Testing in the years ahead: new pressures and new concerns

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In the past, testing by blood banks was intended primarily to ensure product quality or donor safety or to meet existing regulations. As a result of recent pressures, especially the AIDS epidemic, additional reasons to test have become evident. Although some of these reasons are not easy to accept, it is appropriate to review them and to evaluate a new approach to reaching blood bank decisions that have public policy implications. It is suggested that The Institute of Medicine of the National Academy of Sciences sponsor a new and permanent structure for this purpose. TRANSFUSION 1990;30:63-67.

In 1977, GIBLETT, in an article in this journal,[1] articulated the concerns of many blood bankers when she wrote about the need to shift the emphasis in serologic testing from unproductive procedures to more important problems. That article, plus the interest of others, kindled a new awareness that unlimited and unnecessary testing could no longer be justified. Giblett's article stressed what had become a concern of many: that testing without direct benefit to the patient was wasteful. In the years that followed, an evaluation of previously established routines and work patterns continued, with the goal of reducing serologic testing to the amount that could reasonably be expected to help the patient. Questions about overtesting and a desire to see adequate documentation of the value of new serologic tests before they were added became the norm. The benefits from a reevaluation in work patterns plus the demand for data before the institution of new tests were beneficial to all, but especially to the patients who received appropriate services and were not charged for unnecessary work.

The traditional world of blood banking, and with it many of the methods by which decisions had been made, came to an abrupt and painful halt with the acquired immune deficiency syndrome (AIDS) epidemic and the realization of what that epidemic would mean to transfusion medicine. The field has shifted from one dominated by serology to one in which infectious disease transmission, donor concerns, and the quest for total safety have become paramount. In this setting, it seems appropriate to review why we test, how new tests should be evaluated, and how decisions that will need to be made in the years ahead should be made. Decisions about new tests are and will continue to be difficult, and this difficulty is compounded by strong pressures to contain the cost of medical care.

The usual and most obvious reason for testing is to enhance the safety of transfusion. There can be no doubt that the overriding concern when considering any testing is the furthering of the best interests of the patient. But what has become apparent in recent years is that many other factors enter into the decision to test or not to test. Some of these factors are easy to understand and justify, both to ourselves and to others. Others are less easily defended, but they definitely exist. What is needed now is a way to approach testing so that we will be able to make intelligent decisions, know why they were made, and be comfortable that such decisions can stand public scrutiny.

Reasons to Test

There are several reasons to institute (or continue) a particular test:

- Patient safety
- Donor safety
- Staff safety
- Improvement in the quality of the product
- Federal, state, or local requirements
- Requirements of "voluntary" accrediting agencies
- Reduced medicolegal vulnerability
- Liability insurance
- Reduction in costs
- A marketing advantage.

Many of these reasons are self-evident and need little discussion, whereas others are less clear and will cause concern when they suggest the use of a test that appears to offer little in the way of increased patient safety. It does seem, however, that an open and honest appraisal of *why* new tests are suggested can only be beneficial to our decision-making process.

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laborious record keeping) is undertaken only to meet an association's inspection requirements. While this practice was more common in the past, examples can probably be cited today as well.

Reduced medicolegal vulnerability

For blood banks and transfusion services, one of the most frightening consequences of the AIDS epidemic has been the hostile legal climate that now exists. The rash of AIDS-related suits and financial judgments against blood banks have added a new dimension to decisions about testing. Such decisions may no longer be made *only* on the basis of what appears to be good for the patient or donor. Medicolegal consequences must be considered in the decision whether to add tests. For example, there are good arguments for the institution of HTLV-I testing, but one can question whether this decision would have been made so quickly without blood banking's recent experience with AIDS.

Measures designed to reduce medicolegal exposure are now considered along with those intended to enhance patient safety. The long-term consequences of this are yet to unfold, but a new approach to defining standards of practice may help in deciding when new tests should be added. This, in turn, may lessen pressure to increase testing for only "legal" reasons.

Liability insurance

The medicolegal vulnerability with which blood banks now live has led to a situation in which insurance coverage is becoming increasingly difficult to obtain. The natural response on the part of both underwriters and blood banks is to do *everything* possible to avoid even the slightest possibility of liability. And everything often translates to more testing. A test no longer has to be even effective; it need only look like the right thing to do to be considered as one way to guarantee insurability. What is true for lawyers is equally true for insurance underwriters, who represent a new group that must be involved in the decision on what tests will be done. The concept of being uninsured in this age is frightening—hence the need to take any and all steps to maintain coverage. The end result is often a decision to add another test. As with medicolegal exposure, if a decision to test can be based on scientific data coupled with a recommendation from a recognized and unbiased group, insurance underwriters should be satisfied.

Reduction in costs

An argument can be made that, at times, additional testing will reduce costs. For example, HLA testing of donors before apheresis allows only suitable donors to be recruited. If there were a rapid test for antibody to hepatitis B core antigen, it could be worthwhile to institute it rather than to draw blood that may have to be discarded. As patient needs become more well defined, it is likely that more specifically selected donors will be used; for example, only cytomegalovirus-negative donors with high platelet counts will be chosen for some recipients. Testing to reduce cost is unusual today, but it may become more important as we develop additional patient-tailored services.

A marketing advantage

One result of the recent trend of viewing blood banking as an industry has been the increasing application of traditional marketplace values to the decision-making process. The consequences of this are only beginning to be realized, but it is possible that some tests may be offered primarily to increase a blood bank's market share in a competitive environment. Such considerations could apply both to donor recruiting and to the competition to gain more customers for the blood bank's products.

The use of only volunteer donors, along with the continuing difficulty in recruiting enough donors to meet the demand, has forced recruiting personnel to find innovative ways to elicit and maintain interest in blood donation. Because all gifts or incentives with monetary value are considered unacceptable, some banks have offered free testing for substances such as blood cholesterol and blood sugar. This additional testing can be viewed as an effort to increase market share (in this case, donors). Examples of tests offered as donation incentives have been reviewed in the literature,[5] but tests to increase patient or physician requests for a particular blood bank's components have been discussed only in an unofficial way.

It is apparent that all tests cannot be applied to all donations at all blood banks. But it is also apparent that some blood banks can and do offer more extensive testing than do others. In fact, only strong federal intervention has prevented this practice from becoming more widespread. When a particular segment of the blood supply is tested, especially for infectious agents, and when the competitive segment is not similarly tested, problems are sure to arise. The fact that the offered tests may not have demonstrated efficacy, may not be cost-effective, or may not even be of value has little effect when the motivation for their introduction is to increase market share. The problem is even more difficult when, as is often the case, the tests have or can reasonably be expected to have *some* value.

The dilemma is clear. Should a blood bank or transfusion service have the right to add tests and to say that these tests are being done, even without claiming that they increase the safety of the blood supply? Or should there be restraint, governmental or otherwise, that forces all blood banks to a single standard of testing? The latter position may sound unreasonable in our competitive and market-oriented society, but given the realities of today's

to start with, will be a negative factor when new tests are considered by blood banks.

Discussion

Giblett's admonition that "serious thought should be given to the best and most efficient ways we can direct our efforts to protect patients from the hazards of transfusion and provide them with the products they really need"[1] is no less true today than it was in 1977. But the setting in which we work has changed, and considerations over and above patient protection have become important in deciding what testing is indicated. We no longer have the luxury of working in a relatively restricted environment. Blood banks and their practices have become the focus of interest of many individuals and groups, not all of whom are supportive of the traditional blood bank system. There is a need to rethink the way in which blood bank decisions that have public impact are reached and a need to accept that factors in addition to patient safety have a role to play when decisions, particularly those related to testing, are being made.

Pressures to add a new test often arise before adequate data are available, because interested parties demand immediate action. Such parties include researchers who have a special interest in the test, reagent and kit manufacturers, health care activists, legislators who perceive a problem or seek an issue, and the press, all of whom have their own agendas and goals. What is needed is a mechanism to reach proper decisions in such a setting.

Two previous structures, each dominated by the blood banking community, have failed. Neither The Joint Blood Council nor The American Blood Commission was able, in the long run, to react adequately to blood banking's problems. I suggest now that future problems be addressed by an organization responsive to, but not dominated by, blood bankers. The organization should be highly regarded in medical, political, and lay circles; be aloof from blood banking's turf wars and political problems; be able to act quickly and speak with authority; be scientifically based; and include individuals who are seen as patient and donor representatives. The organization should include blood bankers, but not necessarily as "representatives" of existing organizations; it must not be just another blood bank committee. In my view, The Institute of Medicine of the National Academy of Sciences is the ideal organization to sponsor such a group and provide the framework for a new approach to decision making in the area of blood bank practices as they affect public policy. The institute has already shown evidence of an interest by hosting a conference to examine the topic of a zero-risk blood supply.

Any group that attempts to establish policy will need data, and it is incumbent upon the blood bank community to take a leadership role in providing such data. The recent HIV p24 antigen study done jointly by the AABB, the American Red Cross, the Council of Community Blood Centers, and the FDA is a sterling example of how such data can be gathered with a cooperative approach. These groups recognized a problem, designed and implemented a study, and now have data that can be used to reach a decision. There will be other cases where such studies can provide much-needed data, and the results plus unambiguous recommendations from a neutral group can be of great value when blood banks assess the need for new tests. At the same time, this approach should increase public confidence in our blood banks and reduce our exposure to charges of self-serving behavior.

Some pressure for new tests arises from fear of litigation. No approach can eliminate a blood bank's exposure in this area, but following scientifically based recommendations from an organization such as The Institute of Medicine will go a long way in establishing that a particular blood bank's approach met the accepted standard of care. In such a setting, those who make decisions for blood banks should feel less pressure to recommend tests that can be justified only in terms of reducing medicolegal exposure.

Finally, the issue of donor and recipient participation can be addressed—albeit imperfectly—by including representatives from these groups in the decision-making structure, both nationally and locally. Candidates can be found in many places: labor unions, industry, schools, government, social societies, service organizations, and consumer advisory groups, to name a few. The right people can grasp the issues and contribute a meaningful voice to the deliberations. The need now is to accept the new reality, to work constructively in the altered setting, and to accept the fact that new forces have come into play.

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