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The Correlation Between the Levels of Education of Clinical Laboratory Personnel and the Accuracy of Peripheral Blood Smear Results

Susan J. Leclair
Walden University

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by

Susan J. Leclair

M.S., University of Massachusetts Dartmouth, 1977
B.S., Stonehill College, 1968

Submitted in Partial Fulfillment of
the Requirement for the Degree of
Doctor of Philosophy
Health Services

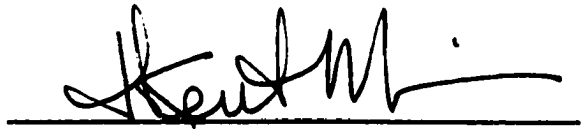
Walden University
August 2001

DOCTOR OF PHILOSOPHY DISSERTATION

OF

SUSAN J. LECLAIR

APPROVED:



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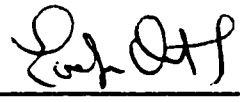

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Professional Psychology Faculty

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Abstract

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ABSTRACT

This study correlated the performance accuracy of peripheral blood differentials evaluated by clinical laboratory scientists and clinical laboratory technicians. Fifty-one senior-year students from four clinical laboratory science baccalaureate programs and 37 second-year students from five clinical laboratory technician programs were given 10 peripheral blood differentials to perform. Results were compared to the values assigned by the Rajamaki method of proficiency testing. There was a significant discrepancy in the levels of accuracy between the two cohorts, suggesting that the results of peripheral blood differentials performed by clinical laboratory technicians is suspect. Facilities wishing to maintain or improve the quality of laboratory services should consider allowing only baccalaureate level clinical laboratory scientists to perform peripheral blood differentials.

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CHAPTER 1: Introduction to the Study

Introduction

The history of the clinical laboratory has two beginnings: first, in ancient times when the primitive evaluation of body excreta was first conceived, and again in the early 1900s when the structure of the modern clinical laboratories evolved. Many elements of the evolution of the modern clinical laboratory deserve inquiry, including the development of personnel standards, the incorporation of automation and computerization, as well as the effects of national regulations and agencies such as managed care organizations now pressing on our ability to deliver reliable services.

One issue impacting the credibility of laboratory data in the diagnosis and treatment of disease has been the evolution of personnel standards for education and training of laboratory employees. If these personnel are not capable of producing accurate and complete results, then the trust in laboratory results by patients and physicians alike may be misplaced.

Background

This study was conducted in an environment that assumed the central and peripheral realities of the development and current organization of the field of clinical laboratory science since 1850 (Williams, 1971). During this time, physician pathologists have had a variable influence on the quality of preparation and service of medical technologists. From the initial significant impact through periods of indifference, apathy, and reasserted influence, this exogenous stress has resulted in an uneven array of regulations, traditions, and practice paradigms with little known or verified underpinning for the current practice, education versus training, skill set and service ability for clinical laboratory scientists, clinical laboratory technicians, or other practitioners at the certificate, graduate or doctoral level in an arena of 600,000 individuals. The confusion and hostilities resulting have only become more acute during the recent times of cost control (Berson, 1989), alternate method of health care delivery (Wolper & Pena, 1981), and practitioner shortage (Griffith, 2000).

While the history of this field can, in technical ways, be traced back to 1550 B.C.E. (Herrick, 1937) with references to diagnostic tests in the Ebers Papyrus, the scientific beginnings were more probably initiated during the 14th century (Fagelson, 1961) and the employment of Alessandra

Giliari at the University of Bologna, and in the United States to the University of Michigan in 1844 (Vaughan, 1926) at the laboratory of Dr. Victor C. Vaughan prior to the opening of a medical school or hospital at the same site. The utility of such an arrangement was so pronounced that other such laboratories were started, leading to the declared "need" for pathologists by the staff of the Cook County Hospital in 1865 (Hirsch & Billings, 1966).

Advances in basic and medical sciences created the demand for clinical pathology laboratories late in the 19th century. Prior to this time, the average physician performed and interpreted nearly all prevailing laboratory procedures himself. These procedures were typically limited to simple blood counts, urinalysis, and histology examinations (Arens, 1952; Starr, 1982). Later, others with varying levels of education and experience performed tests and reported the results. Training of medical students and specialized "technicians" followed in great earnest, including the first university program in 1922 (Hovde, 1957).

What was important from the outset and is important today is the role of accuracy in the performance and reporting of laboratory values. Accuracy can be compromised by many factors: specimen collection, personnel, instrumentation, and reporting. Each attribute can and should be studied independently before one can make supported statements concerning the quality of clinical laboratory results. If one test result is judged to be unreliable, then

all test reports might be similarly devalued in the intense environment of medical diagnosis and monitoring.

Not until the middle of the 20th century was the concept of objective quality control applied to the laboratory, and it has remained one of the most important aspects of laboratory regulation (Sunderman, 1992). While the current proficiency testing construct is concerned with interlaboratory testing, only the work of Lunz, Castleberry, James, and Stahl (1987) has looked at the educational levels of the persons actually performing the tests. This investigation tested and proved the premise that laboratories employing practitioners credentialed by a single agency (the Board of Registry of the American Society of Clinical Pathologists) produced more accurate results than those laboratories that employed noncredentialed practitioners.

Lunz et al. (1987) asked two groups of practitioners to perform a routine chemistry test and their results were compared to the known value of the specimen. This study was quite small in that the tested population consisted of 25 persons and each person reported only one result. The personnel involved were not observed during the performance of this test so there was no way to be sure that the specimens were all handled in the same fashion.

Additionally and perhaps more importantly, the work of Lunz, Castleberry, and Stahl (1987) compared the accuracy of results between baccalaureate level personnel and personnel trained in an informal, on-the-job fashion. The certified

baccalaureate level personnel had all completed identical programs of study and had successfully passed the same national certification examination, while the uncertified personnel could have been exposed to training periods that varied greatly in length and intensity and possessed a high school diploma. Finally, while only these two types of individuals were studied, there are multiple certification agencies and multiple levels of educational attainment within the American clinical laboratory.

The roles of pathologists and other clinical laboratory personnel (certificate holders, associate, baccalaureate, masters, and doctoral degree level prepared practitioners) initially synchronous, have diverged and come together randomly over the past century and more, each driven by different motivations and circumstances. The circumstances have resulted in the training, education, and employment realities of the present day. None of these realities developed from carefully thought-out planning but rather from a haphazard "solve the imperative of the moment" approach. The result is that we now have persons "trained" or "educated" for certain periods of time rather than until the attainment of specific competencies.

For example, it is possible to train a child to recognize the difference between a Chevrolet and a Porsche without his/her understanding any of the principles of internal combustion. Indeed, it is possible to suggest that the pattern recognition inherent in this activity is

independent of any intellectual understanding and that accuracy of the identification might be higher in a person without knowledge of the basic principles of an automobile engine. When pathologists invented the medical laboratory technician (MLT), they took this opinion and made it fact without any study or proof.

The concept was that the MLT would be competent to perform "normal" differentials and able to identify the presence of abnormal cells and then to notify a supervisor who would perform the differential. This meant the MLT should be able to correctly identify all cells normally found in the peripheral blood and to differentiate between those cells and cells that do not belong in the peripheral blood. As the years progressed, it was postulated that the MLT could actually perform all peripheral blood differentials, thus allowing the clinical laboratory scientist to perform other procedures or supervision.

The initial Board of Registry task listing for the MLT included the identification of normal blood cells. The 1980 Board of Registry examination outline stated that one photomicrograph of a hematologic element would be found in the MLT examination format (Board of Registry, 1980). In the 2000 publication of the National Credentialing Agency for Medical Laboratory Personnel Task Analysis, the clinical laboratory technician (CLT) examination contains 0-1 blood cell photomicrograph for identification out of the 40 questions in the Hematology content area (NCA Report, 2000).

These photomicrographs are typically of classic presentations of commonly seen normal cells. Further, the specific cell is clearly marked with an arrow to focus the questioner's response. Because it is only one question out of 40, it is possible for an individual taking these examinations to misidentify the cell in question and still pass the examination. The student is never told which questions were answered correctly or incorrectly. Programs are given grouped accuracy data by question but are never told which question was the photomicrograph, so no analyses at a programmatic level has ever been done.

Neither of these certification examinations is capable of answering if the skill needed to identify cells is related to level of education. Since the basis that exists for associate degree level personnel to perform manual differentials is a combination of the unproven assertion of pathologists and the tacit acceptance by the clinical laboratory science profession, it is necessary to build a solid body of objective evidence on this skill.

Statement of the Problem

There has been no evidence to support the claims of clinical laboratory practitioners who have completed an associate degree program that they are competent to perform

peripheral blood differentials. It has been assumed that, because these practitioners are taught this skill, they can perform it to a high level. Circumstantial evidence from specific questions on certification examinations requiring the candidate to correctly identify a cell is not compelling. There are no published data concerning the national percentage of correct answers on these questions. One study, performed in the late 1980s that provides data for the baccalaureate level clinical laboratory practitioner. In today's managed health care system, laboratory administrators are using more and more associate degree employees in place of higher paid baccalaureate level employees.

The National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) is developing new accreditation standards that would place more routine testing into the hands of the associate degree personnel and less into the hands of the baccalaureate degree personnel (NAACLS, 2000). NAACLS believes that routine testing should move from the domain of the baccalaureate level practitioner and be replaced by additional managerial and administrative activities. Before this shift in curriculum takes place, the one concern that must be addressed is the level of accuracy achieved by these practitioners.

Purpose of the Study

The purpose of this study was to assess the accuracy of peripheral white blood cell identification during the performance of a manual peripheral blood differential test. The study compared the results from 10 different peripheral blood samples as reported by students participating in a baccalaureate degree curriculum and students participating in an associate degree curriculum. The correlation provided a base for the discussion of entry-level competencies for these practitioner levels and, perhaps, a restructuring of laboratory task assignments, pay scales, and career opportunities.

Significance of the Study

The clinical laboratory provides the largest body of objective, scientifically validated data on the individual patient. At the basic level, the purpose of this study tried to determine if the level of education in clinical laboratory science is important in the performance of the complete blood count differential. The complete blood count (CBC) is one of the cornerstone tests in the clinical laboratory. It is performed at least once on every hospital patient upon admission. It is repeatedly referred to throughout a

patient's hospital stay. It is the basis of all decisions concerning the continuation and/or dosage of oncologic drugs and radiation therapy. It provides the information required to support diagnoses of anemias such as iron deficiency and sickle cell disease, leukemias and lymphomas, inherited white blood diseases, platelet associated diseases, and many others. It provides data on the efficacy of many other medications, from the somewhat innocuous (e.g., multi-vitamins) to the life sustaining (e.g., coumarin).

A subpart of the CBC is performed by a single person viewing blood cells with the aid of a microscope. No one else ever sees these cells, yet the differential examination is considered the most important portion of this test. In the text regarded as the standard for hematology, the late Maxwell Wintrobe (1951) described the differential as the "most important of all hematology tests" (pg. 266). Additionally, he warned that physicians in 1951 "were too ready to accept at face value the results of laboratory procedures." This reliance on the laboratory has increased so steadily that physicians now are dependent on laboratory results for a significant part of their diagnostic, therapeutic, and prognostic decision-making without themselves having much (if any) training in the intricacies of performance or correlative interpretation for many of these tests, now numbering over 24,000 (CBC, 1999).

At a more abstract level, this study should help to define minimum standards of practice. And, at an even more abstract level, this study could begin to address a larger societal issue. Over the past several decades, our society has chosen to deliberately lessen entry-level standards in many fields. In health care, we now accept physician extenders such as physician assistants and nurse practitioners. LPNs routinely perform duties once assigned to RNs. Pharmacies routinely employ pharmacy technicians, many of whom have only a high school education. It is important to note that none of these adjuvant roles have ever been evaluated for competence, just as there have never been any studies of which this author is aware to justify the use of paralegal assistants in the legal profession or lesser qualified part-time instructors in colleges and universities. An *ad hominun* case could be made that the contemporary task reassignment or practitioner re-creation has its origin in expedient economy and personnel availability rather than the medical needs of a patient or the legal needs of a client, and so on. These other fields could look to their own entry level competencies and evaluate the accuracy of the practitioners in the performance of their daily activities.

Theoretical Framework

As part of the scientific revolution of the late 1800s and early 1900s, physician scientists took as assistants women who would aid them in the care of the laboratory, in the collection of specimens, and in the performance of certain simple procedures. By the 1920s, pathologists recognized that additional structured training was required of these personnel. As the degree of sophistication and complexity of the laboratory grew, these women took on more tasks, began making clinical decisions concerning the types and number of laboratory tests, modified older technologies, and created new ones. The first step of their nascent professional organization was to demand licensure as recognition as an independent profession.

The pathologist very much saw himself as a director of the strict scientific management structure with underlings who carried out the rules and regulations that the pathologists determined. Personnel in the laboratory regarded self-effacing responses to physician requests to embody the highest principle of professionalism. As changes in instrumentation and test complexity continued to develop, these personnel found themselves in yet another aspect of the clinical laboratory. They became managers. They hired and they fired. They determined the purchasing protocol. They determined the work flow and the needs of the laboratory. By the 1960s, they began to reassert their independence from the

pathologist and the profession of pathology in a more strident fashion.

The desire for licensure as seen by the medical technologists, as they were then known, was the logical next step in the evolution of a profession. As these employees began to assume professional demeanor and authority, they grew less willing to remain subservient to pathologists who were no longer performing clinical testing but held authority over the performance of these tests. In response to this impasse over authority roles and responsibilities, the pathologists created a new category of personnel with a high school diploma and on-the-job training (clinical laboratory assistant or CLA) who performed the same procedures as the baccalaureate-educated staff. This attempt to lower standards and undercut the growing role of the clinical laboratory scientist ultimately failed due to the limited education that made them incapable of adequately addressing the changes in increased technology and sophistication in the laboratory.

The pathologists again chose not to acknowledge the separation of the profession of clinical laboratory science and proceeded to develop another level of personnel. This new third level of clinical laboratory personnel is called the clinical laboratory technician. In order to correct the earlier problem of inadequate basic science knowledge, the clinical laboratory technicians is required to be a graduate of a community college or military program.

To repeat for emphasis, no one ever determined if personnel at this level are capable of providing accurate test results; the pathologists seated on the Board of Registry at the time simply included these competencies into the mix.

The content outlines for the two most well-known certification examinations, American Society of Clinical Pathologists (ASCP) and National Credentialing Agency for Medical Laboratory Personnel (NCA), contain requirements for accurate identification of peripheral blood white and red blood cells. The differences between the two levels of individuals are seen in knowledge of physiologic and pathophysiologic theories, management, budget preparations, problem solving, and evaluation. The content outlines and application material further inform the student that the associate level individual will be questioned at the recall and application level while the baccalaureate individual will be questioned at the recall, application, analysis, and evaluation levels (ASCP, 1980; NCA, 2000). It has just been assumed that there is no difference in test report accuracy between the two levels of personnel.

The combination of increased complexity and the changing face of organizational structure found more clinical laboratory scientists using team and motivational theories of management. Works by Maslow (1943) and Senge (1990) became known and their ideas practiced. Again, pathologists refused to move from the model first articulated by Taylor (1916).

The disharmony in the laboratory reflected the tensions between an authoritarian figure bound to the time-honored hierarchical approach and the employees practicing a day-to-day management style more aligned with Senge. The late 20th century's need for a cheaper medical delivery system strengthened pathology's desire for control and weakened the health care team concept.

What developed over the last 20 years was the archetypal struggle described by Fukuyama (1992). Clinical laboratory scientists have struggled to take control of their profession, only to have hospital redesign and realignment in the wake of cost containment and managed care cause them to falter leading to an attempt at reestablishment of control by pathologists. The profession of clinical laboratory science needs to identify, by educational level, those persons who can perform minimum levels of acceptable results. This would provide a way by the members of the clinical laboratory science profession to establish control over the entry level into the profession.

As destabilization of the U.S. health care delivery system via cost-based analysis continues, it might also be prudent to evaluate if the lessening of education and training seen in the moves from physician to physician extenders such as physician assistants and nurse practitioners and from pharmacists to pharmacy technicians has had any impact on the quality of the care given to patients. Until that question is answered, this country may

be at risk for decreasing quality of care in the name of cost containment.

This situation of emerging professions is seen in a variety of other health related situations. Mental health facilities employ master's degree level therapists rather than psychologists with doctorate degrees. As the profession of physical therapy tried to improve its quality by requiring additional education at the post-baccalaureate level, a new lower level of personnel, the physical therapy assistant, was created at the demand of hospitals and nursing homes. Operators of the pump oxygenator, also known as the heart/lung machine, are one of the few emerging professions in the late 20th century to achieve professional status, thanks in part to the surgeons who recognized their importance and supported them in the recognition efforts.

At this level in the framework, there is a significant problem between the hierarchical philosophy of pathologists and the desire of the clinical laboratory employees, especially those at the baccalaureate level, to be recognized as an independent profession. One aspect of independence is the ability to set entry-level requirements of practitioners. In the past, those levels have been set with a proven arbitrariness by pathologists. To determine if these levels have any credence would begin to develop an answer to the fundamental question, "Is clinical laboratory science a profession?"

No single study will answer this question. However, it is possible to evaluate each of the many aspects of this situation and determine if the data support the desire for independence. In addition, the patient public has a right to know if one of the most essential laboratory tests is performed by personnel who have been proven to provide accurate and consistent data.

Current Context

The organization of the clinical laboratory is consistent with the organizational systems of the beginning of the 20^{th} century: a system of rules, boxes, and autocratic control. Pathologists do seem to belong to the subset of scientific management theorists who believe that managers create a climate in which the prime effect is that they will remain in power (Taylor, 1916).

Rather than objectively reevaluating changing circumstances, decisions makers for the clinical laboratory chose to restructure and downgrade personnel issues in favor of increasing instrumentation and assembly line functionality. Increased productivity occurred but at a cost of disaffection and increasing frustration with the bureaucracy (Weber, 1946). This frustration has reached a significant point as the past decade has seen an almost

universal choice of restructuring for efficiency as the preferred management tool.

Individuals looking for individual satisfaction and acknowledgement for work well done were stymied throughout the 1960s and 1970s, and, as a consequence, there was an attempt to wrest control from the pathologists by the formation of an independent certification agency. Attempts to supplant scientific management at the administrative level with either a motivational or teamwork approach has not been successful (Bennis, 1966; Maslow, 1943). Laboratory managers, like many other managers in the health care arena, use one or the other of these latter two approaches while the facility's administrators still use the scientific management approach.

Thus the chaos in hospital organization structure has not lessened as it has in other enterprises where competing philosophies and management systems have been eliminated (Senge, 1990). Unfortunately, neither philosophy has had the number of people in decision making roles to eliminate the other; the laboratory profession sits on the center point of a precarious seesaw.

Ever since the invention of the clinical laboratory technician in the late 1970s, there have been significant arguments concerning the scope of practice of clinical laboratory technician versus the clinical laboratory scientist. These discussions have occurred routinely at each of the past 20 years of annual Clinical Laboratory Educators

Conferences sponsored by the American Society for Clinical Laboratory Science. In each instance, no evidence is presented, only opinion.

It is the opinion of the clinical laboratory technician educators that CLTs should be performing the vast majority of procedures and that CLSs should be performing highly complex analyses, management, and education only. It is the opinion of the clinical laboratory science educators that this is not the case. They either keep silent in protest, knowing there is no evidence or cite anecdotal information concerning the difficulty in which CLT graduates find themselves when they elect to further their education by completing a baccalaureate degree. In the absence of evidence, assumptions and opinion carry the day.

When the field of medicine accepted the Flexner Report in 1910 as a call to self regulate its broad diversity of educational and experiential levels of training for physicians, there was no body of literature to support their activities, only the realization that something had to be done (Flexner, 1910; 1913). The same is true of nursing, social work, and other professional groups, which in the absence of externally imposed regulations, chose to define levels of practice and entry level competencies (Flexner, 1915). In each of these situations, these groups were more free of interference from exogenous sources and were able to chart their own destiny. Clinical laboratory science is at the same place in its evolution as medicine was at the time

of the Flexner Report and has the added burdens of pathologist control, hospital financial needs, and federal and state regulations.

There are thousands of laboratory tests and many tests have multiple methodologies. To test all of these would be impossible. To choose a smaller number would require that the chosen test or tests possess some combination of knowledge, skill, and technical abilities rather than a fully automated or single step procedure. In each laboratory speciality, it is possible to determine those few tests that possess both this level of knowledge, skill, and abilities and a level of criticality to patient care. In the hematology laboratory that test would be the complete blood count's differential.

With sufficient numbers of contributing personnel, it would be possible to determine if educational levels played a role in the accuracy of the peripheral blood differential. The results of this study should have a profound effect on the educational structure and work force utilization of the clinical laboratory personnel. Facilities should then review the job descriptions and entry level qualification for all personnel who will be called upon to perform this test. This review, in turn, would cause further evaluation of any advancement pathways (career ladders) for those who work in the clinical laboratory.

While some European countries (e.g., Finland) have used a modification of the proficiency evaluation, the educational

background of their laboratory professionals is quite different than that of the United States. Only one state Public Health Agency (Wisconsin) uses this method of evaluation, but it does not require any specific person to perform the test and only one report is expected from each laboratory. Putting the more precise testing situation together with the ability to group responders according to their education background has never been done.

Although this study could never be said to be definitive, its results provide the basis for additional testing in order to validate its conclusions. If these conclusions are validated, patients would have, for the first time, an objective method by which to determine the potential for accurate evaluations of their peripheral blood smears.

Another aspect of the current situation that would be impacted would be the educational process of both levels of personnel. Educators might revamp their curricula to support a new work paradigm by eliminating differentials from the associate degree curriculum. The National Accrediting Agency for Clinical Laboratory Personnel might also revise its *Essentials For Accredited Programs* to eliminate the performance of the peripheral blood differential as a required classroom objective.

If, on the other hand, there had been no statistically significant separation in accuracy, then baccalaureate programs could move away from routine testing in favor of newer or more sophisticated testing and management.

Employers would also take the opportunity to restructure their pay scales according to the work performed.

Assumptions, Delimitations, and Limitations

The proposed study was guided by these assumptions:

1. Participants were willing to cooperate in the data-gathering process. The invitation letter to the program suggested that not all students were required to become involved in the process. Further, to prevent a faculty member from using these differential as part or all of a student's grade, the faculty members were not given the known results of the blood smears and the smears themselves were sent to the program after the completion of the didactic hematology course.

2. Data gathering was value-free and unbiased. All communication between the participants and the author was to be filtered by the faculty member on site. No names or other identifying marks were put onto the reports so that no potential for prejudice was possible. The background information on ethnicity and age was used to describe the participants but that information was on a separate sheet of paper so again, prejudiced evaluation of the results was not possible.

3. Data gathering instruments yielded accurate and reliable information. While it could be possible to say that the instrument being used had been created for this purpose, it is also true that the instrument is a compilation of forms used nationally for this purpose and was critiqued by leading authorities in the field for its completeness and reliability.

The specific populations participating in this study came from a nationwide pool. They were between the ages of 20 and 25 and had completed at least one didactic course in hematology at their institution but had not experienced a clinical rotation in a hematology laboratory. Traditionally, clinical laboratory science is a field in which women are the majority; therefore, a gender shift was noted. Also, there is a level of diversity that does not completely reflect the national breadth of ethnicities. Although there was a concern that associate degree program students may be a little older than their baccalaureate counterparts, this was not the case.

One of the limitations of this study was the willingness of participants, specifically the associate degree level students, to undertake a project that might adversely limit their career growth. Clinical laboratory technician programs have been expanding in the last several years as cost-containment strategies have used this assumption to restructure the personnel levels in many facilities. For clinical laboratory technician students, a

negative outcome in this study could be seen to diminish personal career growth potential.

Another limitation was the lack of true randomness to the populations. The only way to address this issue was to invite all students in National Accrediting Agency for Clinical Laboratory Sciences approved schools to participate. As expected, there was sufficient antagonism to the study that only a few programs were willing to participate and fewer than 100% of the report forms were returned. In the interest of fair play, the proposed limit to the number of clinical laboratory science students was upheld, even though several additional programs offered to participate.

Yet another limitation was the time frame. The time between the completion of a didactic hematology experience and experience in a clinical facility was a few weeks, so the window of opportunity for participation was such that some facilities which had requested to participate could not complete the project in the proposed timeframe.

One important caveat to this study lies in its randomness. As with the study of medicine, the clinical laboratory is composed of four major specialties which require significantly different knowledge, skills, and abilities. It is possible that, through the randomness of the selection process, the clinical laboratory technicians who participated were simply not as competent in hematology than they are in clinical chemistry or immunology or microbiology. The small number of participants may have

unjustly inflated the significance of the differences measured.

Finally, it was important to limit the level of difficulty found in these various differentials. Throughout their existence, clinical laboratory technician programs have stated that their graduates should not be performing complex or highly abnormal differentials; their graduates should perform normal differentials only. This statement directed the choice of blood smear differentials into the more common, less fulminant presentations. This study sought to test only one *de facto* assumption about the currently installed base of skill sets as it relates to actual scientific and medical information provided. This is a situation in which a social context has been implemented with no proof and can only be examined by the development of a body of scientific and educational evidence.

Given the totality of assumptions, delimitations, and limitations, it was possible to derive valid data from this study to indicate the importance or lack thereof of additional examination of the differences in skill levels between clinical laboratory technicians and clinical laboratory scientists.

Definition of Terms

The majority of terms used throughout the study are part of the daily language of a clinical laboratory professional. These terms are included in order to provide a common language set to be used in the course of the study. The definitions are taken from Clinical Diagnosis by Laboratory Methods and Management (Henry, 1998).

Blood count (BC) - a determination of the number of formed elements in a measured volume of blood, as in red blood cell count, white blood cell count, or platelet count.

Clinical laboratory scientist (CLS) - a person with a baccalaureate degree in medical laboratory science and successful completion of a nationally-recognized certification examination.

Clinical laboratory technician (CLT) - a person with an associate's degree in medical laboratory science and the successful completion of a national recognized certification examination.

Clinical laboratory assistant (CLA) - a person with a high school diploma and successful completion of a 6 month training program in a hospital. This title is no longer used.

Complete blood count (CBC) - Dependent on the specifics of the instrument involved, this is a collection of blood counts that includes the red blood cell count,

quantification of hemoglobin, hematocrit or packed red cell volume (PCV), red blood cell indices, white blood cell count, platelet count and platelet indices, and the peripheral blood differential. If the differential is not included in the report, the results are termed the hemogram.

Differential - the identification and qualitative evaluation of peripheral white blood cells. Typically performed by counting 100 white cells smeared onto a glass slide, stained with a traditional Romanowsky-based stain, and viewed under a microscope, the actual number of cells will vary according the white cell count. If a patient has a severely decreased white blood cell count, fewer than 100 cells will be evaluated on the smear while more than 100 cells will be counted on a smear from a patient sample in which there is an increased white cell count.

Hematology - the study of the formed elements of the blood and their relation to disease.

Hematocrit - the determination of the percentage of whole blood that is made up of red blood cells as determined by centrifugation or other separation technique.

Hemoglobin - the oxygen carrying protein found in red blood cells.

Hemoglobin test - the quantification of the weight of hemoglobin found in 100 mL of whole blood.

Platelet count - the measurement of peripheral blood platelets in one liter of whole blood.

Platelet indices - the measurement of the mean platelet volume (MPV) and the platelet distribution width (PDW) in a given platelet population.

Red blood cell count - the measurement of the number of erythrocytes in one liter of whole blood.

Red blood cell indices - the measurement of the average size (mean corpuscular volume or MCV), the average weight of hemoglobin per average red cell (mean corpuscular hemoglobin or MCH), the percentage of volume used by hemoglobin in the average sized cell (MCHC) and the coefficient of variation in the size of the red cells in a given population (red cell distribution width or RDW).

White blood cell count - the measurement of the number of nucleated cells in one liter of whole blood. For the normal patient, the number of nucleated cells is equal to the number of white blood cells in the stated volume. However, for patients with specific conditions, nucleated red blood cells may be present in the peripheral bloodstream. It is therefore possible to have a falsely elevated white blood cell count by the inclusion of the abnormal red blood cells. In this instance, a correction of the white blood cell count would be required.

Hypothesis

The choice between the use of a problem statement and a null hypothesis was one of potential interpretation. To use the question "Is there a difference in the quality of results?" implies that there could be subtle differences that could be statistically significant but are not clinically significant. To use the sentence, "There is no difference in the quality of results" requires a higher level of sustainable evidence. Given the potential impact that this study could have, it was determined that the stronger statement requiring more evidence in its favor was the preferred model.

The null hypothesis states that there is no difference between the competence of an entry level clinical laboratory technician and an entry level clinical laboratory scientist in the performance of a peripheral blood smear differential as evidenced through a comparison of the results of arithmetic means, chi square test, and other appropriate statistical tools.

Evidence of this shall include the following:

1.0 correlation to the consensus report of

- 1.1 polymorphonuclear neutrophils and bands
- 1.2 granulocytes and lymphocytes
- 1.3 lymphocytes and reactive lymphocytes
- 1.4 eosinophils
- 1.5 basophils

1.6 metamyelocytes

1.7 myelocytes

1.8 promyelocytes

1.9 blast forms (myeloid, lymphoid, and erythroid)

2.0 correlation to the consensus report of

2.1 red cell morphology

2.2 nucleated red blood cells

3.0 correlation to the consensus report of

3.1 red cell inclusion bodies

3.2 white cell inclusion bodies

4.0 correlation to the consensus report of

4.1 platelet estimates

4.2 platelet morphology

Summary

Results from the clinical laboratory are considered essential information for the diagnosis, treatment, and prognosis of patients. It is important that all laboratory results be as accurate as possible. The utilization of personnel with multiple levels of education to perform the same tasks calls to question either the accuracy of the test result or the proper use of trained personnel. This study provides a baseline for investigation into one or the other of these potential causes.

CHAPTER 2: REVIEW OF THE LITERATURE

Introduction

A review of the history of clinical laboratory science as a profession is important in order to demonstrate the degree of control that one profession exerted over the entry level qualifications of another field. That pathologists arbitrarily defined minimum entrance levels into this profession without any justification or assessment resulted in the confusion of roles and responsibility in today's clinical laboratory science practitioners.

In order to clarify the procedures used in the clinical laboratory to assess proficiency and to ground the proposed study in the milieu of those methods, an explanation of concepts of quality control and proficiency is presented.

By 1968, quality control was seen as a process that viewed and reviewed the day-to-day consistency in the performance of an individual procedure while proficiency testing was seen as an external test of accuracy (Bauer, Ackermann & Toro, 1968, p. 2). Several variables, each one as important the others, are involved in this process. The most obvious one is the sensitivity and specificity of the procedure and its attendant instrumentation. Equally important are the abilities of the person who is performing

the test while a third is the quality of the specimen. Another is the accuracy and clarity by which a report is transmitted or communicated.

History of Clinical Laboratory Science in the United States

Entrance of Women into the Scientific Process

While not considered in this work as a variable for the performance of peripheral blood differentials, an investigation into the historical bias concerning women in the scientific workplace could be of interest. At present, approximately 80% of the personnel in clinical laboratory science are women, while less than 15% of pathologists are women (Kotlarz, 1999b).

In colonial times, it was believed that women were destined for marriage and motherhood so they were taught enough to be able to prepare their sons for responsible citizenship (Rudolph, 1962). Even after the Civil War, it was expected that college-educated women interested in science would participate in amateur scientific societies or engage in observations in botany, zoology, and other fields

(Glazer & Slater, 1987). Women who graduated from the few colleges and universities that accepted them found their opportunities for employment limited by a highly segregated and usually subordinate labor market in which they were confined to special female-designated or "sex-typed" fields that evolved as a consequence of changes in the nature of scientific work (Glazer & Slater, 1987). The availability of large amounts of money supporting "big science" required many assistants to work at newly established research centers. Subsequently, the development of new technologies and a growing concern over the nation's social problems gave rise to several new hybrid professions or semiprofessions, which created new roles for women.

Clinical Laboratories at the Turn of the Century

In 1919, the American College of Surgeons developed a plan for standardizing hospital organizations to assure minimum standards of care. Included among these were provision for the establishment of clinical laboratories. By 1926, standards for accreditation required every hospital to have a clinical laboratory with a physician, preferably a

pathologist, in charge. By 1925, nearly every hospital in the country reported having a laboratory (White, 1969).

As the workload grew, pathologists hired assistants to perform routine procedures for less money than the pathologist received for the same service (White, 1969). As early as 1912, female laboratory technicians held supervisory posts within the various departments of the clinical laboratory. The Accreditation Standards for the American College of Surgeons took these technicians for granted, requiring that clinical laboratory facilities be available in hospitals and that these laboratories should be in the charge of a trained technician (Sunderman, 1992). Pathologists recognized that laboratory technicians were capable of performing many tasks in place of medical personnel.

Pathologists also recognized that these assistants had to be sufficiently competent to continue the work in the pathologist's absence yet not impinge on his authority. They found they could maintain their autonomy without losing control by encouraging a subtype of responsible professionalism among the higher ranks of subordinate health workers and by employing professionally trained women in auxiliary roles (Starr, 1982). Finally, some pathologists felt that having subordinates performing routine tests would elevate clinical pathology to a specialty status, thus

protecting pathologists while relieving them of the routine testing (Starr, 1982).

One of the earliest descriptions of the work of a laboratory technician appeared in a 1927 book entitled *Occupations for Women*, edited by Lydia Hatcher. In this text, laboratory technicians are described as being "mechanicians" rather than scientists, particularly when the laboratory technicians possessed only a high school education and had received on-the-job training for the positions. They performed analyses and simple tests and reported the results of these tests to a physician, chemist, or some other scientist in charge. Most were employed by hospitals, public health agencies, and research facilities. They were rarely permitted to do anything beyond their routine duties because they lacked a college education or professional training that would have enabled them to fully understand the significance of their work and to grow through experience (Hatcher, 1927).

At the same time, another level of personnel was just beginning to emerge. This new "higher professional type" presupposed a minimum of 2 years of premedical course work at a college. Even as early as 1927, a bachelor's degree was preferred. Persons possessing this degree could advance to the professional supervision of a staff of assistants, while those who aspired to become chief laboratory technician were advised to earn a medical degree or Ph.D. in a scientific

field related to the laboratory. In 1922, the University of Minnesota offered the first Bachelor of Science degree with the specialization in Medical Technology (Hovde, 1957).

Clinical Laboratory Science: 1930 through 1960

Between 1928 and 1945, clinical laboratory science became more widely recognized as an occupation distinct from pathology. Partially due to the explosion of tests being developed and the increasing reliance of physicians on the outcomes of the those tests and the increasing educational level of the technicians, the American Society of Clinical Pathologists (ASCP) reacted to these pressures by creating the Board of Registry (BOR).

When ASCP was established in 1922, one of the issues that confronted pathologists was the need to differentiate between technicians, whose work was primarily mechanistic and learned through apprenticeships, and pathologists, whose educational background was more extensive. Another source of concern was the widely disparate educational backgrounds, training, and experience of laboratory personnel and the absence of recognized standards that could be used to evaluate competence (Montgomery, 1970). Many institutions

had developed training programs, unique to the needs of their own facility, to help alleviate the shortage of trained personnel. Because there was no mechanism for providing systematic instruction, each training program established its own standards. These ranged from the shortest period of time of 6 weeks to the longest of 96 months. Some were little more than experiences in indentured servitude while others provided lectures and formalized training sessions.

Some pathologists, notably Dr. Kano Ikedo, supported the development of a method to register qualified technicians by a central agency and the establishment of a national society for these technicians. He believed the laboratory technicians should be recognized as professional and that in achieving this goal, both the quality of laboratory services and the status of clinical pathology would be improved (Ikedo, 1940). Not all pathologists agreed. They were afraid that formalized education, registration, and professional status would be costly and these technicians might want to usurp the pathologist's functions and to unionize for higher wages. Further, they believed that no education was truly necessary since the technicians did not require knowledge of fundamentals in order to do their jobs (Ikedo, 1940).

Ultimately, ASCP agreed that the control of laboratory training would continue their control of the personnel and

would regulate "diploma mills" in the manner used by the American Medical Association. In 1926, four pathologists were appointed to serve on the "Committee on the Registration of Technicians." The committee was charged to define and classify laboratory technicians and to establish a bureau to register laboratory technicians who met the standards and qualifications set forth by this bureau (Arens, 1952).

In 1928, the Committee on the Registration of Technicians (as cited in Montgomery, 1970, p. 435) reported their findings and six recommendations:

"1. To establish the minimum standard of educational and technical qualifications of various technical workers in the clinical, research and public health laboratories;

2. To classify them according to these standards;

3. To receive applications for registration and issue certificates of registration to those who meet the minimum standards of requirements;

4. To register schools which offer an acceptable course of laboratory training;

5. To conduct a placement bureau for registered technicians; and

6. To cultivate a high ethical standard among laboratory technicians in accordance with the code of ethics established by the American Society of Clinical Pathologists".

These recommendations were adopted and officially marked the establishment of the BOR. After surveying the variety of

educational programs, the BOR made recommendations concerning college course content, the inclusion of technical training in hospitals approved by the BOR, and an examination was developed. The registration examination consisted of a didactic portion, a practical portion, and the testimony of a pathologist that the person evaluated the personal and psychological attributes of the individual and had been found to be of good moral character (Montgomery, 1970).

After the establishment of the BOR in 1939, a group of technicians, unwilling to be registered by an agency whose central premise was the maintenance of the pathologist's authority, developed their own professional society (the Association of Medical Technicians or AMT) and developed its own certification agency (Kotlarz, 1999a). This organization is still extant today and has steadfastly refused to work with any other clinical laboratory group. Its certification agency has identical education requirements to both of the other larger certification agencies (Kotlarz, 1999b).

In 1948, the practical examination by which one could prove that a candidate could actually perform clinical laboratory tests correctly was discontinued because the BOR found it inefficient. Educational requirements increased while the Pennsylvania Medical Society developed an assessment of the actual performance of clinical laboratory workers (Sunderman, 1975). During the time that the BOR

raised education and technical expectations, two schools of thought developed concerning the purpose of this education. One group believed that it should be based on the same pedagogical principles as any other educational system; that is, both knowledge and independent judgment were required in the clinical laboratory. Another group of pathologists believed that the practice of medical technology was purely mechanical and required little thought (Arens, 1955).

The BOR played a significant role in shaping the clinical laboratory science profession through the mid-1950's. It developed standards for competence for entry level practitioners, established and upgraded requirements for education and training of students, and devised a registration process to evaluate graduates of training programs.

Clinical Laboratory Science: 1960 through the present

With the ASCP-created BOR and Board of Schools (BOS) controlling entry into the medical laboratory, the practitioners formed the American Society of Medical Technologists (ASMT) in 1935. ASMT changed its name to the American Society for Clinical Laboratory Science (ASCLS) in

1995. In the mid 1960s, ASMT believed that medical technologists, or as they were increasingly calling themselves "clinical laboratory scientists" (CLS), were independent health care professionals according to the traditional definitions defined by Abraham Flexner in 1915. ASMT successfully argued in court against ASCP's contention that, in order to remain certified by the BOR, a medical technologist must always work under the direct supervision of a clinical pathologist, thereby opening the way for an increase in private, commercial laboratories as competition to the hospital laboratory (Lindberg, Britt, & Fisher, 1987).

Possibly as a retaliation for this action and as a response to increased demand for trained staff engendered by the rapid advances in automation and variety of testing procedures, ASCP developed a second level of laboratory employee. Called the Certified laboratory assistant (CLA), this person received a post-high school certificate after a training period in a hospital facility. There was no requirement for any post-secondary didactic experience. The CLA was paid less than the medical technologist but performed the same tests (**Differentiation among MT, MLT, and CLA expected capabilities at career entry**, 1973).

As the difficulty level of even routine laboratory practice proved too much for the certificate level worker, the CLA was allowed to fade out of existence and yet another

level of practitioner was invented by the BOR. This was an associate degree level worker called the medical laboratory technician (MLT), now called clinical laboratory technician (CLT). Again, as with the CLA, this level practitioner performed the same tests and received less pay than the bachelor's degree practitioner (Differentiation among MT, MLT, and CLA expected capabilities at career entry, 1973). An extensive survey of the literature suggests that no published study has ever been implemented to determine if either of these two classes (CLA and CLT) achieved the same level of accuracy as that achieved by the medical technologists in the 1987 Lunz study.

In the late 1970s, ASMT withdrew from the BOR and established its own certification agency, the National Certification Agency for Medical Laboratory Personnel (NCA) in the belief that a profession should control its own certification process (ASMT Minutes, 1977). While the scopes of practice and levels of responsibility of CLSs and CLTs are clearly differentiated on the basis of educational objectives and in the certification examinations, these distinctions are still not consistently maintained in clinical practice. It is doubtful that CLSs have the power to enforce this separation strictly for there has been no evaluation of the levels of proficiency demonstrated by these two levels.

With the advent of managed care and cost control, many facilities that relied on bachelor level clinical laboratory scientists are now hiring clinical laboratory technicians. At the same time, as cost cutting forced physicians to spend less time with their patients, the medical professional began to rely extremely heavily on the data generated by the clinical laboratory.

Yet, at no time has anyone compared the skill level of the associate level practitioner to that of the bachelor level practitioner. It is assumed, however, based primarily on competence statements from the various certification agencies (Castleberry, 1996) and the single paper (Lunz, Castleberry et al., 1987), which compares the accuracy of certified medical technologists to uncertified on-the-job trained personnel that both the CLS and the CLT perform their tasks with the same levels of accuracy.

Who Performs Proficiency Testing

From the beginning of clinical laboratories, patients have had to accept on faith that the values reported to their physicians were correct. Yet, assuring accuracy among the approximately 600,000 laboratory employees in the United

States is a difficult task. Federal law has limited impact as the concept of health care is almost totally absent from the United States Constitution, making federal control over the nation's 171,000 laboratories difficult and indirect. Because of the interstate commerce provisions in the Constitution, however, federal mandates have been easier to apply to large facilities. So with the passage of the Clinical Laboratory Improvement Act of 1967 (CLIA '67), patients could at least be sure that the approximately 12,000 interstate laboratories were staffed by personnel with minimum education and that the testing performed in that laboratory included specific quality control and proficiency testing (P.L. 90-174). While both of these quality parameters provide some information about the overall level of accuracy achievable in a laboratory, neither can make any claims about the accuracy of the individual performing a test.

Pathologists strongly opposed imposing quality control and proficiency tests, claiming that costs would be high enough to compromise patient care and that such controls were too expensive. Although costs did rise during this time, it was also a time of great expansion for clinical laboratories in three other major areas: (a) the range of tests made available at hospital sites instead of reference laboratories; (b) the significantly increased sensitivity of

these tests, and (c) the increased availability of multi-channel instruments capable of providing a predetermined set of tests to be performed on a given sample.

These economies of scale as well as the increased use of laboratory information by physicians more than offset any cost increase due to staff educational levels, time off for professional development, and quality control purchases. Personnel pay ranges did not significantly increase during this time, given that more tests could be done by a lesser number of people due to the level of automation and the ability of non-interstate laboratories to hire non-certified persons and train them on the job.

But CLIA '67 was not as effective in achieving higher quality laboratory results as its proponents had hoped. The number of laboratories that fell under this statute was too small (approximately 17,000) to effect a significant increase in quality, and the personnel regulations were too limited in their scope. Additionally, too many affected institutions had the departmental supervisor or senior person perform the proficiency tests in a manner different from that which was used for routine patient testing. Finally, for the hematology laboratory, there existed no acceptable method for proficiency studies for the peripheral blood differential. This test is performed by a single individual identifying and evaluating 100 white blood cells on a single slide. Red

blood cells and platelets are qualitatively examined as well. Given the number of cells on a slide, it was thought impossible to develop a proficiency process for this procedure. Yet, the differential is the single most important hematological test performed.

CLIA '88, or Son of CLIA '67

By the middle of the 1980s, societal pressures were beginning to focus on the cost and benefit of health care. Medical care costs were continuing to increase at a rate far ahead of all other aspects of the economy, including defense. The federal government and its administrative insurance carriers instituted a form of price control called Diagnostic Related Groups (DRGs) as one attempt to control costs, but this pricing system concerned Medicare patients only and the costs not covered by the DRG system were simply built into the charges applied to non-Medicare patients, a practice known as cost shifting (Marmor & Blustein, 1994).

As an example of how one person's experience can affect the outcome for the whole, the mother of Senator Barbara A. Milkuski (D-MD) became ill and had laboratory tests performed by a non-CLIA'67 approved laboratory. In compelling

testimony before her colleagues at the Senate Labor and Human Resource Committee meeting on April 18, 1988, she argued that regulations needed to be applicable to all laboratories by recounting that faulty laboratory test results almost killed her mother. Her testimony among others turned the debate in Congress and CLIA'88 was passed. It made all CLIA '67 regulations applicable to all clinical laboratories, unless those laboratories chose not to accept any federal health dollars (Medicare, Medicaid, CHAMPAS, etc.). Further, CLIA'88 tried to develop a correlation between the complexity of the performance of a test and the qualifications of the person allowed to perform it.

The intent of Congress was to ensure a level base of quality available in all clinical laboratories. Through its regulations, Congress sought to analyze the issues involved in laboratory testing by dividing the entire process into sections: preanalytical (patient preparation and identification, specimen collection, transport and storage), analytical (the performance of the test itself from sample utilization through instrument quality to results), and post-analytical (the significance of the result itself, the proper assessment of the clinical correlation of the result with other data and communication with the appropriate authorities). Congress wished to make sure that the more significant or difficult a test, the more well trained the

person assigned to perform it (CLIA '88-Intent of legislation, 1988).

Between 1988 and 1992 when the regulations were first promulgated (Federal Register, December 6, 1992), a task force of the American Society for Clinical Laboratory Science (ASCLS), headed by Professor James T. Griffith of Massachusetts, developed a complexity model that was used to determine the educational and professional level of persons capable of performing specific procedures. In 1992, this model was submitted to the Centers for Disease Control and Prevention to be applied to all existing laboratory analyses. Subsequently modified by oversimplification, the model has not been as important as originally conceived.

Much of the pressure for modifications came from physicians who owned and/or operated private physicians' office laboratories and who believed that the increased federal government influence would be too expensive and overly burdensome (American Family Physician, 1989; Hurst, Nickel, & Hilborne, 1988). The data indicated that their office laboratories were not as well run as one might have assumed (Bloch, Cembrowski, & Lembesis, 1988). Despite the concerns and attempts to avoid the regulations entirely, all laboratories, including physician office laboratories, applying for reimbursement to the federal government through any of its agencies must obey the regulations promulgated

under CLIA '88 by the Health Care Finance Administration.

Although one of the more dire predictions, few physician office laboratories have closed because of federal regulations, although many have merged into larger and more complex facilities serving group practices (Crawley, Belsey, Brock, Baer, & Loshchen, 1986). Remarkably, as all of this change was swirling around it, the laboratory as a whole has remained one of the most regulated parts of the health care delivery system while its individual practitioners are some of the least regulated.

Scope of Proficiency Testing in the Clinical Laboratory

Proficiency testing is the accepted method by which laboratory results are compared to known values (Tholen, 1988) and has been deemed by CLIA '88 as a required method of quality assessment (Federal Register, March 14, 1994; May 14, 1998; June 15, 1998; Morbidity and Mortality Weekly Report, March 8, 1996). Several studies have evaluated the statistical methods (Grannis, 1978; Lawson, 1995; Lawson, Gilmore, & Tholen, 1988; 1993). Two additional studies have reviewed the effect of storage and transport on aqueous

samples (Hyvarienen, 1985; Jenny, 1994). Finally, studies have been performed to ascertain the effect of proficiency testing as a management tool (Castaneda-Mendez, 1992; Haven, 1978). Since the early 1960s, proficiency testing has been accepted world wide in clinical and public health laboratories (Beeser, Nerten, Drescher & Fischer, 1975; DeClerq, 1988; England, Rowan, van Assendelft, Bull, Coulter, Fujimoto, Groner, van Hove, Jones, Kaneter, Klee, Koepke, Lewis, d'Onofrio, Tatsumi, & McLaren, 1998; Havelaar, Hogeboom, Sekhuis & van Erne, 1987; Rajamaki, 1980).

Proficiency Testing in the Clinical Chemistry Laboratory

Because their discipline is most closely allied to the concept of proficiency testing, clinical chemistry laboratories were the first to use such testing in great part due to the ease with which specimens could be aliquoted, stored, and tested (Miller, 1979). At the time of proficiency testing's inception, clinical chemistry methods varied wildly, with no single method judged better than another, and with many home-grown modifications or methods available. It was common practice to have a clinical chemist on site whose responsibilities included the development of

procedures for use in the laboratory.

These multiple and, at times, conflicting methods caused a major difficulty in the determination of acceptable ranges. For example, blood glucose was sometimes reported as all reducing substances (reference range: 80 -120 mg/dL) or as a combination of the three important similar sugars: glucose, fructose and lactose (reference range: 70-100 mg/dL) or as only glucose (reference range: 60-90mg/dL). A result of 118mg/dL might be considered acceptable or unacceptably too high. Thus, method became the important criteria in assigning acceptable ranges(Ross, 1998; auBuchon, 1991). Sample preparation, in-house error, variability in instrument sensitivity and specificity all contribute to the difficulties in assigning acceptable ranges (Bennett, Eckfeldt, Belcher, & Connelly, 1991; Ehrmeyer, Laessig, Leinweber, & Oryall 1990; Lawson, Williams, & Long, 1993; Mitchel & Doran, 1985).

Proficiency Testing in the Microbiology Laboratory

The Centers for Disease Control and Prevention (CDC) initiated a national proficiency testing program in mycobacteriology through the use of lyophilized (freeze dried) samples (Griffin, Cook & Mehaffey, 1986; Griffin, Mehaffey, Cook, Blumer & Podeszwik, 1986). Proficiency testing for reportable organisms such as *Mycobacterium tuberculosis* (Morbidity and Mortality Weekly Report, August 11, 1950) to nosocomial infections to food microbiology (Peterz, 1992; National Nosocomial Infections Study Report) is routine. Proficiency testing is required in the other subspecialty areas of microbiology: mycology, parasitology and virology (Eamsobhama & Boranintra, 1993; Smith, 1974; Wood, Palmer, Missett & Whitby, 1994).

Proficiency Testing in the Immunology/Serology Laboratory

While the serology laboratory uses similar specimens (serum, plasma, urine, etc.) with those of the clinical chemistry laboratory, its methods involving the use of monoclonal antibodies and ligand assays are sufficiently different to cause a unique set of problems (Francis,

Peddecord, Ferran, Benenson, Hofherr, Garfein, Schalla, & Taylor, 1992; Haven & Lawrence, 1977). Thus, it is the testing methods again that pose a set of issues for proficiency testing in the serology laboratory.

Another set of issues involves the qualitative aspects of several of its test procedures. Pregnancy tests, for the most part, are positive or negative. Only in rare medical situations, such as hydatiform mole or certain malignancies, is it necessary to determine "how much" pregnant. In those circumstances, the sensitivity of the method, and the ability of the method to provide quantitative as well as qualitative results must be taken into account.

Finally, the immunology laboratory and its close cousin, the immunohematology or blood bank laboratory make significant use of red blood cells and white blood cells for testing. Once stabilized cell suspensions became a reality, these laboratories too could participate in proficiency testing (Ezer, Burnie, Carstairs, Ley, McBride, Pinkerton, 1981; Goguel, Crainic, Ducailar & Quinn, 1993; Polesky & Hanson, 1990; Rickman, Monical & Waxdal, 1993).

Proficiency Testing in the Cytology Laboratory

Although not usually included in the traditional clinical laboratory but more closely allied with pathology, cytology laboratories have a great deal in common with the hematology laboratory. Both laboratories use microscopic evaluation of cells that requires (a) knowledge of cellular structure, (b) reactivity to stains, and (c) quantitative and qualitative assessment of specific cell lines. Above all, the process is performed by a single individual who is examining the specimen. As a consequence, the cytology laboratory has issues and procedures similar to those in hematology (Collins, Kaufman & Albrecht, 1971; Haven, & Lawrence, 1978). Recent investigations have suggested that the use of Kodachrome slides are inferior to the use of the actual microscope slide examination for the assessment of proficiency (Hincklin, Plott, & Wood, 1981).

Studies in Canada, through the auspices of the national health care program (government of Canada), have proven the feasibility and success of using either Kodachrome slides for specific cell identification and actual cytology preparations for overall evaluation (Carney, 1984; Curry, Thompson, Dietrich, Lipa, Massarella, Taves, Wood & Zuber, 1987; DeBoy & Jarboe, 1991; Gifford & Coleman, 1994).

Proficiency Testing in the Hematology Laboratory

Proficiency testing in hematology is a complex mixture of clinical chemistry-like analytes such as hemoglobin, function assays such as prothrombin time, and qualitative assessment such as peripheral blood differentials. Analytes for which there are standards available from the National Bureau of Standards and Technology are tested for in exactly the same manner that proficiency testing in clinical chemistry is performed (Mahoney, Wong, & Van Kessel, 1993). Similarly, coagulation testing based on the functionality of a specific or group of factors has been possible through the same stabilization process used in clinical chemistry for enzyme assays (Beeser, Nerten, Drescher & Fischer, 1975; Han, Lawson, Dodds & Lawrence, 1985).

Red cell, white cell, and platelet counts and accessory calculated results such as the hematocrit, MCV, MCH, MCHC, RDW, and MPV can be stabilized using the same method that commercial companies such as Bering, R&B Labs, CMSCoulter, and others use to provide daily quality control materials.

This left (a) the microscopic evaluation or differential and (b) the reticulocyte percent assay as the two major tests performed in the hematology laboratory without proficiency testing. The original and still more common method of proficiency testing is to provide Kodachrome slides of

specific cells to be identified. This method is used by the College of American Pathologists Hematology & Clinical Resource Committee because it is inexpensive, consistent in duplication, easily stored or transported and has the advantage of retrospective evaluation after the final report has been received by the laboratory.

However, this method does not evaluate the ability of the laboratory practitioner to choose an appropriate site to evaluate or to identify cellular abnormalities within the context of an entire slide. Only a few services such as the Wisconsin State Laboratory Proficiency Testing Program provide such a method.

Supporters for this style of proficiency testing for differentials list disadvantages of the automated differential instruments (Spielman, 1968; Cornbleet, 1983; Lindenbaum & Nath, 1983; Knecht, Eichhorn & Streuli, 1985; Beris, Graf & Miescher, 1983). They cite the need for (a) the use of actual peripheral blood smears as the only legitimate method because the use of the smear requires the practitioner to identify the appropriate screening area, (b) to utilize the microscope to best advantage, and (c) to correlate the findings into a coherent report.

The Finnish System

Beginning in the 1980s, the Finnish medical community adopted a system that relied on the complete specimen rather than the Kodachrome slide of individual cells. Based in part on the geography of a small country in which there were several large regional hospitals providing laboratory services to physicians' offices and rural facilities, the use of prepared glass slides was seen as an effective method. This is in contrast to the United States' quality assessment service, which believed that the less breakable, more easily duplicated Kodachrome slides were a better choice for the over 500,000 hospital, physicians' office, and reference laboratories.

Anton Rajamaki was the medical officer in charge of developing and implementing a national proficiency program for Finland. As part of that national program, Rajamaki (1980) described an external quality control process to assess the performance of individuals in estimating blood cell morphology by bright light microscopy. The method is based on the application of a detailed result form to collect the results from the participants in a standardized manner and the application of a reference board of hematology experts to establish the morphological "truth" as correlated with the patient's condition and status.

Eighty percent of the board must reach consensus for acceptance of a morphological detail as a "target finding" for the participants. For each proficiency testing survey, a score for mean percentage performance is calculated for each participant. This score indicates the percentage amount of correct identification of the "target findings" of the survey specimens and is an overall measure of performance of the individual. This method tests the quantitative and qualitative aspects of this procedure. No national methodology used in the United States does this. By choosing a consensus point of greater than 80%, mild or subtle details that could legitimately be missed in a routine setting are avoided.

Rationale for Study

Introduction

To gain a proper perspective of the strengths and limitations of proficiency testing in the clinical laboratory, the ground on which the clinical laboratory was built needs to be reviewed. By the end of the 19th century,

rudimentary procedures were available to count blood cells, to measure hemoglobin and sugars (glucose is not the only one) in the blood stream. The concept of the clinical laboratory was controversial then, as it is now. Concerns were raised that laboratories were scientific luxuries, that they required too much space, that they were too expensive, and that the tests performed were too time consuming (Kotlarz, 1999a).

With the rapid advances in medicine during the first 4 decades of the 20th century, it became clear that standards of laboratory medicine and personnel must be elevated in cooperation with medical societies, universities, and scientific institutions. Good intentions, however, did not become deeds until after World War II.

Initial Use of Proficiency Testing

One of the first issues addressed was the perceived inconsistency among laboratories. Physician directors would divide a specimen into multiple samples, send them to different clinical laboratories for analysis, and expect to obtain similar, if not identical results. More often than not, they obtained markedly different results. By 1945, a

group of physician laboratory directors formed the Committee on Laboratories of the Pennsylvania Medical Society (Sunderman, 1972). Their early replicate testing revealed significant dichotomies among laboratories. In 1946, this committee organized the first anonymous testing system (Bulk & Sunderman, 1947) with an astonishing and sobering level of inadequate to grossly incorrect results from the tested facilities.

The College of American Pathologists (CAP) was also forming at this time and, due to the inclusion of many of the Pennsylvania pathologists on the initial Board of Directors, chose to apply this method nationally. These initial studies confirmed that validity of laboratory data can seldom be determined by mere inspection and that unsatisfactory laboratory work is prone to escape detection by those not fully qualified to pass critical judgment (Sunderman, 1975). As a result of these surveys, it became recognized that, to maintain high standards, the accuracy of measurements must be under constant professional surveillance.

CAP decided that the most efficient method with which to undertake this constant surveillance was the preparation of solutions whose concentrations were unknown to the analyst. Samples for clinical chemistry determinations were the first items for use since they could be made up in large batches, could be allocated into sealed ampules, and, most

importantly, were stable enough to withstand transportation. Thus, proficiency testing for blood sugars, non-protein nitrogen, and other substances in the serum were born. Specimens for hematology, immunohematology, and microbiology were unavailable for some time due to the inability to find stable, transportable, and standard concentrations for testing samples. For these tests, either no proficiency tests or in-house samples for replicate testing were used.

Proficiency Testing Goes Formal and National

In 1949, the Virginia Pathology Society was the first to ask Sunderman to develop a monthly self-auditing proficiency testing service for their group. Some time after, the Alabama and Indiana Societies followed suit. For the next 36 years, the Sunderman Proficiency Testing Service provided to each of the participants in the service two ampules containing different sera or solutions which were received by the participating laboratories on the first day of each month. Results of the tests were then reported to the Service within 48 hours of the sample's arrival. On the 15th day of the month, participants received a report that included the results of a statistical analysis of the values reported by

all the participating laboratories, a current review of pertinent methodology, a comprehensive bibliography, and validation of the results of that specific laboratory.

From its inception, all results were held in confidence, and every precaution was taken to avoid disclosing exact data without a specific request from the laboratory director. When the results of analyses for the solutions of any given month fell outside allowable range of values, the directors of the laboratories were encouraged to take an understanding and constructive approach in their efforts to ascertain the causes for the inaccuracies and to bring about correction.

End of an Era and the Beginning of Another

In 1967, the National Bureau of Standards (now the National Institute of Standards and Technology) became active in the development of clinical standards for other clinical chemistry analytes. As physicians began to rely more and more on the steadied accuracy of the numerical data produced by clinical laboratories, and as patients began to realize the necessity of the accuracy of these data, an effort to obtain legislature to assure this accuracy developed. The pathologists' view was that legislation, rules, and

regulations from governmental agencies were inordinately time consuming, undeniably wasteful, and excessively costly. The proponents believed that the public was at risk in the choice of laboratory in which their specimens were tested. In 1967, Congress passed the Clinical Laboratory Improvement Amendments to the Social Security Act.

Based in the Constitutional right to control interstate commerce, this federal law set minimal standards for professional education of personnel and requirements for proficiency testing for all laboratories that were engaged in the receipt of specimens from out-of-state facilities. For the most part, these requirements were active for private laboratories such as Smith Kline (now Smith Kline Beecham) and hospitals that served patients from states other than their own. Facilities (large or small) not engaged in interstate commerce were not included.

By the mid 1970s, the process of freeze drying had left the confines of the space program and was incorporated into the storage of bacteria. This process allowed microbiological samples to be transported to distant sites, reconstituted, and used for bacteriologic proficiency testing Griffin, Cook, & Mehaffey, 1986). Methods developed for quality control specimens to be used in multiparameter hematology instruments were also transformed into the processing of proficiency testing for the red blood cell

count, white blood cell count, platelet count, and hematocrit (hemoglobin determination proficiency tests having been developed earlier through the use of aqueous standards similar to clinical chemistry analytes). With the stabilization and preservation of human cells having been accomplished, specimens for proficiency testing in the immunohematology and serology laboratories became available (Taylor, Fulford, Przybyszewski, & Pope, 1979).

Summary

Clinical laboratory practitioners were conceived out of a need for accurate, reliable clinical data. Throughout the years, these individuals have been provided entry level qualifications at multiple levels without anyone ever determining if these levels were appropriate or provided a "value-added" concept of quality for the patient.

Proficiency testing methodology is the accepted method for ascertaining laboratory and interlaboratory consistency and, one hopes, accuracy. For the majority of analytes, the major weakness is the very essence of a proficiency sample for the sample is known to be a proficiency sample. Many laboratories prefer their senior scientists to perform the

evaluation. In addition, it is possible to rerun the test multiple times in order to assure the most correct answer prior to reporting the result.

Both of these occurrences violate the essential assumption that a proficiency test must be performed in the same manner as all routine tests. This one weakness, however, is not sufficient to claim that proficiency testing is not worthwhile. Even with this limitation, significant numbers of laboratories through the years have proven themselves unable to attain the minimum level of proficiency. Proficiency testing is a cost-effective, consistent method to assess laboratory competence.

Clinical laboratory science has had an erratic history in its attempts to be recognized as a profession. Pressures by pathologists and hospitals added to the prejudice surrounding women in the scientific workplace have caused multiple educational levels, training experiences, and certifications to occur with little to no evidence of which gives the better quality result to the patient. While only a small step, perhaps this dissertation will stimulate interest in assessing the proficiency of the individual, not the facility.

A study was designed to evaluate the accuracy of CLS and CLT practitioners at entry level. Entry level practitioners were chosen in order to eliminate two variables. By

restricting the study to entry level personnel, participants in each of the cohorts were at the same level of didactic and clinical laboratory experience. Second, because laboratories vary widely in their scope of practice (walk-in clinics to tertiary medical centers), the choice of entry level practitioners also eliminated the additional exposure and learning that occurs in the laboratory.

CHAPTER 3: METHOD

Introduction

Ever since the invention of the clinical laboratory technician in the late 1970s, there have been significant arguments concerning the scope of practice of this level of practitioner versus the clinical laboratory scientist. These discussions have occurred routinely at the annual Clinical Laboratory Educators Conferences sponsored by the American Society for Clinical Laboratory Science. In each instance, no evidence is presented - only opinion.

Clinical laboratory technician educators argue that CLTs should be performing the vast majority of tests and that CLSs should be performing highly complex tests, management, and education only. Clinical laboratory science educators believe that this is not the case. They cite anecdotal information concerning the difficulty in which CLT graduates find themselves when they elect to further their education by completing a baccalaureate degree. There is no objective evaluation of the assumed competencies of these individuals. In the absence of evidence, assumptions and opinions carry the day.

When the field of medicine accepted the Flexner Report as a call to self-regulate its broad diversity of educational and experiential levels of training for physicians, there was no body of literature to support their activities (Flexner, 1913). The same was true of nursing, social work, and other professional groups, which in the absence of externally imposed regulations, chose to define levels of practice and entry-level competencies. Clinical laboratory science is at the same place in its evolution as medicine was at the time of the Flexner Report and has the added burden of federal and state regulations.

Proficiency Tests

There are thousands of laboratory tests, and many tests have multiple methodologies. To test all of these would be impossible. To choose a smaller number would require that the chosen tests possess some combination of knowledge, skill, and technical abilities rather than a fully automated or single-step procedure. In each laboratory speciality, it is possible to determine those few tests that possess this level of knowledge, skill, abilities, and a level of criticality to patient care. In the hematology laboratory

the test that possesses these attributes would be the complete blood count's differential.

How, then, can one evaluate the accuracy of peripheral blood differentials when performed by different people with different levels of education and training and in a manner that does not lend itself to comparisons? The College of American Pathologists uses Kodachrome slides highlighting a single cell or single set of cells to identify (Sunderman, 1975). These slides are easy to duplicate and distribute, have relatively good precision in color development, and allow for comparison of answers since only one cell or set of cells is available to identify.

But the deficiencies of this system include the fact that the person looking at the slides must focus on the specific cell shown as the only cell in the picture or the cell identified by an arrow. There is no way to test if the person being tested would find this cell or recognize it as something important. Additionally, and perhaps more importantly, there is no method to determine who actually looked at the slide or if reference materials or support was used. Since the average peripheral blood smear is looked at by one person and rarely, if ever, does anyone else see those cells, it is ludicrous to assume that a slide is evaluated in the same way. In most clinical laboratories, proficiency testing is performed by the most senior or most well-educated

person who has access to additional texts. Occasionally, that slide is passed around for everyone to see and express an opinion, but only one opinion is returned to CAP for judgment.

A much more cumbersome but much more accurate method is to distribute replicate copies of the peripheral blood smear itself and to take steps to ensure that every person performing differentials in a laboratory perform the test. Those answers, then, would be forwarded for evaluation. Another refinement is to require the same time span for routine analyses to be used for the proficiency sample.

With sufficient numbers of contributing personnel, it could be possible to determine if educational levels played a role in the accuracy of the peripheral blood differential. Either answer would have a profound effect on the educational process, hiring practices, and advancement potential of the people who work in the clinical laboratory.

While some European countries (e.g., Finland) have used this technique of evaluation, the educational background of their laboratory professionals is quite different than that of the United States. Only one state public health agency (Wisconsin) uses this method of evaluation, but it does not require any specific person to perform the test, and only one report is expected from each laboratory. Putting the more precise testing situation together with the ability to group

responders according to their education background has never been done.

Although a single study of this type could never be said to be definitive, its results would provide the basis for additional testing by others in order to validate its conclusions. If those conclusions were validated, the patient public would have, for the first time, an objective method by which to determine the potential for accurate evaluations of their peripheral blood smears.

Research Design

This study was designed to investigate any qualitative difference in the performance of peripheral blood differentials performed by baccalaureate degree clinical laboratory scientists and associate degree clinical laboratory technicians.

Participants at both educational levels in this study were tested after they completed their college courses in hematology but before they had any clinical experience, thus lessening the complication of experiential learning. Each participant received prepared smears on which to perform the procedure.

In this correlational study, one cohort of students were in their 2nd year of a clinical laboratory technician program, having finished a didactic course in hematology and prior to their clinical laboratory experience. The second cohort of students were in their 4th year of a clinical laboratory science program, having finished a didactic course in hematology and prior to their clinical laboratory experience. These two cohorts of students completed a set of 10 peripheral blood smear differentials. Results from each student were determined to be within the accepted ranges as defined by Rajamaki. These values were correlated to the level of education defined in the cohort.

The independent variable was the level of education completed by the participants. The dependent variable was the accuracy of the peripheral blood differentials achieved by these participants as compared to the predetermined results. The variables were discrete in that the participants came from two distinct, easily identifiable groups and that the results of the testing procedure were compared to predetermined values (Christensen, 1997).

Sample

In order to determine if there is any correlation between accuracy in the performance of a peripheral blood differential and the individual's educational level, it is necessary that populations of practitioners at two different levels of education perform the procedure on the same peripheral blood differentials. These practitioners should be at parallel points in their educational careers in order to minimize experiential learning. As a consequence, the individuals involved in the study had completed their campus-based hematology courses but not yet begun their clinical practicum experience.

Two cohorts of students from clinical laboratory science and clinical laboratory technician programs were given a set of 10 peripheral blood smears on which to perform peripheral blood smear differentials. These results were assessed for accuracy against known values developed by the Rajamaki method. Once determined to be acceptable or unacceptable, the results were subjected to standard statistical tools of mean, chi square test, Pearson product-moment, and other appropriate tools.

There are over 500 programs in clinical laboratory science at the associate degree and baccalaureate degree levels (NAACLS, 1999). In an average year, approximately

4,000 students graduate from these programs. To test all of them was impossible. Thus the issues of sample and sample size were resolved. In order to lessen the potential for local irregularities or colloquial usage, these participants were gathered from more than one state or region. Letters describing this study were sent to the directors of clinical laboratory science and clinical laboratory technician programs throughout the country soliciting volunteers.

It was also critical to this study that the participants be at parallel points in their professional education. Participants who are nontraditional by virtue of entering into a second career or by virtue of a late entry into a collegiate program and those who have experienced one of the United States military programs in clinical laboratory science would have altered the sense of "entry level" comparison necessary to determine the issues of educational attainment rather than individual expertise. It is fair to state that that only one CLT student out of the total of 37 was old enough to be termed "nontraditional."

Sample Size

Of the 500-plus programs, there are 288 programs in clinical laboratory science and 239 programs for clinical laboratory technicians. Between both levels, over 3,000 students were graduated. The original Lunz study in 1987 used 25 medical technologists and 25 nonregistered laboratorians.

This study proposed to use a total of 100 participants. The peripheral blood smears reviewed by a cohort of some 50 clinical laboratory technician students; another cohort of 50 clinical laboratory science students performed similar manual differentials on each of 10 peripheral blood smears. The students had just completed their final didactic and practical experiences prior to graduation so that they were as close to entry level competence as possible yet had not begun to practice, so that experience did not affect their judgments. Each used the attached result sheet (see Appendix B) in order to neutralize local area/hospital jargon.

Sample Diversity

The clinical laboratory scientist and clinical laboratory technician programs were chosen on a first reply

basis with the caveat that they represented at least 3 different states in order to minimize local area teaching or colloquial expressions or techniques. There was no requirement by the school that all of the students participate in the survey. Since programs vary in size, the number of individual programs was determined based on the number of students who chose to participate in the study.

Instrumentation

Ten replicate peripheral blood smears of 10 different case presentations were made, stained, and cover slipped prior to assessing that they met the criteria necessary for inclusion in the study. This post-processing assessment was important to assure that no cellular artifact had been caused and no important element lost during the processing. By using replicate peripheral blood smears instead of photomicrographs, the participant performed actions required for an accurate differential. Because of the small number of participants, it was important to provide multiple opportunities in order to diminish any statistical skew due to small sample size. Thus, each participant performed 10 peripheral blood differentials.

Validity and Reliability of the Report Form

Over a dozen different instrument manufacturers in the United States alone sell instrumentation for the CBC. Each one has its own basic report form. Each facility then tailors that report form to suit the needs or desires of the physicians using that facility. Because there is no single universally agreed upon report form for the CBC, and because local colloquialisms must be accommodated, the data collection device was a compilation of the most commonly used forms.

This reporting mechanism was understandable to any participant from any region of the country, but it would not have been used previously by any of the students by virtue of its length and comprehensiveness. Review and approval of the form was given by Prof. Bernadette Rodak of Indiana University (personal communication, April 17, 2000), Prof. Anne Stiene Martin of the University of Kentucky (personal communication, May 10, 2000), and Prof. Shirlyn McKenzie of the University of Texas Health Science Center at San Antonio (personal communication, April 29, 2000). Each of these university faculty are internationally known experts in the field of hematology and have written textbooks in the field.

It was necessary to construct a form that was understandable to all participants. The base of the report form was taken directly from the computer report form used at the facility at which the peripheral blood smears were made. All differential requisitions use these terms in their reporting mechanism, although each facility may place them in different groupings, depending on the type of software or paper requisition form used.

In this study, it was important to use a much larger report form so that as many parochial issues of nomenclature as possible could be isolated. By using a form that included every known variant or presentation, the participant was not influenced to include or exclude elements. It was also important to expand an existing tool in order to prevent bias among those participants who may have used or not used a more commonly seen form. Additionally, since every participant used the same report form, there was greater ease in statistical analysis.

Peripheral Blood Smears

The ten patient presentations chosen reflect alterations in erythrocytes (red blood cells), leukocytes

(white blood cells), and thrombocytes (platelets). These presentations accurately reflect the classic presentation of these cells in the respective disease/condition of each case. In order to protect patient confidentiality, not only were these smears made, stained, and initially evaluated at an institution not participating in this study, data concerning age, gender, admitting diagnosis, and the quantitative portion of the CBC were not provided. This data suppression proved to be a limitation in only one case in which the individual cell counts would have made the evaluation more precise. (See Appendix A for the complete analysis of each peripheral blood smear used in the study).

Nature of the Study

In order to discern if there were critical differences in the ability of laboratory employees educated at the two different levels of study, it was necessary to provide participants with the same material and ask that a routine peripheral blood differential be carried out. This study provided the correlation that has not been done in this field. It was not enough to simply discern if one cohort did

better than the other; this study developed a body of evidence necessary to state whether there is or is not a correlation in the accuracy of differential examinations based on the type of education received.

Factors involved in the creation of the study included: number of participants, location of the participants, level of education which the participants have obtained at the time of the study, the quality of the material to be used, and the scope of the reporting mechanism.

Peripheral blood smears were made, stained, and cover slipped prior to assessing if they meet the criteria necessary for inclusion. By using replicate peripheral blood smears instead of photomicrographs, the participants performed actions that required for an accurate differential as would actually be experienced with a real patient specimen. This assessment after the sample processing was important to assure that no cellular artifact was caused and no important element lost during the processing. Because of the small number of participants, it was important to provide multiple opportunities in order to diminish any statistical skew due to small sample size. Thus, each participant performed 10 peripheral blood differentials.

Procedure

Each participant used the report form seen in Appendix B. All descriptors are widely used throughout the United States and, where necessary, synonyms are available for use.

Each participant received one complete set of peripheral blood smears and used their own or their program's microscope for the procedure. By indirect means, the participants were encouraged to complete these smears within the time frame usually associated with routine work by paying each participant $10.00 for one hour's work. This amount of money was small to the individual yet provided an incentive and encouragement to finish within a reasonable span of time.

Rajamaki's method for differential proficiency testing achieved consensus on both cellular identity and qualitative aspects of those cells on the multiples of 10 peripheral blood smears used in the study. The consensus was performed by the clinical laboratory science hematology specialists at a hospital chosen because it is a teaching facility with an international reputation in hematology. None of the educational programs in the area is affiliated with it, lessening any chance of familiarity. Each specimen was chosen because it is a classic presentation of the disease state/condition of the patient. In this manner, there were likely to be no anomalous readings.

Statistical Tools

Each participant's response was evaluated using the Rajamaki method to determine acceptability/non-acceptability. These values then were examined using categorical data analyses such as arithmetic mean, chi square, Pearson's, continuity correction, and Mantel-Haenszel testing for linear association.

The first evaluation was to determine if the participant's results were within the accepted Rajamaki ranges. This was done by a comparison of the results to the mean and standard deviations listed in Appendix A. The second level of analysis determined if there was a pattern of correct/incorrect results.

Summary

This study compared the accuracy of results from peripheral blood differentials between two cohorts of clinical laboratory students in order to determine if there was a statistical significance in the quality of the results obtained by students finishing an associate degree curriculum and students finishing a baccalaureate degree curriculum.

CHAPTER 4: RESULTS

Introduction

As result of the letters of invitation, four programs for clinical laboratory scientists and five programs for clinical laboratory technicians agreed to participate. The four baccalaureate programs were from Indiana, Massachusetts, Michigan, and Texas. The five associate degree programs were from Colorado, Hawaii, Illinois, North Carolina, and Rhode Island. At the outset, a total of 63 students in the baccalaureate programs and 47 students in the associate programs agreed to participate. By the end of the study, 51 fully completed sets of data were returned by the clinical laboratory science students and 40 completed sets of data were returned by the clinical laboratory technician students. There was a 79.3% return rate for the CLS students and 85.1% return rate for the CLS students.

More than the four CLS programs were willing to participate. Because the first four programs to reply had more than a sufficient number of students; the others were told that the study was closed.

Because of the smaller student enrollment in the clinical laboratory technician programs, it was expected that

more programs would need to be used in order to acquire the number of students originally intended. As anticipated in the study construction CLT students were less likely to be willing to participate. There were three types of replies among the communications received in response to the original letter of invitation (see chap. 1). The smallest number of replies indicated a willingness to participate. A slightly larger number refused without explanation, and the largest number refused, citing an attempt, as one writer put it, to sabotage a valuable career.

Description of Participants

The clinical laboratory science students ranged in age from 20 to 25. With the caveat that each participant self identified themselves according to the demographic rubric used in the study, the majority, 80%, were as white. Of the remainder, 16% were Hispanic, and 4% were black. The majority,82%, were female and 18% were male. Forty-seven of the participants had entered college immediately after high school. Of the four who did not, two entered the military but were not assigned to any clinical laboratory or medic experiences and two chose not to explain the delay.

The clinical laboratory technician students ranged in age from 19 to 30 years of age. As with the first cohort, the majority, 62%, were white; 25% were Hispanic, and 8% were black, and 5% were other. Again, 28 participants entered the program immediately after high school. Of those who did not, four entered the program after marriage, three had worked in various jobs to save money for college, and two did not explain the delay.

It was anticipated that the combination of racial/ethnic and gender backgrounds would not reflect the nation; however, they seem to reflect the characteristics of this field.

Method of Evaluation

Preparation of the raw data for statistical evaluation was done in the following manner. First, the numeric white cell identifications were compared to the Rajamaki numbers. Item 1.0 of the hypothesis is performed by identifying the first 100 white cells seen on the peripheral blood smear after choosing a location on the smear that is deemed appropriate. Because the differential is based on a total of 100 cells, relative increases or decreases in one cell line will cause perturbations in the other values. A value of one

(1) was given to the quantitative white blood cell differential whose values fell within the Rajamaki consensus. A value of zero (0) was given to the quantitative white blood cell differential whose values fell outside of the Rajamaki consensus.

These white cells will have variations in their nuclear structure, cytoplasm size, inclusions, and granular numbers. These attributes are usually not included in the quantitative portion of the differential but are included in a section for comments. A value of one (1) was given to the qualitative white blood cell differential whose values fell within the Rajamaki consensus. A value of zero (0) was given to the qualitative white blood cell differential whose values fell outside of the Rajamaki consensus.

The examination of the red blood cell population is a qualitative one. The cells may vary in size, shape, color, and the presence of inclusions. A value of one (1) was given to the qualitative red blood cell examination whose values fell within the Rajamaki consensus. A value of zero (0) was given to the qualitative red blood cell examination whose values fell outside of the Rajamaki consensus.

The examination of the platelet population is also a qualitative one. The platelets may vary in size, shape, color, and the presence of inclusions. A value of one (1) was given to the platelet examination whose values fell within

the Rajamaki consensus. A value of zero (0) was given to the platelet examination whose values fell outside of the Rajamaki consensus.

It was possible for a differential report to be unacceptable in one or more of these four aspects and still, by virtue of one category, provide the physician with some information that would be of clinical significance. Each report was evaluated for that clinical significance. A value of one (1) was given if the clinical significance of the overall evaluation was reported. A value of zero (0) was given if the clinical significance was incorrect.

Thus, each report was evaluated against specific and different criteria a total of five times. What follows is a report of the level of accuracy as compared against the five categories achieved by the individual cohort for each slide.

Reports of the Individual Peripheral Blood Smear Examinations

Slide 1025

As described in Appendix A, chronic myelogenous leukemia has a wide array of immature while blood cells and rare (infrequent, not abnormal or unusual) nucleated red blood cells to be identified. More CLS students than CLT students correctly identified the white cell variants present. The CLS students were more likely to find and over-report spurious cytoplasmic anomalies than CLT students; thus only 75% of the CLS students correctly reported the qualitative aspects of the white cells while 97% of the CLT students did.

The red blood cell examination was correctly described by fewer of the CLS students than CLT students. The major discrepancies for the CLS students were in estimating the degree of frequency while the CLT students more frequently did not report the presence of a red cell abnormality. Over one half of the CLT students did not complete the platelet examination or, if they did, they chose not to report it while all of the CLS students did complete and report their observations.

Clinically significant alterations were noted in four categories (white cell numbers, white cell quality, red cell quality, and platelet estimations). These were provided by more CLS students than CLT students.

Slide 2641

As described in Appendix A, chronic lymphocytic leukemia is characterized by the absolute increase of mature, monotonous looking lymphocytes with essentially normal appearing red cell and platelet populations. More CLS students than CLT students correctly identified the white blood cells. More CLS students than CLT students correctly described the qualitative changes such as toxic granulation seen in these cells. Because white blood cells tend to be distributed in an uneven pattern based on their adhesion and motility attributes, the only way that someone could have reported an incorrect numerical answer for the white cells would have been to have chosen an incorrect area of the slide to view.

Approximately the same percentages of CLS students and CLT students correctly described the red cell population. As with the first slide, the CLS students had a tendency to over call small and essentially unremarkable changes in the cells

while several CLT student did not report the red cell description. The platelet estimation was correctly reported by most of the CLS population and fewer than half of the CLT students. Whether due to a failure to report their findings or a failure to evaluate the platelet population is unknown.

Clinically significant alterations were noted in two categories (white cell numbers and white cell quality) and were provided by more CLS students than CLT students. Additionally, several CLT students incorrectly identified cells found only in acute leukemias. This information, if reported, would have constituted a serious error, causing the physician to perhaps misdiagnose an indolent malignancy with a preferred "watch and wait" form of treatment as a condition requiring immediate, expensive, and dangerous chemotherapy and potential bone marrow transplantation.

Slide 3037

As described in Appendix A, megaloblastic anemia is characterized by the presence of significant numbers of larger than normal red cells with an oval rather than biconcave appearance. Adequate to decreased numbers of platelets and white cells are common. A specific white cell, polymorphonuclear neutrophil, frequently displays an aberrant

nuclear form called hypersegmented. The three major criteria for the diagnosis of a megaloblastic anemia are macro-ovalocytes, basophilic stippling, and hypersegmented polymorphonuclear neutrophils.

All of the CLS students and half of the CLT students correctly identified the white blood cell portion of the differential. Of the cells misidentified, 4 of the 37 CLT responders reported seeing very immature cells that do not belong to the neutrophil family.

All but one CLS student correctly described the red cell population. That one student did correctly describe the cell type but incorrectly assessed its frequency. Approximately one half of the CLT students failed to describe the red cell population correctly. While every one of the CLS students correctly assessed the platelet population, only 29% of the CLT students commented on them at all and all were correct.

Clinically significant alterations were noted in three categories (white cell quality, red cell quality, and platelet estimations). These were provided by more CLS students than CLT students.

Slide 4599

As described in Appendix A, the peripheral blood differential from a patient with no spleen is characterized by the presence of increased mature neutrophils, occasional immature granulocytes, significant alterations in the size and shape of the red cells, and adequate to increased platelet numbers. The *sine qua none* feature of status post splenectomy is the presence of Howell Jolly bodies which are remnants of nuclear material. Frequently nucleated red blood cells are seen.

Most CLS students correctly identified the white blood cells and the subtle changes in the granulation of the neutrophils, while half of the CLT students correctly identified the white blood cells in the sample. Almost no CLT students noted the qualitative changes present.

Twice as many CLS students as CLT students correctly noted the presence of Howell Jolly bodies and nucleated red blood cells. All CLS students noted the appropriate comments for the platelets while only 48% of the CLT students did. Again there was significant numbers of responders who did not note anything in this category.

Clinically significant alterations were noted in three categories (white cell quality, red cell quality and platelet

estimations). These were provided by more CLS students than CLT students.

Slide 5797

As described in Appendix A, a leukemoid reaction has striking similarities to chronic myelogenous leukemia. The major differences are in the absence of increased numbers of progenitor cells such as myeloblasts, typically normal appearing red cells and essentially unremarkable platelets. Qualitative changes in the neutrophils include changes in the granule number and character as well as the presence of an inclusion known as a Döhle body.

Almost all of the CLS students correctly identified the white blood cells and their qualitative changes while fewer CLT recognized the cells. In one instance of unexpected results, all of the CLT students did report qualitative changes.

All CLS students noted that the red cell population was within normal range, while only 83% of the CLT students agreed. Those finding abnormal red cells noted cells typically seen in chronic myelogenous leukemia. Again, fewer than 50% of the CLT students correctly identified this portion of the report while the majority of CLS students did.

Clinically significant alterations were noted in two categories (white cell numbers, white cell quality). These were provided by more CLS students than CLT students.

Slide 8924

As described in Appendix A, myelodysplasia is a condition in which the relative numbers of abnormalities fall somewhere between acute leukemia and a leukemoid reaction. More CLS students than CLT students correctly identified the white cells. As one of the hallmarks of this condition is the presence of qualitative disturbances in the granulation of the neutrophil series, it is important that these changes be identified. Eight out of 10 CLS students identified these changes while only half of the CLT students did so. In addition, the CLT students reported cells that are only seen in lymphocytic diseases such as lymphoma, which have no connection with myelodysplasia.

Changes in the red cell population were identified correctly by more CLS students than CLT students. About one half of the incorrect results provided by CLT students concerning platelet estimations were no notation given.

Clinically significant alterations were noted in each of four categories (white cell numbers, white cell quality, red

cell quality, and platelet estimations). These were provided by more CLS students than CLT students.

Slide 81902

As described in Appendix A, the response to an acute bacterial infection is characterized by a stress reaction seen in the white cells and platelets. Although the percent correct for the CLS students was less than other comparisons, more CLS students than CLT students correctly identified the cells. Twice as many CLS students than CLT students identified the changes seen in a stress reaction.

Fewer CLS students than CLT students correctly described the red cells. In most instances, from both cohorts, there appeared to be a trend toward overcalling the frequency of the abnormalities rather than not seeing or misidentifying them. Platelet estimates were correct for both groups.

Clinically significant alterations were noted in each of two categories (white cell numbers and white cell quality). These were provided by more CLS students than CLT students.

Slide 80506

As described in Appendix A, the blood smear from a patient with HIV infection has decreased lymphocytes with significant alterations in red cell morphology and decreased platelets. More CLS students than CLT students correctly identified the number and quality of the white cells.

The red cell changes were identified by fewer of the CLS students than CLT students. Platelet assessment was performed correctly by all of the CLS students and fewer than half of the CLT students. There appears to be a consistent pattern of no-reporting of platelet estimations as those CLT students who performed the assessment were correct.

Clinically significant alterations were noted in each of two categories (white cell numbers and white cell quality). These were provided by more CLS students than CLT students.

Slide 9279

As described in Appendix A, compensated hemolytic anemia is primarily a condition involving altered red cells and an increase in platelets. The white cell population is essentially within reference ranges. More CLS students than CLT students correctly identified the normal white cells and

the qualitative aspects of the white cells. More CLS students than CLT students correctly described the various changes seen in the red cell population and the platelet population. Comments concerning clinically significant alterations present in one category (red cell quality) were provided by more CLS students than CLT students.

Slide 9326

As described in Appendix A, microangiopathic anemia is another red cell population disorder. Accompanied by lesser changes in the white cells and platelets, it is the characteristic changes of the red cells that separate this red cell condition from others. More CLS students than CLT students correctly identified the white blood cells and changes in the white cell quality. CLT students noted the presence of abnormal lymphoid elements.

Nearly three times as many CLS students than CLT students reported red cell alterations. More CLS students than CLT students correctly reported the platelet assessment. Comments concerning clinically significant alterations present in each of four categories (white cell numbers, white cell quality, red cell quality, and platelet estimations) were provided by more CLS students than CLT students. See

Table 1. for the summary comparison of percent correct reports for each evaluation performed on a peripheral blood smear differential.

Table 1

Summary comparison of percent correct reports for each peripheral blood smear differential

Slide		WBC	Q-WBC	RBC	PLTs	Cl.Sig.
1025						
	CLS	82.35	78.43	43.14	78.43	72.55
	CLT	51.35	97.30	62.16	27.03	48.65
2641						
	CLS	80.39	82.35	68.63	98.0	80.39
	CLT	45.95	35.14	64.86	43.24	29.73
3037						
	CLS	100	98.04	98.04	100	98.04
	CLT	72.97	70.27	51.35	29.73	56.76
4599						
	CLS	92.16	94.12	92.16	100	100
	CLT	51.35	5.41	43.24	43.21	37.84
5797						
	CLS	96.08	96.08	100	100	96.04
	CLT	72.97	100	83.78	48.65	72.97
8924						
	CLS	98.24	86.27	90.20	98.04	98.04
	CLT	64.86	54.05	83.78	43.24	37.84
81902						
	CLS	74.51	90.20	72.55	100	70.59
	CLT	35.14	40.54	86.49	100	43.24
9279						
	CLS	88.24	98.04	100	98.04	100
	CLT	75.68	100	67.57	70.27	56.76
9326						
	CLS	86.27	100	88.24	100	96.04
	CLT	54.05	72.97	24.32	62.16	40.54

Legend

WBC = Correct identification the white blood cell population
Q-WBC = Correct identification and frequency of any qualitative anomalies present in white blood cells
RBC = Correct qualitative description of the red cell population
PLT = Correct estimate of the number of platelets
Cl.Sig = Correct assessment that provides meaningful information

Overall Mean Result

A comparison of the mean levels of acceptable performance for all peripheral blood slides shows that CLS students were correct more often than CLT students through the entire procedure, even though there were a few instances of the reverse. In those instances, the CLS students were overcalling elements and finding alterations or concerns where none existed, while in the majority of situations the CLT students were missing or misidentifying cellular elements. (See Table 2.)

Table 2

Mean levels of acceptable performance for all peripheral blood slides

	WBC	Q-WBC	RBC	PLTs	Cl.Sig.
CLS	90.22	90.61	84.10	95.20	90.63
CLT	63.49	62.16	73.15	55.25	50.00

Legend

WBC	=	Correct identification the white blood cell population
Q-WBC	=	Correct identification and frequency of any qualitative anomalies present in white blood cells
RBC	=	Correct qualitative description of the red cell population
PLT	=	Correct estimate of the number of platelets
Cl.Sig	=	Correct assessment that provides meaningful information

Statistical Evaluations of Correlation

Introduction

Each peripheral blood slide was subjected to the same statistical processes for quantitative white blood cell accuracy, qualitative white blood cell accuracy, qualitative red blood cell accuracy and qualitative platelet accuracy. All reports were analyzed first by the chi square method and then subject to the Pearson product-moment correlation with and without a continuity correction, a likelihood ratio, and Mantel-Haenszel test for linear association. Those results that had an expected value of less than 5 were subject to Fisher one-tailed and two-tailed exact tests.

Chi Square Analysis

The chi square test was used to test whether a significant difference existed between the observed number of correct reports and an expected number based on the null hypothesis. Each differential result was compared to the Rajamaki range and given a value of 1 if correct or a value of 0 if incorrect. These values were then placed into the

traditional chi square. As was seen in the raw percentages and will again be seen in the additional statistical methods, chi square analysis demonstrated significant difference between the two levels of clinical laboratory personnel in the performance of the 10 peripheral blood slide differentials.

In 46 out of the 50 evaluations, the CLS students demonstrated greater accuracy than the expected chi square value. CLS students were more accurate 9 out of 10 times in the category of quantitative interpretation of white blood cells. CLS students were more accurate 8 out of 10 times in the category of qualitative identification of white blood cells. CLS students were more accurate 7 out of 10 times in the category of qualitative interpretation of red blood cells. CLS students were more accurate 10 out of 10 times in the category of qualitative interpretation of platelets. Finally, CLS students were more accurate 10 out of the 10 times in the category of qualitative interpretation of clinical significance.

Table 3

Values of chi square analysis for the five evaluative areas on each peripheral blood smear.

Slide	WBC	Q-WBC	RBC	PLTs	Cl.Sig.
1024	2.80908	4.89136	2.80908	24.41338	32.84976
2641	0.32378	22.41139	0.32378	38.01856	47.04603
3037	27.60959	14.04037	27.60959	50.86661	23.44652
4599	25.22514	68.78094	25.22514	38.01856	42.92058
5797	8.86541	1.48472	8.86541	33.40071	15.55094
8924	0.80612	11.22346	0.80612	34.33881	39.18106
81903	2.46048	24.85973	2.46048	NA*	6.63291
80506	2.04015	62.73998	2.04015	18.28612	24.42625
9279	19.15220	0.7383	19.15220	14.04037	26.95495
9326	35.84291	14.2215	35.84291	21.65203	36.79104

Legend

WBC = chi square value for the white blood cell population
Q-WBC = chi square value for any qualitative anomalies present in white blood cells
RBC = chi square value for qualitative description of the red cell population
PLT = chi square value for qualitative description platelets
Cl.Sig = chi square value for an overall description that provides meaningful information
NA = both cohorts achieved a 100% accuracy in this category on this peripheral blood slide.

Pearson Product-Moment Correlation and Continuity Correction Tests

The Pearson product-moment correlation demonstrates a relationship between the two variables, level of educational attainment and degree of accuracy achieved by each cohort in the identification of white blood cells and the qualitative interpretations of white blood cells, red blood cells,

platelets, and clinical significance. The degree of freedom (df) was 1. The probability of observing a value was ≤ 0.05. This level of probability provides for a wider latitude for the potential of an incorrect evaluation because (a) the number of participants is small and (b) the potential does exist that those persons who report incorrect findings may in time be able to identify the cells and anomalies correctly. Statistical significance as determined by a value equal to or less than 0.05 was present in 9 out of 10 quantitative white blood cell evaluations; in 8 out of 10 qualitative white blood cell evaluations; in 5 out of 10 qualitative red blood cell evaluations; in 10 out of 10 qualitative platelet evaluations; and in 10 out of 10 qualitative assessments for clinical significance.

Quantitative White Blood Cell Evaluations

The degree of significance as represented by the Pearson product-moment correlation ranged from 0.00001 to 0.00183. When adjusted for the small sample by the continuity correction, the range was from 0.00004 to 20784. For slide 3037, where the expected value for occurrence was less than 5, the continuity correction was 0.00031. For slide 5797, where the expected value for occurrence was less than 5, the

continuity correction was 0.0506. For slide 80506, where the expected value for occurrence was less than 5, the continuity correction was 0.00189. Thus, in all of the four instances the continuity correction supported an assessment that there was correlation between the accuracy of performance and the educational level of the two cohorts. See Table 4 for statistical values for quantitative WBC evaluations

Qualitative White Blood Cell Evaluations

The degree of significance as represented by the Pearson product-moment correlation ranged from 0.00000 to 0.39164. When adjusted for the small sample by the continuity correction, the range was from 0.00000 to 1.0000. For slide 1025, where the expected value for occurrence was less than 5, the continuity correction was 0.06125. For slide 3037, where the expected value for occurrence was less than 5, the continuity correction was 0.00060. For slide 5797, where the expected value for occurrence was less than 5, the continuity correction was 0.62132 For slide 9279, where the expected value for occurrence was less than 5, the continuity correction was 1.0000. In only one of the four instances did the continuity correction support an assessment that there was correlation between the accuracy of performance and the

educational level of the two cohorts. See Table 5 for statistical values for qualitative WBC evaluations.

Qualitative Red Blood Cell Evaluations

The degree of significance as represented by the Pearson product-moment correlation ranged from 0.00000 to 0.09373. When adjusted for the small sample by the continuity correction, the range was from 0.00000 to 0.73597. For slide 5797, where the expected value for occurrence was less than 5, the continuity correction was 0.01075. For slide 8924, where the expected value for occurrence was less than 5, the continuity correction was 0.56776. For slide 80506, where the expected value for occurrence was less than 5, the continuity correction was 0.22049 For slide 9279, where the expected value for occurrence was less than 5, the continuity correction was 0.00005. Thus, in only one of the four instances did the continuity correction support an assessment that there was correlation between the accuracy of performance and the educational level of the two cohorts. See Table 5 for statistical values for quantitative RBC evaluations

Qualitative Platelet Evaluations

The degree of significance as represented by the Pearson product-moment correlation ranged from 0.00000 to 0.00018. When adjusted for the small sample by the continuity correction, the range was from 0.00000 to 0.00060. For slide 9279, where the expected value was 5, the continuity correction was 0.00060. Thus, in all of the four instances the continuity correction supported an assessment that there was correlation between the accuracy of performance and the educational level of the two cohorts. See Table 6 for statistical values for qualitative PLT evaluations

Clinical Significance Evaluations

The degree of significance as represented by the Pearson product-moment correlation ranged from 0.00000 to 0.01001. When adjusted for the small sample by the continuity correction, the range was from 0.00000 to 0.1848. For slide 5797, where the expected value was less than 5, the continuity correction was 0.000031. Thus, in all of the four instances the continuity correction supported a correlation between the accuracy of performance and the educational level

of the two cohorts. See Table 7 for statistical values for clinical significance evaluations.

Overall Pearson Product-Moment Correlation Evaluation

The Pearson product-moment demonstrated a significant difference between the CLS students and CLT students in the performance of 6 out of 10 quantitative white blood cell evaluations, 9 out of 10 qualitative white blood cell evaluations, 5 out of 10 qualitative red blood cell evaluations, 10 out of 10 qualitative platelet evaluations, and 10 out of 10 assessments for clinical significance. The continuity correction is a similar statistic although it is a more conservative tool than the Pearson product-moment and it also demonstrated significant difference between the CLS students and CLT students in the performance of 7 out of 10 quantitative white blood cell evaluations, 9 out of 10 qualitative white blood cell evaluations, 5 out of 10 qualitative red blood cell evaluations, 10 out of 10 qualitative platelet evaluations, and 10 out of 10 assessments for clinical significance.

Likelihood Ratios

The likelihood ratios again correlated the relationship between level of education and accuracy in the performance of the five sets of evaluations for the peripheral blood smear differentials. The degree of significance as represented by the likelihood ratio for the Quantitative White Blood Cell Evaluations ranged from 0.00001 to 0.12426. The degree of significance as represented by the likelihood ratio for the Qualitative White Blood Cell Evaluations ranged from 0.00000 to 0.29441 with three comparisons out of 10 that could be considered random occurrences. The degree of significance as represented by the likelihood ratio for the Qualitative Red Blood Cell Evaluations ranged from 0.00000 to 0.57012 with 5 out of 10 instances showing potential random results. The degree of significance as represented by the likelihood ratio for the Qualitative Platelet Evaluations ranged from 0.00001 to 0.12426 and one out of the 10 comparisons was shown to be random. The degree of significance as represented by the likelihood ratio for the Evaluations of Clinical Significance ranged from 0.00000 to 0.00010 and there were no instances of statistically random results.

Again, as with the Pearson product-moment and the continuity correction, the Likelihood Ratio demonstrated a significant difference between the CLS students and CLT

students in the performance of 7 out of 10 quantitative white blood cell evaluations, 9 out of 10 qualitative white blood cell evaluations, 5 out of 10 qualitative red blood cell evaluations, 10 out of 10 qualitative platelet evaluations, and 10 out of 10 assessments for clinical significance. See Tables 4 through 8 for specific results.

Mantel-Haenszel Test for Linear Association

The Mantel-Haenszel test for linear association also correlated the relationship between level of education and accuracy in the performance of the five evaluations for the peripheral blood smear differentials. The degree of significance as represented by the Mantel-Haenszel test for linear association between CLS and CLT students in the evaluation of the quantitative white blood cell evaluations ranged from 0.00001 to 0.12408. The degree of significance as represented by the Mantel-Haenszel test for linear association between CLS and CLT students in the evaluation of the qualitative white Bblood cell evaluations ranged from 0.00000 to 0.39435.

The degree of significance as represented by the Mantel-Haenszel test for linear association between CLS and CLT students in the evaluation of the Qualitative Red Blood Cell

Evaluations ranged from 0.00000 to 0.57155. The degree of significance as represented by the Mantel-Haenszel test for linear association between CLS and CLT students in the evaluation of the Qualitative Platelet Evaluations ranged from 0.00000 to 0.00019. The degree of significance as represented by the Mantel-Haenszel test for linear association between CLS and CLT students in the evaluations of Clinical Significance ranged from 0.00000 to 0.01044.

In summary, the Mantel-Haenszel test for linear association demonstrated a significant difference between the CLS students and CLT students in the performance of 7 out of 10 quantitative white blood cell evaluations, 9 out of 10 qualitative white blood cell evaluations, 5 out of 10 qualitative red blood cell evaluations, 10 out of 10 qualitative platelet evaluations, and 10 out of 10 assessments for clinical significance. See Tables 4 through 8 for specific results.

Fisher One Tailed and Two Tailed Examinations

For those situations in which the expected value in the chi square examination was less than 5, Fisher one-tailed and two-tailed exact tests were performed to ascertain a more complete appreciation of significance. These procedures also correlated the relationship between level of education and

accuracy in the performance of the peripheral blood smear differentials numbered 3037 and 80506 in the category of quantitative WBC evaluations; 1024, 5797, 9279, and 9326 in the category of qualitative WBC; 5797, 8924, and 80506 in the category of qualitative RBC evaluations; and 5797 in the category of clinical significance. In each instance, the statistics reported a significant difference in the accuracy of the performance between the two cohorts. See Table 9 for specific results.

Table 4.

Statistical Values for the Evaluation of Accuracy in the Performance of the Quantitative White Blood Cell Category, using a df of 1 and a probability value of <0.05.

Slide	Pearson product-moment	Continuity Correction	Likelihood Ratio	Linear Association
1024	0.00101	0.00227	0.00097	0.00108
2641	0.00077	0.00171	0.00171	0.00082
3037	0.00008	0.00031	0.00001	0.00009
4599	0.00001	0.00004	0.00001	0.00001
5797	0.00182	0.00506	0.00153	0.00194
8924	0.00003	0.00009	0.00001	0.00003
81903	0.00022	0.00051	0.00019	0.00024
80506	0.00050	0.00189	0.00001	0.00053
9279	0.12194	0.20784	0.12426	0.12408
9326	0.00137	0.00315	0.00137	0.00146

Table 5.

Statistical Values for the Evaluation of Accuracy in the Performance of the Qualitative White Blood Cell Category, using a df of 1 and a Probability Value of <0.05.

Slide	Pearson Product Moment	Continuity Correction	Likelihood Ratio	Linear Association
1024	0.02699	0.06125	0.01662	0.02789
2641	0.00000	0.00001	0.00000	0.00000
3037	0.00018	0.00060	0.00010	0.00019
4599	0.0000	0.00000	0.00000	0.00000
5797	0.22304	0.62132	0.13661	0.22568
8924	0.00081	0.00189	0.00078	0.00087
81903	0.00000	0.00000	0.00000	0.00000
80506	0.00000	0.00000	0.00000	0.00000
9279	0.39164	1.00000	0.29441	0.39435
9326	0.00016	0.00064	0.00003	0.00018

Table 6.

Statistical Values for the Evaluation of Accuracy in the Performance of the Qualitative Red Blood Cell Category, using a df of 1 and a Probability Value of <0.05.

Slide	Pearson product-moment	Continuity Correction	Likelihood Ratio	Linear Association
1024	0.09373	0.14455	0.09254	0.09564
2641	0.56935	0.73597	0.57012	0.57155
3037	0.00000	0.00000	0.00000	0.00000
4599	0.00000	0.00000	0.00000	0.00000
5797	0.00289	0.01075	0.00091	0.00305
8924	0.36927	0.56776	0.37256	0.37200
81903	0.11674	0.19150	0.10927	0.11884
80506	0.08123	0.22049	0.03386	0.08298
9279	0.00001	0.00005	0.00000	0.00001
9326	0.00000	0.00000	0.00000	0.00000

Table 7.

Statistical Values for the Evaluation of Accuracy in the Performance of the Qualitative Platelet Category, using a df of 1 and a Probability Value of <0.05.

Slide	Pearson product-moment	Continuity Correction	Likelihood Ratio	Linear Association
1024	0.00000	0.00000	0.00000	0.00000
2641	0.00000	0.00000	0.00000	0.00000
3037	0.00000	0.00000	0.00000	0.00000
4599	0.00000	0.00000	0.00000	0.00000
5797	0.00000	0.00000	0.00000	0.00000
8924	0.00000	0.00000	0.00000	0.00000
81903	NA	NA	NA	NA
80506	0.00002	0.00005	0.00002	0.00002
9279	0.00018	0.00060	0.00010	0.00019
9326	0.00000	0.00001	0.00000	0.00000

NA - both cohorts achieved a 100% accuracy in this category.

Table 8.

Statistical Values for the Evaluation of Accuracy in the Performance of the Clinical Significance Category, using a df of 1 and a Probability Value of <0.05.

Slide	Pearson product-moment	Continuity Correction	Likelihood Ratio	Linear Association
1024	0.00000	0.00000	0.00000	0.00000
2641	0.00000	0.00000	0.00000	0.00000
3037	0.00000	0.00000	0.00000	0.00000
4599	0.00000	0.00000	0.00000	0.00000
5797	0.00008	0.00031	0.00001	0.00009
8924	0.00000	0.00000	0.00000	0.00000
81903	0.01001	0.01848	0.00985	0.01044
80506	0.00000	0.00000	0.00000	0.00000
9279	0.00000	0.00000	0.00000	0.00000
9326	0.00000	0.00000	0.00000	0.00000

Table 9

Results of Fisher one-tailed and two-tailed Exact Tests for those Peripheral Blood Slide Reports that had less than the Minimum Expected Frequency of 5.

Category	**Slide**	**One-tailed test**	**Two-tailed test**
quantitative WBC	3037	0.00008	0.00008
	80506	0.00060	0.00060
qualitative WBC	1024	0.02574	0.3920
	5797	0.33307	0.50705
	9279	0.5795	1.00000
	9326	0.00018	0.00018
qualitative RBC	5797	0.00429	0.00429
	8924	0.28167	0.51582
	80506	0.10717	0.13549
clinical significance	5797	0.00008	0.00008

Interpretation of the Data

For 9 of the 10 peripheral blood smear reports for quantitative white blood cell examination, the Pearson product-moment revealed significant differences between the CLS and CLT student forms. When a more conservative examination, the continuity correction, was applied, the same 9 out of 10 results were significant.

For 8 of the 10 peripheral blood smear reports for qualitative white blood cells, the Pearson product-moment revealed significant differences between the CLS and CLT student forms. When a more conservative examination, the continuity correction, was applied, 7 out of 10 results were significant.

For 10 of the 10 peripheral blood smear reports for qualitative red blood cells examination, the Pearson product-moment revealed significant differences between the CLS and CLT student forms. When a more conservative examination, the continuity correction, was applied, 10 out of 10 results were significant.

For 9 of the 10 peripheral blood smear reports for identification of clinically significance findings, the Pearson product-moment revealed significant differences between the CLS and CLT student forms. When a more conservative examination, the continuity correction, was

applied, the same 9 out of 10 results were significant.

When chi square data did not achieve a minimum expected value of 5, these data were were analyzed using Fisher Exact Tests. Six out of the 10 data sets examined in this fashion were deemed clinically significant. The likelihood ratio and the Mantel-Haenszel test for linear association were included in this study as additional verification of the degree of statistical significance shown by the more traditional statistical analyses of chi square, Pearson product-moment and continuity correction.

The data clearly demonstrated a significant difference between the abilities of these cohorts. While true in the other categories, the difference described in the category of clinical significance is especially important. In the clinical laboratory, the issue of false positive and false negative reactions is always present. Typically one prefers false positive values over false negative ones in that follow up or confirmatory tests can be used to clarify the situation. But the situation of a false negative results can be grave. To fail to recognize cellular elements that are essential to the development of a diagnosis can result in inappropriate or no therapy and could be life threatening.

Summary

Given the extent of the statistical examination presented, it is fair to state that both the examination of the raw data by arithmetic means (mean and standard deviation) and the detailed comparison and correlation studies performed suggest rejection of the null hypothesis that stated there would be no difference between the competence of an entry level clinical laboratory technician and an entry level clinical laboratory scientist in the performance of a peripheral blood smear differential as evidenced through a comparison of the results of means, chi square tests, and other appropriate statistical tools.

CHAPTER 5: SUMMARY, CONCLUSIONS, AND RECOMMENDATIONS

Introduction

> There can be no more important task for the director of a clinical laboratory than to assess the precision and accuracy of the analytical procedures under his/her supervision. Maintenance of high standards of analysis not only serves as a scientific stimulus for the laboratory but is also of direct benefit to patients. (Sunderman, 1992, page 1205)

F. William Sunderman, M.D. wrote that statement in his retrospective series on the conceptual origins of proficiency testing and quality control. Most practitioners in the clinical laboratory would agree on the need for accuracy and precision. Toward that end, they use multiple level quality control specimens, standards produced at the highest level of accuracy, moving averages, replicate testing, and other in-house protocols to assess, correct, or maintain quality. The one element that has been lacking in this process is the evaluation of the quality of the personnel performing the laboratory procedures. If one were to believe the current employment practices, then one might believe there is no significant difference between clinical laboratory scientists and clinical laboratory technicians in the performance of laboratory tests. Throughout their early history, pathologists claimed that a more highly educated work force

would provide laboratory results of better quality. The assumption that education would have a positive impact on the level of accuracy has only been tested once in the Lunz, Castleberry, James, and Stahl study between certified medical technologists and on-the-job trainees. This study was flawed in that the on-the-job trainees were from diverse educational backgrounds and the medical technologists had varying years of experience.

In contradiction to their own history, pathologists created laboratory position for lesser trained personnel and claimed that accuracy would not be affected as laboratory tests became more sophisticated and complex. During the 20+ years of this situation, no study was performed to verify that claim. This study was an attempt to assess that claim more rigorously that the previous attempt by developing cohorts with educational attainment proportional to their program of study in clinical hematology.

Proficiency tests have, for several decades, been used to monitor and improve performance of clinical laboratories. Peer group comparison is the most frequently used basis for judgment of performance in the United States. In Germany and Finland, the use of means established by referee laboratories or groups is preferred. Specifically, in Finland, the proficiency test specimen for peripheral blood differentials is a glass slide with a stained sample of blood. With the exception of the state of Wisconsin, in the United States this method has been given limited use on the grounds of

preparation,cost, and transport issues. As a consequence, the preferred method is Kodachrome slides.

In addition, as with all forms of proficiency testing used in the United States, there is no consideration of the person identifying the cells in the proficiency program. This allows the "laboratory" to be tested without the actual persons who comprise the laboratory staff to be tested. As a consequence, it is possible to assert that the "laboratory" is capable of performing cell identification when, in point of fact, only one person in that laboratory has been proven to do so. The fallacy to this approach is, of course, that only one of these persons (not in a group) will be performing this test on the next patient while in fact, only the one person (or the unofficial group mind) who always performs the proficiency tests has been proven to be competent *via* proficiency tests to perform this procedure.

This dehumanization of the individuals who perform laboratory procedures takes away both the responsibility of the individual and the acknowledgement of their essential worth. According to Fukuyama (1993), this situation sets up a situation in which the fundamental needs of respect and acknowledgment are missing.

The certification examinations taken by both associate level and baccalaureate level practitioners provide one to two opportunities during the examination to identify blood cells through color plates. A candidate taking the examination is directed to a specific cell on a specific

plate. The various certification agencies do not currently believe that the inability to correctly identify that cell is sufficient cause for the agency to deem the candidate as unsuitable for certification.

Eighty-seven students from programs throughout the country completed 10 peripheral blood microscopic evaluations. Students from baccalaureate clinical laboratory science program were significantly more accurate in their assessments of all phases of the microscopic evaluations. Where they were the weakest, although still statistically significantly better than their clinical laboratory technician counterparts, their consistent error in the qualitative white blood cell and red blood cell evaluations was in overcalling elements, not in failing to recognize them.

For example, in the most egregious case, slide 2641, clinical laboratory science students overstated the degree of red cell abnormality, although over 80% correctly identified the aberrant white blood cells that diagnosed the condition. One could posit that they recognized the condition represented on the peripheral blood slide and "went looking" for the classical red cell representation, which was not present in this case. Of more importance are the data that showed that more than half of the clinical laboratory technician students actually did not recognize the diagnostic white blood cells found in chronic lymphocytic leukemia. There are only two equally damning conclusions for this

error: (a) the students simply did not recognize the cells or (b) the areas of the peripheral blood slide on which they chose to perform their evaluation were inappropriate. The failure to report platelet evaluations which was the single most common reporting error of the clinical laboratory technicians either speaks to a somewhat cavalier attitude towards the study that cannot be discounted or a more serious lack of commitment to thoroughness or detail that might cause serious consequences to the patient.

Based on the data and their interpretation, the null hypothesis has not been supported by any arithmetic or statistical tests.

Conclusions

This study suggests that there are clear and provable differences in the abilities of clinical laboratory science students and students in clinical laboratory technician programs. If Howard Gardner is correct in his thesis on robust and naive learning theories, then it is possible to postulate that the abilities of clinical laboratory technicians to correctly identify peripheral blood cells will not improve in any significant way unless directed probing reeducation and/or retraining is undertaken (Gardner, 1991). While the public may have assumed that more education and/or technical training would result in increased accuracy and

precision in the clinical laboratory, the pathologist overseers of the evolution of this field did not think that it would matter. Clearly, in this study, it does. Although small in number of participants, this study has shown that there are educationally based differences in the ability of personnel to perform accurate peripheral blood differentials. Sufficient levels of accuracy were not obtained by the associate degree personnel and this outcome has to be evaluated by organizations as they view the structure and work flow of our national hematology laboratories.

Individual Laboratory Implications

In this era of cost containment and reorganization in the medical care delivery system, it has been economical to replace higher paid clinical laboratory scientists with clinical laboratory technicians. This replacement has been justified by the belief that both are equally capable of performing many, if not all, of the testing procedures available in the standard clinical laboratory. That belief, as mentioned previously, was never put to any test until now. These data suggest that this supposition is not the case for the performance of peripheral blood differentials. Clinical

laboratory technicians who perform peripheral blood differentials may not be providing the high level of accuracy or precision that they should. As a result, patients may not be receiving the quality of care that they need.

If the conclusions of this paper are supported by additional data, then administrators of clinical laboratories should seriously consider their hiring practices and their functional scheduling. This has financial impact in that the clinical laboratory scientists will be expected to be paid more and treated differently. In turn, one might be able to predict the potential for a cost savings reflecting a greater trust in the accuracy of the results as expressed by fewer repeat requests for CBCs.

Professional Implications

From the early part of the 20th century, pathologists have dominated the professional of clinical laboratory science, arbitrarily determining the entry levels for a profession not their own. While it is true that their initial desire for an educated work force was beneficial, their continued restructuring and manipulation of these entry levels has created disharmony and contention throughout the field. That there are over 15 professional organizations all claiming to represent the interests of the clinical laboratory is evidence to this.

The pathologists' continued control over one of the two national certification examination agencies (Board of Registry of the American Society of Clinical Pathologists) and the category of associate membership without voice or vote in the American Society of Clinical Pathologists speaks to an issue that Fukuyama discusses in his book, *The End of History and the Last Man*, in which he claims that that each person carries within himself or herself a need for respect and acknowledgement from others. For the past century, pathologists have placed clinical laboratory practitioners in a subservient position. Historical documents have proven that clinical laboratory practitioners have continuously sought to wrest their profession away from the pathologists by first creating an independent professional organization, followed by the court cases that removed the requirement to work only for a pathologist from the standards of certification maintenance, and finally the creation of an autonomous credentialing agency run for and by the practitioners of laboratory science. One element of the pathologist control has been in the creation and delineation of the various roles and responsibilities of the practitioners. No one ever questioned that right to do so. This study proves their assumptions to be less than correct and adds more credence to the belief that this profession should be independent of pathologist intervention if serving the needs of the patient being examined is a goal worthy to be attained.

Recommendations

Technical Issues

This study was limited in the number of participants. Because of its potential impact, it needs to be replicated either in multiple small studies or in a national study. One problem with either of these options will be the willingness of the students in the clinical laboratory technicians programs across the country to participate. Another issue will be the potential for these students to utilize texts, seek out advice or otherwise treat the study as most clinical laboratory practitioners do traditional proficiency testing specimens - simply keep redoing and redoing the differential until they are satisfied with their results or by devising a "group" report.

Because the statistically weakest component of the study was the qualitative analysis of the red blood cell population, the next study might emphasize the red blood cells population. This emphasis should not diminish the importance of the white blood cell identification since many of the most serious diseases (e.g., leukemias, lymphomas, infections) are demonstrated in the white blood cell population.

One study that might be possible on a large scale would be to review several iterations of both levels of the

certification examination to excerpt the data applicable to those questions that required identification of peripheral blood cells. While this would assess the ability of individuals to correctly identify cells once they have been pointed out, it would not assess their ability to chose the correct area on the peripheral blood slide, a concept of concern given the data on slide #2641.

Another aspect of the current situation impacted by this study would be the educational process of both levels of personnel. If, as was shown, there was significant difference in accuracy with the baccalaureate personnel as the more accurate, employers should not allow the associate degree employees to perform the test. This would cause educators to revamp their curricula to support the new work paradigm by eliminating differentials from the associate degree curriculum, for example. If, on the other hand, there was no separation in accuracy, then baccalaureate programs could move away from routine testing in favor of newer or more sophisticated testing and management. Employers would also take the opportunity to restructure their pay scales according to the work performed.

Social Issues

If the level of education is important to the accurate performance of a peripheral blood cell evaluation, then is it

possible to ask if levels of education are important in other arenas that have experienced the creation of lesser educated personnel? Certainly, the pages of the Chronicle of Higher Education have been filled in recent years with anecdotal but passionate discussions concerning the relationship between the purported decrease in quality of education found at colleges and universities throughout the country and the increased reliance on part-time instructors. A recent news items in the lay press concerning the error rate of pharmacy technicians in the preparation and dissemination of prescription medications could give one pause (Hendren, 2001).

In an interesting coincidence, during an informal conversation that touched upon the medical importance of the laboratory, a physician commented that most of his colleagues would not be surprised at the outcome of this study since they routinely experience a significant difference between the CBCs reported by the night staff and the CBCs reported by the day staff.(personal communication, March 26, 2001) Is the health care delivery system providing inaccurate data at a level that interferes with appropriate and timely patient care? While outside of any data from this study, one might wonder if this same difference in quality occurs in other fields that have experienced the recent development of assistants. For the past decade and more, the business mantra of "more with less" has been a powerful force in the health care delivery system in the United States. If this

study is an indication, the patient public might be getting "less with less."

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Appendix A

The Values and Standard Deviations for the Ten Peripheral Blood Smears as Constructed by the Rajamaki Method

#1025 Chronic Myelogenous Leukemia

The differential to be achieved by the test participants is:

Cells	**average results of experienced practitioners**	**Range of results acceptable by Rajimaki method**
polymorphonuclear leukocytes	69	+/-6.0
lymphocytes	12	+/-3.50
monocytes	5	+/-2.50
eosinophils	1	+/-0.23
basophils	1	+/-0.43
bands	5	+/-4.71
metamyelocytes	4	+/-2.22
myelocytes	5	+/-3.32
promyelocytes	1	+/-0.65
myeloblasts	2	+/-0.71
anisocytosis	2+	+/-0.59
poikilocytosis	2+	+/-0.79
hypochromia	2+	+/-0.87
macrocytosis	1+	+/-0.51
polychromasia	1+	+/-0.24
spherocytosis	1+	+/-0.67
leptocytosis	1+	+/-0.46
NRBC	1	+/-0.49
burr cells	1+	+/-0.32
tear drop cells	1+	+/-0.00
ovalocytosis	1+	+/-0.00
toxic granulation	2+	+/-0.40
platelets	adequate	adequate

Typically diagnosed by the hematology laboratory utilizing the differential, this malignancy is characterized by the presence of all stages of cellular maturation in the myeloid (bone marrow) cell lines. The presentations can range from purely granulocytic to a mixed granulocyte/monocyte to a mixed granulocyte/monocyte/erythroid/megakaryocytic dyscrasia. In this presentation, the more classic picture of granulocyte immaturity is present. Immature red cells (nucleated red blood cells or NRBC's) are seen in small numbers although the degree of red cell distortion and damage is significant and the platelet estimate is within reference limits.

Appendix A

#2641. Chronic Lymphocyte Leukemia

The differential to be achieved by the test participants :

Cells	average results of experienced practitioners	Range of results acceptable by Rajimaki method
polymorphonuclear leukocytes	21	+/-3.83
lymphocytes	68	+/-4.75
monocytes	4	+/-3.26
eosinophils	2	+/-1.44
basophils	2	+/-0.75
bands	1	+/-0.73
reactive lymphs	3	+/-2.11
anisocytosis	1+	+/-0.50
poikilocytosis	1+	+/-0.61
macrocytosis	1+	+/-0.48
microcytosis	1+	+/-0.50
polychromasia	1+	+/-0.51
leptocytosis	2+	+/-0.54
NRBC	2	+/-0.82
burr cells	1+	+/-0.43
toxic granulation	2+	+/-0.67
platelets	increased	increased

This disease is also first diagnosed by the peripheral blood differential as it usually has no overt signs or symptoms in its early stages. It is characterized by a malignant increase in a single clone of mature looking lymphocytes. In early stages, both the red blood cells and

the white blood cells will show adequate numbers but with a significant degree of abnormality in size and shape. The platelet populations can have an extremely wide range, appearing as decreased, increased, or within reference limits.

Appendix A

#3037 Megaloblastic anemia

The differential to be achieved by the test participants is:

Cells	average results of experienced practitioners	Range of results acceptable by Rajimaki method
polymorphonuclear leukocytes	67	+/-5.5
lymphocytes	25	+/-5.25
monocytes	4	+/-1.13
eosinophils	3	+/-1.45
basophils	1	+/-0.73
bands	2	+/-1.36
reactive lymphs	2+	+/-1.42
anisocytosis	1+	+/-0.62
poikilocytosis	2+	+/-0.73
macrocytosis	1+	+/-0.70
microcytosis	3+	+/-0.43
polychromasia	2+	+/-0.32
ovalocytosis	2+	+/-0.35
basophilic stippling	2+	+/-1.98
toxic granulation		
hypersegmented polys	5	+/-1.56
platelets	adequate	adequate

One of the most common side effects of oncologic chemotherapy is the establishment of a folic acid deficiency through the use of drugs that interfere with folic acid utilization by cells. The principle is to deprive the malignant cells of mitotic activity, thus

causing cell death. As a consequence, all oncologic patients taking "folate antagonist" drugs become functionally folic acid deficient. The leukocyte count is generally low with a normal distribution of cells. However, the granulocytes display a characteristic set of damages, specifically toxic granulation and hypersegmentation of the nucleus. Red cells show changes in size (macrocytic) and shape (ovalocytes) while the platelets remain either within reference range or decreased.

Appendix A

#4599 *Status* post splenectomy

The differential to be achieved by the test participants is:

Cells	**average results of experienced practitioners**	**range of results acceptable by Rajimaki method**
polymorphonuclear	86	+/-4.99
leukocytes	5	+/-1.59
lymphocytes	4	+/-1.73
monocytes	3	+/-1.08
bands	2	+/-0.81
myelocytes	2	+/-0.98
promyelocyte	2+	+/-0.79
anisocytosis	2+	+/-0.57
poikilocytosis	1+	+/-0.53
macrocytosis	1+	+/-0.20
microcytosis	3+	+/-1.19
Howell Jolly bodies	3+	+/-1.81
Nucleated RBC	1+	+/-0.32
burr cells	2+	+/-0.79
toxic granulation	4+	+/-2.06
hypersegmented polys	0	0
platelets	adequate	adequate

The spleen is responsible for the final quality of both red cells and platelets. During the red cell's first and second passage through the spleen, assorted inclusions such as Howell Jolly bodies, Pappenheimer bodies, nuclei, and RNA are removed by the splenic macrophages. During this removal process, sections of the membrane are also

lost and the cell shape changes from flat to biconcave. Thus, when the spleen is removed, all of these inclusions as well as highly distorted shapes can be seen in the peripheral blood. The spleen is also responsible for the final maturation of the platelet. During its time in the spleen, the platelet membrane fully matures and the concentration of various coagulation factors such as Factors V and VIII are accumulated. At any time, over 30% of the total platelet mass is stored in the spleen. Thus spleen removal will cause an increase in the total circulating platelet count. Just as platelets are stored in the spleen, a small number of granulocytes are also stored in the spleen so another consequence of splenectomy is a slight increase in granulocytes.

Appendix A

#5797. Leukemoid Reaction

The differential to be achieved by the test participants is:

Cells	average results of experienced practitioners	range of results acceptable by Rajimaki method
polymorphonuclear leukocytes	64	+/-5.16
lymphocytes	20	+/-4.31
monocytes	5	+/-3.10
eosinophils	4	+/-2.23
bands	3	+/-0.38
metamyelocytes	1	+/-0.98
myelocytes	2	+/-1.13
promyelocytes	1	+/-0.83
myeloblasts	1	+/-0.77
reactive lymphs	1	+/-0.79
anisocytosis	1	0.00
poikilocytosis	1	+/-0.49
platelets	adequate	adequate

In patients with several bacterial infections, there can occur an unusual granulocytic presentation, not unlike that seen in chronic myelogenous leukemia. This presentation is identified only by the differential; clinical data such as the history, physical and current status rpovide important information to discriminate be4tween these two diferentials. But there are many

situations in which the initial diagnosis of chronic myelogenous leukemia is made as a result of an initial presentation of bacterial infection. The final elements needed to verify the diagnosis include additional specialized laboratory testing. The RBC cellular elements are less striking than those seen in CML. However, the white blood cell features are impressive with the presence of multiple stages of granulocyte maturation including myeloblasts.

Appendix A

#8924 - Myelodysplasia

The differential to be achieved by the test participants:

Cells	average results of experienced practitioners	range of results acceptable by Rajimaki method
	75	+/-3.58
polymorphonuclear leukocytes	7	+/-3.85
lymphocytes	4	+/-2.44
monocytes	7	+/-2.13
bands	2	+/-1.84
metamyelocytes	3	+/-2.43
myelocytes	2	+/-1.97
promyelocytes	2	+/-0.86
anisocytosis	1	+/-0.78
poikilocytosis	1	+/-0.59
macrocytosis	1	+/-0.24
basophilic stippling	3	+/-0.57
toxic granulation	2	+/-0.69
hypersegmented polys	2+	+/-0.52
platelets	9	+/-1/28
	adequate	adequate

One of the more difficult groups of disorders to diagnose from either clinical or laboratory data are the myelodysplastic syndromes. Ranging from a mild pancytopenia to an overt leukemia, these presentations closely resemble each other. One common characteristic is

the universal decrease in all cell lines which can be appreciated through the cell counts by the estimation of cells found on the peripheral blood smear. The addition of the actual cell counts in this one situation makes the separation of the myelodysplastic syndromes much easier. However, for the purpose of this study, diagnosis or the subcategoriation of a particular condition is not required. This study requires that the paticipants correctly identify the cells which are common to all of the myelodysplastic syndromes. The presence of low numbers of immature granulocytes in the absence of an elevated white cell count, together with cellular anomalies such as toxic granulation and hypersegmented polys, are the most common clues.

Appendix A

#81903- Acute Bacterial Infection

The differential to be achieved by the test participants is:

Cells	average results of experienced practitioners	range of results acceptable by Rajimaki method
polymorphonuclear leukocytes	62	+/-11.90
lymphocytes	16	+/-9.61
monocytes	5	+/-3.33
eosinophils	1	+/-0.97
bands	9	+/-6.50
metamyelocytes	2	+/-1.41
myelocytes	2	+/-1.70
promyelocytes	2	+/-1.45
anisocytosis	2+	+/-1.13
poikilocytosis	2+	+/-1.22
macrocytosis	1+	+/-0.82
microcytosis	1+	+/-0.33
polychromasia	1+	+/-0.20
schistocytes	1+	+/-.117
toxic granulation	4+	+/- 1.33
platelets	slt. decreased	adequate to decr.
Döhle bodies	1+	+/-0.26
degranulation	1+	+/-0.21
Pelger Huët Cells	1+	+/-0.28
nuclear twining	1+	+/-0.41

One of the most important differentials to perform requires the identification of the signs of an acute bacterial infection. The stress of combating the infection

forces a shorter transit time during the cells' maturation, causing immature cells to be forced into the peripheral blood and immaturity seen in the organelles of the cell itself. These attributes of immaturity include toxic granulation, Döhle bodies, and pseudo Pelger Huët cells. In addition, because the cell's function is phagocytosis and intracellular killing of bacteria, it is common to see areas of degranulation within those cells that have emptied the contents of their granules during intercellular kill. Red cells are typically not affected by this process unless the bacteria is producing some type of specific toxin against them. Platelets are typically increased due to the presence of acute phase reactants as part of the body's national defense of itself.

Appendix A

#80506 HIV infection

The differential to be achieved by the test participants is:

Cells	average results of experienced practitioners	range of results acceptable by Rajimaki method
polymorphonuclear leukocytes	83	+/-2.69
lymphocytes	12	+/-2.62
monocytes	3	+/-1.42
eosinophils	1	+/-1.13
bands	2	+/-0.94
anisocytosis	2+	+/-0.83
poikilocytosis	1+	+/-0.93
hypochromia	1+	+/-1.00
macrocytosis	2+	+/-0.93
microcytosis	1+	+/-0.44
tear drop cells	1+	+/-0.51
ovalocytosis	2+	+/-0.35
hypersegmented polys	3	+/-1.26
platelets	decreased	decreased

This serious disorder's differential is marked by a significant decrease in the presence of lymphocytes which, due to the reporting mechanism of percentages, appears as an increase in the number of granulocytes. This may also occur if the patient is experiencing a bacterial or fungal infection which are common consequences of this disease.

Appendix A

Due to the various medications found in the currently accepted "HIV cocktail," there is a significant malabsorption in the small intestine which causes a combined iron and folate deficiency. This combined deficiency is seen in the wide range of red cell sizes and shapes. Hypersegmented polys, a hallmark of both vitamin B12 and folate deficiencies are also present. Platelet production is typically depressed.

Appendix A

#9279 Compensated hemolytic anemia.

The differential to be achieved by the test participants is:

Cells	average results of experienced practitioners	range of results acceptable by Rajimaki method
polymorphonuclear leukocytes	69	+/-4.52
lymphocytes	20	+/-4.43
monocytes	5	+/-2.70
eosinophils	2	+/-1.63
basophils	1	+/-1.13
bands	2+	+/-2.19
anisocytosis	2+	+/-0.72
poikilocytosis	2+	+/-0.56
hypochromia	1+	+/-0.95
macrocytosis	2+	+/-0.90
microcytosis	2+	+/-0.79
polychromasia	1+	+/-0.56
spherocytosis	1+	+/-0.64
burr cells	1+	+/-0.39
ovalocytosis	1+	+/- 0.53
platelets	adequate	adequate

Appendix A

Diuretics frequently produce the adverse side effect of a mild hemolytic state. This is typically compensated by increased red cell production. This often results in a variation of red cell size and shape with little to no change in white cell or platelet numbers or quality.

Appendix A

#9326 Microangiopathic anemia

The differential to be achieved by the test participants is:

Cells	average results of experienced practitioners	range of results acceptable by Rajimaki method
polymorphonuclear leukocytes	68	+/-3.47
lymphocytes	16	+/-4.11
monocytes	12	+/-4.22
eosinophils	2	+/-1.11
basophils	1	+/-0.84
bands	2	+/-0.63
anisocytosis	2+	+/-0.83
poikilocytosis	3+	+/-0.75
hypochromia	1+	+/-0.50
macrocytosis	1+	+/-0.23
microcytosis	1+	+/-0.39
polychromasia	1+	+/-0.58
leptocytosis	2+	+/-0.74
basophilic stippling	2+	+/-0.37
schistocytosis	1+	+/-0.45
toxic granulation	2+	+/-0.50
platelets	decreased	decreased

Patients who have had vascular surgery e.g., valve implantation, venografting, stent implantations, or joints) or who have damage microvasculature linings due to inoperable damage (ie.g., fibrosis, metastatic malignancy, and the like) frequently develop a hemolytic anemia due to the destruction

the red cells against the artificial or abnormal surfaces. This condition is frequently accompanied by a stress on the bone marrow which is evidenced by the presence of toxic granulation of the leukocytes and a decrease in the number of platelets as they are used up by the secondary clotting process that is occurring in the micro circulation.

Appendix B

Directions for the Differential Report Form

Thank you for volunteering to perform this survey. Please take the time to read over the directions carefully. If you have questions, please contact me before you begin. My office phone number is (508)999-8786.

You have been given 10 slides on which to perform standard differentials. Write your results on these forms. They are lengthy in order to provide you with all possible answers. If you see something that I forgot to list, please add it. It is impossible to construct a concise and usable form that will list all of the varied presentations that can be found in a peripheral blood smear. As a consequence, I am asking that you include what you see and not be biased by any omissions from the file you might notice.

Perform these differentials as if they were part of your routine workload. When you are finished, bring the forms to your faculty member. When all of the sets are completed, they will be mailed to me.

Please do not ask for any help or discuss your findings until all of your colleagues have completed their differentials. Since this survey will determine consistency of results, its validity depends upon your complete independence.

You will notice that I have included various synonyms for certain white blood cells (polys and bands *vs.* segmented and nonsegmented forms as well as atypical *vs.* reactive

lymphocytes). Please use the terms with which you are most familiar.

Specific Differential Directions

1. The differential should total 100 white blood cells plus any nucleated red cells. Cells not seen need not be given a "0".

2. If a characteristic of a cell line is seen (ex., polychromasia) or a specific cell type (ex., hypersegmented poly), report it as you would in your facility.

Appendix B

DIFFERENTIAL REPORT FORM

School Identification number: _____

Peripheral blood smear number _____

____ (1) polys	____ (11) toxic granulation
____ (2) bands	____ (12) degranulation
____ (3) segmented neut.	____ (12) abn. granulation
____ (4) non-seg. forms	____ (13) vacuoles
____ (5) metamyelocytes	____ (14) Pelger Huët polys
____ (6) myelocytes	____ (15) hyperseg. polys
____ (7) promyelocytes	____ (16) abn. nuc. appen.
____ (8) myeloblasts	____ (17) Auer rods
____ (9) eosinophils	____ (18) Döhle bodies
____ (10) basophils	____ (19) bact. inclusions
____ (21) lymphocyte	____ (31) monocytes
____ (22) reactive lymph	____ (32) degran. mono's
____ (23) atypical lymph	____ (33) vacuoles in mono's
____ (24) abnormal lymph	____ (34) young monocytes
____ (25) prolymphocyte	____ (35) monoblasts
____ (26) lymphoblast	____ (36) macrophage/
____ (27) vacuolated lymphs	histiocyte
____ (28) plasma cell	____ (41) white cell blast,
____ (29) Mott cell	undifferentiated

Appendix B

____ (51) orthochromic normoblasts
____ (52) promegaloblasts
____ (53) basophilic megaloblasts
____ (54) polychromatophilic megaloblasts
____ (55) orthochromic megaloblasts
____ (56) red cell blast, undifferentiated

____ (61) adequate platelets
____ (62) decreased platelets
____ (63) increased platelets
____ (64) large platelets
____ (65) gray/nongranular platelets
____ (66) megakaryocytic fragments
____ (67) megakaryoblast
____ (68) micromegakaryoblast

____ (71) other (please explain)

_____
_____
_____
_____

Please tell me a little about yourself:

age _____ Program: associate
baccalaureate
gender _____ (please circle)
ethnicity _____

Have you had any experience in a clinical laboratory prior to this degree program? YES NO
If yes, how long _____ and in what department _____

Appendix B

Appendix C

DEFINITIONS OF BLOOD CELLS THAT MAY BE VISUALIZED ON A PERIPHERAL BLOOD SMEAR

Myeloblast: They are variable in size but usually large (15–20μm). The nucleus is delicate, with prominent nucleoli. The meager cytoplasm contains rough endoplasmic reticulum, a developing Golgi apparatus, and, as it matures through its life cycle, an increasing number of azurophilic granules. The presence of this cell in a peripheral blood smear is strongly suggestive of leukemia or myelodysplasia.

Promyelocyte (Progranulocyte): After several days in the blast stage, the cell progresses to the promyelocyte stage. Its size is variable, often exceeding 20μm, which is occasionally larger than the size of its precursor cell. The nuclear chromatin pattern may be as delicate as that of a myeloblast or may show slight clumping. Nucleoli begin to fade. Granules are present throughout the larger cytoplasm and on top of the nucleus. The presence of this cell in a peripheral blood smear is strongly suggestive of leukemia, myelodysplasia, or life threatening infection or trauma.

Neutrophilic Myelocyte: This cell is usually smaller than the promyelocyte and constitutes less than 10% of the

total marrow cell population. The nucleus may be round to oval with a flattened side near the well-developed Golgi apparatus. The nuclear chromatin shows clumping, and nucleoli are usually no longer visible. The secondary granules alter the staining reaction within the cytoplasm. They cause a "dawn of neutrophilia," or faint blush of pink first seen near the Golgi apparatus within the cytoplasm. They are seen in the peripheral blood in leukemia, myelodysplasia, infections, trauma, and drug reactions and occasionally in association with fevers and severe exercise.

Neutrophilic Metamyelocyte: The traditional discriminator between myelocyte and metamyelocyte is the shape of the nucleus; that of the metamyelocyte becomes indented. In reality, the shape of the myelocyte nucleus varies from round to deeply indented. By this stage, the cytoplasm has a complete collection of primary and secondary granules

Neutrophilic Band (Nonsegmented Form): The definition and name of this intermediate form have been debated extensively. In one classification system, its discrimination is based on the presence or absence of nuclear segments made up of dense heterochromatin. The terms segmented and

"nonsegmented" are used in this definition of these cells. Another classification requires that the outer shape of the nucleus have uniform or parallel width (C or S shape) as its basis and identifies a cell whose nucleus is so described as a "band" and cells with all other nuclear forms as "polymorphonuclear neutrophils." Finally, a third classification system defines a band as a cell whose nuclear indentation is less than half the width of the nucleus and a polymorphonuclear neutrophil as a cell whose nuclear indentation is more than half the width of the nucleus. This third system reflects an appreciation of the role of change and maturity within the cell, for chromatin maturity is also used as a criterion.

Polymorphonuclear Neutrophil (Segmented Neutrophil, PMN, Gran): The cell's nucleus continues its indentation until thin strands of membrane and heterochromatin form into segments and create a lobated nucleus. This nucleus is easily deformable because of the active motility of the cell. The name polymorphonuclear means "many-shaped nucleus" and accurately describes the nuclear shapes. Most nuclei have visible segments, although some appear grossly twisted or folded. According to the traditional Arneth count, nuclei should have between two and four lobes. A lesser amount

Appendix C

indicates either immaturity or genetic anomaly; a greater amount suggests difficulty in maturation.

Eosinophil: The adult eosinophil typically contains a nucleus that is in band form or bilobed. Nuclei with higher lobe counts are seen rarely. The cell is slightly larger than the average neutrophil and may have an irregular border as a result of motility. The eosinophil is distinguished from the neutrophil by the presence of numerous, large, round granules containing a crystalloid compound made up of major basic protein (MBP). Eosinophils are increased in parasitic infections, allergic responses, drug reactions, and lead poisoning.

Basophils: Similar in size and shape to eosinophils, basophils are characterized by the presence of large, heavily staining granules. These granules differ from those of the eosinophil in that they are irregularly shaped, unevenly distributed throughout the cell, and turn a deep purple to black with Romanowsky stains.

Monocyte to Macrophage: Macrophages are large, actively phagocytic cells with a size range of between 15-85μm in diameter. Their shape is pleomorphic and, because of their

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motility, are frequently seen with pseudopods. The function of the monocyte/macrophage is phagocytosis, and the material ingested is seen in variably sized phagosomes.

Lymphocytes: The morphology of the lymphocyte, when seen with the aid of Wright's stain, varies mostly by size. The size discrepancy may be due to the activity of the cell or the location in the smear in which it is found. Cells in thick areas of the smear tend to be rounded up and to appear smaller and thicker than they actually are. The most common form is the small lymphocyte, which is approximately 9μm in diameter with skimpy cytoplasm and a few azurophilic granules. The nucleus is round to oval, and its chromatin pattern is a block type. This cell has been described as nondividing or resting.

The medium-sized lymphocyte is approximately 11–14μm in diameter. Its cytoplasm usually contains azurophilic granules that are more clearly discerned, probably as a result of the larger amount of cytoplasm in which they are found. Although these cells are larger than the small lymphocytes, their nucleus-to-cytoplasm ratios are essentially the same. Like the small lymphocytes, these cells are considered nondividing.

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The rarest of the peripheral blood lymphocytes is the large lymphocyte. It is approximately 15μm or more in diameter, and the more generous cytoplasm usually turns a deeper shade of blue when stained. The usual block-type DNA is spread a little more loosely.

Reactive Lymphocyte: These cells are highly pleomorphic. In comparison with the nucleus of a common lymphocyte, the nucleus of the reactive lymphocyte is less clumped; faintly stained multiple nucleoli are more likely to be seen. Chromatin patterns are generally less striking in the reactive lymphocyte; some patterns appear quite similar to those of a blast. The shape of the common lymphocyte nucleus is round to oval; that of the reactive cell nucleus ranges from elliptic to cleft to folded. The cytoplasm has greater variability in morphology than does the nucleus. The cytoplasm may range from large, deeply basophilic, and abundant to unevenly stained and granular. A Golgi apparatus is commonly seen. A variant of reactive lymphocyte is the plasmacytoid lymphocyte whose appearance is somewhere in between those of the lymphocyte and plasma cell.

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Pelger-Huët anomaly: Clinically insignificant because there is no loss of cellular function, and inherited through autosomal dominance, the keys to identification are (1) nuclei that are round, oval, or bilobed with a characteristic pinched or pince-nez appearance; (2) clumping of the chromatin is overly mature for the overall shape of the nucleus; and (3) most cells look alike. The rare homozygote has rounded nuclei. Pseudo Pelger-Huët cells are acquired phenomena that may be clinically significant. These cells have nuclei that are less dense than those of normal cells or true Pelger-Huët cells, and they may have hypogranular cytoplasm. Pseudo Pelger-Huët cells are found in high stress situations (such as burns, drug reactions, and infections), myelodysplastic syndromes, chronic granulocytic leukemia, and acute leukemia.

Hypersegmentation: Having more than 5 lobes in the nucleus is classified as hypersegmentation and is seen in the megaloblastic anemias (vitamin B12 or folate deficiency or point mutations affecting DNA replication) and from acquired hypersegmentation (also known as twinning deformity). Hereditary hypersegmentation of granulocyte nuclei, inherited through autosomal dominance, is clinically insignificant.

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Twinning: A term that describes a nucleus exhibiting axial symmetry or presenting a sense of mirror imagery in the construction of the nucleus. Twinning is an acquired anomaly and is clinically significant in stress situations, malignancies, and treatment with some oncologic regimens

Drumsticks: These are small extrusions of nuclear material may be found in persons with trisomy of group E chromosomes, with extra 'X' chromosomes, or with other aneuploidy states.

Alder-Reilly anomaly: This presentation may be transmitted as a possible recessive disorder in which decreased mucopolysaccharide degradation results in deposition of mucopolysaccharides (lipids) in the cytoplasm of most, if not all, cells. When stained, these deposits called Alder Reilly bodies, appear as metachromatic (deep purple to lilac) granules and may be difficult to distinguish from toxic granulation. they condition is life threatening with death occurring form infections.

Chédiak-Higashi syndrome: this is a rare autosomal recessive state in which abnormally large peroxidase-positive lysosomes in all cells of the body, especially those of the

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peripheral blood. This condition is lethal by the age of 10 years.

May-Hegglin anomaly: This is a rare autosomal dominant condition in which patients are at risk for infections and bleeding. This anomaly is characterized by the presence of large, Döhle body - like formations in all cells, thrombocytopenia, and giant platelets with abnormal platelet function and lifespan. Döhle bodies develop in the cytoplasm of granulocytes of patients with infections or in stress states, are round to oval, are approximately 1-5μm in diameter, and are composed of parallel rows of ribosomal RNA. Patients with May Hegglin do not live past their teenage years.

Toxic Granulation: This acquired demonstration of abnormally large or dominant primary granules is called toxic granulation and is a stress response to infection, inflammation or treatment with stimulants and must be differentiated from Chédiak Higashi and May Hegglin anomalies.

Phagocytic vacuoles: These unstained areas in the cytoplasm may be found in neutrophils as a result of various

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situations. Autophagocytosis (phagocytosis of self) is usually seen with prolonged exposure to drugs such as antimicrobial agents and to toxins such as alcohol and radiation. Vacuoles caused by the ingestion and degradation of bacteria or fungi are larger than those seen in autophagocytosis, are not as evenly distributed, and are considered clinically significant, especially when associated with toxic granulation, degranulation, and/or Döhle bodies.

Auer Rods: A fused collection of primary granules in the myeloid cells that is pathognomic acute leukemia.

Platelets: As platelets enter the peripheral blood circulation, their average diameter is 2.5 microns. Unstimulated platelets are lentiform discs with smooth margins. The platelet structure can be divided into the peripheral, sol-gel, organelle and membrane zones. Increases and decreases in platelet numbers can be associated with bleeding or clotting. Qualitative alterations in the platelet themselves also mirror changes in function. Immature and abnormal forms include large, gray, nongranular platelets. Megakaryocytic fragments, megakaryoblasts and micro megakaryoblasts are seen in leukemias and myelodysplasia.

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Plasma Cell: The fully committed B lymphocyte is found in rare numbers in the normal peripheral blood. Increases occur in myeloma and responses to vaccinations.

Mott Cell: A variant of the plasma cell can be seen in myeloma or severe immunology responses.

Pronormoblast: The earliest recognizable red cell is 20 - 25μm in diameter with a rounded to oval nucleus that occupies 80% of cell. The nucleus has fine chromatin and one or more well defined nucleoli while the cytoplasm is intensely blue

Basophilic normoblast: The next cell is 6 - 18μm in diameter with a - nucleus that occupies 75% of cell. There is some nuclear heterochromatin; a Golgi apparatus is visible. In the cytoplasm, there is a possibility of some hemoglobin production visible

Polychromatophilic normoblast: This cell is 12 - 15μm. The nucleus occupies less than 50% of cell and its heterochromatin is well defined. A nucleolus is no longer visible. There is significant hemoglobin production completed.

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Orthochromic normoblast: Also known as the nucleated red blood cell is 10 - 15μm, this is the smallest cell in the red cell series. Its nucleus is pyknotic and the cytoplasm has approximately 80% of hemoglobin completed.

Anisocytosis: A change in the size of the red cell, this is important in the diagnosis of all of the anemias.

Poikilocytosis: This terms means change in shape of the red cells. There are over 2 dozen different shape possibilities from sickle (diagnostic of sickling hemoglobins to spherocytes (diagnostic of hemolytic anemia.)

Howell Jolly bodies: Remnants of the red cell nucleus, they are found in the blood stream after splenectomy, during severe stress and malaria.

Cabot Rings: Rarely seen, these pieces of RNA structure are found in megaloblastic anemias.

Pappenheimer Bodies: These are pieces of unincorporated iron in the cytoplasm of the cell. No red cell is supposed to have unincorporated iron so any Pappenheimer bodies are signals of disturbed hemoglobin synthesis.

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Malaria: This disease is the number one parasitic disease in the world. There are four different species, each with their own life cycle and treatment. Diagnosis is first made in the hematology laboratory during the differential and then speciated by microbiologists.

All definitions taken from Rodak, B (ed.) (1997) Diagnostic Hematology. Philadelphia, PA: W.B. Saunders.

Appendix C

Susan J. Leclair
134 Hathaway Road
Dartmouth, Massachusetts 02747-2715

Education:

Walden University Minneapolis, Minnesota Doctoral Studies in Health	1994 - present
University of Massachusetts Dartmouth North Dartmouth, Massachusetts M. S. in Medical Laboratory Science	1977
St. Vincent Hospital School of Medical Technology Worcester, Massachusetts Certificate in Medical Technology	1968
Stonehill College North Easton, Massachusetts B.S. in Medical Technology	1968

Certification: & Licenses

CLS (NCA) National Certification Agency for Medical Laboratory Personnel	1978 - present
CLS - license from the state of Rhode Island #RI CLS101	1994 - present

Present Employment:

University of Massachusetts Dartmouth Department of Medical Laboratory Science	1980 - present
Professor of Medical Laboratory Science	1992 - present
Associate Professor of Medical Laboratory Science	1984 - 1992
Assistant Professor of Medical Laboratory Science	1980 - 1984

Employment History:

Hematology Technologist Rhode Island Hospital Providence, Rhode Island	1979 - 1980
Guest Instructor, Hematology IMS courses Brown University Program in Medicine Providence, Rhode Island	1978 - 1980
Faculty Member, Division of Continuing Studies Southeastern Massachusetts University North Dartmouth, Massachusetts	1978 - 1987
MLS 525 - Pathophysiology I for High School Science Teachers	1987
MLS 525 - Pathophysiology I for High School Science Teachers	1986
MLS 524 - Health Care Legislation: Health Planning	1983

MLS 601 - Bone Marrow Interpretation	1982
MT 411 - Senior Seminar	1979
MT 429 - Clinical Hematology	1978

Education Coordinator/Program Director
1972 - 1979
School of Medical Technology
The Miriam Hospital Providence, Rhode Island

Hematology Supervisor Morton Hospital Taunton, Massachusetts	1970 - 1972
Medical Technologist Union Hospital of New Bedford, Massachusetts	1968 - 1970

Professional Organizations:

American Society for Clinical Laboratory Science (ASCLS)
(formerly American Society for Medical Technology - ASMT)

Member	1968 - present
Editor-in-Chief, CLS	2001 - present
Creator and Director, Response Team, ASCLS Consumer Laboratory Testing Information Web Page	1999 - present
Program Chair, ASCLS Advanced Hematology/Hemostasis Symposium, Providence, RI	1999
Chair, Position Paper on Ethical Responsibility	1997 - 1998
Editor, Clinical Practice Section of CLS, ASCLS's journal	1996 - present
Member, Web Page Task Force	1996 - present
Editor, Hematology In Practice Section of CLS, ASCLS's journal	1994 - 1996
Member, Task Force on Electronic Communication	1994 - 1995
Vice - Chair, ASCLS Scientific Assembly	1993 - 1995
Chair, Name Change Task Force	1992 - 1993
Member, Editorial Board for CLS, ASMT's journal	1992 - 1994
Member, Review Board for CLS	1990 - 1992
Moderator, Workshop on the Immunological Evaluation for Leukemias and Lymphomas - ASMT Annual Meeting	1990
Editor, Hematology/Hemostasis Section Newsletter	1988 - 1995
Participant in ASMT Consensus Project for Hematology/Hemostasis Section (to identify minimum levels of practice acceptable for each Hematology/Hemostasis test)	1988 - 1990
Chair, Hematology Section Awards Committee	1983 - 1987
Member, Competence Assurance Council Adv. Committee	1983 - 1987
Editor, Focus on Learning Series - Hematology *Acute Leukemias* - Journal of Medical Technology	1986 - 1987
Chair, Region I Annual Seminar Workshop Committee	1983
Member, ASMT Elections Committee	1979 - 1981

Member, ASMT Reference Committee #3	1978
Region I Representative to the Hematology Section of the Scientific Assembly	1976 - 1978
Chair, Registration Committee for the ASMT Region I Annual Seminar	1976
Assistant to the Coordinator of the Scientific Assembly	1976
Member, Subcommittee to Review Professional Competence Statements	1976
Member, ASMT Reference Committee #2	1975
Member, Committee on the Guidelines for the Scientific Assembly	1975
Chair, ASMT Hematology Section Awards Committee	1973 -1977
Assistant to the ASMT Region I Director	1973 - 1976
Delegate from the MAMT to the ASMT Annual House of Delegates	1972 - present
District Chair, CDC Census	1971

National Certification Agency for Medical Laboratory Personnel — **NCA**

Chair, Job Analysis Task Force for Hematology/Hemostasis	1998 - 1999
Member, Exam Council	1995 - 1998
Chair, Hematology/Hemostasis Committee	1995 - 1998
Chair, Subcommittee for Hematology/Hemostasis Special Level Examination Committee	1986 - 1988
Item writer for Hematology	1977 - present
Reviewer for Hematology	1977 - present

American Society for Medical Technology Education and Research Fund, Inc. — **E&R Fund**

Elected member, Board of Trustees	1977 - 1982
Appointed member, Board of Trustees	1982 - 1987
Chair, Policy and Procedure Manual	1984 - 1986
Past Chairperson	1985 - 1986
Chairperson	1983 - 1985
Member, Robin H. Mendelson Memorial Award Committee	1983 - 1985
Chairperson-elect	1982 - 1983
Secretary	1978 - 1982
Chairperson, Scholarship Committee	1978 - 1981
Member, Scholarship Committee	1977 - 1978
Chairperson, Robin H. Mendelson Memorial Award Committee.	1977 - 1983

Alpha Mu Tau Honor Fraternity

elected member	1986 - present
Chair, Nominations Committee	1996 - 1997
Past President	1994 - 1995
President	1993 - 1994
President - elect	1992
Member, Board of Directors	1990 - 1992
Member, Nominations and Elections Committee	1988 – 1989

Clinical Laboratory Science Society of Central New England CLS/CNE
(formerly Massachusetts Association for Medical Technology - MAMT)

Member	1968 - present
Advisor, Student Chapter (formerly MSAMT)	1985 - 1999
Chair, Long Range Planning Committee	1992 - 1995
Chair, Public Relations Committee	1992 - 1994
Resource Editor, *The Paul Revere*	1992 - 1994
Member, Image Task Force	1990 - 1992
Chair, Awards Committee	1982 - 1988
Health Planning Liaison	1981 - 1988
Chair, Program Committee for the Annual Meeting	1979 - 1980
Coordinator of the MAMT Scientific Assembly	1978 - 1979
Chair, Education Committee	1978 - 1979
Chair, Planning and Scope Committee	1977 - 1978
Past President	1978 - 1979
President	1977 - 1978
President-elect	1976 - 1977
Chair, Nominations Committee	1976 - 1977
Founding Editor and Publisher, *The Paul Revere*	1974 - 1976
Member, Board of Directors	1974 - 1976
Secretary	1973 - 1974
Member, Constitution and Bylaws Committee	1972 - 1973
Chair, Registration Committee for Annual Meeting	1972
Chair, Credentials Committee	1972
Co-Chair, Recruitment & Guidance Committee	1971 - 1972
Member, Registration Committee/Annual Meeting	1968 - 1970

Bay Chapter : Clinical Laboratory Science Society of Central New England
Bay Chapter: CLS/CNE
(Southeastern New England Society for Medical Technology - SNESMT)

Charter Member	1970 - present
President	1975 - 1976
President-elect	1974 - 1975
Secretary	1973 - 1974
Chair, Continuing Education Committee	1970 - 1973
Editor, **SMS LabNewsLine**	1988 - 1991

National Commission for Clinical Laboratory Sciences **NCCLS**

Reviewer for Standards and Regulations (Hematology and Hemostasis) for the Erythrocytes Sedimentation Rate andQuantitative Hemoglobin Determinations	2000
Reviewer for Standards and Regulations (Hematology/Hemostasis) for Physician Office Laboratories and Decentralized Testing Sites	1986 - 1989

Publications:

Leclair SJ: *Leukopoiesis* - in **Diagnostic Hematology,** 2nd Ed. Rodak B, WB Saunders, Philadelphia, PA,in press.

Leclair SJ: *Benign Disorders in Leukocytes* - in **Diagnostic Hematology,** 2nd Ed. Rodak B, WB Saunders, Philadelphia, PA, in press.

Leclair SJ: *Introduction to Leukemias* in **Diagnostic Hematology,** 2nd Ed. Rodak B, WB Saunders, Philadelphia, PA, in press

Leclair SJ: *Acute Leukemias* in **Diagnostic Hematology,** 2nd Ed. Rodak B,WB Saunders, Philadelphia, PA,in press

Leclair SJ: *Chronic Leukemias* in **Diagnostic Hematology,** 2nd Ed. Rodak B, WB Saunders, Philadelphia, PA,in press

Leclair SJ: *Megakaryopoiesis* in **Diagnostic Hematology,** 2nd Ed. Rodak B, WB Saunders, Philadelphia, PA,in press

Leclair, S. J. *Acute Myelogenous Leukemia.* in **Textbook of Hematology,** 2nd Ed. McKenzie S. Prentice Hall, Upper Saddle River, NJ, in press.

Leclair, S. J. *Acute Lymphocytic Leukemia.* in **Textbook of Hematology**, 2nd Ed. McKenzie S. Prentice Hall, Upper Saddle River, NJ, in press.

Rodak B and Leclair SJ: *Hematology and Hemostasis* - in The NCA Review Book for Clinical Laboratory Science Ed. Beck S. Lippincott-Raven (formerly Little-Brown and Company), Boston, MA, 1996.

Leclair SJ: *Hematologic Changes: Part of Breast Cancer Disease Therapy.* **Advance.** 7:22 (Nov. 6, 1995) King of Prussia, PA, 1995

Leclair SJ: *Leukopoiesis* - in **Diagnostic Hematology** Ed. Rodak B. W.B.Saunders, Philadelphia, PA,1995.

Leclair SJ: *Benign Disorders in Leukocytes* - in **Diagnostic Hematology** Ed. Rodak B. W.B. Saunders, Philadelphia, PA, 1995.

Southern D, Leclair SJ: *Platelet Maturation and Function* in **Diagnostic Hematology** Ed. Rodak B.W.B. Saunders, Philadelphia, PA, 1995

Leclair SJ: *The Hematologic Effects of Oncologic Agents used in the Treatment of Beast Cancer.* **Tech Sample**. ASCP. Chicago, IL , 1995.

Leclair, SJ: *Case Studies Reveal Laboratory Characteristics of ALL.* **Advance**. 6:17 (May 2,1994) King of Prussia, PA. 1994.

Leclair, SJ:*The Hematologic Effects of Oncologic Drugs*: part I and II (audio tape, paper) **Educational Reviews, Inc.** Birmingham, AL , 1992.

Leclair SJ: *Acquired Non-Immune Anemias of Increased Destruction* - in **Clinical Hematology: Principles, Procedures, Correlations** Ed. Steine-Martin A & Lotspeich-Steininger C, J. B. Lippincott, Philadelphia,PA , 1991.

Leclair, SJ: *Iron Metabolism and Hypochromic Anemias* - in **Clinical Hematology and Fundamentals of Hemostasis, 2nd Ed.** Ed. Pittiglio D, F.A. Davis, Philadelphia, PA, 1991.

Leclair SJ: Hematology Course Ware Using Mentor™ and Videodisc Technology. **EduDisc** Nashville, TN, 1988.

Leclair SJ: *Chemotherapy of Acute Leukemia in Adults.* **AJMT**, 1987.

Auerbach W and Leclair SJ: *Case Report of Polycythemia in Twins.* **AJMT**, 1982.

Leclair SJ: *Case Study in Hematology: a Hemolytic Crisis.* **AJMT**, 1976.

INTERNET

Activities

Clinical Laboratory Testing Consultant for international bulletin boards for hematology oncology patients (Hematologic Malignancies Discussion <HEM-ONC@LISTSERV.ACOR.ORG>, Chronic Lymphocytic Leukemia Discussion<CLL@LISTSERV.ACOR. ORG> Myeloproliferative Disease Discussion <MPDNET@LISTSERV.ACOR.ORG>, Coagulopathies Discussion<COAG@LISTSERV.ACOR.ORG> , andMultiple Myeloma Discussion<Myeloma@LISTSERV.ACOR.ORG>. — 1996 - present

Special Appointments

Host, European Union/Shuman Foundation/ UMass Dartmouth Ceremony to award the Medallions of Two Worlds for distinguished Service in the fields of Cultural and Humanitarian Activities (Recipients were The United Nations High Commission on Refugee, The Children's Hospital of Brescia, Italy, Dr. Allan Robinson of Harvard University, and Hon. Enrico Vinci of the European Union — 2000

Leader and Developer, Dwight D. Eisenhower People to People Ambassador Program to the People's Republic of China — 1997

Papers/Workshops Presented:

Writing for Publication
Clinical Laboratory Educators' Conference, Salt Lake City, Utah — 2000

When A Patient Asks ...
American Society for Clinical Laboratory Science Annual Meeting, San Francisco, CA.

Career Options of the Future: Counseling In and Out of the Hospital
Georgia State Society for Clinical Laboratory Science Annual Meeting

Review of Red Cell Moprhology for the Georgia State Society for Clinical Laboratory Science Annual Meeting

Tech Refresher: Hematology in the 1990's — 1999
Region IX Northwest Symposium, Portland, OR

Laboratory Testing Counselor
Region IX Northwest Symposium, Portland, OR

The Clinical Laboratory in the People's Republic of China
Region IX Northwest Symposium, Portland, OR

Laboratory Testing Counselor
ASCLS Advanced Hematology/Hemostasis Seminar
Providence, RI

The Role of the Laboratory in the Diagnosis and Treatment of Waldenström's Macroglobulinemia

the second annual meeting of the International Waldenström's Support Group, San Francisco, CA.
Getting Students Published
ASCLS Clinical Laboratory Educators' Conference
The Laboratory and Human Relations, Part II
ASCLS Annual Meeting,
Bioethics: What is it and why to do we need it
MSCLS/CLMA/AMT Annual Seminar

Update on the Treatment of Acute Progranulocytic Leukemia 1997
New York Society for Clinical Laboratory Science Seminar
Update on the Treatment of Acute Progranulocytic Leukemia
Vermont Society for Clinical Laboratory Science Annual Seminar
Update on Treating Acute Myelogenous -3 Leukemia
Bay Chapter/BRISMeT/RIBBs Seminar
ASCLS Editors' Forum: Writing Abstracts for Presentations and Publications
ASCLS Clinical Laboratory Educators Conference, Washington, DC
National Certification Agency for Medical Laboratory Personnel Update
ASCLS Clinical Laboratory Educators Conference

Breast Cancer: Controversies and Causes
ASCLS Region I Annual Seminar 1996
Update on the Treatment of Acute Progranulocytic Leukemia
ASCLS Region I Annual Seminar
Innovative Teaching Strategies in Hematology and Hemostasis
ASCLS Annual Meeting
What Students Need to Know about Computers
ASCLS Annual Meeting

Breast Cancer and Hematology Changes with Morphology Due to 1995
Disease and Treatment
ASCLS Region I Annual Seminar
Breast Cancer and Hematology Changes with Morphology Due to Disease and Treatment
University of Wisconsin - Madison Continuing Medical Education Teleconference Series

Hematologic Effects of Breast Cancer Therapy 1994
(P.A.C.E. approved 1 CEU's) ASMT Annual Meeting
Review of the Hematologic Effects of Oncologic Agents
(P.A.C.E. approved 6 CEU's) Joint Meeting of the Association for Oregon Medical Technology and the Oregon State Society of American Medical Technologists
What Tests to Order Next? - A review of Red Cells (P.A.C.E. approved 3 CEU's)
Joint Meeting of the Association for Oregon Medical Technology and the Oregon State Society of American Medical Technologists

How Can Changes in White Blood Cells be Both Good and Bad? - 1993
A review of Conditions that affect White Blood Cells
(P.A.C.E. approved 3 CEU's)

Joint Meeting of the Association for Oregon Medical Technology and the Oregon State Society of American Medical Technologists
The Impact of Health Care Delivery System Reform on clinical laboratory science
20th Anniversary Celebration of the University of Connecticut School of Allied Health Professions
Panelist: Surviving Hard Times: Saving MT Programs
ASMT Region I Annual Seminar, Cromwell, Connecticut

Classification of Lymphocytes and Monocytes 1992
Rhode Island Blood Center, Providence, RI
Careers in Clinical Laboratory Science: Graduate School Options
MAMT Annual Meeting

Update on the Myelodysplasias (P.A.C.E. approved 3 CEU's) 1991
Southeastern New England Society for Medical Technology

Hematologic Effects of Oncologic Agents (P.A.C.E. approved 3 CEU's) 1990
Empire State Association for Medical Technology Annual Meeting

Case Studies in Hematology (P.A.C.E. approved 1 CEU's) 1989
MAMT Annual Meeting
The Role of Macrophages
Rhode Island Blood Bank Society
Review of the Thalassemias
Rhode Island Blood Center

How to Computerize a Medical Technology Curriculum 1988
1 day P.A.C.E. approved workshop - 6 CEU's
ASMT Annual Meeting
Case Studies in Hematology (P.A.C.E. approved 1 CEU's)
MAMT Annual Meeting

How to Teach Hematology/Hemostasis (P.A.C.E. approved 3 CEU's) 1987
ASMT Annual Meeting
Computer Assisted Instruction in Hematology Using a Macintosh™
(P.A.C.E. approved 3 CEU's)
ASMT Annual Meeting

Computer Assisted Instruction Higher Education Computing Conference
Massachusetts Board of Regents
Bridgewater State College

Effects of Oncological Drugs on the Patient 1986
(P.A.C.E approved 3 CEU's)
ASMT Annual Meeting
Hematologic Effects of Oncological Drugs
(P.A.C.E approved 3 CEU's)
Maine/ASMT, Maine/New Hampshire AMT/Maine CLMA Annual Meeting

Art of Phlebotomy
(P.A.C.E. approved 3 CEU's)
MAMT Annual Meeting
Test Construction (P.A.C.E. approved 3 CEU's)
MAMT Annual Meeting

Evolution of a Four Year Curriculum(P.A.C.E. approved 1 CEU's) 1985
ASMT Annual Meeting
Stem Cell Dynamics in the Erythrocyte (P.A.C.E. approved 3 CEU's)
ASMT Region I Seminar

Phlebotomy Workshop (P.A.C.E. approved 3 CEU's) 1984
ASMT Region I Seminar
Moderator, Fisher Lectureship Series
ASMT Annual Meeting
Certification Examination Formats (P.A.C.E. approved 1 CEU's)
MAMT Semi-Annual Meeting

Enzyme Deficiency Hemolytic Anemias 1983
(P.A.C.E. approved 1 CEU's) ASMT Region I Annual Seminar
The Art of Phlebotomy
(P.A.C.E. approved 3 CEU's) MAMT Semi-Annual Meeting
Phlebotomy: Specimen Collection and Handling and Collection
(P.A.C.E. approved 3 CEU's) MAMT Annual Meeting
Entrance into Graduate Programs
MAMT Annual Meeting

Hematology/Hemostasis Problem Solving Session -Moderator 1982
ASMT Region I Seminar
Help for the First Time Author/Researcher
MAMT Annual Meeting
The Senior Year
MAMT Annual Meeting

Career Awareness Panel 1981
MAMT Annual Meeting
Scholarship Opportunities in the 80's
MAMT Annual Meeting
Phlebotomy Workshop for Students
MAMT Annual Meeting

The Art of Phlebotomy Workshop
(P.A.C.E. approved 3 CEU's) MAMT Semi-Annual Meeting
Opportunities for the Graduate
MAMT Semi-Annual Meeting

ASMT Professional Expectations and the Clinical Year 1980
MAMT Annual Meeting
Coping with the Senior Year
MAMT Semi-Annual Meeting
Differentials - Decision Making
(P.A.C.E. approved 3 CEU's) MAMT Semi-Annual Meeting

Hematology Question Session - Panel 1979
MAMT Annual Meeting
The Necessity of Anatomy and Physiology in the College Curriculum
MAMT Annual Meeting

Correlations of Bone Marrow and Peripheral Blood Smears
(P.A.C.E. approved 6 CEU's)Ohio Society for Medical Technology Annual Meeting
Introduction to Bone Marrows Workshop
(P.A.C.E. approved 3 CEU's) MAMT Region I Seminar
Correlations on Peripheral Smear Morphology and Case Histories
(P.A.C.E. approved 3 CEU's) ASMT Region I Seminar

The Case Approach to Learning Hematology 1978
(P.A.C.E. approved 3 CEU's) MAMT Annual Meeting
A Hematology Review
Scientific Products Seminar, Pittsburgh, PA

Affiliations and You - Panel 1977
New Jersey Society for Medical Technology Annual Meeting
Introduction to Bone Marrow Morphology Workshop
P.A.C.E. approved 3 CEU's)
MAMT Annual Meeting
The Problems with Certification Systems
MAMT Semi-Annual Meeting
The Internship Problem: Update 1977
(P.A.C.E. approved 3 CEU's) MAMT Annual Meeting
Advanced Red Cell Morphology
(P.A.C.E. approved 3 CEU's) ASMT Region I Seminar
Licensure and Certification - an Updated Perspective
(P.A.C.E. approved 3 CEU's) ASMT Region I Seminar
Hematology Problem Solving Session - Moderator
ASMT Region I Seminar

What's the Diff - More Case Presentations 1976
(P.A.C.E. approved 3 CEU's)MAMT Annual Meeting
Licensure, Certification, Registration and Continued Competence:
WHO, WHAT and WHY
MAMT Annual Meeting
The Internship Problem
MAMT Annual Meeting
How to Survive a Self Study
ASMT Region I Seminar
Hematology Problem Solving Session
ASMT Region I Seminar

What's the Diff - Case Presentations 1975
(P.A.C.E. approved 3 CEU's)MAMT Annual Meeting
Basic Red Cell Morphology Workshop
(P.A.C.E. approved 3 CEU's) ASMT Annual Meeting

Differentiation of Lymphs and Monos in the Peripheral Blood
(P.A.C.E. approved 3 CEU's)
MAMT Continuing Education Series
Hereditary Anemias
Southeastern Massachusetts University Student Association for Medical Technology "Human Body Institute"
Comprehensive Review of Hematology - 2 day workshop
(P.A.C.E. approved 12 CEU's) Maine Society for Medical Technology Annual Mtg.

Lymphocyte Morphology #2 1974
Massachusetts Department of Public Health Continuing Education Series

Problem Solving in Hematology
SMSMT Continuing Education Series
Differentiation of Lymphs and Monos in the Peripheral Blood
(P.A.C.E. approved 3 CEU's)
MAMT Annual Meeting
Lymphocyte Morphology #1
Massachusetts Department of Public Health Continuing Education Series
Leukocyte Physiology Workshop
ASMT Annual Meeting
Basic Erythrocyte Morphology Workshop
ASMT Annual Meeting

Red Cell Inclusions 1973
SMSMT Continuing Education Series
Basic Erythrocyte Morphology
ASMT Annual Meeting
Leukocyte Physiology Workshop
ASMT Annual Meeting
Lymphocyte Physiology
Massachusetts Department of Public Health Continuing Education Series

Advanced Hematology 2 day Workshop 1972
MAMT Annual Meeting
Case Studies in Hematology
MAMT Annual Meeting
Problem Solving in Hematology
ASMT Region I Seminar

Honors and Awards:

Robin H. Mendelson Memorial Award for the development of the consumer information web page	2000
Sherwood Kendel Medical Award: Hematology/Hemostasis Section	
University of Massachusetts Dartmouth "Yvonne Sandstroem Memorial Award for Outstanding University Service	
ASCLS Omicron Sigma Award	1999
ASCLS Board of Directors' Award	
Biographee: Marquis' ***Who's Who*** in America	1997
Biographee: Marquis' ***Who's Who*** in Medicine and Health	
ASCLS Omicron Sigma Award	
Biographee: Marquis' ***Who's Who*** in American Education	1996
ASCLS Omicron Sigma Award	
Biographee: Marquis' ***Who's Who*** in the East	1995
ASCLS Omicron Sigma Award	
Biographee: Marquis' ***Who's Who*** in Health Service Professionals	1994
Biographee: Marquis' ***Who's Who*** in American Women	
ASCLS Omicron Sigma Award	
ASMT Omicron Sigma	1993
ASMT Board of Directors Award - recognition of a successful implementation of the society's name change	
ASMT Omicron Sigma award	1992
ASMT Board of Directors Award for outstanding service to the professional in the construction of the profession's response to federal regulatory initiatives in CLIA'88	
EduCom/Joe Wyatt Challenge Award for Educational Uses of Computers	1991
Biographee: ***Who's Who*** in Health Service Professionals	
ASMT Omicron Sigma award	
Robin H. Mendelson Memorial Award for service to the AMT Education and Research Fund, Inc.	1989
ASMT Omicron Sigma award	
MAMT nominee for ASMT Member of the Year	1988
ASMT Omicron Sigma award	
ASMT/Sherwood Medical Award: Hematology/Hemostasis Section	1987
ASMT Omicron Sigma award	

Elected Member of Alpha Mu Tau, National Honor Society of Clinical Laboratory Science	1986
Biographee: Outstanding Biographies in America	1985
ASMT Omicron Sigma	
ASMT Presidential Certificate of Appreciation	
Omicron Sigma Award	1984
ASMT Presidential Certificate of Appreciation	
ASMT Presidential Certificate of Appreciation	1983
ASMT Presidential Certificate of Appreciation	1982
ASMT Presidential Certificate of Appreciation	1981
Omicron Sigma Award	1980
ASMT Presidential Certificate of Appreciation	
MAMT Member of the Year Award	1979
MAMT nominee for ASMT Member of the Year Award	
Omicron Sigma Award	
ASMT Presidential Certificate of Appreciation	
Omicron Sigma Award	1978
MA Student Association for Medical Technology Board Award	
MAMT Board Award	
Omicron Sigma Award	1977
MSAMT Board Award	1976
Member, Lambda Tau Honor Society	1972

Community Activities

The Role of the Laboratory Values in Chemotherapy Decisions http://healthtalk.com/laboratory	2001
Understanding Your Laboratory Values http://healthtalk.com/ASCLS	
Waldenström Syndrome and the Clinical Laboratory New York City Waldenström Macroglobulinemia Support Group Seminar,New York City, NY	2000

The Role of the Laboratory in the Diagnosis and Treatment of Hepatitis C
http://healthtalk.com/hepc.htm
The Role of the laboratory in the diagnosis and Treatment of Breast Cancer
http://healthtalk.com/bcen/

Waldenström Syndrome and the Clinical Laboratory 1999
National Waldenström Macroglobulinemia Support Group
Seminar, San Francisco, CA

The Role of the Laboratory in the Diagnosis and Treatment of Chronic 1998
Lymphocyte Leukemia
http://www.healthtalk.com/cll.html

Waldenström Syndrome and the Clinical Laboratory 1997
National Waldenström Macroglobulinemia Support Group
Seminar, Washington, DC

Cancer: What do we know about it and what can we do about it?
Boston Museum of Science High School Science Series

Sex Education in the 90's - lectures for 7th and 8th grade students 1992
St. James/St. John the Baptist Parochial Grammar School

Sex Education in the 90's - What your students need to know - lecture for teachers
St. James/St. John the Baptist Parochial Grammar School

two hour AIDS Lectures for each of the 7th and 8th grades 1991
St. James/St. John the Baptist Parochial Grammar School
St. Francis Xavier Grammar School
St. Anthony of Padua Parrish Youth Group

Special Lectures on AIDS education for 2 Biology Classes and 2 Psychology Classes
1988 at Dartmouth High School

AIDS Information Lecture 1987
Biology Dept. Lecture Series
Roger Williams College, Barrington, RI

In-Service Series on AIDS Education
(different presentations for teachers, parents, junior high and high school students) for
West Bridgewater School System
East Bridgewater School System
Whitman-Hanson School System
Series on AIDS Education
2 hour cable TV presentation by the Old Colony Cable Co.
potential viewers: city of Taunton and the surrounding towns of East and West Bridgewater, Raynham, and Wrentham

Southeastern Massachusetts Health Planning and Development, Inc. (SMHPD)	HSA V
member	1970 - 1988
President - Board of Directors	1985 - 1988
Chair, Management Committee	1985 - 1988
Vice-President - Board of Directors	1984 - 1985
Chair, NMR/MRI Guidelines Task Force	1984
Member, Search & Screen Committees for Acute Care Analyst and Executive Director	1984
Secretary - Board of Directors	1983 - 1984
Reelected member, Board of Directors	1983 - 1988
Chair, Acute Care Committee	1981 - 1985
Chair, Long Term Care Committee	1980 - 1981
Vice-Chair, Acute Care Committee	1980 - 1981
Chair, Plan Development Committee	1980
Member, Management Committee	1980 - 1985
Member, Plan Development Committee	1979 - 1980
Member, Board of Directors	1980 - 1982
Chair, Acute Care Task Force	1979 - 1980
Member, Acute Care Task Force	1977 - 1979