

Laboratory Issues in Office Practice

Frank M. Reed, M.D.
Family Physician
Englewood, Colorado

Abstract: Laboratory testing in office practice is an important element in the comprehensive delivery of ambulatory health services to both primary care and specialty patients. Laboratory testing occurs in 10-20% of ambulatory office visits, but its impact on patient care outcomes remains largely unknown. Efforts to understand better laboratory problems in office practice should focus on pre- and post-analytic phases as well as on the impact of other forces currently shaping office practice (e.g., managed care). The process of obtaining adequate tests is becoming at least as complex and expensive as the issues surrounding the accurate performance of the tests themselves.

Future research efforts should examine which office-based laboratory testing is essential for timely clinical decision making and favorable patient care outcomes. Wherever possible, methods of streamlining and consolidating the process of laboratory testing should be pursued, while appropriate safeguards for accuracy and adequacy of results are maintained.

Realizing that we all approach the issues involved with the Clinical Laboratory Improvement Amendments (CLIA) from different perspectives, it would be valuable if we occasionally attempted to view these issues from each other's perspective. I am reminded of the metaphor of how each discipline in the medical enterprise is like a house. If everyone took care of what is in their own house we all would have a very good neighborhood. This neighborhood is a place that patients percolate through. In case you're wondering what my real agendas are, I have two: The first is that whatever we do, whether it is in the house of laboratory or the house of hospital or the house of community or the house of physician's office (wherever that might be), we had better do something that helps the patients we see live better and happier lives. The second agenda is of a more personal nature: It involves determining the "method of entry" for

patients into the medical neighborhood. It must be a system that is functional, manageable and driveable as we proceed into the future. Many of the active discussions that I have with colleagues concern the relationship between this portal, through which we are passing, and the clinical laboratory issues we see in CLIA.

As I proceed, I would like to continue my discussion from a non-laboratory frame of reference. My perspective of what the state of primary care is today is similar to that of being stranded at a railroad crossing with the train's engine stalled. There are numerous issues today that, I believe, are severely impacting those of us in primary care. Dr. Collins made references to many changes that have taken place during the years within the neighborhood of laboratory medicine. Likewise, from my focal point the hospital community has experienced significant changes. The hospital where I currently

practice was purchased in 1995 by Columbia Health Corporation of America. After 50 years of being a not-for-profit community hospital, it suddenly was swept into corporate America. As a result, my perspective as a primary care physician has been somewhat altered by the intertwining of public health versus individual patient perspectives.

As an example of the latter, when someone comes into the office and has expressed a fear because their grandmother died of bowel cancer and now wants to know whether they should have a flexible sigmoidoscopy, there is that one-on-one moment when you are not thinking about the entire country, but rather about the needs of that individual patient. The laboratory issues that permeate my life are those decisions that are not made on the basis of the quality of the reagents but rather on a myriad of other factors such as technology, accuracy, precision and validity. These are the important matters in one house in the neighborhood.

If one were to consider my perspective, as a primary caregiver who deals with a larger patient population, they would probably see the role in which I am serving as one that is slowly becoming extinct. Despite the fact that this country is currently focusing so much of its attention on the future's need for additional primary care physicians, it is comparable, I believe, to investing one's hope in the snow leopard. There is little chance that our efforts will be successful in convincing medical students why they should pursue a career in primary care. The curve, as seen in Figure 1, represents several studies and demonstrates in the broadest scope what is happening in primary care offices such as mine. Although there are some exceptions, in general, the

revenue realized by primary care practices will continue to decline relative to expenses.

If future projections are correct, these factors will soon become inversely proportional to one another. In providing more quantitative support to this discourse, let me briefly describe the staffing requirements in a small practice. A certain number of personnel are needed to support one full-time equivalent, (i.e. physician). In 1990, 2.3 to 2.4 support personnel were required for each physician on staff. Currently, in some regions of this country 7.4 support personnel are required for every physician. In my office the number of support personnel is 4.9 compared with the national average of 5.3. No study to my knowledge has shown that increase in support personnel is correlated with an improvement in the quality of patient care. The increase in the number of these employees has helped in managing the burden of paperwork resulting from regulatory requirements, which I hope have produced some beneficial outcomes.

I am not particularly encouraged by what I see in the future. We were taught in medical school that if we practiced good medicine, the business side of our practice would take care of itself. Numerous primary care physicians, not only specialists, are being forced to leave their practices either because they can't get contracts or because it's just not possible to run a business when you have to operate within the narrow profit margins that are offered. Patient survey demonstrate that problems remain with access to physicians. Reducing the number of primary care physicians does not appear to be a logical solution, however. This presents an incredible challenge not only for current family practitioners, but also for interns who are coming into primary care.

THE OFFICE MILIEU

- ▶ MORE PATIENTS
- ▶ MORE EMPLOYEES
- ▶ MORE OVERHEAD
- ▶ LESS REIMBURSEMENT

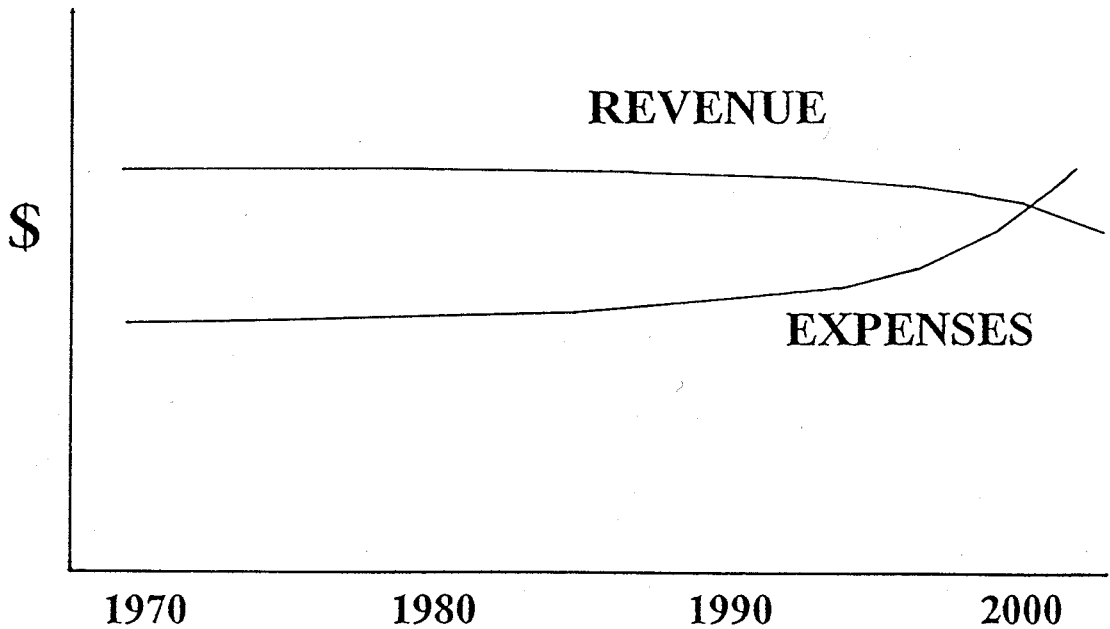


Figure 1

The Role of Laboratory Testing in Primary Care

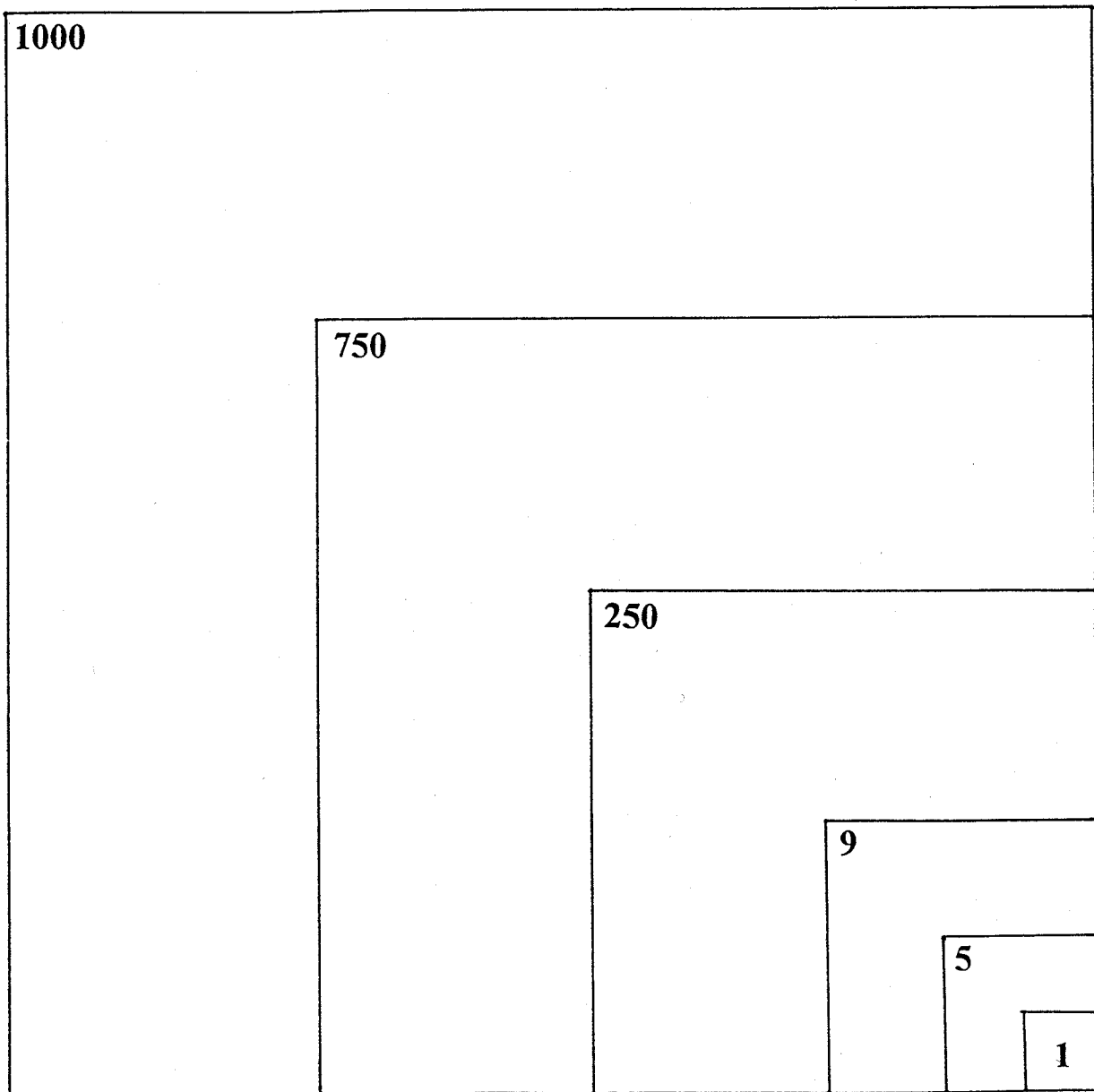


Figure 2. The Nature of Patients.

Figure 2 represents something that many of you have probably seen. These boxes represent someone very important, the patient.

They are the denominators in this case. I think that this figure illustrates a very important point in terms of the nature of patients -- because if you don't understand who you're doing the testing on, you will very likely make poor decisions both in terms of what patients are likely to have and also what laboratory tests should be used in helping to take care of them. In an article published in 1961 in the New England Journal of Medicine, Dr. White of the University of Vermont looked at 1000 adults over 16 years of age and found that in any given 1 month period about 750 would sense some sort of disease or feel something was wrong. About 250 would seek the services of a physician, about 9 would seek the services of a specialist physician, about 5 would be hospitalized and at least 1 adult would be admitted to the university teaching center. It doesn't require a degree from the Johns Hopkins School of Public Health to realize that all the subjects in this study are different from one another, as represented by the boxes in Figure 2. An important point to be made here is that the patients we, as primary care physicians, see daily in our practices reside in the larger boxes. The concern with the role of laboratories and the services that they provide to that particular patient in the small box, the one admitted to the university teaching center, is totally different from the concerns that are shared by people we see in our daily practice. The values assigned to the different test results don't carry much weight with patients, those found in the larger boxes, who aren't experiencing any physical problems. It doesn't matter to any of them whether their

blood sugar is 40 or 80 when they arrive at the office. Most of them live just fine without any laboratory tests.

This is not to say that laboratory test values are not important. There are, though, differences in the nature of maladies. Quite often they are much less acute. I consider laboratory testing to be a helpful adjunct, but very often one can get along quite well without it -- almost entirely. I once practiced in an area where there was no hospital, no nearby laboratory. Dr. Collins' talk perfectly stated that 0 to 9 tests are about all that are required. Having said this, we fight hard to comply with CLIA regulations that enable us to provide laboratory services for our patients.

Table 1 comes from a study in the Ambulatory Sentinel Practice Network (ASPN) that replicated the National Ambulatory Medical Care Survey (NAMCS), a survey of office-based primary care practices. Although the survey lacks a certain amount of detail, it groups patients into 19 boxes. A comparative study was done between the national practices and those within ASPN, concerned with practice-based research, and results showed that the profiles for each were very similar. Although most of the commonly performed tests didn't qualify as "standard laboratory tests," urinalysis, Pap smear, cholesterol measure, and strep throat were commonly performed in both sets of office-based primary care practices. Keeping in mind that is an office-based survey and that most participants (the very young, the very, old and women in their reproductive years) averaged approximately 2.7 visits per year, there were not a lot of esoteric tests, such as serum prolactin, performed.

Table 2 shows data from a collaborative study between ASPN and the CDC that

	Frequency (n = 5849)	%
Blood Pressure	3113	59.7
Urinalysis	707	13.6
Pap Test	239	4.6
Cholesterol Measure	233	4.5
Other Radiology	166	3.2
Strep Throat Test	150	2.9
EKG-Resting	101	1.9
Chest X-Ray	95	1.8
Mammogram	87	1.7
Visual Acuity	74	1.4

Table 1. Most commonly performed tests in U.S. 1990-91. Source: ASPN/NAMCS.

Nature of Problems
<ul style="list-style-type: none"> • 180 Problems • 160,714 Visits • Crude Rate: 1.1 “Problems”/1,000 Patient Visits • 27% Impacted Patient Care • About half of these judged as having affected diagnosis or treatment

Table 2. Nature of Problems from a collaborative study between ASPN and CDC.

attempted to delineate the laboratory problems experienced in an office practice. The rate of problems or perceived problems, and this is clearly an acknowledged limitation of the study, is significantly small. Despite our definition of “problems”, this study, in my mind, indicated that the significant office-

based problems are not laboratory-related. In relating back to Dr. Collins’ slides, concerned with the ever-increasing number of tests per Medicare enrollee and subsequent increase in cost of testing, the future costs to the elderly alone are only going to be a small portion of our cost

Test	Problem	Nature and Source of Problem	Impact on Patient Care
HIV Antibody	False Positive	Referred test; analytic error	Diagnosis delayed
Urine Pregnancy Test	False Positive	Referred test; inconsistent results (exact source of problem not known)	Test repeated
Pap Smear	Specimen lost	Referred test; specimen collection & handling problem (specimen lost between practice and referral laboratory)	Test repeated
Pap Smear	Endocervical cells reported in a post-hysterectomy patient	Referred test; Inconsistent result (exact source of problem not known)	Test repeated
Pap Smear	Specimen lost	Referred test; specimen collection & handling problem (specimen lost between practice and referral laboratory)	Test repeated
Potassium	Delayed report on a stat test	Referred test; post-analytic	Patient hospitalized for hypokalemia
Urine Culture	False negative	In-house test; post-analytic (result misreported by practice nurse)	Treatment delayed
Stool Culture	Delayed reporting of Campylobacter	Hospital lab; post-analytic (delayed reported by lab)	Treatment delayed and hospital stay prolonged
Prothrombin Time	Therapeutic range miscalculated by lab	Referred test; analytic error	Hematoma developed
Prothrombin Time	Delayed report	Referred test; analytic error	Delay in adjustment of coumadin dosage

Table 3. Problems judged to have a significant impact on patient care.

problem. The problem rate is 1 per 1000 visits (Table 2) with about 27% having any impact on patient care involved, one false positive AIDS test, which did wreak havoc on one family, a false positive urine pregnancy test, a lost Pap smear specimen, and a Pap smear report indicating the

presence of endocervical cells in a post-hysterectomy patient (Table 3). These examples, I believe, are still not sufficient reasons to believe that there is a wolf at the door. It must be kept in mind that these data

	Total	Physical Office Lab	Referral Lab
Phase of Testing	N(%)	N(%)	N(%)
Pre-Analytic	100 (55.6)	19 (42.2)	81 (60.0)
Test Initiation	39 (21.7)	8 (17.8)	31 (23.0)
Specimen Collection & Handling	61 (33.9)	11 (24.4)	50 (37.0)
Analytic	24 (13.3)	18 (40.0)	6 (4.4)
Post-Analytic	50 (27.8)	8 (17.8)	42 (31.1)
“Inconsistent Result”	6 (3.3)	0	6 (4.4)
TOTAL	180 (100)	45 (100)	135 (100)

Table 4. Distribution of the Reported Problems by Phase of Testing.

were collected through a study involving a network of several hundred physicians in both the United States and Canada.

In discussing the distribution and type of problems encountered (Table 4), it is apparent that most problems don't occur in the laboratory, that is, in the analytic phase. Rather, most are distributed in the pre- and post-analytic phase of testing involving a myriad of test initiation and specimen handling problems, while only 13% occurred in the analytic phase of testing. These findings are consistent with the patient specimen results that we were obtaining from our referral laboratories.

As a family practitioner, my problems are not concerned with the laboratory's results but rather with the administrative errors, i.e., improperly matching patients with their laboratory test results, incorrectly placing labels on specimens and providing the laboratory with patient specimens in a timely fashion. Having recently installed a printer to receive test results has been critical in eliminating a significant number of

telephone-related transcription errors.

The question probably arises concerning whether the office laboratories, involved in the ASPN, are a representative population of office laboratories in regard to their test-ordering practices. Table 5 shows the comparative frequency, relative to percentage of patient visits, of laboratory tests ordered by U.S. family physicians within ASPN to those family physicians participating in the 1991 NAMCS Survey. Similarly, 1993 data are available from Green et. al.² which substantiate the fact that patterns of test ordering have remained relatively constant over this period.

As for my own practice, I am seeing approximately 200-250 patients per month on a part-time basis, while some colleagues are seeing as many as 700 patients per month. This practice sees about 12,000 patients generating close to 27,000 annual visits, equating to >2+ visits per patient with about 1 test per patient per year. Obviously, some patients receive more tests while others receive fewer. The question arises, what

Test	ASPN Clinicians		NAMCS Physicians	
	Males	Females	Males	Females
Cholesterol	5.6	4.2	4.9	4.2
HIV Serology	0.51	0.43	0.35	0.25
Strep Test	3.0	2.4	3.5	3.1
Pap Smear	NA	7.0	NA	5.9
Urinalysis	8.8	13.9	7.9	13.7
Other Lab Test	16.4	21.0	16.5	18.3

Table 5. Comparison of frequency (in % of patient visits) of testing ordered by 83 U.S. family physicians in ASPN and 229 family physicians participating in 1991 NAMCS Survey. Frequencies are adjusted by age and pregnancy status using the pooled denominator from both samples.

A Look at One Practice and the Impact of Managed Care
4 MDs
2 PAs
11,000 - 12,000 Patients
27,000 Annual Visits
11,002 Laboratory Tests
In 1990: 2.3 support FTEs/MD FTE
Now: 4.8 support FTEs/MD FTE
(National Average: 5.3; Range 2-7)

Table 6. A look at one practice and the impact of managed care.

defines a test? Is an SMA 22 one test or is it 22 tests? For these purposes, we've counted the initiation of a specimen as a test. Our findings indicated, however, more than 11,000 test results (Table 6). I found this to be quite interesting as a primary care benchmark. As we revisit the discussion of

support issues, we did not observe an increased number of laboratory tests being requested in our practice. A combination of reasons might explain this, but one main reason is cost-containment. We have made a conscious effort to keep our overhead down. We have found, with the extent of managed

care that exists, that it is much less expensive, when patients become cost centers, to have the reference laboratories perform the testing. It is no longer our choice but rather a monetary necessity to send out these specimens, despite the fact that technology has made testing affordable not only for the larger reference laboratories, but for those of us, in office practices, whose testing requirements are often similar. It has been my belief that, as primary caregivers, performing office laboratory testing provides convenience and service to our patients, products that still have value. I don't think we'll see, however, a trend to family physicians' ordering an inordinant number of tests in their office, though this was probably never the case, primarily because of the reimbursement issue.

The issue of ordering laboratory tests is well known in our office. Our medical assistants have been reminded to look at a color-coded chart that hangs on the office wall when they say, "I'd like to order a CBC on Mrs. Jones." This chart (Table 7) causes them to inquire about which managed care system Mrs. Jones is associated with, Comprecare/FHP, Cigna HMO, Cigna PPO, etc.. Currently, our office has 508 different sources of payment. 508! That explains, in part, a portion of the 4.9 FTE per MD support staff (Table 6).

This arrangement provides no additional value, medical or otherwise, to anyone. It does, however, incur an enormous cost. This, then, becomes the initial point at which a laboratory test result can become an error. You receive a result but there's no reimbursement grid. At other times, you don't receive the results because people don't want to perform testing if they are not going to be reimbursed for their work. Over the years, we've required new color dots for

both the additional laboratories and more space in which to include the different payment plans and the specific procedures that they prescribe. The point is that problems in my office laboratory are not only due to CLIA or OSHA but instead result from increasing reimbursement or regulatory requirements. It is this additive effect that constitutes an ever growing burden to a medical practice that is attempting to provide quality health care.

A study was conducted in our practice to determine if all the offices that have had problems in the ASPN study had been cited for CLIA-related deficiencies. The question posed by this study asked whether the required CLIA inspection was sufficiently sensitive to detect problems associated with the laboratory and finally was CLIA able to resolve these problems? It was interesting to learn that all the ASPN practices had passed their inspections. It came as no surprise that these practices passed due to the laboratory practice standards adhered to by the ASPN. Provider-performed microscopy procedures (PPM) (Figure 3) are a new subcategory of moderate complexity tests. This is an important area currently being addressed by primary caregivers. We began to look at what it cost us, last year, to stay in business, post-CLIA (Figure 4). The initial training expense involved \$2500.00 for consultants to come into the office for training. Subsequent costs involved approximately an hour of technician time for each of the two laboratories, 5 days a week for 52 weeks. This resulted in a net annual cost to us of \$5200.00. Weekly reporting and documentation, which was redundant, resulted in an annual cost of \$780. This brought the total annual cost to about \$6000.00. When I asked my staff what they believed was wrong about CLIA the

Waived Tests
⇒ Physician Performed Microscopy
Moderate Complexity Tests
High Complexity Tests

Figure 3. Cost of Complying with CLIA 1988

Classification: Physician Performed Microscopy			
Start-up/Training	\$2,500	one time	
Daily Procedures	\$100	1 hour tech time x 2 labs x 5 days x 52 weeks	\$5,200
Weekly Reporting /Documentation	\$15	45 minutes tech time x 52 weeks	\$780
Annual Cost			\$5,980

Figure 4. Costs associated with Physician Performed Microscopy

resounding word was “redundancy.” Despite the fact that 4 medical doctors and 2 physician assistants gross more than \$2 million in revenue, this is not much money. The question I would ask myself about the CLIA regulations is “has the investment of time and effort been beneficial?” Has it really helped us to standardize hemocrits, or take the temperature in rooms, or has it accomplished some other time-consuming efforts? More important questions that could be asked would be, “what are the things that we could do instead that would improve quality?”

I would like to revisit the original question: What things are required to benefit the patient and yet allow physicians to do

what they do best -- provide care to their patients (Figure 5)? With regard to attending to the needs of patients, it is difficult for a woman with vaginitis to go home without a diagnosis and a treatment. If you were to take a wet prep out of our office it would basically block access to a simple service and a reasonable outcome. Currently, the drug companies are attempting to resolve these access and service problems by producing everything “over the counter.” As a result of being under capitation, we could easily become a telephone service and answer all their “self-prescribing” questions. So, there you have it, patient service.

One could reasonably argue that strep

- 1) Which tests are essential to a functional practice?
 - Patient Services
 - Timeliness of physician decision making
 - Impact on important clinical outcomes

- 2) How does setting impact laboratory testing?
 - Primary Care vs. Specialty Care
 - Rural vs. Urban
 - Population Mix (ages, sex, & “local” epidemiology)

Figure 5. Key Laboratory Issues/Hypotheses from the Practice Perspective

screens are not that important, and maybe they are not. But certainly, the care issue, the ability to have a Pap smear performed in one place, this is important. Some issues are important for timely and sufficient decision-making and I would suggest that we examine these closely to determine what is truly important in this whole “slippery-slope” of clinical outcomes, and how would those laboratories that could support that type of care best be identified. If you were to observe an oncologist’s office, the platelet count is a decision-based procedure that determines if the physician will infuse poisons into someone’s body. It is therefore important that this procedure be done quickly and accurately.

So then, what type of practice is it? Where is the practice located? When I was in Bailey, Colorado, there was not a hospital within 60 miles of my practice. We were it! You try getting into a car in the midst of a blizzard and going down the mountain to have a throat culture only to end up as a trauma victim in a ditch. Yes, I think that practice type and location are very important issues.

Before I end, I would like to go back to Dr. White’s boxes, because I don’t think that this point can be overstated, which is, who are we taking care of? How old is the

patient? Are they male or female? And, is there something special about them? We had some patients who were hard-rock miners. Now here is an epidemiologist’s dream waiting to happen...patients who develop lung disease as a result of handling molybdenum. Just north of my practice there are migrant workers who are exposed to phosphate. We still see organs that have been poisoned by excessive phosphate levels.

The laboratory needs of doctors, who work with this migrant population, are very different than those who practice in mining regions of the country and, of course, the needs of somebody who is practicing in Vail, Colorado, are different still by making certain that every knee is fixed in a timely manner. These are not usually primary care physicians, I might add.

In closing, I hope that some of the issues that I have covered have helped you to understand my perspective of the neighborhood. I need, however, to learn a lot more about each house because the “system” has suggested that primary care doctors need to quarterback the neighborhood. I hope we don’t “gatekeeper” it, by the way. I think that installing us as a gatekeeper, as an obstruction or an obstacle to care, is the worst possible use of primary care.

Currently, I don't think we are appropriate for this function. However, I feel we are well positioned to help coordinate some of the changes occurring in our health care system if we can learn about all of the neighborhood houses and how to help use them for the benefit of our patients.

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