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Establishing a Direct Laboratory Access Program

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Direct Laboratory Access (DLA) refers to a program whereby individuals who wish to have laboratory testing performed can avail themselves of such testing independently of a physician referral. DLA benefits both physicians and consumers. Physicians benefit by not having to invest time and office resources for consumers who do not seek medical intervention but rather who visit physicians for the sole purpose of obtaining permission to have laboratory tests performed. Consumers benefit by avoiding physician encounters they do not want, by receiving state-of-the-art laboratory testing they do want, and by avoiding the added expense and inconvenience of a physician office visit. DLA appeals to an anxious, educated, and somewhat affluent niche market. The program fills a void in the provision of health services while providing a small stream of revenue for laboratories.

Indexing Terms: *economics of laboratory operation/laboratory management/over-the-counter tests*

Background

Many health-conscious individuals wish to have laboratory testing performed but want to avoid the inconvenience and expense of a physician office visit. These individuals are willing to pay for such testing out of their own pockets, and they are willing to accept most or all of the responsibility for acting on the results of these tests (*1, 2*). Most are educated and reasonably sophisticated relative to the meaning and consequences of the testing they desire, which in turn is usually related to a specific question, such as: "Am I infected with HIV?" "Am I pregnant?" "Have I taken too much Coumadin®?" "Is my cholesterol too high?" or "Can I serve as a directed blood donor for a sick relative?"

For the most part, the testing desired by these individuals is standard fare and appropriate to their circumstances. Despite this, laboratories have not embraced the opportunity to provide these would-be clients with services. The reasons are many and include inertia, concern about alienating their physician-clients, fear of litigation, lack of protocols to manage the encounters and the follow-up should this be needed, and the need for physician laboratory directors to become directly involved in providing parts of these services. The result is that most laboratories have missed an opportunity to provide medically relevant services to a unique niche market. Unlike most market segments, which require a sales force and constant nurturing, this segment pursues the services on its own without the need for marketing representatives, discounts, promotions, and so forth. Filling this unmet demand is what Direct Laboratory Access (DLA) is all about.[1]

DLA is a simple concept. It refers to programs whereby individuals who wish to have laboratory tests performed can either test themselves, using Food and Drug Administration (FDA)-approved home testing kits, or they can approach a laboratory directly without being referred by a clinician in a traditional clinician–patient encounter. Home testing is of some value, but the menu of FDA-approved analytes is quite limited: urine and blood glucose, fecal occult blood, pregnancy tests, cholesterol, and tests for ovulation (*1*). The FDA has been slow to expand this list, despite the fact that test kits for several other analytes would be simple to format for home use. Although the FDA has not issued a policy statement regarding its assessment of the benefits and risks of home testing, the go-slow approach the FDA has pursued suggests that the Agency is at best ambivalent about permitting consumers to test themselves in the privacy of their homes.

Exclusive of home testing, DLA takes two forms. The first is the health fair. Most larger communities conduct health fairs, offering cholesterol, blood pressure, hearing, and vision testing, plus a potpourri of other physiological and laboratory tests. These fairs are scheduled events that may be held once or twice a year. The test menus available to health fair participants are limited and of a general screening nature. Accordingly, although health fairs provide valuable information to individuals who want data relating to their overall health assessment, they do not offer the flexibility to address specific medical questions in a timely manner. For these latter situations, a different program is required, one that offers a large variety of tests with high quality and rapid turnaround, easily understood reports, and hassle-free access on an as-needed basis. The service must be reasonable in cost and must be monitored by physicians who will intervene should there be a medical indication to do so. The logical entity to package such services into a program is a licensed clinical laboratory with an on-site medical director.

The Las Vegas laboratory with which I am affiliated first became involved with direct access because of the large tourist population attracted to this community. It was not uncommon for visitors from out-of-state to

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[1] Nonstandard abbreviations: DLA, direct laboratory access; FDA, Food and Drug Administration; STD, sexually transmitted disease; and HIV, human immunodeficiency virus.

appear at one of our outpatient centers because of what they perceived as a minor medical emergency. These were sometimes individuals receiving Coumadin who had experienced minor bleeding or a suspected clot and wanted to have a prothrombin time done. Occasionally, a patient receiving theophylline had developed wheezing and wondered whether the dosage needed to be adjusted. Many other situations arose as well. Originally, it was laboratory policy to advise such patients that requested tests would only be performed if ordered by a Nevada-licensed physician. Because their own physicians were out-of-state, this policy forced these tourists to develop a physician–patient relationship with a local physician or to forgo service. Tourists often became irate, and a war of words and nerves ensued. Although our personnel prevailed in enforcing laboratory policy, it eventually became apparent that the policy was inappropriate; it served neither the would-be clients' medical needs nor the laboratory's mission of providing timely and quality services to those who would benefit from them.

Eleven years ago, management reversed its long-standing policy regarding these encounters. Because each pathologist on our staff was licensed by the state as a medical doctor and could therefore order laboratory tests on behalf of individuals who requested them, management elected to perform all tests requested by "walk-in" individuals with no questions asked. This change in policy eliminated the negative encounters that had previously erupted in these situations. Moreover, the service was appreciated by clients and provided the laboratory an additional, albeit small, stream of revenue.

To provide safeguards for the individuals on whose behalf tests were ordered, as well as safeguards for our facility, we evolved formal guidelines for this program. These included methods and procedures for phlebotomists, client services personnel, pathologists, and others involved in the DLA program. So as not to alienate referring physician-clients who might view the DLA program as competitive with their practices, no formal announcement of the program's inception was made. In fact, the program has never been formally acknowledged or advertised. Despite this, it has gradually expanded on its own and, currently, the majority of the individuals seeking service are local residents of the community rather than tourists.

The specifics of the program are lengthy and are contained within various methods and procedures of the departments to which they pertain. Although these details are not within the scope of this presentation, two short lists of the program's principal features are shown in Tables 1 and 2.

Table 1. Essential elements of a DLA program.

A physician orders all tests on behalf of the individual requesting testing.
A physician reviews all test results in timely manner.
No sample will be drawn unless the requesting individual provides an address or phone number in case it is necessary to contact him or her concerning abnormal results.
A disclaimer is present on each DLA laboratory report.
Reports are made available to the patient only. Results must be picked up with photo identification.
Letters are written whenever an abnormal result triggers a physician response as defined by protocol.
In such letters, the individuals addressed are invited to call the pathologist if they wish assistance obtaining a physician's appointment.
A permanent file is maintained of all letters sent.
Phone calls are made if a life-threatening critical value is obtained.

Implementation of DLA

There are several prerequisites for developing a successful DLA program. The first and most critical is a commitment from management to do it right. In this regard, DLA is similar to Total Quality Management and Autologous Blood Donation programs. In institutions where management is committed to such programs, they flourish; elsewhere, they languish. To "do it right," DLA requires formal protocols and related staff training concerning encounters with individuals seeking service, method of payment, record keeping, pretest preparation (e.g., fasting samples, timed sample collection), and follow-up of abnormal and critical values. The latter entails a willingness on the part of a licensed physician (usually the pathologist medical director or designee) to initiate contacts with DLA clients if results are significantly abnormal as defined by various protocols.

A second prerequisite is the availability of a licensed physician (once again, this is usually the pathologist medical director or designee) who will order tests on behalf of individuals seeking such service and will review results after completion. Note that, in view of the 1989 Stark Law, this physician cannot have an ownership interest in the laboratory to which he or she refers patients for testing (*3*).

A third prerequisite is the establishment of a DLA client account with its own distinctive client number. This facilitates the sequenced generation of reports for pathologist review and also the generation of computerized summaries of account activity for purposes of monitoring the program.

Table 2. Practical considerations for DLA testing.

The DLA program is not advertised.
Individuals must pay for testing at the time of service.
Copies of reports will not be mailed by the laboratory to designated physicians.[a]
Individuals eligible for Medicare must sign a release indicating that testing is not a covered Medicare benefit and that they agree to be personally responsible for the cost.
An HIV pamphlet is handed out to patients in advance of HIV tests.
Pretest counseling available on request.
Contact with a physician is attempted if the HIV test result is positive.

[a] To avoid presenting the physician with an abnormal value for a patient the physician does not know or has not seen for many years.

Over and above these prerequisites, formal protocols must be developed to address both the mundane and the difficult issues that DLA raises. The mundane issues include such things as the wording of disclaimers on DLA reports, standard letters notifying individuals of significantly abnormal results, methods of payment, and record keeping regarding client encounters. The more difficult issues relate to testing for sexually transmitted diseases (STDs), testing requested by minors, attempted coerced toxicology or parentage testing on minors by parents or guardians, toxicology testing requested by individuals who wish to know whether they are likely to pass their upcoming preemployment drug screens, identification of individuals who come to pick up their reports, disturbed or patently psychotic individuals who desire inappropriate testing services, providing telephonic reports without compromising confidentiality of data to unauthorized individuals, handling of critical ("life-threatening") values, and counseling of individuals seeking services, should this be medically necessary or desired by them.

Regulatory and Legal Considerations

In all 53 states and territories, laboratory tests can be ordered by licensed physicians, which of course includes physician-laboratory directors. According to a survey conducted in April 1989 (*4*), 30 states and territories put statutory or regulatory limits on DLA testing; in the remaining 23 states and territories, laws permit consumers to order any-and-all laboratory tests on themselves should they wish (by default). As a practical matter, however, although the laws in those 23 states and territories do not restrict consumer access to laboratories, it does not follow that consumers can secure the testing they want unless the laboratory they approach has already initiated a DLA program. At present, this is unlikely.

What Tests Are Most Often Requested?

To determine what tests consumers are most interested in having performed, we tabulated the requests for DLA tests performed at Associated Pathologists Laboratories in Las Vegas over a 4-month period from March through June 1994. The most commonly ordered test was for human immunodeficiency virus (HIV) antibody, followed closely by urine or serum pregnancy tests. The remaining tests, in order of frequency of request, were: cholesterol and lipid panel testing, chemistry profiles and single chemistry tests (mainly glucoses), ABO/Rh blood typing, culture and antibiotic sensitivity, semen analysis, and thyroid testing. Therapeutic drug monitoring, for which the DLA was initially instituted, constitutes a relatively small number of requests at present. There are two reasons for this shift. First, although a trickle of tourists continue to request such tests, the program now caters to a much larger population base, local residents. Local residents tend to use their own physicians—or emergency rooms/urgent care centers—for therapeutic drug monitoring and for other situations that might require immediate physician intervention. But many local residents select the DLA option to obtain answers to medical questions that do not require immediate physician intervention. Second, the past two decades have seen a fundamental shift toward convenience throughout American society. Automated teller ("cash") machines, home pizza delivery, and disposable diapers are but a few examples. Individuals who were once willing to go through the "ordeal" of a physician office visit to learn whether they were pregnant or had high blood cholesterol now seek more convenient alternatives for obtaining such information.

Test Results of High Emotional Impact

Certain test results, particularly those for HIV antibody, pregnancy, and genetic disease carrier status have high emotional impact on recipients. The decision by many laboratories not to initiate DLA programs has been promoted by their concerns about how to handle these situations. With regard to pregnancy testing, however, over-the-counter home pregnancy test kits are now available in drugstores and supermarkets, and kit sales are brisk. A 1989 report from the Office of the Inspector General, Office of Analysis and Inspections, indicated that between May 1976 and January 1989, 38 self-test pregnancy kits were licensed by the FDA (*5*). This same document quoted an industry source who estimated that 20% of American households have already used at least one home testing product, for a total annual sales of $600 to $800 million, and predicted that all American households will engage regularly in home testing of some sort by the year 2000.

The emotional impact of test results from these do-it-yourself pregnancy kits has not been an issue. Because of concern about what advice to give women who request pregnancy tests through the DLA program, several drugstore kits were purchased, and the package insert circulars were reviewed. An interpretation was synthesized from these package inserts. This interpretation is affixed to all pregnancy tests requested by DLA clients.

Another test result with high emotional impact is HIV antibody. Although HIV antibody testing is readily available at the local health department through the STD clinic, there is a disadvantage to the use of this service; being seen and recognized at an STD clinic has obvious implications. On the other hand, being seen and recognized at a clinical laboratory has no stigma attached. Consequently, many local residents use the DLA option for HIV antibody testing. Individuals requesting an HIV antibody test are given a short pamphlet prepared by the US Public Health Service entitled, "What about AIDS testing?" They are asked to read the pamphlet and are asked whether they would like pretest counseling—at no charge—by a pathologist. With rare exceptions, such pretest counseling is declined. Fortunately, the majority of HIV antibody tests are nonreactive. Consumers who pick up their test results, also receive a letter, as well as the results for all Western blot-confirmed positive HIV

antibody tests. The letter invites the individuals to make an appointment to be counseled by a pathologist, again at no charge. In a review of the last 10 consecutive Western blot-confirmed HIV positives, only 2 individuals requested counseling.

Genetic testing has not been an issue. A few health fairs at a local synagogue have offered Tay–Sachs carrier testing, and a few health fairs in predominantly black neighborhoods have offered sickle cell testing. Over and above these health fair-promoted genetic screening tests, a combined total of <20 of these two tests has been ordered by DLA clients during the 11 years of the program. No individuals requesting carrier status testing for genetic disorders other than Tay–Sachs or sickle cell disease have yet been encountered. Only one pregnant woman requested α-fetoprotein testing on herself. This woman was contacted by a pathologist and was found to have a previous history of a child with neural tube malformation. The woman appeared to be retarded and was not under the care of an obstetrician. She was referred to the state welfare division, which in turn assisted her in obtaining obstetrical care.

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