The subject of ethics has become relevant once again since the 2004 expose of fraudulent laboratory practices involving HIV and hepatitis testing at the Maryland General Hospital. After congressional hearings into accrediting organizations entrusted to assure healthcare standards and patient safety, which had inspected Maryland General, vital changes were made — and laboratories are now subject to unannounced inspections. Here, we present a quondam cover story (June 1995) with a companion article (March 1998) that prove the subject of ethics never goes out of fashion.

Ethics is one part of the larger subject of philosophy. You may have studied it in college as one element of a good liberal arts education. Like the rest of us, however, you probably took ethics for granted thereafter.

Today, ethics is revisiting us all, especially those working in the healthcare field. Accusation of fraud, abuse, waste, kickbacks, the sacrifice of quality for financial gain, and conflict of interest all herald a new era of greater accountability and ethical guidelines of healthcare workers.

The right thing. What is ethics? How does one act ethically? How do I know if I am ethical? What should I do if I find that practices in my laboratory are not passing the “ethical test”? Is a code of ethics absolute or are it relative? If the latter, does it make any difference what we decide is ethical?

Ethical behavior means doing the “right” thing. It is quite possible that the ethical solution is not the most cost-efficient way to solve a problem, however. Neither might the ethical approach always result in greater short-term profits. Yet society’s moral structure and government’s legal framework encourage us to walk the ethical high road. Failure to do so can lead to public humiliation — not to mention legally enforced penalties.

Tell the truth. Ethical values include telling the truth, providing full disclosure, being impartial, and having respect for the individual and the law. These values must be put into practice in the clinical laboratory. To that end, I have created three sets of ethical commandments, one for each of the following:

- lab administration;
- business aspects of the laboratory; and
- human resources department and lab employees.

Let these ethical commandments serve as guidelines to appropriate behavior. Here is a closer look at them.
Ethics for laboratory administration

1. Do not release results of questionable quality. If the runs or batch of results do not meet the criteria of acceptability, do not accept them. Even if it means a longer turnaround time or costs more money, treat the specimens as though they come from you or a family member. There is no excuse for releasing results of questionable quality.

2. Do not compromise patient confidentiality. A patient and a patient’s physician jointly own the results. Be vigilant about keeping all test reports confidential and secure. This is especially important when testing for HIV, substance abuse, and pregnancy. Resist the temptation to divulge lab results with patient identification during idle chatter. That chatter could be injurious to the patient’s finances, emotions, or reputation. Be sure that HIPAA requirements are observed.

3. Do not cheat on proficiency testing surveys. Assay survey material in the same fashion that you analyze patient specimens. Do not conduct the survey in duplicate if you assay patient specimens singly. Do not compare your results with those that are produced in some other clinical laboratory until all of the proficiency results are available publicly.

4. Adhere to all environmental laws and regulations. Handle hazardous wastes, radioactive material, toxic fumes, and carcinogenic chemicals according to acceptable standards. Do not expose employees to the potential risks of infectious agents in sputum or blood specimens without adequate protection. Follow universal precautions.

5. Train all laboratory employees adequately for their tasks. A primary cause of laboratory error is inadequate training. It is unethical to expect a medical technologist to do a quality job without sufficient training and orientation. This education includes safety, fire, emergency, and proper laboratory technique.

6. Be honest and explicit in contractual agreements with vendors. Full disclosure is key to all contractual agreements. State fairly and completely the volume of testing anticipated. This is important in that vendors price reagents based on volume considerations. Vendors have a reciprocal obligation to customers in terms of exposing all hidden costs and revealing any upcoming changes that might make the model you have just purchased obsolete.

7. Admit all potential conflicts of interest to your supervisors. Occasionally, a laboratory manager may have a commercial or personal interest in a particular company. Perhaps your spouse is an employee of that firm or you consult for it. Such information must be revealed to avoid even the slightest hint of prejudice.

8. Do not accept gifts of significant value from vendors. Can you truly make an unbiased decision when you have received valuable gifts from a vendor? Such presents might be free tickets to the Super Bowl or the payment of all expenses to attend a meeting many miles from work. It is imperative that you draw a defined line as to what is a reasonable gift and then apply that standard to all vendors.

To deal with ethical conflicts, our laboratory organization has implemented an ethics/compliance program for all our employees.

9. Inform all employees of the ethical guidelines of your organization. Your defined code of ethics must be shared with all employees. It should be presented both in a formal written manner and as part of an ethics/compliance training program.

10. Regularly audit your ethics/compliance program. Is the code of ethics always followed? Are complaints of potential ethical misconduct always investigated? Does the clinical laboratory adhere to all government regulations? Are all billing procedures performed according to appropriate protocols? These issues must be assessed on a regular basis.

Business aspects of the laboratory

- Ethics in business. Here I refer to a commercial laboratory, an in vitro diagnostics company, a physician who tests in his office, or a hospital laboratory that performs outreach testing.

1. Do not provide kickbacks or any other improper incentives to clients. A prime example would be offering a phlebotomist’s services to a physician client. That is ethical as long as phlebotomy is all she does. If she spends much of her time assisting in other office work, that is not appropriate. A myriad of other potential incentives must also be carefully scrutinized. Providing improper incentives may be illegal as well as unethical.

2. Do not exaggerate, misrepresent, or make misleading claims about laboratory services. Be objective in your presentations. If you do not do a particular test, do not say, “We can do it without any trouble,” unless you are certain you will be able to keep your word.

3. Do not make false or misleading statements about competitors’ products or services. Ideally you should not even discuss a competitor’s product or service. But if you must, present the competitor’s case fairly and impartially. Do not spread unfounded rumors or half-truths about rivals.

4. Present all test requisition forms in a clear and explicit manner. The loop of laboratory testing begins with the test requisition form, which should offer a clear choice of available assays. Explicitly define all profiles in terms of what tests are included and which ones must be ordered separately.

5. Do not perform any assays that have not been validated. The validation of new tests should include analytical reproducibility, analytical accuracy, establishment of reference values, and assessment of sources of interference. Only after a test has been thoroughly validated and signed off by the laboratory director should it be offered.

6. Report a lost specimen as “lost” and not as a “laboratory accident.” In spite of the best quality assurance programs, some specimens inevitably become lost. Report them as such. Do not hide behind the mask of “laboratory accident.” Of course, work diligently in order to decrease the frequency of lost specimens.

7. Do not sacrifice quality merely for financial gain. Treat each specimen as if it were your own. Do not use an inferior method just because it saves you money. Do not hire technical support for the lowest salary if they are not qualified to fulfill the job requirements.

8. Perform only those tests requested. Carefully monitor the tests performed vs. those actually requested by the physician. This is especially important in the case of reflex testing. Only if a physician requests a particular follow-up test (e.g., HDL
Cover Story

cholesterol if total cholesterol is elevated) should you perform one.
9. Do not bill for tests not performed. Carefully monitor the tests billed, comparing them with the test actually performed. A clinician may request multiple assays, but sometimes the amount of specimen obtained from the patient is insufficient for the complete analysis. In that case, be sure that the bill is modified to reflect only those tests performed and reported.
10. Do not release products of questionable quality. This related mainly to vendors of laboratory testing devices and reagent systems. All such products must meet acceptable standards based on analytical and clinical guidelines. If they do not, they should be rejected and not released to the client.

HR and lab employees
□ Ethics for personnel. These standards help HR and lab workers to behave ethically in day-to-day situations and encourage them to expect the same conduct from others.
1. Do not violate the law under any circumstances. Here we refer to those regulations promulgated by the FDA, OSHA, CLIA, HIPAA, CMS, and the individual states. All of them must be followed at all times. There are no excuses that justify violating any law. When the regulation seems unfair, communicate with the appropriate agency. Do not disregard any law just because you do not like it.
2. Do not discriminate on any basis. Never discriminate on the basis of age, sex, gender, ethnic background, race, or any other factor unrelated to job performance. This applies to hiring, disciplining, promoting, or dismissing employees.
3. Do not punish employees who criticize. Be open to criticism from employees. In no case should you punish the worker who speaks his piece, especially if it disagrees with management policies or procedures. Of course, the employee in question should present such criticism in the appropriate manner and forum.
4. Take seriously the health and safety concerns of all employees. Make hepatitis B vaccine available for employees at risk of exposure. Make the workplace safe for employees in terms of preventing falls or other accidents. Enforce standard infectious-disease precautions.

Vent all toxic fumes. Protect staff members against exposure to tuberculosis organisms.
5. Do not abuse the phone, mail services, laboratory property, or secretarial support for personal, non-laboratory purposes. Do not use the laboratory telephone for your personal long-distance calls. Do not use any laboratory-owned personal computer for private tasks. Never take any laboratory supplies home for personal use. Do not ask the secretaries to type personal, non-laboratory work.
6. Hire only qualified personnel for each position. Be absolutely certain that hiring is based on merit and qualifications. Never recruit any individuals who are not appropriately credentialed for the job. Follow all state and federal government regulations regarding hiring.

Be vigilant about keeping all test reports confidential and secure.
7. Do not come to work under the influence of drugs or alcohol. Doing laboratory work is serious business. Never compromise your performance by using or abusing mind-altering substances. In my national reference laboratory, we have adopted a substance abuse screening program for all new employees. We also perform random drug testing on everyone, not only to protect our employees but also the patients they serve.
8. Report all violations or possible violations of laws, regulations, or laboratory policies to the appropriate person(s). Each employee has a duty to inform the appropriate individual of any observed unethical behavior. Protect the complaining person’s identity by using an anonymous ethics hotline (or similar mechanism). The success of any ethics/compliance program is based on all employees having direct or indirect access to the compliance officer.
9. Discipline employees who violate the laboratory’s ethical guidelines. Do not accept unethical behavior by any employee without sending the clear message that your organization will not tolerate such action. If necessary, discipline and even dismiss those individuals who act in an unethical manner. The rest of the staff will get the message.
10. If in doubt about an action, ask for guidance. Certain issues regarding ethical behavior are extremely difficult to evaluate. For instance, what represents a significant gift from a vendor? When should a laboratorian accept data in a run even though the run misses one of the many criteria of acceptability? In actual practice, the list of ambiguous situations is a long one. In all of these cases, you must ask for guidance from a supervisor. If necessary, confer with the compliance officer.

From theory to practice
At the outset of this article, I asked whether a code of ethics are absolute or relative. Here is an example of an ethical dilemma in the lab.

We should always maintain confidentiality, I have said. But what if a patient calls for his result and our rule is that we only tell the physician? In that case, the patient’s right to know conflicts with our obligation to maintain confidentiality and tell only his doctor. The prudent course of action is to follow the organization’s policies and procedures for release of medical information.

To deal with this and other issues, our laboratory organization has implemented an ethics/compliance program for all our employees. The elements of the program include:
- commitment from top management;
- selection of a compliance officer and a staff to support his work;
- a code of ethical conduct;
- employee training;
- internal auditing; and
- an ethics action line.

Commitment from top management is crucial. Unless the president of the company strongly endorses the program, it is doomed to a short life. Our company’s newsletter stated, under the signatures of top management, “At every level, company-wide ethics and compliance must become part of our culture. We are extraordinarily serious about and firmly committed to ethical conduct.”

□ Who is in charge? A key way to assess management’s commitment to the ethics/compliance program is to note who is directing the program and the staff who are allocated to support the effort. In our organization, a high-ranking executive directs this program; he has management and clerical assistance. It is critical for a company to put its money where its heart is.
Ethos and the laboratory leader

By William Umiker, MD

Ethics represents what people should do, not necessarily what they must do. Ethics express one’s conscience or morality rather than acquiescence to legal decrees. Some people believe ethics to be "plain common sense — just doing the right thing by people you deal with." Ethical behavior means more than following rules or codes of conduct with a list of thou-shalt-nots. It is a set of guiding principles. Work-related ethics is involved in performance reviews, promotions, assignments, disciplinary actions, protection of personal privacy — including e-mail and facsimile messages — and the sharing of information. Ethical considerations have received more attention recently, more so because of the threat of legal liability than because of a strong concern for people. Some observers feel that ethical violations are on the increase; one-third of respondents to a survey by Geber reported that they had seen violations in the preceding year.

Unfortunately, a clear definition of right and wrong can be elusive. Committees that address quality assurance, utilization review, and medical audits often find themselves struggling with ethical concerns. There is little discordance with regard to agrant violations, but views become murky with less obvious ethical questions. For example, everyone agrees that theft of property is dishonest, but only a few people would seriously label an occasional long lunch break as an unethical act ("time theft"). Problems also occur when the ethics of an institution are not congruent with those of its employees. Differences in awareness and interpretation of ethical standards create many dilemmas. There is also the danger of unequal rights. The same organization that disciplines a nurse aide for coming to work late may ignore a high-revenue-generating surgeon who reeks of alcohol. Examples of ubiquitous ethical violations are shown in Table 1. According to Geber, the top three unethical acts in the workplace are lying to supervisors, falsifying records, and stealing.

Executive actions to enhance ethical conduct

Ethics programs. Some large organizations have established comprehensive ethics programs. These programs begin with a review of the mission statements, values, systems, and policies. These documents must convey a commitment to ethical practice. Corporate values deal with honesty, integrity, loyalty, communication, and customer service — foundations of a moral organizational culture. Statements of values also describe the general boundaries of allowable actions. Next, companies must translate ethical guidelines into sound personnel management policies. CEOs establish ethics committees, appoint ethics officers, revise employee selection and orientation procedures, and develop special training programs. Some even set up ethics departments.

Selection of ethical employers and employees. Job interviewers may be trained to detect job applicants whose ethics seem in conflict with stated company codes of conduct. Panels of appropriate questions may reveal character flaws of an ethical type. Special employment questionnaires and computer-assisted interviews are also helpful. Thorough reference checks can screen out some undesirable candidates.

Ideally, job seekers consider the values of an institution when looking for employment. They inquire about how the organization has dealt with issues that frequently present ethical problems — such as handling lay-offs, downsizing, or the practice of promoting from within. Flawed systems and policies. Put a good performer in a bad system and the system will win every time. Reports indicate that ill-conceived operational systems and policies may provoke ethical lapses in employees. According to Geber, in one study, 29% of respondents reported that they felt pressured to act in ways that violated their organization’s codes of behavior.

In June 1995, Bernard E. Statland, MD, PhD, (now deceased) was president and CEO of a national reference laboratory and director of several large university laboratories. As part of his illustrious career, Dr. Statland was also an official of the Food and Drug Administration. He served on MLO’s editorial advisory board member, and as an editor of the “Tips from the clinical experts” column.
of this abound in our health institutions. Staff size may be reduced to the point that quality service is no longer feasible. Quality improvement is stressed, but employees may be encouraged to take cost-cutting shortcuts. For example, phlebotomists are lectured on compassionate care giving but are chastised when they deliver specimens to the laboratory later than usual because they took time to make a few patients more comfortable during their collection rounds. Some organizations formulate policies that attempt to restrict workplace romances, but these policies may only make employees lie or meet covertly.

The switch from “snitch lines” to “help lines.” Old ethics programs consisted largely of “snitch lines,” in which employees were encouraged to report on others. Such programs may result in calls about petty incidents, such as employees taking long lunch breaks, or complaints about unfair performance reviews.2 Most employees are reluctant to report on the misdeeds of others, thinking that no remedial actions will be taken, fearing retribution, or not trusting the organization to keep the information confidential. They know that “whistle blowers” are seldom popular or appropriately rewarded — and are usually viewed as “snitches.”

This does not mean that employees should ignore serious ethical violations such as a physician physically abusing an aggressive child, or an employee selling illegal drugs. The emphasis has shifted to giving guidance to employees and communicating organizational expectations through ethics training while minimizing the need to catch and punish miscreants. “Snitch lines” are giving way to “help lines” or “assist lines,” in which employees call for personal advice on handling personal ethical dilemmas, or for clarification of company conduct, guidelines, as well as to report miscreants. According to Geber, Texas Instruments Corp. found that 40% of its help-line calls have been for advice; for example, whether or not to accept a gift from a supplier, or if an employee can hire a member of his own family.2

There are other benefits of help lines. They can serve as a needs assessment tool for employees training. If managers receive an inordinate number of questions about a specific ethical dilemma, they can request a specific training session on that topic. These lines can also sound warning bells for problems, especially those that pertain to morale. For example, employees in a downsizing organization may encounter serious problems in dealing with the decisions of who is to be let go and who is to be retained. If nothing else, the help lines provide an opportunity for employees to vent their emotions.

Orientation of new hires. Employees are most impressionable when they are first hired. Institutional orientation programs should emphasize the values that reflect the philosophy of the organization and encourage decision making based on these values.

The role of supervisors and middle managers

As authority and responsibility shift down the organizational hierarchy, supervisors and middle managers are increasingly involved in ethical, professional, and institutional decisions.3 These people set the ethical tone of the work setting, largely by modeling ethical behavior. In any given situation, what they perceive as “right” affects not only their own actions but also the behavior and attitudes of the employees who report to them. In short, ethical managers should see themselves as culture-change agents.

If a supervisor is perceived as unethical, then employees are likely to feel that similar behavior on their part is acceptable. Although workers may not use the word “ethical,” a disturbing number of them question the integrity or honesty of their leaders. Some receive a long litany of broken promises. They note how closely their managers adhere to stated values, especially during a crisis. All too often, they witness a sudden shift in the relative importance of quality when services get behind schedule. Leaders should see the unfurled flag of ethics when they hear employee statements that include “unfair,” “bad,” “should,” “double talk,” “wrong,” or “responsibility.” Table 1 lists a few of the more common ethical violations on the part of supervisors and other managers.

Coping with unethical behavior of supervisors and colleagues. Leaders at any corporate level may come face to face with situations in which the actions of a supervisor are so unethical that the leader feels compelled to do something about it. Options include direct confrontation or reporting the situation to higher authorities, to a regulatory agency (e.g., the Equal Employment Opportunity Commission or the Occupational Safety and Health Association), or to the press. Because disclosures to outside agencies breach the confidentiality and trust that the organization has placed in the employee, this course of action is best limited to major violations and when all other courses of action have been exhausted.

Sometimes the best course of action is to resign. Resignation is the best option when attempts to get a major ethical problem resolved are not made, when there are legal implications, or when the protestor is uncomfortable with the lack of action to the point of causing stress or interfering with one’s job performance. This move also makes it easier to report the unethical or illegal actions of the supervisor to the proper authorities. In the case of misbehavior by one’s colleagues, it is usually best to confront the person to say that you are aware of what is going on, and will have to report it if the transgressions continue.

When one of your employees behaves unethically. If you are the responsible supervisor, gather solid proof, not just rumor or the word of an associate. Document all facts carefully and completely, possibly consult with your supervisor, and then confront the employee before submitting a formal report of a breech of ethics. In other situations, a formal report should be made without prior warning. Good judgment is required in many ethical dilemmas. In some instances, your supervisor should participate in the initial confrontation.

When an employee asks for your advice on an ethical dilemma. Use the same process you would use when an employee asks for your advice on any problem. Instead of giving your opinion directly, walk the person through the thought process so he can reach the right decision by himself. This approach not only leads to conclusions that are satisfactory to the employees but also increases the employee’s self-reliance.

When the same ethical problems keep cropping up or problems are anticipated. Keep ethics in mind whenever operational personnel decisions are under consideration. Hold periodic staff meetings to discuss ethical policies and guidelines. Case studies sensitize the staff to concerns such as confidentiality, the patient’s right to autonomy, issues of age, race, and sex discrimination.4 Table 2 lists some steps for making a decision about an ethical problem. Remember to measure your effectiveness by how many people

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<th>Examples of violations of workplace ethics</th>
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<td>Lying or distorting facts</td>
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<td>Blaming others for one’s mistakes</td>
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<td>Taking credit for the ideas of others</td>
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<td>Divulging confidential information</td>
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<td>Abusing sick-time benefits</td>
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<td>Behavior in a manner that represents disloyalty to superiors or employers, for example, purposely creating crises or disharmony</td>
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<td>Unauthorized “borrowing” of equipment for personal use</td>
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<td>Falsifying expense accounts</td>
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Table 1.

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<th>Common ethical violations by laboratory group leaders</th>
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<td>Condoning any of the behaviors listed in Table 1</td>
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<td>Tolerating or ignoring work violations</td>
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<td>Protecting substandard performers from corrective measures</td>
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<td>Suppressing or not reporting grievances or complaints</td>
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<td>Demonstrating favoritism in assignments, work schedules, approval for attending meetings</td>
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<td>Practicing discrimination or favoritism when evaluating performance</td>
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<td>Depriving supervisors of honest feedback about how employees are reacting to a new directive</td>
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<td>Trying to impede the career of a disliked person, or recommending that the position of that person be eliminated</td>
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<td>Falsifying data while preparing for an inspection</td>
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<td>Condoning overcharging by unnecessary diagnostic testing (deliberate double-billing, charging for tests that are part of a research project and would not otherwise have been ordered, or billing deceased patients for diagnostic procedures not reported until after the patient has died)</td>
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Table 2.
between employees or between employees and supervisors. Organizations, such as the American Medical Association, publish formal codes of ethics to guide their members on professional behavior, although these codes may be too broad for daily use. Religious leaders are always able and willing to advise on interpersonal ethical issues.

**Conclusion**

Ethical considerations enter many facets of everyday functions in healthcare institutions, including laboratory practices. Managers and their employees must reflect on their values and the values of their organization whenever they plan or carry out their duties. Leaders must ensure that everyone knows what is regarded as ethical and unethical behavior. Rules and regulations should reflect ethical values.

William Umiker, MD, is adjunct professor of pathology, Pennsylvania State University, Milton S. Hershey Medical Center, Hershey, PA.

**References**


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**Clarification:** In MLO’s June 2007 issue, the cover story on page 12—— “Potential and pitfalls of NBS, and the reference lab’s role” by Dennis William Bartholomew, MD—— was followed by a sidebar written by Dennis J. Ernst, MT(ASCP), on page 19 entitled “Pain reduction during infant and pediatric phlebotomy.” The photograph of a small boy on page 22, provided courtesy of Terry Bleeker, Columbus Children’s Hospital, Columbus, OH, should have been part of the former article instead of appearing in the sidebar. We extend an apology to Terry Bleeker and to the providers of the cover article for having used the photo in an article other than Dr. Bartholomew’s.

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**What is an Acceptable Rate for False Positive Test Results?**

1 in 5000?

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