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Point of Care Testing: Online Symposium

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At a glance ...

I. Introduction & Overview

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A New Challenge: Point-of-Care Testing

The journal *Clinical Laboratory Science* has published several articles on POCT over the past few years which illustrate the impact on our profession of this new concept in testing. A seminar on this topic was presented in November of 1995. The goal was to bring this concept out in the open and clarify important details of this new model for clinical testing which seemed to hold some mystery for us. The seminar which was held in Buffalo, NY was sponsored by the Department of Clinical Laboratory Science of SUNY at Buffalo and MRC Consulting. In the following introduction, I have provided an overview of point-of-care-testing and tried to project its impact on our profession. Several of the key speakers who participated in the seminar have contributed to this online presentation.

What Does it Mean to the Clinical Laboratory Scientist?

Point-of-Care Testing (POCT) represents a challenge to our professional maturity. Embracing this concept, which on first impression seems foreign (even suspect) to us, can be viewed as a test of our ability to make use of the Body of Knowledge which describes our profession in detail; and a variety of social and educational skills that are universal indicators of mature professional practitioners. Kurec in writing about his experiences with POCT states that "implementing POCT is complex and requires a cooperative effort at many levels of a health care system."[1] This truth is evident when we examine the tasks to be undertaken by health care personnel (in a cooperative spirit) when establishing the POCT site. The responsibilities that require cooperation between clinical scientists and other hospital personnel include assessing testing needs, planning for purchases, accessing curricula and other information from professional organizations, training the personnel who will perform testing, calculating cost benefit analyses, and obtaining the requirements of certifying and accrediting agencies. When these objectives have been met, the final challenge is to sustain the established site over time. Indeed, the successful execution of this series of tasks calls for a profound commitment and frequent interaction of mature health care professionals.

Informing The Consumer

According to some economists, clinical laboratory science does not have a prominent place in the "managed care" scene of today. Payers are interested in balancing cost efficiency and patient (member) satisfaction. The clinical laboratory is a less visible component of the health services continuum so it is easily ignored. As a result, it is an easy target for reimbursement cuts and cost savings. Because of this, the clinical laboratory scientist must inform policy makers and consumers of laboratory services about the true contribution of these services. The consumer and public policymaker must realize that test results and the information output of a clinical laboratory are indispensable to the effective practice of medicine.[2]

Fact or Fancy?

Clinical laboratory science managers and industry representatives who have researched health care trends provide evidence that POCT is here to stay. Studies of what health care will be like in the year 2000 indicate that the delivery of health care will be broadly decentralized. According to current projections the purchases of diagnostic products in US markets will increase markedly for diagnosing infectious diseases, central nervous system disease, cancer diagnosis/monitoring, and gastrointestinal illnesses, to mention the most prominent.[3] The logical place for this wellness testing to occur is the decentralized clinical laboratory.

Why Is It Popular?

The purpose of establishing the POCT site seems to be quicker delivery of information in a manner which will facilitate rapid diagnosis and treatment. Hospitals are no longer the primary diagnostic centers. Important goals today are shorter length of stay, and movement to out-patient and ambulatory settings for health care. These demands compress the time frame for performing testing, require shorter TAT, and increase the volume of stat testing. But the fact remains that POCT is a "supplement, not a replacement for the central laboratory services."[4]

Why The Many Names For It?

There are at least three terms used when discussing near patient testing and care. One term is "patient-focused care" which means bringing ancillary services to the bedside and implementing "care teams" to improve communication among different health care providers.[5] These teams may include a radiology technologist, a physical therapist, respiratory therapists, medical laboratory technicians, clinical laboratory scientists, and nurses. The cross-training of these professionals (when necessary) is an extensive task and the cost can be prohibitive. Add to this the fact that in some facilities the central laboratory can meet the turnaround time of the POCT site. As a result, some hospitals which began the team approach abandoned the testing, but found that cross-trained nurses could perform phlebotomy and specimen collection efficiently for the central laboratory.

A second term is the "multiskilled worker." This health care professional performs duties that cross the boundaries of the scopes of practice of traditional health care disciplines. Their tasks are patient-focused, and the duties, educational preparation, supervision and competency evaluation varies from setting to setting.[6] New categories of multiskilled workers are emerging with different levels of preparation. For example, the personnel could have experienced "on the job training" or have earned an associate degree or a baccalaureate degree in the health sciences. A differing degree of involvement in providing clinical laboratory services to the patient is appropriate for each level of personnel.

The ASCLS encourages the participation of coalitions of health professional organizations whose members can develop job descriptions and educational curricula to prepare multiskilled workers for their tasks. One position paper on the

subject reminds us of the central role of the clinical laboratory scientist in all aspects of testing no matter what type of site is established.[7]

The third frequently used term is "point-of-care testing" which is defined as, a laboratory procedure performed at a facility that is not part of the main clinical laboratory in a hospital, and could exist in an outreach facility.[8] This concept is easier to conceive, implement and sustain for the clinical laboratory scientist. It provides the needed aspect of control over the operation. The successful POCT programs address a specific patient-care need, that is, test results in the shortest time performed accurately and reliably. When these conditions exist, the program is successful.

Why Take On These Formidable Tasks?

It is clear that at issue in POCT is the capability of the centralized laboratory to meet the demands for timely and valuable testing information. As stated earlier, there are some patient-care situations in which the relationship between clinical utility of test information and turnaround time is of great value.[9] This can be a tangible goal if quality assurance is not sacrificed. The lure of POCT for administrators and other hospital personnel has been a shorter length of stay, and the refinement and ease of application of new instrumentation for near patient testing. Patient demand for off-site testing is also a factor. Examples of the tests and instruments found in the POCT sites are urine dipsticks, glucose meters, blood gases, portable chemistry analyzers, automated clotting times, stool guaiacs, hemoglobin / hematocrits, pregnancy tests, and streptococcus tests.[10]

How Do You Define Cost Saving?

Another frequently stated advantage of POCT is cost saving in testing. However, a cost benefit analysis (CBA) for testing of this type could be a futile exercise because it does not fit the usual formula for CBA. When using the traditional methods two technologies are compared expressing all costs and benefits in financial terms. When calculated in this way, near patient testing is more costly than other test delivery systems.

There is a logical explanation for its acceptance however. In order for this type of testing to be worthwhile the total cost associated with each patient encounter has to be examined. For example, if clinical test information is delayed (in the central laboratory) it may force prolonged treatment or longer patient length of stay. Rabbitts points out that when focusing on the "program's process improvement benefits", steps that are eliminated from the patient-care system are given equal weight as the direct costs of the system.[11] It can be concluded that extra steps *are taken out* of the patient care system when using POCT.

Starting A POCT Laboratory

When starting a POCT site the approach and steps in the implementation will be different in every instance. It has been stated that "when you have seen one POCT implementation plan you have seen one."[12] In defense of this statement, it makes sense that each approach used to establish a decentralized laboratory has to be different from every other. The organizational characteristics and health care professionals employed in each institution varies, so the process is never the same. However, there are some universal recommended essentials that must be accomplished.

We must assume that there has been an institutional request for near patient testing. Additionally, the rationale including cost and turnaround time have been discussed by a POCT committee or task force. The committee ideally consists of laboratory personnel, nursing personnel, hospital administrators, and medical staff. It is important for the clinical laboratory staff to make a commitment to provide training, technical assistance, and supervisory capacity, due to the variety of health care personnel now performing ancillary testing.[13] A final important requirement is that all planning committee members have a commitment to see this program through and continuously sustained.

The Leader of the Operation

An important requirement in establishing this new type of testing site is that early in planning the responsibility and control of testing is with the clinical laboratory. To ensure this a new job description must be written for a POCT coordinator that includes review and oversight of all aspects of the decentralized laboratory. An important additional task for this leader is that of "in house" consultant. The coordinator works from guidelines obtained from accrediting and clinical standards agencies such as the CAP, JCAHO, and NCCLS so that compliance can be monitored as the project progresses.[14]

Preparation of the Off-Site Practitioner

According to a study conducted by the Committee on Undergraduate Education of the ASCLS, the education of personnel who perform testing in decentralized locations is equivalent to the Clinical Laboratory Assistant or Level I Practitioner. In patient-focused care the multiskilled worker may be the health care professional doing clinical testing and other near-patient tasks. This type of health care practitioner has variable education and training, and may be required to develop Level I Practitioner skills when performing clinical testing. A curriculum for this level of practice drafted by the ASCLS committee members includes a "task list" for tests to be performed in hematology, chemistry, urinalysis, immunology, and microbiology. Body of Knowledge references are provided for each test procedure in these disciplines. Behavioral objectives for all of the tests are also provided.[15] It is logical to conclude that programs must be established, or in some cases expanded, in colleges and universities to respond to this need.

In a position paper on POCT, the ASCLS states that "this new arena of laboratory testing expands our scope of practice and leads to an important new consultative role for clinical laboratory scientists."[16] I would like to add that the challenge to succeed in the task of establishing POCT sites must be met so that in the 21st century clinical laboratory science exists for the professionals who practice it.

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II. Guidelines for Implementing and Monitoring POCT: The Laboratorian's Role

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Point of Care Testing Defined

CLIA '88 defined laboratory testing as analytical testing on specimens withdrawn from patients, such as blood, urine, stool, ascites fluid, sputum, vaginal secretions, biopsy samples, etc.. The law also classified tests by their complexity level. Point of Care testing is any laboratory testing, at any complexity level, performed and results documented within the hospital at sites that are physically located outside the central laboratory and not performed by laboratory personnel.

Clinical laboratories have witnessed and initiated many changes in clinical testing as a result of technological advances. One important change witnessed in recent years has been the evolution of point of care testing - from satellite laboratories to bedside testing. Point of care technology is changing the future of laboratory operations, providing an opportunity to restructure responsibilities and improve the way in which clinical customers are serviced. At the same time, laboratorians usually were left out of the laboratory testing performed on the nursing units and clinics within their own institutions. Initiating a point of care program requires some careful interdepartmental planning to ensure that laboratory standards of excellence relative to quality, regulatory compliance, billing, medical record documentation and safety are achieved.

To initiate a management program that provides consulting or resource services from the laboratory not only requires a cooperative program, but also requires administrative support. CLIA regulations have created a window of opportunity for the laboratory administration to offer the same services to their own institution that many laboratorians have offered through the creation of consulting services for physician office laboratories. The hospital laboratory is an irreplaceable part of the health care institution with resources that are often needed outside the physical walls of the laboratory. Laboratory testing is bursting the constraints of the physical laboratory and is creating an exciting challenge for the laboratorian to outreach their services and knowledge. The laboratorian assigned as the Point of Care Coordinator is actually an "In-House" Technical Consultant.

The Road to Quality Testing Outside the Laboratory

The Point of Care Policy Committee

There are many ways this committee can be formed. In order to have authority and regard from the rest of the institution it needs full support from senior administration. The chair should be held by a laboratory pathologist. This position and membership can be held for a specific term or be permanent. The members of the committee should be representatives from the areas affected by point of care testing. Some suggestions are as follows:

Laboratory Administration
Pathology
Point of Care Coordinator
Medical nursing
Surgical nursing
Ambulatory nursing
Purchasing and/or Distribution
Hospital Information Services
Risk Management
Medical Staff
Diabetes Education and Training

Other personnel could be involved in an ad hoc basis as subjects are brought up concerning their area of care, i.e. specific testing in a Neonatal Intensive Care Unit. Smaller task force groups may be formed to deal with specific issues such as the variety of urinalysis strips and tablets used throughout the institution.

- We ***are*** accountable via regulatory agencies.
- ***We*** have the expertise
- ***We enhance our position*** within the institution providing this as customer service
- We should ***embrace and manage*** the POCT concept

The purpose of the committee is:

1. To ensure compliance with the requirements of the regulatory agencies; Clinical Laboratory Improvement Act of 1988, FDA, etc., and the accreditation agencies; JCAHO, CAP, etc. in regard to point of care testing.

2. To serve as an advisory resource on point of care issues such as test and instrument choices, documentation, cost vs .benefit analysis, affect on length of stay, test implementation and QC and QA issues. All of these issues need to be considered weather the laboratory testing is performed under the CLIA license held by the main laboratory or under a separate license.

3. To **assist** in the evaluation of new technology, instrumentation and supplies and make recommendations as appropriate.

4. To determine the policies governing point of care testing within the institution.

The Point of Care Policy Committee can assume the responsibility for ensuring the review and approval of all new requests to add instruments and/or testing outside the main clinical laboratories. The committee can also provide advice, assist in development of correspondence to ensure regulatory compliance and development of protocols to meet accrediting agency regulations. The committee can serve to advise senior management, as appropriate, of changes in regulations that effect hospital point of care testing.

With the authority and support of the laboratory and Point of Care Policy Committee, the person can be chosen from the laboratory staff to be the coordinator of the program. It is also very useful to have a nursing liaison for fostering a cooperative environment.

The Discovery Tour

To begin a quality management program of the testing performed at bedside one first must determine what is currently being performed within the institution. Contact should be made with each nursing unit and clinic to assess the testing being performed. A survey form could be utilized for a large institution, but nothing can supplant the personal contact with the area supervisor and visual observation of the circumstances of the testing in each area. The implementation of new testing, such as glucose meters or other point of care analyzers, creates the perfect opportunity to bring other testing up to the same compliance required for new testing. Since some of this testing has been utilized on nursing units for many years, the addition of a quality assurance plan can be met with some skepticism or resistance if not handled with tact and support from the laboratory.

One example of this testing is macroscopic urinalysis with various dipsticks. A review of the products in use through the stockroom can give an idea of what to look for. Checking products in use for outdates is suggested. The formation of an ad hoc committee through the authority of the Point of Care Policy Committee should propose the policy for determination of the areas where this testing is appropriate and should be continued and a limitation of the dipsticks or tablets that should be in use. Many patient care areas use hydrometers or refractometers and these could be replaced with a dipstick that includes a specific gravity. The point of care coordinator then assumes review and management of the testing.

Another test done on most nursing units is for occult blood. It is necessary to promote the utilization of the performance monitors with each test and proper documentation of both the test result and the performance monitors in the nursing record. Proper storage of test cards is an issue to which users need to pay attention. Clinics that send test cards home with patients must utilize postal service approved envelopes for mailing the cards back to the hospital. Occult blood in gastric samples needs a separate testing card product. The education and support to ensure this testing is performed with site neutral quality is an appropriate responsibility of the point of care coordinator.

TABLE 1 - Sample of Location List

HOSPITAL LOCATION	TESTS PERFORMED	TECHNICAL CONSULTANT	AREA SUPERVISOR EXT.
RENAL - CHRONIC	ACT, Whole blood glucose	Susan Perkins, POC Coordinator	C**** G*****, RN #5214
RENAL - ACUTE	ACT, Whole blood glucose	Susan Perkins, POC Coordinator	C**** G*****, RN #4351
EAST 1	Whole blood glucose hemoccult, gastroccult	Susan Perkins, POC Coordinator	M****** J******, RN #2148
EAST 2	Whole blood glucose hemoccult, gastroccult	Susan Perkins, POC Coordinator	M****** J******, RN #2467
Neighborhood Health Clinic	Whole blood glucose Occult blood, Hct. Preg test, Rapid Strep KOH, Wet Preps, Urinalysis Dipstick	Susan Perkins, POC Coordinator	S**** A*******, RN #2514
ENDOSCOPY	Whole blood glucose hemoccult, gastroccult Clo test	Susan Perkins, POC Coordinator	L** T*****, RN #5410
EAST 3	Whole blood glucose hemoccult, gastroccult	Susan Perkins, POC Coordinator	S*e S****, RN #2345
CHAPIN 3	Whole blood glucose hemoccult, gastroccult	Susan Perkins, POC Coordinator	S** B******, RN #4125
EAST 4 - ADOL	Whole blood glucose hemoccult, gastroccult urinalysis dipstick	Susan Perkins, POC Coordinator	J***t S***, RN #4432
Medical Daystay	Whole blood glucose	Susan Perkins, POC Coordinator	L** T*****, RN #4821
EAST 5	Whole blood glucose hemoccult, gastroccult	Susan Perkins, POC Coordinator	S** S***t, RN #5512
EAST 6 - PACU	Whole blood glucose	Susan Perkins, POC Coordinator	L** T*****, RN #334442
DAYSTAY Main 5	I - STAT	Susan Perkins, POC Coordinator	L** T*****, RN #4535
Cardiac Cath Lab	ACT	Susan Perkins, POC Coordinator	J*** H****d

Creating a list of testing sites and the testing being performed is necessary before any management can be initiated. (See Table 1.) From this starting point any additional testing will be initiated with the full support and the same quality of the central laboratory.

Building Bridges

Just as a POL Consultant would establish a good working relationship with the personnel in the physician's office and keep the physician appraised of areas needing improvement as well as areas doing a good job, it is good practice to build good working relationships with the appropriate nursing personnel and keep the appropriate QA Committees as well as the Point of Care Policy Committee appraised of compliance with QA guidelines. The mechanism for withdrawing testing privileges from any area comes from the authority of the Point of Care Policy Committee, and can be reinstated with the submission of a compliance action plan agreeable to the committee and the POC Coordinator. Building quality into the program can only be achieved with a team effort by all personnel involved.

Point of Care Coordinator Responsibilities

A. Determine QA/QC protocols for each test that will effectively monitor all aspects of the testing that is also based on accrediting agency requirements.

B Prepare procedures in NCCLS format for all tests done in each area. A manual clearly labeled POINT OF CARE TESTING should be placed in each area performing laboratory testing. These procedures should contain information on patient identification, patient preparation,

specimen collection and handling and test policy and procedures for each test. This manual is also a good place to maintain the list of certified or trained personnel for any testing, QA reports from the Point of Care Coordinator, communication, any memos or newsletters pertaining to POCT. Quality Control and maintenance documentation should also be available in this manual. Perform and document an annual review of all procedures and ensure distribution and knowledge of any revisions.

C Training: Documentation that all personnel who are performing any laboratory testing have received adequate training is a primary requirement for quality performance of any laboratory procedure. The routes taken to ensure this are varied and may well need to be determined to fit the circumstances unique to each institution. Vendors are often willing to provide training personnel. This is a good cost saving measure as long as the laboratory POC Coordinator is able to determine the content, consistency of sessions, and post-training quizzes or observation for competency. In other situations, the POC Coordinator can conduct the training sessions either training all the testing personnel or by a train the trainer mode which utilizes nursing educators.

D Determination of appropriate Proficiency Testing Programs may be based on the complexity of the testing. Some programs may be tested with in-house specimens and others may be appropriate for commercial programs. The programs available for POLs may be just what is needed for a clinic that performs primarily waived testing and some tests classified as moderately complex.

E Ensure specimen collection technique for both capillary and venous collection are adequate to provide a quality specimen

F Familiarity with accrediting agency regulations to ensure appropriate compliance in each area. Any testing of a moderate complexity requires an even more diligent training program and even more diligent oversight by the laboratory to ensure the quality of the program. Usually testing on this level is for electrolytes and/or blood gases, with new technology where the manufacturer takes a greater responsibility for building in quality control functions into the instrumentation usage by non-laboratorians becomes more feasible. These are tests where turnaround time has always been an issue with the main laboratory. In the current environment where length of stay is such a vital concern to the efficiency of the institution, if this testing can be performed with a quality program managed by the laboratory everyone can benefit.

TABLE 2 - Waived Testing Accreditation Agency Regulations

CLIA '88

- No specific; regulations

JCAHO

- All operators are listed
- Training and periodic verification proficiency
- Written procedures
- QC performed according to manufacturer's recommendations
- Documentation remedial actions and maintenance

CAP (Selected items)

- Testing is performed under the supervision of the laboratory.
- All operators, are listed
- Training and periodic verification of proficiency
- Written procedures
- QC performed and evaluated each day of patient sting
- Documentation of glucose Meter performance '
- Linearity checked initially and semiannually
- CAP PT Surveys
- Policies for positive identification of patient specimen and result report
- Policies for safe handling and disposal of patient specimens and infectious waste

G Arrange for all employees who could be performing testing to be tested for color discrimination at their new employee physical

H Billing for laboratory testing should also be site neutral. Therefore the laboratory should also put in place mechanisms to ensure all tests is appropriately billed. Summations of this billing by each area should be available for Point of Care Coordinator to review and prepare a periodic report. The laboratory should have the appropriate familiarity with proper CPT codes

The Point of Care Coordinator must act as the resource person and technical consultant to ensure it is clear to each area supervisor the responsibilities involved in the decision to perform any laboratory testing in their area.

Area Supervisor Responsibilities

A Maintain documentation of all personnel certified to perform point of care testing, with operator ID, codes when appropriate, with a copy sent to the Point of Care Coordinator.

B Assure participation and documentation of quality control, remedial action for out of range controls, maintenance and proficiency testing programs by all certified personnel.

C Assure proper documentation of patient test results.

D Review and retain area performance reports and prepare corrective action plans when there is a failure to meet QA guidelines.

E Assure all testing done is accompanied by documentation of the person who performed the test.

Vendor Policy

Vendors who market laboratory test kits, reagents, and instruments should be required to present any new products to the laboratory for review, evaluation and recommendation before purchase or acquisition of each item. If vendors make their initial contact with medical, nursing and/or ancillary staff(such as respiratory therapy, pharmacy, etc.) the vendor should be referred to the laboratory as well.

Equipment

Equipment used for point of care testing should be limited to that approved by the Point of Care Policy Committee

Cessation of Testing

Cessation of testing should occur when QA guidelines are not properly followed. See sample pages at the end of this document for a form that could be used in those situations

Implementation of New Tests

Standard policies should be in place to utilize when requests for new tests have been submitted to the Point of Care Policy Committee and been approved. The protocol is the same as it would be to implement any new testing or instrument in the main laboratory. Determination of accuracy and precision, comparisons to primary laboratory instrumentation, establishment of test ranges and linearity are examples of procedures to follow. The Point of Care Coordinator should work with the support of the appropriate laboratory section to ensure this is done.

The hospital area that will be performing the testing should be informed of the results of these studies. The following is an example of a request and resolution.

The Labor and Delivery floor of our institution requested approval for the purchase of an instrument to perform a scalp pH. This testing had been somewhat problematical for some time. Specimens were collected and sent to a STAT lab on another floor for testing. Specimens were often inadequate, either qns or already clotted. One of the physicians had seen an instrument in use in another institution that only required 15 microliters of whole blood and was easy to operate.

The physician submitted a proposal to the Point of Care Policy Committee and the request was considered. The pathologist on the committee discussed the request with the manager of the Chemistry service in the laboratory for input and suggestions. With the submission of that report, the vote to obtain an analyzers for trial passed. All studies were conducted by the laboratory. The test results were adequate and although the cost per test was higher than that done by the main lab, all felt that the quality of the service for the patient would be improved. The analyzer was purchased by the Labor and Delivery Department. House staff and residents were required to attend training sessions on performing patient tests and quality control tests. The surgical techs from the Labor and Delivery surgical area were also trained to perform quality control procedure. The Point of Care Coordinator prepared a written procedure in standard laboratory format and quality control log sheets. Copies of the procedure were distributed during the training sessions. During the first month of use, the electronic quality control cartridge that cost $300 was accidentally thrown away and testing was stopped until a new one was purchased and available for use. The area nursing supervisor informed the Point of Care Coordinator when the cartridge was lost. A special container well labeled with instructions to be sure to replace QC Cartridge has prevented any further problems. The POC Coordinator reviews the QC log sheets weekly. A similar procedure was followed to implement a point of care analyzer that measured HbA1c in a Pediatric Endocrinology Clinic.

Point of Care testing programs are good opportunities for Continuous Quality Improvement projects. The cooperative efforts of these programs lend themselves to assessment for the ways and means to improve the procedures on an ongoing basis.

(See several example pages at the end of this document.)

III. POINT-OF-CARE TESTING: College of American Pathologists Laboratory Accreditation Program Perspective

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Overview

The Laboratory Accreditation Program (LAP) of the College of American Pathologists (CAP) was founded in 1961 with the primary objective of improving the quality of clinical laboratory services throughout the United States. Since its inception, the program has become widely acknowledged as a program of excellence. Through the program the CAP accredits approximately 5,000 laboratories throughout the United States and several other countries. Although the LAP has grown considerably in size, complexity, and effectiveness, and has been granted deemed status by JCAHO and also by HCFA under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), the primary goal of the program continues to be laboratory improvement through voluntary peer review, education, and compliance with established performance standards.

CAP-LAP Definition of Point-of-Care Testing

Point-of-Care Testing - CAP definition

- Performed outside of main primary lab
- Does not have dedicated space
- Standards independent of CLIA "complexity"
- Centralized coordination by primary lab required

Point-of-Care Testing (POCT) as defined in the CAP-LAP refers to those analytical patient testing activities provided within an institution which are performed outside the physical facilities of the main or primary clinical laboratories. The central criterion of POCT is that it does not utilize permanent dedicated space. The scope and utilization of such testing is continually expanding as technology evolves. Examples of POCT include kits and instruments that are hand-carried or otherwise transported to the vicinity of the patient for immediate testing at that site (e.g., whole blood glucose, activated clotting time), or analytic instruments that are temporarily brought to a patient care location (e.g., portable chemistry analyzer in operating room or intensive care unit). POCT does not include limited service or satellite laboratories with fixed dedicated testing space, e.g. blood gas lab in ICU or ER. Such a laboratory would be treated by the CAP-LAP as a separate laboratory section or a special function laboratory.

The CAP makes no distinction between the Federal definitions of "waived," "moderate complexity," "high complexity", "provider-performed microscopy", or "accurate and precise technology" testing as defined under CLIA'88. CAP-LAP Standards are considered "site-neutral" since it is presumed that all tests must be correctly performed for patient care.

POCT Programs would not meet current eligibility criteria for the CAP-LAP so that such programs would not be accredited unless they have a relationship with a larger primary laboratory which does meet the eligibility criteria. To be accredited by the CAP-LAP, POCT programs must comply with all current Standards for Laboratory Accreditation of the CAP, regardless of scope of testing and be under the direction, authority, and responsibility of the Director of the primary laboratory. There should be centralized coordination of the POCT program with designated primary laboratory personnel who review testing procedures and quality control, as well as conduct training of the individuals who perform the tests.

CAP Accreditation Process for POCT Programs

CAP Accreditation Process

- Biennial on-site inspection using :
  - Point-of-Care Testing Checklist (30)
  - Laboratory General Checklist (1)
- CAP Proficiency Survey enrollment required

The CAP accreditation process includes two major components: (1) On-site inspection and (2) Monitoring of proficiency survey performance.

On-site inspection occurs every two years and is coordinated with the inspection of the primary laboratory. This inspection is conducted by a volunteer inspector(s) who utilizes the CAP checklist(s) as a guide to measure compliance of the POCT program with the Standards for Laboratory Accreditation. Because the checklists are continually being updated, laboratories are also required to conduct an interim self-inspection in the year between the on-site inspections.

The POCT program at a facility is inspected using CAP-LAP Checklist 30. This checklist is always used in conjunction with the Laboratory General Checklist 1, as the contents of that checklist apply to all laboratory testing at a facility, whether occurring in dedicated space or not. If the POCT program is covered by the same CLIA certificate as the primary laboratory, the POCT program is treated as an additional section(s) of that laboratory and is inspected with the same copy of Checklist 1 as the primary lab. If the POCT program has a separate CLIA certificate under the same laboratory director, it is treated administratively as a separate laboratory by the LAP and is inspected with its own copy of Checklist 1.

When documentation for the POCT program is maintained within the primary clinical laboratory, only one copy of Checklist 30 must be completed. The inspector will review all centrally maintained records and visit a sample of the testing sites in order to evaluate compliance with the Standards. If records are not maintained centrally, the inspector must visit each POCT site, and a separate checklist must be completed for each location. In the latter case, each POCT site will be treated administratively as an additional laboratory section. The latter arrangement would result in higher fees for CAP accreditation since billing is based on the number of checklists required to complete the inspection.

The other component of the accreditation process is the ongoing ***monitoring of performance in external proficiency surveys***. CAP accredited laboratories are required to participate in the CAP Surveys (Interlaboratory Comparison) program for all analytes for which the laboratory performs patient testing. For the purposes of satisfying this requirement, whole blood glucose is considered a different analyte than serum glucose. Thus, if a POCT program includes testing for whole blood glucose, the program must be enrolled in the WBG Survey. Enrollment of the primary laboratory in the Comprehensive Chemistry Survey for serum glucose would not satisfy this requirement even though such enrollment might be sufficient for CLIA certification. When CAP Surveys are not available for analytes in a POCT Program, another mechanism must be developed to monitor proficiency. This could include analysis of previously analyzed patient or commercial samples or direct comparison with methods utilized in the primary laboratory.

The requirement for participation in CAP Surveys as opposed to other proficiency programs is based on the fact that the CAP Surveys have been designed to interface directly with the LAP and can be readily monitored. The Commission on

Laboratory Accreditation is currently developing criteria for acceptance of alternate PT surveys which would allow laboratories to subscribe to such programs and use them in lieu of CAP surveys for accreditation purposes. Survey enrollment is reviewed at the time of application/reapplication for accreditation and the inspection includes review of PT survey records for evidence of review by the laboratory director and documentation of corrective action where appropriate.

Inspection of POCT Programs

CAP Inspection Process for POCT

- Similar to inspection of any other lab section
- Procedure Manuals
- Personnel Training
- Reagent/Instrument System Calibration and Monitoring
- Quality Control
- Proficiency Survey Performance

Since CAP-LAP Standards are considered "site-neutral" from the perspective that all tests must be correctly performed for patient care, the inspection of POCT programs focuses on the same areas evaluated in the inspection of every other area of the laboratory: procedure manuals, personnel training, reagent and instrument monitoring and calibration, quality control and proficiency testing programs, etc. The best way to understand how the CAP-LAP inspection process works is to review this process by following the checklists. The Checklist Commentary accompanying each checklist *(available on diskette or in paper from the CAP Central Office and provided to each participating laboratory at the time of application / reapplication)* contains the references to pertinent CAP Standards, CLIA regulations and laboratory medicine literature upon which each checklist question is based. The checklist questions, including those with explanatory text, are not Standards. They are tools for inspectors and laboratory directors to use in evaluating whether or not the laboratory is meeting the Standards for Laboratory Accreditation at the time of the on-site inspection. The following comments indicate how the inspector would utilize the checklist questions during an on-site inspection.

Procedure Manuals/Personnel Training

Just as testing performed in the clinical laboratory utilizes procedure manuals developed in compliance with the National Committee on Clinical Laboratory Standards (NCCLS) Guideline for Technical Procedure Manuals GP2-A2, POCT also requires such a manual. In this setting, it is especially important that principles of testing, specific instructions for performance of testing including QC, calibration and reagent requirements, and limitations or special instructions for result interpretation be clearly defined. This manual provides the basis for training and periodic validation of performance of POCT personnel. The frequency of such training and periodic recertification will depend on individual circumstances but should be based on the frequency and volume of testing and/or the occurrence of problems with QC or PT surveys which signal a need for retraining. The training process for POCT personnel must be coordinated by the primary laboratory with appropriate documentation centralized for review by the inspector.

Reagent/Instrument System Calibration and Monitoring

The verification of reagent performance is especially important for POCT because reagents may be stored under a variety of uncontrolled conditions. Since such storage can have a deleterious effect on reagent performance, POCT programs must have protocols in place to verify that all of the components of the test system are functioning properly. Any of several methods may be appropriate, such as direct analysis with reference materials, parallel testing of old vs. new reagents, and checking with routine control samples. The results of such reagent checks must be recorded before being placed in service. Where individually packaged reagents/kits are used, there should be criteria established for monitoring reagent quality and stability, based on volume of usage and storage requirements. Processing of periodic "wet controls" to validate reagent quality and operator technique is a typical component of such a system.

Each POCT program must have an organized system for monitoring and maintaining all instruments used for point-of-care testing. Function checks should be designed to check the critical operating characteristics to detect drift, instability or malfunction before the problem is allowed to affect test results. This must include, but is not limited to electronic, mechanical and operational checks, with documentation of compliance. All servicing and repairs should be documented. The procedures and schedules for instrument maintenance must be as thorough and as frequent as specified by the manufacturer.

Calibration and standardization procedures for POCT are required to verify the initial and continued accuracy of a test method. These procedures are often confusing for POCT personnel who may be inclined to assume that such procedures are either unnecessary or need to be performed only by the manufacturer prior to initial use. Calibration is the process of testing and adjusting a test system to provide a known relationship between the response measurement and the value of a substance measured by the procedure. Calibration procedures for each method should be performed with at least the frequency of manufacturer's instructions or when calibration verification fails to meet acceptable limits using calibrators or calibration standards with defined values. Calibration verification is the assaying of appropriate matrix materials with known values in the same manner as patient samples to confirm that calibration of the test system has remained stable. Calibration verification requires at least a minimum, mid-point, and maximum value. Criteria must be established for POCT method calibration verification. Criteria for determining the need for calibration or calibration verification typically include: (1) at complete changes of reagent lots, unless the laboratory can demonstrate that changing reagent lots does not affect either the range used to report patient test results or the control values, (2) when indicated by quality control data, (3) after major maintenance

or service, (4) when recommended by the manufacturer, (5) at least every six months as mandated by the CLIA '88 regulations.

Linearity of the instrument/reagent system must be verified initially and when calibration verification fails to meet the laboratory's acceptable limits. Linearity is a test system property that specifies a correlation between the system output and the analyte concentration. Calibration verification may be used to establish linearity, but simple linearity verification cannot establish calibration verification, the difference being the lack of known values.

Validation of Method Performance

As is the case for all clinical laboratory methods, overall performance of POCT methods should be checked periodically with appropriate reference materials (assayed serum, regional pools, etc.) as noted above, and by other appropriate procedures such as: split sample analysis with reference or other laboratories, split samples with an established in-house method, clinical validation by chart review, or other systematic quality assurance procedures. The frequency of such validation will vary depending on the clinical setting in which POCT is utilized and the characteristics of each test system and may be incorporated into the quality control program and clinical quality management programs for patient care areas where POCT is performed.

Quality Control of POCT

The QC program for POCT must be clearly defined and well-organized. It must provide a system to assure proper patient identification and preparation; specimen collection, identification, preservation, and processing; and accurate result reporting. There must be a documented process by which limits for acceptable analytical performance are established and monitored. This is no different than the QC process for other clinical laboratory testing but may need to be tailored to the specific needs of the POCT program. As for all laboratory testing, the upper and lower limits for all reportable parameters must be defined for the test system so that results which fall outside such limits may be confirmed or repeated using alternate methods before reporting.

Control specimens must be used for POCT to assure that the system is stable. Controls are samples that are periodically processed like a patient sample in order to validate that calibration status is accurately maintained for quantitative tests, and that reagents are yielding the expected results for qualitative tests. The frequency with which controls are run depends on the stability of the test system but must be at least once each day testing is performed. More frequent testing of controls may be necessary if recommended by the manufacturer or if the integrity of the testing process requires that controls be run at greater frequency. In some instances, it may be necessary to run controls with each testing event. Individuals performing POCT must be qualified to recognize when the system is out of control and to initiate appropriate corrective action and refrain from reporting patient test results if controls are unacceptable. This is especially important for POCT programs since such testing is often performed by non-laboratory personnel who may not have an understanding of the importance of QC to the validation of the accuracy of such testing. Often, POCT personnel will simply assume that, if they can get a result from an instrument, it must be correct. Some POCT devices now feature a QC lockout which prevents testing of patient samples unless QC samples are run and meet acceptable tolerance limits. Any corrective actions must be adequately documented. It is essential that control materials be treated in the same manner as patient samples since that is the only way that these can function as a true control for the entire testing process.

In some systems, especially those using single use reagent packs, manufacturers may provide an electronic simulator as a quality control device to assess the instrument system. However, this does not adequately assess reagent stability or operator technique. For that reason, use of a quality control protocol involving use of control samples is still required. Electronic controls alone are not considered sufficient for quality control of the entire system. This issue is currently under active debate because the rapid and continuing enhancements in technology occurring for POCT instrumentation have forced re-evaluation of traditional approaches to QC as it applies to such testing. For example, where POCT devices employ single use cartridges it is not possible to validate each test cartridge by analyzing control materials. The Commission on Laboratory Accreditation is aware of this continuing evolution of POCT technology and an interdisciplinary task force is actively evaluating the devices and testing systems on the market to determine whether it is appropriate to alter existing QC requirements.

The POCT QC program should include a system to detect clerical errors, significant analytical errors and unusual or unexpected test results. For POCT, where each test may be performed individually at the bedside, procedures for patient identification should be defined. If specimens for different patients are analyzed together, procedures for specimen identification and labeling must be defined. Analytical errors or unexpected test results may be detected by use of delta checks using consecutive samples from the same patient or by confirmatory testing in the primary laboratory. Where POCT personnel are also the individuals who will act upon test results (e.g., by altering insulin dosage in response to whole blood glucose results, or altering heparin dosage in response to activated clotting time or APTT), there should be defined criteria for correlating unexpected test results with other clinical findings to validate such results whenever possible. In order to permit identification and follow-up of any problems with test results, the system should allow for identification of testing personnel for each test result. The system for reporting of POCT results should include provision for their inclusion in the patient's permanent medical record and for immediate notification of physicians regarding critical results which require a prompt change in patient management.

The quality control program for POCT must be under active surveillance to identify any trends or other behavior which signals deterioration in the stability or integrity of the testing system. QC data must be reviewed at least weekly by an individual qualified as a technical supervisor as defined under CLIA '88. Secondary review should occur at least monthly by

the laboratory director or designee. A system which involves medical technologists or supervisory staff from the primary laboratory in this secondary review can facilitate an enhanced cooperative and collaborative interaction between POCT personnel, usually nursing staff, and the primary laboratory staff. This provides an opportunity for laboratory staff to become more involved in direct patient care and also gives them greater insight into the issues and problems faced by POCT personnel performing testing outside of the laboratory. Review of QC protocols and documentation is a critical part of the inspection process.

External Proficiency Testing

Participation in external PT surveys provides an ongoing mechanism for monitoring performance in POCT using unknown samples which mimic patient samples. PT surveys also provide valuable data which permits interlaboratory comparison to identify any significant bias or other unusual behavior for a particular system. The PT survey samples must be tested in the same way as patient samples since that is the most appropriate measure of proficiency and is also a CLIA requirement. This concept is important to emphasize since in many cases individuals performing POCT view PT as a "test" where they must do whatever it takes to assure a "correct" answer. PT samples should be rotated among different analyzers performing such testing and rotated among different testing personnel. This is especially important for POCT where large numbers of different testing personnel and multiple portable analyzers may be in use. There should be a mechanism by which all units and individuals performing POCT are periodically evaluated through some form of PT. The frequency and extent of such evaluation will be determined by the volume and frequency of testing at each site. Every unit does not need to be enrolled in an external PT program. The primary laboratory must design a system to accomplish the periodic evaluation of each site and its testing personnel, e.g. by comparing results from samples tested concurrently by POCT and primary laboratory methods or by using commercially prepared control materials.

Closing

This summary of the CAP-LAP inspection for POCT has reviewed the process by which such programs are evaluated for compliance with the CAP Standards for Laboratory Accreditation. This process is guided by the checklists which are continually being updated and revised. It should be emphasized that the CAP-LAP treats POCT the same as all other laboratory testing. The application of the CAP Standards outside of the traditional laboratory setting can present challenges for both the inspectors and the individuals responsible for POCT programs. There may be differences in interpretation of checklist questions at different sites. The discussion that ensues during each inspection and in the course of the subsequent review of laboratory responses by the Commission provides the starting point for the continuing refinement of the accreditation process to reflect the highest standards of laboratory testing. The thoughtful insights provided by CAP inspectors and accredited labs participating in the CAP-LAP is one of the strengths of this voluntary peer review laboratory improvement program.

Summary - Quality Control of POCT

- Specimen collection and identification
- Control samples processed as patient samples
- Frequency of controls based on system stability
- Documentation of corrective action when tolerance limits exceeded
- Mechanism for detection of clerical or analytical errors
- Correlation with clinical findings where appropriate
- Mechanism for reporting results
- Monitoring of external proficiency survey performance
- Documentation of active surveillance by supervisory personnel

IV. POCT: Why It Won't Go Away

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Point of Care Testing: Why it Won't Go Away

Point of Care Testing has actually been with us since the early 1960's, but it has only been recent that it has become known as POCT. Technically, one of the first was urinalysis testing. This was followed by glucose testing with new technologies that provided values from whole blood. Next came ion selective electrodes (ISE) for electrolytes that enabled testing to move to a critical care area which had previously been "off limits" to testing methods utilizing the conventional open flame. This innovation was followed by monoclonal antibodies which further simplified testing for many tests like HCG and Strep. All the while, micro processors and personal computers began to find their way into invitro diagnostic devices which accelerated further innovations.

The earliest beginnings of POC, as we know it today, came along in 1984 with the Protime ® 1000 developed by Biotrack, Inc., a novel whole blood method for prothrombin times. In 1988, a similar method for APTT was completed, followed by unitized test to monitor many epilepsy drugs, Carbamazepine (Tegretol) and Phenytoin (Dilantin) and Theophyilline for asthmatics.

The term POC arrived in our vernacular around 1988, with the release of the GEM6 ® from Mallinckrodt Sensor Systems, the first cartridge-based blood gas system for use in the operating room. Additionally, Mallinckrodt has been responsible for five separate MLO supplements all focused on point of care.

In 1991, I-STAT Corporation launched their system. A single use cartridge that provided six analytes all on whole blood in less than three minutes. A technological breakthrough, a "6-60" in your hand.

Since the early 1990's, POC has gone by many names, including alternate site, alternative site, bedside, decentralized and near patient testing, but POC seems to be the most widely accepted. However, the speed with which the term POC was adopted has been exactly opposite to the speed at which the actual concept has been implemented. This is due to several reasons, including:

- Government regulations (CLIA '88 and various states)
- Politics ("turf issues")
- Financial issues
- Operator training
- Unproven clinical improvements
- "Black box" technology

In spite of this environment, POC has gained a foothold in many areas:

ICU/CCU	Blood gases, electrolytes, pulse oximetry, coagulation
OR	Blood gases, electrolytes, pulse oximetry, coagulation
Dialysis	Coagulation, urea
Cath Labs	Coagulation, urea
Ward	Urinalysis, glucose
ED	Cardiac markers, drugs of abuse
Screening	Glucose, cholesterol, lipids, drugs of abuse

The actual POC market in the U.S. in 1994 was estimated to be approximately $1.5 billion with over 2/3 of that being glucose testing. Moreover, estimates for POC revenues to reach $5 billion in the next 10 years has caused many manufacturers to actively invest in POC, both in R & D and market development.

Market forces will be the primary drivers to adoption of POC, for both inpatient and outpatient settings. These market forces are due to several factors: 1) the demographics of the baby boom population; 2) the need to reduce overall healthcare delivery costs; 3) the growth of home healthcare and alternative care centers; 4) increased inpatient acuity; 5) simplified technology 6) greater emphasis on patient outcomes.

In this discussion, we will first review the historical drivers of point of care, then take a brief look at key-market indicators that are continuing to drive point of care testing, next move into overall healthcare delivery today and investigate trends that are shaping the future of healthcare delivery, specifically managed care, capitation, disease management, outcomes, technology and data management; all in an attempt to bring these together into a coherent argument as to why point of care will not go away, but be adopted an integrated into existing systems.

Historical Drivers

The historical drivers for point of care can be looked at in three different areas: government, industry and the market (**Figure 1**).

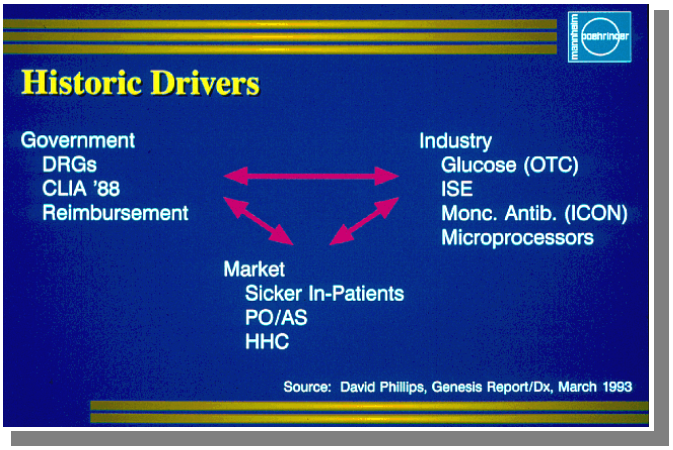

Figure 1

Government has had significant impact on test volumes and test modalities due to various legislative initiatives. The first sweeping initiative came about in 1983 with the implementation of diagnosis-related groups or DRG's. This had a dramatic impact upon the central clinical laboratory because prior to DRG's, the central clinical laboratory was a significant profit generator. Post DRG's, the laboratory became one of the larger cost centers within the hospital. This meant that laboratorians must rethink the way they had done business previously. Specifically, how they interacted with the patient and other departments within the hospital.

DRG's meant that hospitals would not be reimbursed on each "encounter", but rather paid on the entire patient's stay. For instance, a patient is admitted with a heart attack, prior to DRG's, each specific test ordered on the patient would be paid on an itemized basis; post DRG's, the hospital would be reimbursed on one prevailing cost, based on the entire treatment for a patient with a heart attack. If the hospital spent more money on the patient than would be reimbursed under that DRG code, the hospital made up the difference. If the hospital was able to provide adequate care for the patient for less than the DRG, they were able to "pocket" the difference. This began the forced movement towards shorter length of stays for the inpatient. Which in turn lead to the inpatient population becoming much "sicker". It also meant more patients were being treated on an outpatient basis which lead to greater testing volume in the physician's office and alternate site. This decentralized testing was also being driven by the reimbursement of third-party payers. That is, single physician practices could afford to buy capital equipment to do testing in their lab because their cost of testing was less than what they were being reimbursed. Therefore, the physicians began to make money on testing within their laboratory. Industry, meanwhile, was reacting to

this by developing better and better technology that allowed less trained healthcare professionals to provide laboratory quality results outside of the traditional laboratory. One example of this is glucose, which became an over-the-counter (OTC) product in 1976. Another example is ion selective electrodes or ISE's which became available in the late 1970's which enabled testing to move to critical and areas outside of the central laboratory which had previously been off limits because it utilized an open flame (i.e. the sodium and potassium flame photometer).

Another new technology was introduced in the early 1980's, monoclonal antibodies. These methods further simplified testing for many tests like HCG and Strep. In fact, this technology is the basis for most OTC test products now, e.g. cholesterol and ovulation. All the while, microprocessors and personal computers began to find their way into in-vitro diagnostic testing devices which accelerated further innovations.

Key Market Indicators

There are several key market forces that will contribute to the growth of point of care testing. The most significant of these is the population demographics (**Figure 2**).

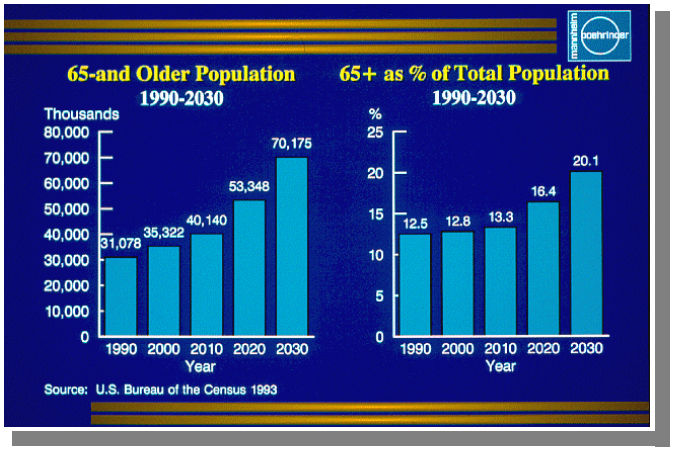

Figure 2

From now till the year 2030, the baby boom generation will double the number of individuals over the age of 65. The 65 or over total population today is approximately 35 million and will increase to over 70 million. This is significant for a number of reasons. The baby boom population tends to be much more comfortable with technology and certainly more informed as to their personal health. The baby boomers will take a much more active role in managing their health, and the technology will allow this to happen. More decentralized testing because the demand will be there.

A second key market driver is the movement in healthcare delivery today from a fee for service basis to managed care (**Figure 3**).

The fee for service is an individually focused healthcare delivery system as opposed to managed care which is

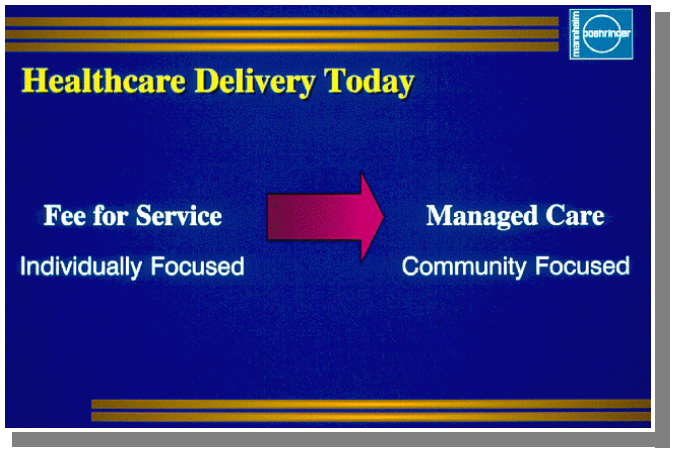

Figure 3

community focused. Fee for service is system driven by admissions and reimbursement. Hospitals compete for patients and physicians; there are virtually no spending limits under a fee for service delivery system (**Figure 4**).

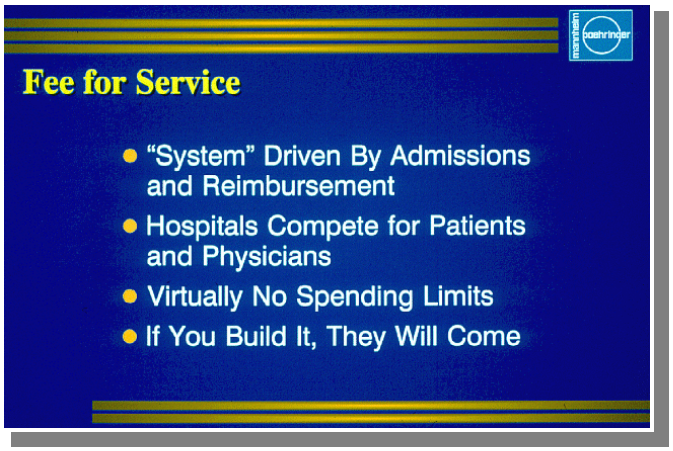

Figure 4

Managed care, on the other hand, deals with a fixed pre-paid sum to cover all healthcare for a defined population **(Figure**

Figure 5

5). Managed care is diligent in their search for innovations in delivery. They are focused on outcomes measurement and have made wellness a key component in their strategy, as indicated by this quote from Gary Meyer, President and COO of Friendly Hills Healthcare Network. Mr. Meyer says, "The real trick is managing care throughout the access points that make up the continuum of care. If you wait until the patient comes to the hospital, then you've waited too long. We see hospitalization as a failure of the system." This sums it up very well for managed care deliverers. They want to invest their money up front to keep the patient out of the hospital. If the patient is admitted, they want to move that patient through the system as rapidly as possible.

A closer look at Managed Care indicates five stages (**Figure 6)**.

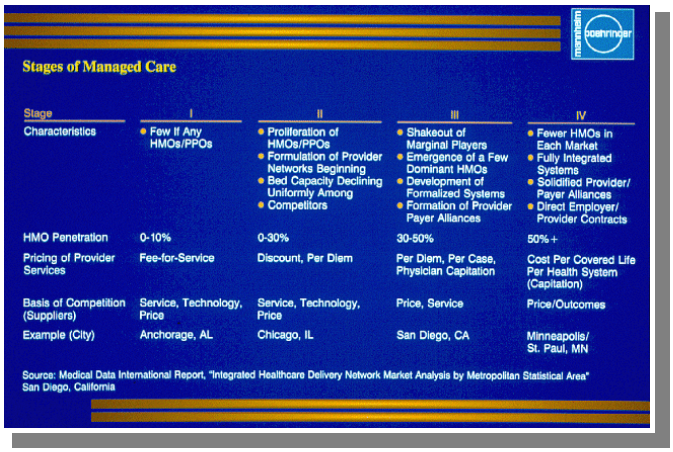

Figure 6

Only four are illustrated here because there is no area within the U.S. that has reached Stage V. There are many characteristics of note, HMO penetration, the pricing of the provider services and the basis of competition.

Capitation

As we move more into managed care, capitation becomes the next key component (**Figure 7**).

Capitation reverses the logic of all payers. Under a fee for service, market share can be measured by a number of admissions, procedures or visits. Under capitation, it is strictly the number of covered lives, per member per month, PMPM. Cost under a fee for service is reimbursed on a cost per procedure or a cost per stay, the DRG again. Performance measures under capitation is cost per life, inpatient days per thousand or visits per thousands, and the management focus in a fee for service looks at high occupancy rates; whereas, capitation looks at low occupancy rates and correct modality. So, capitation looks at and tests for appropriate care by looking for the right care, the right procedure and the right setting in the right amount. Therefore, capitated systems will look for innovations and delivery and point of care can provide that in various venues; and,

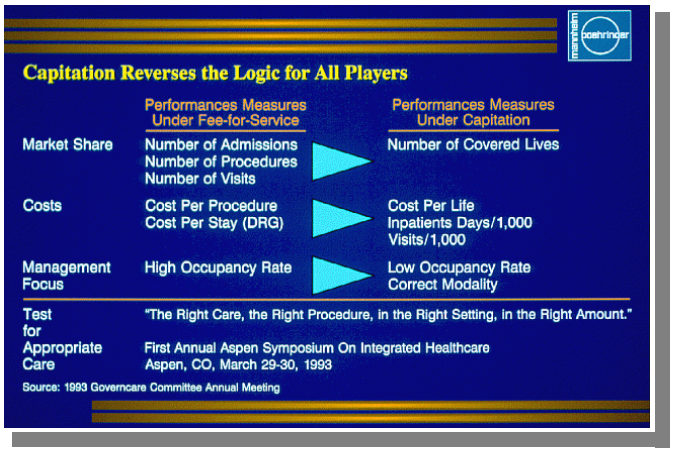

Figure 7

therefore, will be utilized to a greater degree in these practice settings.

The next trend shaping the future that will contribute to point of care being utilized is disease management. Disease management is a long-term integrated process in which quality outcomes from a clinical perspective are the paramount goal. Disease management generally refers to services that may increase expenditures in one cost center, but are designed to reduce total medical cost. Point of care is generally more expensive on a cost per test basis when compared to centralized laboratory testing. However, point of care testing, when implemented properly, in specific settings can have an overall impact on reducing the total medical costs.

There are a number of disease states and medical conditions that respond favorably to disease management techniques, specifically certain types of cancer, AIDS, diabetes and heart disease. In many of these, such as diabetes, patients have already taken over, not only their own blood testing but also the administration of the drug, in this case insulin, so that they have a vested interest in maintaining their health and they do it in the least costly setting, home.

The final driver is outcomes measurements. These have begun to proliferate outside of the historical area of interest which were pharmaceutical, and are now being driven from a number of points. The government, through the Department of Health and Human Services has funded the Agency for Healthcare Policy and Research (AHCPR) and has begun over 20 patient-oriented research teams or PORTS to develop practice guidelines. As these guidelines are developed and published, certainly public payers like Healthcare Financing Administration (HCFA) will adopt these and it is expected that private payers, while developing many of their own, may follow some of the AHCPR guidelines. These guidelines will utilize many of the fundamentals being implemented by managed care and capitated systems and will be able to determine the most cost effective methods of healthcare delivery. Moreover by using claims data bases they will be able to find inefficiencies in the systems and focus on providing standardization in those areas. If the methods developed identify a point of care technology that can lower

the overall cost of the healthcare delivery, it will be implemented and incorporated in standard guidelines that will be utilized throughout all provider systems.

One example of this is a study done by George Despotis, M.D. published in the Journal of Thoracic Cardiovascular Surgery, entitled "Perspective Evaluation in Clinical Utility of On-Site Monitoring of Coagulation in Patient's Undergoing Cardiac Operation". This prospective, randomized study showed significant difference between the standard group and the test group in blood product utilization during cardiopulmonary bypass surgery. In instances of a potential coagulopathy, the surgeon is prepared to close the surgical site, but due to excessive bleeding, closure is not possible. In these cases, Stat PT, APTT and Platelet count are ordered. Also ordered are four units of FFP and three units of platelets. Many times, the blood products arrive into the OR before the diagnostic results. Therefore, the surgeon transfuses based on empirical data and most often the bleeding stops. But why? Which blood component was the most effective? Did the patient need all seven units? In Dr. Despotis's trial, the study cohort was tested using POC technology, three minute test time on the results. This rapid turn around time, coupled with a transfusion algorithm was successful in saving over $215,000. Even though the actual cost per tests was significantly higher for the POC. This is one example of not comparing cost per test, but cost per episode of care. Disease management, on the other hand, looks to understand the diseases' natural course and cost drivers. The diagnosis and treatment is based on the disease not a reimbursement scenario. In order to impact the disease, resources need to be directed towards the best and most cost effective approach, which includes educating and raising the compliance of the patient for better chronic disease management. In some instances this will mean empowering the patient to take a more active role in their therapy, their management of the disease. Additional "encouraging" and "inhibiting" factors effecting the growth of disease management are outlined in (**Figures 8 & 9**).
Overall improvements and technology will continue. Improvement in miniaturization of whole blood sensors; continued development of continuous invasive monitoring, first for blood gas and electrolytes; development of in-line extra corporeal devices and finally non-invasive monitoring technologies using infrared or near infrared methods and transcutaneous sensors. We will continue to see market forces continuing to reinvent healthcare delivery, but it will also favor general provider capitation as its reimbursement endpoint. Capitation will lower the inpatient encounter while favoring preventive disease management with early outpatient intervention. Government reform will boost managed Medicare and Medicaid, driving a decline in inpatient treatment and consumers will adopt a more intelligent, self-guided approach towards healthcare and assume increased responsibility for routine and experimental treatment. We can expect to see a better informed healthcare consumer, one who uses on-line health information systems and communications via the Internet and dramatically change the patient/physician relationship. People with computers can already buy programs that make it possible for them to diagnose their illnesses. They will be able to organize routine medical needs from their own homes, via telephone and interactive media. These will benefit the market for self-testing and home care medical products and alternative healthcare and services. In the next five to ten years, the Human Genome Project will be completed, whereby all twenty-three pairs will be mapped by the year 2005. We will begin to see nanomedicine, from the Greek word "dwarf", meaning extremely small sample sizes and extremely small sensors. Robotics will become a player in central clinical laboratory testing and in surgical procedures. Synthetic body parts, such as artificial blood and the beginnings of telemedicine for remote transmissions from patient to care giver.

All of these are drivers to decentralized testing. Inpatient acuity will continue to increase, and lead to reduced lengths of stay. Shifts from inpatient care to outpatient care will continue, perhaps at a slower rate, but nevertheless continue.

In conclusion, all of these factors can be put on a matrix, (**Figure 10**), where the volume of point of care testing is along the y-axis and time along the x-axis. We know inpatient volume is decreasing while outpatient testing volume is increasing. Home healthcare is becoming an integral part of the healthcare delivery and technology can provide the means to self manage. The re-engineering of healthcare is moving us from fee for service through HMO/MCO to capitation,

Figure 8

Figure 9

disease management and prevention. The effect of the population demographics has been observed in practically every aspect the baby boomers touch. In vitro diagnostic testing has evolved from large continuous testing systems to discreet analysis and now to unitized test devices. These unitized devices are small enough to be implanted no different than defibrillators are today. As further breakthroughs occur in gene mapping, technologists will be able to customize to specific patients and predict who is likely to develop a disease or condition that could require medical intervention. But the prediction will allow less expensive treatment to prevent the need for more costly procedures. And finally the continued improvement in data management can tie it all together. Patients will be able to interact directly with healthcare providers in the least costly setting with the least costly professional.

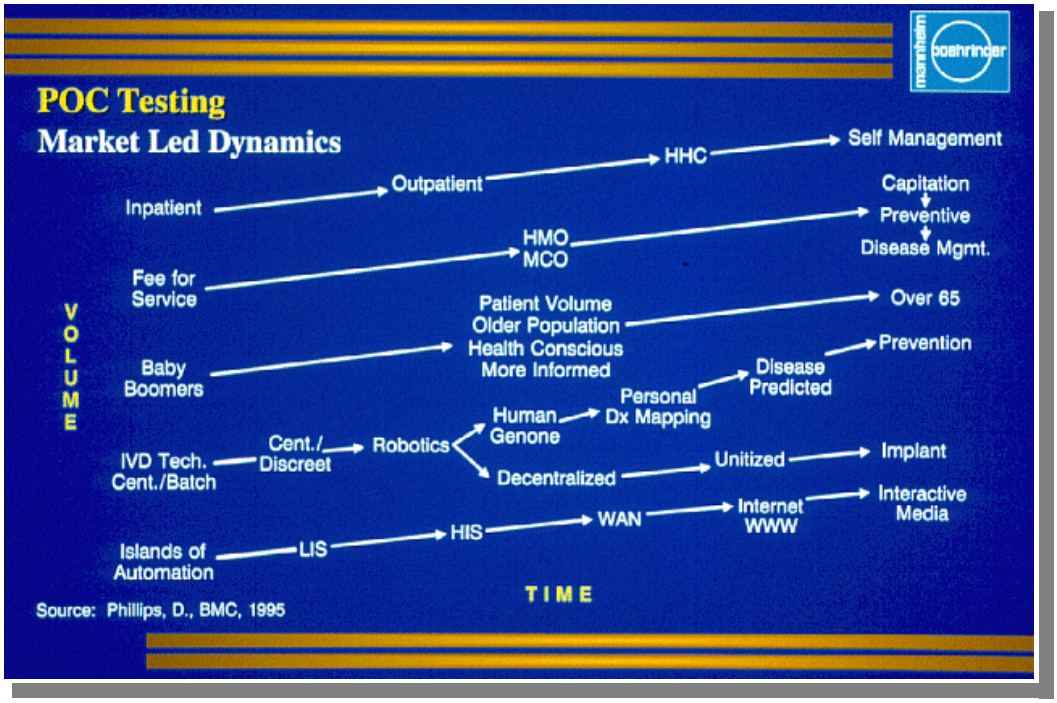

Figure 10

Begin to educate yourself for the many changes that will be occurring. By anticipating and preparing properly, you will be able to position yourself appropriately to optimize the changes.

V. Data Integration: Historic and Future Trends in Health Care Information Systems

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Review of Current Trends in Health Care

In todays environment, all providers of health care including the clinical laboratories are being challenged by many internal and external forces to maintain quality of care, increase productivity and efficiency and minimize health care costs. These challenges are creating an unprecedented wave of mergers, take-overs and closures to occur throughout the country, causing consolidation within the health care industry.

Quality of Care Issues

As an industry we need to maintain the patient's quality of care in today's managed care environment. With this in mind, we will need to have systems in place to determine the appropriateness of care, deliver better turn-around time for that care and meet all regulatory standards for providing care.

Increased Productivity and Efficiency

Health care providers and clinical laboratories will need to automate more processes because in order to compete, they will need to do an ever larger number of procedures. The future will bring more computerization, robotics, instrumentation and hand held devices. Services will be provided closer to the patient, be it at the bedside in a hospital, community health care facility or the patient's home. In order to invest in these new services, health care providers and clinical laboratories will need to reduce overall labor costs, work smarter not harder, and do even more with less than ever before.

Minimizing Health Care Costs

Management of health care costs and controlling utilization through managed care programs will become common place. Providers will need to conserve resources through better financial and cost accounting skills and systems. Inventory control systems will need to be better integrated with purchasing and resource consumption processes. Health care providers and politicians must work together to eliminate or reduce unneeded or antiquated health care regulations increasing the cost of providing patient care at the State and National levels.

Consolidation of the Health Care Industry

In order to compete in today's market place; health care providers are aggressively consolidating by outright merger,

others unable to compete will be eliminated. There will be a decrease in the number of free-standing institutions and solo practice M.D.'s. Vertical integration through provider networks will be formed. (Cradle to grave philosophy) These networks will integrate: Primary care providers, Out-patient services, In-patient services, Nursing homes and Insurance providers. In order for providers to be successful in the future, the emphasis in providing health care to any given population will be to manage its health status and prevent sickness or disease.

What can Health Care Information Systems do to help us in today's environment? Insight may be found by exploring a chronological history of System Integration yesterday, today & tomorrow!

System Models

In this section I will be discussing four different current and future health care information system models which will include the; Financial model, Network model, Data depository model which will include multiple disparate departmental systems and one vendor, single database solutions, and the Community model.

The Birth of the HIS (Hospital Information System)

During the 1960's most health care information systems were financially focused. Their main focus at that time was to create a patient's bill. These systems usually ran on IBM or other main-frame computers. Control of both the physical and logical system was centralized. After the billing software was installed, other software applications were purchased including ADT's (Admissions, discharges and transfers) and departmental order systems. Many internal point to point interfaces were required to interface these systems. Many data sets were stored redundantly on each of the applications. (ie; Patient demographics)

The Birth of The Lis (Laboratory Information System)

Moving into the 1980's, health care information systems became departmentally focused and revolved around automating the major departments in the hospital. These systems included, the laboratory information system (LIS), pharmacy information system (PIS), radiology information system (RIS) and other smaller departmental systems. These systems were purchased by the hospital on the basis of "Best of Breed" for their specific purpose. These systems were rich in departmental functionality. The systems were usually run on Digital VAX or other mini-computer systems. In order to connect these systems to the HIS and other systems, complicated communication networks were used to connect many disparate systems. In addition, many complicated point to point interfaces were required to be installed. Departmental systems rich in functionality were and continue to be, limited to the most common denominator when interfacing to another system. Once again, data was stored redundantly in all departmental systems.

The Birth of the Electronic Medical Record (Network/Data Model)

In the 1990's, a new direction was evolving to solve many of the problems encountered in the previous two models. Health care systems began to advance into a more patient focused, data depository model. Many providers around the country began and are currently developing a single relational database which would store patient focused data from the institution's many disparate departmental systems and allow for the availability of a more complete Electronic Medical Record. The systems being developed are hardware and operating system independent and available on many currently installed platforms. The data depository model minimizes point to point interfaces, but still must be interfaced to the many departmental systems within the institution. Continued redundant departmental databases remain intact. This model will provide the ability to integrate important shared and stored clinical data for the first time.

Two Strategies Available to Integrate Health Care Systems and Maximize Functionality

There are two strategies available to health care providers in order to integrate and maximize overall system functionality. These strategies include the interface engine and the one vendor solution.

The Interface Engine

First, we must define what an interface engine is. An interface engine facilitates the development and installation of system point to point interfaces. Interface engines (hardware and software) can be purchased through a multitude of vendors. With an interface engine, the user controls the interface formats from multiple disparate systems. Utilizing a standardized internal dictionary and format such as HL-7, inbound data is translated internally, converted to another format and routed to the appropriate destination system. Many internal point to point interface may be eliminated by using this tool and reduce modifications to all interfaces when one interface is changed. Network/data models will use less multiple point to point interfaces connected to an interface engine in order to integrate disparate systems in turn minimizing some of the limitations placed on departmental software functionality. Unfortunately, departmental systems continue to maintain multiple databases. Management and maintenance of the interface engine is required. (Although vendors may argue differently, advanced programming skills may be needed to develop the engine.) On a positive note, the interface engine solution will protect your investment with legacy systems and are typically hardware and protocol independent.

One Vendor Single Database Solution

Another integrating strategy which can be used is to purchase a one vendor solution for your institution's system needs. This system will provide a single database with a high level of system integration and functionality using internal departmental systems. This solution will minimize or eliminates the need for point to point interfaces and redundant departmental databases. Although initial implementation

may be more costly, cost savings due to superior system integration may develop over the long run. This solution may be cost prohibitive due to the replacement of many legacy systems at your site.

The Birth of the Community Information System (CIS)

Starting in the Mid 1990's and into the future, we will see the birth of community based databases and knowledge systems. Molded by the financial climate and driven by managed care, individual institutions (including competing health care providers) will cooperate and accept community integration. The first step needed to bring this vision to life requires the creation of a community wide unique patient identifier. Safe guards will also need to be developed to protect the confidentially and security of patient data. Once these issues are resolved, future networked health providers, payers, employers, laboratories, pharmacies regulators and researchers will be linked together analogous to the network model of a hospital. The community-wide model may evolve into the development of a community- wide electronic medical record depository. Transmission of patient health care data may be as easy as using an ATM machine (Given the appropriate level of security.). Once the community based model is in place, knowledge based systems can query the depository for standardized quality of care indicators and outcome measures. We will also see the development of computer assisted diagnostic tools which will decrease many costs by eliminating duplicate or unneeded procedures and expedite the ordering of appropriate tests through clinical algorithms.

The Birth of Point of Care Technology

(VIRTUAL HEALTH CARE. Do not limit your scope to hospitals, laboratories etc.)

Although the infra-structure of the CIS model is just beginning to be built, where does system integration go from here? The next logical choice will be to integrate health care data directly from the patient's home or any other free standing site where the point of care is provided.

Why should we focus on the point of care? Point of care technologies will provide better timeliness and documentation. Point of care technology will integrate patient information beyond the boundaries of the laboratory (departmental data) or the hospital (institutional data). The system will focus on the patient's health status and the inter-relationships within the community he or she lives in. A cradle to grave coverage mentality will become the norm of the day. The need to access clinical patient data for all care-givers and other ancillary services will finally become a reality, allowing the delivery of quality care to the patient, in the most cost efficient manner.

Enabling Technologies

Point of care enabling technologies which are currently available include pagers, faxes, scanners, multimedia, imaging / video conferencing / voice, knowledge based systems, barcoding, and handheld technology via radio frequency or cellular. These technologies can all be applied within the point of care, CIS model or network.

What Is a Network?

The American Heritage Dictionary, 2nd College Edition says a NETWORK is; "Something resembling a net in consisting of a number of parts, passages, lines or routes that cross branch out or interconnect. A group or systems of electronic components and connecting circuitry, designed to function in a specific Manner."

Point of Care Networks

There are basically two types of networks which can be used to integrated point of care enabling technologies in providing health care services. These alternatives include cabled networks consisting of cabled local area networks (LAN's) and Wide Area Networks (WAN's) and wireless networks using radio frequency technology for LAN's and cellular, microwave or satellite technology for WAN's.

Next, let us take a journey to a fictional system that applies these technologies.

An Integrated Health Care System

A Look into the Future. You are watching TV and you are complaining about your favorite football team's 4th straight loss in a row, (I can sympathize with the situation, I am a Buffalo Bills fan) you just can't believe it. You slouch over in your couch and complain to your wife that the game gave you a real bad case of indigestion. You tell her that you feel like you personally played the game, because your chest feels like it was hit by a 300 pound defensive end. Your throwing arm also has pain radiating down it. Your wife takes one look at you and doesn't like what she sees. She calls for an ambulance.

The ambulance arrives at you home. As one emergency technician assesses your clinical situation, another technician begins to ask your wife some questions regarding your membership in one of the local healthcare cooperatives. Your wife is slightly hysterical, but grabs for your wallet. She pulls out your membership card (It looks just like a credit card with your picture on it.) and hands it to the technician. The technician comments to your wife that you belong to the EZ CARE healthcare cooperative. The membership card contains your magnetically digitized medical record including a unique patient identifier. He takes your card and swipes it through a credit card type reader. The card reader connected via modem and cellular communication queries the EZ CARE's healthcare computer database for all pertinent demographic, insurance status, employment and any additional clinical data not yet stored on the membership card. The data is sent back to the ambulance terminal with treatment authorization to send you to EZ CARE GENERAL for treatment. The technician hands your wife a Personal Digital Assistant, (PDA) and asks her to read and sign the authorization form for treatment displayed on the screen. Your wife's digitized signature is then uploaded to the onboard computer for future reference.

Upon completion of the authorization record, a barcoded wristband with all your pertinent demographic data is printed and placed around your wrist. While all the business part of your case is being transacted by your wife, the other technician has already checked your vital signs and is connecting EKG leads to your chest. Temperature and blood pressure is also being monitored. He also does a fingerstick and analyzes your blood for electrolytes with a handheld analyzer. All instruments are interfaced with their digital output stored on the onboard computer. As the ambulance rushes off to EZ CARE GENERAL, the emergency technician calls the EZ CARE GENERAL emergency room. He informs the ER admissions officer that a patient is on the way and uploads all your demographic and clinical data (Received from the EZ CARE Healthcare Cooperative.) to the hospital's computer system. Behind the scenes, the hospital system will utilize your uploaded demographic data and search the hospital's Electronic Medical Record Depository for all relevant historical data including laboratory, pharmacy and radiology result. The computer will automatically admit you into the ER, download the historical clinical data and alert your primary physician via a digital pager notifying him of your status and arrival to the ER. Your currently monitored vital signs are transmitted continuously to the hospital computer system. Upon electronic admission to the ER, an emergency room physician has already been assigned to your case and is currently reviewing your EKG and vital signs (A graphical representation found in the electronic chart.) on an ER physician computer workstation.

In addition to the graphical representation of the EKG, expert systems using clinical algorithms analyze the incoming data and make recommendations to the physician for an appropriate course of action. The physician continues to review your electronic medical electronic chart for clinical history, he finds that you had a recent angiogram. With a click of a mouse pointing to Radiology, full motion video of your angiogram is retrieved from the electronic medical record depository and displayed on the screen. Next, he points to the Laboratory icon and discovers that you have had TDM Digoxin levels. He requests a graphical representation of the past years Digoxin levels. He then looks in the Pharmacy section and finds out that you still have open orders for Digoxin at the EZ CARE Pharmacy. After reviewing the remainder of the chart he recommends that the admitting diagnosis should be to "Rule out Myocardial Infarction". He dictates his observations directly into the computer workstation where it is stored digitally for future audio playback or translated into a written format via a voice to ASCII conversion.

The physician gets on the phone and begins to communicate instructions to the technician of your incoming ambulance. As the ambulance pulls up to the front door of the ER and your are moved inside, a nurse , using a barcode reader, reads the barcoded wristband. Positive ID with your unique patient identifier is confirmed, and you are physically admitted to the ER. The physician assigned to your case begins his assessment. He requests a nurse to enter an order on you for a standard cardiac protocol. The nurse orders the procedure on the workstation, which automatically orders multiple standardized laboratory and EKG procedures. Within a minute barcoded labels are generated on a printer for the requested procedures. The nurse draws your blood in the appropriately labeled tubes and sends them directly to the laboratory via the pneumatic tube system. The doctor now advises you that he recommends you be admitted into the CCU. Hearing the doctor's recommendation, you adamantly disagree with the doctor's diagnosis, stating that the problem was caused by a combination of beer, pizza with the works and another loss of your favorite football team. Your wife disagrees with your diagnosis and you reluctantly agree to the hospitalization.

The ER admissions officer makes the transfer from the ER to the CCU. In the ER you have EKG leads placed on your chest for 24 hour telemetry. The bed you are in is one of those smart beds which allow for the automatic monitoring of your vital signs. The data is uploaded from the bed to the Nursing computer workstation located next to your bed . Standardized nursing care plans will be initiated for your care. They are also begin to monitor your urinary output. As you continue to look around the room, your physician arrives.

He asks how you're doing and begins to access your GUI-based, Electronic Medical Record Chart. He clicks on various icons representing different clinical areas of the chart and begins his review. Results have already been posted for the CKmb indicating a mild MI. A rules based system has already automatically ordered a confirmatory CK isoenzyme analysis. Your potassium results have also been posted and border abnormally high. (These results were analyzed on a bidirectional interfaced whole blood analyzer which read the barcoded label on the specimen and download the test request and demographic data from the host LIS. The specimen was analyzed and results were uploaded to the LIS and made available to the electronic medical record depository.)

After his review, he orders additional, laboratory tests including a TDM digoxin, a K+, ABG's , creatinine and electrolytes. Barcoded labels are printed immediately at your bedside. An E-Mail message is automatically routed to the phlebotomist for stat draws. Next he orders your normal prescription for Digoxin and a diuretic (Propranol) under the pharmacy window. Moving to the angiology icon, he requests available time slots for an angiology exam. The monitor displays available times through an automated scheduling system for the procedure. He confirms 8:00 tomorrow morning.

As he leaves your room, his digital pager goes off. "Rush Pathology results are now available for patient John Doe." He walks into the hallway and looks for a house phone. He dials the extension , his security ID and the patient's Unique identifier. The report that was just dictated and verified is currently being read back to the physician via an ASCII to voice conversion. All the doctor has to do is listen to the pathology report as dictated through a digital dictation system. The phlebotomist appears to draw your blood.

Later that day, multiple rule based algorithms are processed by the hospital's computer system. Some of the following events occurred. Urinary output has decreased and levels of creatinine and K+ have increased. These results have triggered other events to occur automatically. The order for the angiology exam has been canceled due to increased

hypertension and decreased urinary output and has been automatically rescheduled for the following day pending stabilization of the current problem.

An E-mail is also initiated to your doctor's office notifying him of the change in orders. Your TDM Digoxin level was high (Probably due to the decreased urinary output.) which triggered a modification of your Pharmacy order to decrease your Digoxin dosage. Although you were looking forward to that great tasting food they serve at the EZ CARE GENERAL, your dietary order has also been modified to insure a diet low in salt. This rule was triggered by the pharmacy order for propranol.

By the next day it appears that your condition has stabilized enough to undergo the angiogram the next day. At 8:00 a.m. on the third day you are rolled into angiology and the procedure begins. The entire procedure is being recorded as a full motion digital video and uploaded to the hospital medical record depository. The findings show an occlusion of the left arterial descending coronary artery. A successful balloon angioplasty is performed on you immediately. All your vital signs and chemistries are appearing to return to normal.

You rest the remainder of the day and are discharged the following day. Although many other procedures occurred during your hospital stay, many of the other interactions have not been described. Upon discharge your doctor has ordered additional out-patient services, including a prescription for propranol, in order to lower that high blood pressure. The order is sent electronically via modem to the EZ CARE Pharmacy. An E-Mail message via FAX alerts the pharmacist of your impending order. He also schedules an out-patient visit at the EZ CARE Cardiac Rehab Center in one week.

Before you check out of the hospital, a visit to the discharge planning department is warranted. Your wife completes and signs some additional paperwork. These documents are scanned, digitized and uploaded to the hospital electronic medical record depository. Another rules based system, queries your case and prints a copy of future healthcare and lifestyle changes recommended for you to insure future disease prevention. (For example, diet change, exercise and stress management for that type A personality you exhibit at work)

Once again, in the background, your case is being reviewed in the Medical Records department. An algorithm utilizing the electronic medical record depository reviews all your diagnosis and procedures ordered, it then automatically codes the appropriate ICD-9 and or CPT-4 codes. Your case is electronically available for case sign-out by your physician the next time he signs on. He will verify the discharge diagnosis of your case via an electronic signature only he can produce.

Your case has also been analyzed to ensure the quality of care you received by assessing standardized Quality Assurance Indicators. This analysis is reported electronically via and electronic data interchange (EDI) communication link to national and state regulators such as JCAHO and New State Department of Health.

Algorithms developed at the national and state level will utilize the data to determine the cost effectiveness of medical intervention and the clinical outcome derived from specific clinical and diagnostic procedures. These types of indicators will also be transmitted to the EZ CARE Heathcare Cooperative for future use in determining, the successfulness of specific clinical and diagnostic procedures, future reimbursement rates and contractual agreements for service of its patient population.

Hospital billing and payment will also be simplified utilizing a standardized billing layout sent directly to the EZ CARE Healthcare Cooperative via an EDI link, for services rendered to you on their behalf. Funds for services rendered will also be automatically transferred to the hospital.

Continued future monitoring of the patient's diet, exercise and simple in home testing will be monitored at home and data entered on a home PC. Data will be transferred to your EZ Care Medical Record.

Reality Check!

Now that you have seen what could be done, can we do it today? The answer to this question is yes, health systems across the country are beginning to develop these systems today.

An Integrated Health Organization (IHO) Kansas City, MO

In Kansas City, MO, urban, suburban and rural communities covering 123 counties within a 150 miles radius are developing an integrated health organization.

The Health Care Provider

The health care providers include 13 general acute care, rehabilitation and mental health centers in and around Kansas City, MO. In addition numerous out-patient facilities, medical office buildings, physician practices are participating. There are 2,500 physicians, 11,100 nurses and numerous other health care professionals delivering the service.

The Insurer

Blue Cross and Blue Shield of Kansas City, the area's largest managed care provider provides the network of physicians to be used increasing the value of the network by linking health care management to financial processes. While integrating the process, BC/BS is attempting to cut waste and improve on efficiencies. They are also in partnership with the Kansas University Medical Center, Olathe Medical Center and Province Medical Center.

The Information Provider

Cerner Corporation has a 10 year contract to provide the information network which will connect all of the parties. They will be responsible for the coordination and integration of the health care delivery system in the Kansas City, Missouri region. Cerner is dedicated to the creation of a lifetime comprehensive electronic medical record for the patient.

In Conclusion, Our Challenge!

Reorganization in health care, financing and delivery systems have or will occur in emerging integrated health organizations across the country, under a common care objective.

The result of this integration is a mandate for common clinical processes to be automated throughout multiple provider entities.

INTEGRATION, HOW WE DO IT IS THE CHALLENGE!

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BAYSTATE MEDICAL CENTER
Proficiency Testing Data Review Form

Location: _____ Department: _____

Survey year: _____ Shipment Date: _____ Received Date: _____

PT Supplier: _____ Survey Name: _____

Received by: _____ Results Due Date: _____

Received in Acceptable Condition: Yes_____ No_____
If not, Action Taken:

_____

_____

Tests included in normal patient run: Yes_____ No_____

Signature: _____ Date: _____

Results Acceptable: Yes_____ No_____ Score_____

Tests Unacceptable: _____

Reason: _____

Action Required: Yes_____ No_____

Action Taken: _____

_____

_____

_____

_____

Reviewed by: _____ **Date:** _____

Title: _____

Wesson Women's Clinic
Urinalysis Quality Control Log

NORMAL ROOM #

STRIP LOT# EXP. DATE: BEGAN USE:	STRIP LOT# EXP. DATE: BEGAN USE:	STRIP LOT# EXP. DATE: BEGAN USE:

CONTROL LOT#: EXP. DATE:
MONTH: YEAR:

DATE	GLU	BILI	KETO	SpGr	BLD	pH	PROT	URO	NITE	LEUK	Initials
QC→											
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4											
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Circle each day to document daily calibration
Turn instrument off then on each day to calibrate

Circle your initials to document weekly cleaning
Disinfect strip holder in bleach each Friday

Reviewed by: **Date:**

Comments:

POINT OF CARE ANNUAL RE-VALIDATION

NAME:_____
Location:_____DATE:_____
HOSP#_____ONE TOUCH ID #_____

	YES	NO
One Touch II Glucose Meter		
1. Explains the procedure to the patient when appropriate.		
2. Use personal protective equipment appropriately.		
3. Has read and knows the location of test policies/procedures		
4. Demonstrates proper Quality Control / Test procedures		
* Checks that meter code and test strip code match		
* Checks expiration dates of strips and/or controls		
* Obtains sample using proper skin puncture technique		
* Performs test as outlined in procedure		
* Records results and enters results in PCIS		
"Hemoccult" for Occult Blood in Feces		
* Uses Performance Monitor on Hemoccult cards.		
* Records results of Performance Monitors with patient results in patient;'s chart and PCIS		
* Records patient and QC results appropriately		
Pregnancy Test		
* Demonstrates proper test technique		
* Interprets Test and Quality Control results appropriately		
* Records patient and QC results		
"Dipstick" Macroscopic Urinalysis		
* Checks expiration date of strips		
* Dips specimen and reads after 1 minute		
* Records patient results and/or Quality Control samples appropriately		
"Hemocue" Hemoglogin		
* Fills test cartridge properly		
* Uses test cartridge and Meter Trax for QC		
* Records results appropriately		
Rapid Strep		
* Demonstrates proper technique		
* Interprets Test and Quality Control results appropriately		
* Records patient and QC results		

Re-certified by:_____**Date:**_____

BAYSTATE MEDICAL CENTER

ONE TOUCH II HOSPITAL BLOOD GLUCOSE METER

Weekly Maintenance / Corrective Action Log

NURSING UNIT _____

METER SERIAL # _____

METER SERIAL # _____ **IN USE AS OF** _____

METER SERIAL # _____ **IN USE AS OF** _____

STRIP LOT # _____

EXP. DATE

DATE	OPERATOR NUMBER	METER CLEANED	BATTERY CHANGED	ANY QC FAIL?	ACTION TAKEN	LAB CALLED	METER NOT IN USE

Corrective Action Code:

1. Cleaned the meter
2. Opened a new bottle of Test Strips
3. Opened a new bottle of Control Solution
4. Replaced damaged Check Strip
5. Made a change in technique; repeated control
6. Meter not used

Monthly Review: (Nursing)
Initials: _____,_____,_____,_____
Date: _____,_____,_____,_____

Monthly Review: (Laboratory)
Initials: _____,_____,_____,_____
Date: _____,_____,_____,_____

BAYSTATE MEDICAL CENTER
GLUCOSE METER REPLACEMENT FORM

Unit:_____ **Date:**_____ **Time:**_____ **AM / PM**

Returned Meter Serial #:_____ **New Meter Serial #:**_____

If after troubleshooting (see reverse of this form) you need to replace the meter, please complete this form and bring with the malfunctioning meter to the main lab to obtain a replacement.

Check off all that apply:

_____ Frequent **"Clean Test Area"** message.

4. Remove, clean and dry test strip holder
5. Clean sensor window with a damp soft cloth or tissue ( ) Cleaned
6. Replace test strip holder with a new one ( ) Changed strip holder
7. Re-test QC, if OK use, if not OK, replace meter

_____ **"Battery"** Replace battery with fresh new battery ( ) Changed battery
(Available from distribution or stockroom)

_____ **"High and/or Low Fail"** which has not been resolved after troubleshooting

_____ **"Check Strip Failure"** Strip must be inserted and removed when indicated

_____ **"Not OK"** Sometimes corrected with a new battery

_____ **"Other"** (Please describe below) _____

_____

_____ _____ _____ _____
Person describing the problem Ext. Person completing the form Ext.

To be completed by laboratory personnel:

Follow-up_____ Settings OK Y N

_____ New Battery Y N

_____ New Strip Holder Y N

_____ Strip Code/Exp. Date:____/____

_____ Lot#:_____

_____ Check Strip:_____

_____ High:_____

_____ Low:_____

By:_____ Date:_____ Returned to pool_____ Floor:_____ LifeScan_____

Remedial Action:_____

_____

_____

By:_____ Date:_____