Sigma theories for time and process efficiency.

Managed-care organization An organization formed by a third-party insurer as an alternative healthcare delivery system in an attempt to control the escalating costs of healthcare to large employer groups and the government.

Management Getting things done through other people.

Management by objectives Setting goals for the individual to achieve, dovetailing with larger organizational objectives.

Management science Management techniques based on mathematical models.

Medicare severity DRG (MS-DRG) Revised DRG system introduced in 2007.

Mission statement A written statement that clearly defines what the organization does and why it is important.

Moral maze Unclear ethical issues.

Net revenue Gross revenue minus contractual allowances and sales discounts.

Nonprogrammed decisions Unusual or atypical situational solutions.

Organizational chart A diagram showing relationships among functional areas within an organization.

Organizing The process of structuring resources and activities in a way that promotes the accomplishment of specific activities.

Operating budget Detailed projection of what an entity expects its revenue and expenses will be over a period of time.

Operations management Applied management technique, utilizing mathematical modeling and industrial engineering to promote efficiency and effectiveness.

Performance evaluation Formal feedback on job performance.

Point-of-care testing (POCT) Usually refers to tests performed near the patient. Often performed by a nonlaboratorian. POCT is frequently managed or overseen by clinical laboratory personnel within a larger organization.

Process reengineering Rethinking current work in favor of doing something new.

Profit Earnings above the expenditures for salaries, benefits, and direct and indirect costs.

Quantitative theory Management theory based on improving efficiency using a variety of metrics and strong quantitative approaches.

Revenue center Area of an organization which is responsible for generating a portion of the total revenues expected by the organization.

Revenue cycle Process of billing and collecting. The seven steps of the revenue cycle for medical services include preregistration, registration, charge capture, claim submission, remittance processing, accounts receivable (AR) follow-up, and patient collections.

Satellite laboratory A laboratory separated from the main laboratory, usually with a limited test menu, that is dedicated to a specific set of patients and/or locations in a medical facility.

Situational management Acting only on what needs to be addressed at a particular moment and recognizing that there is no best way to get a job done.

Six Sigma A highly disciplined process focusing on developing and delivering near-perfect products and services.

Standard operating procedures (SOPs) A written set of instructions that codify technical and administrative activity in the laboratory.

Strategic decision Focus on an organization's relationship with the external environment, competitive posture, and major policies.

Strategic planning A methodical and structured process whereby an organization defines its mission, identifies directions, develops a unified approach, prioritizes long- and short-term goals, assigns accountabilities, and allocates financial resources.

Strategy The technique, approach, or mechanics developed by the management team to facilitate the organization's ability to perform successfully.

SWOT analysis Analysis of the laboratory's strengths, weaknesses, opportunities, and threats. Strengths and weaknesses are often internal to the organization, while opportunities and threats are often externally derived.

Systems theory The merger of the theories from scientific management and the human relations movement.

Tactical decision Steps toward the implementation of organizational strategy.

Taylorism and scientific management An approach to work and the workplace where every job is divided into the smallest possible segments and each segment is examined and improved.

Theory X and theory Y Defined by McGregor, a theory highlighting the difference between those who believe people need to be forced to work versus those who believe people want to work.

Total quality management Designed-in product quality, with the focus on customer wants and needs as the key drivers in product and process improvement.

Vision statement A written statement that clearly and concisely articulates what the organization expects to become.

Workflow Tasks organized and accomplished in a particular way to achieve a specified result.

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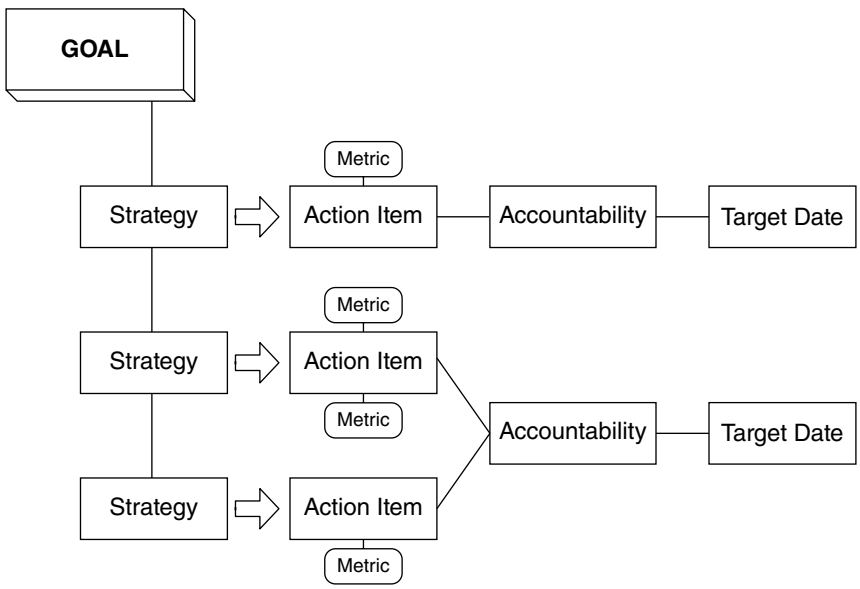
APPENDIX 1.1 Laboratory Strategic Plan



APPENDIX 1.2 Laboratory Organizational Chart