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MMI 405 HIT Integration, Interoperability and Standards

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Continuum of Care: Laboratory Integration

Modern medicine relies on clinical laboratories to help physicians make accurate diagnoses and implement plan of care or treatment. Tests performed in clinical laboratories costs billions of dollars and are expected to increase annually. Physicians are able to make more definitive diagnoses earlier, as a result of advances in clinical laboratory procedures. The clinical laboratory usually includes Chemistry, Hematology, Microbiology, Blood Bank and is further divided into specialty areas such as Immunology and Toxicology. [1] Hospitals and physician office laboratories perform 75% of all laboratory analyses, while the remaining 25% are performed by independent reference laboratories.

1.0 Stakeholders

Stakeholders are individuals and constituencies that contribute, either voluntarily or involuntarily, to its wealth-creating capacity and activities, and that are therefore its potential beneficiaries and/or risk bearers. [2] Identifying the stakeholders and recognizing their expectations is important to ensure success of the integration process. The diagram below identifies the internal and external stakeholders in the laboratory.

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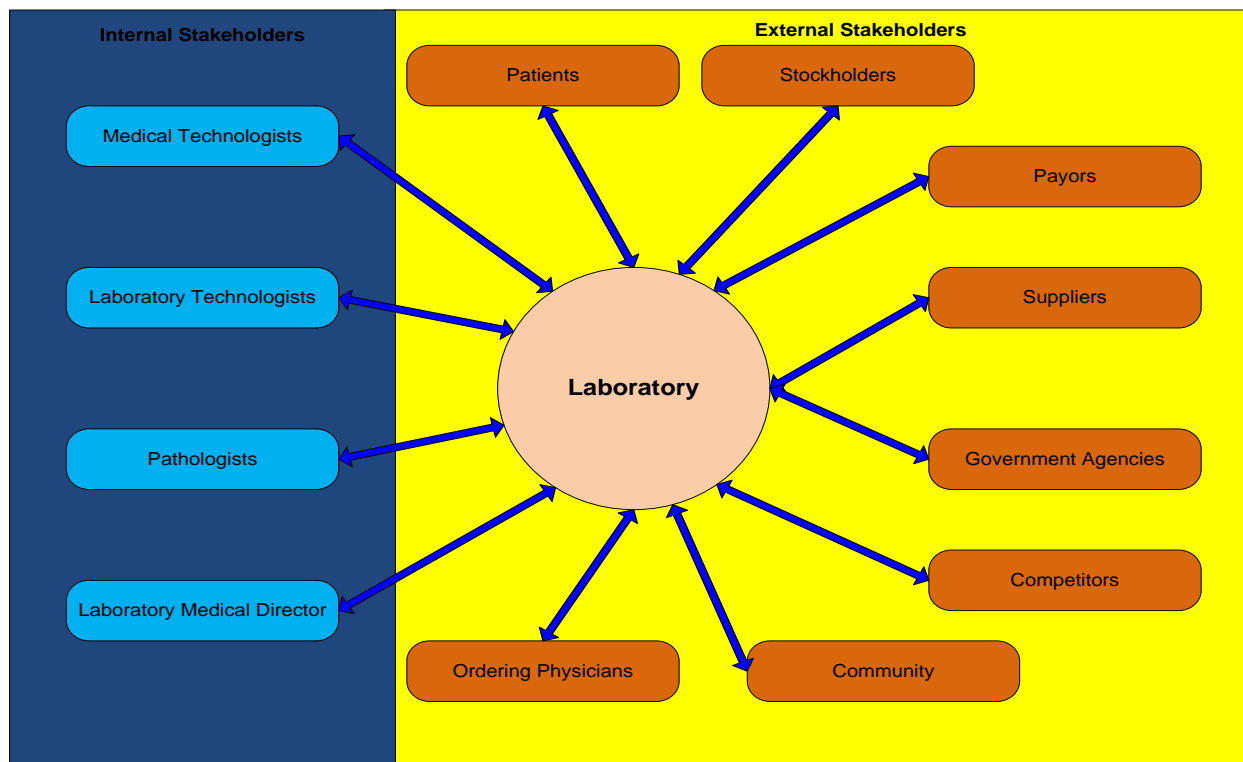
[1] Wikipedia, "Medical Laboratory," n.d., http://en.wikipedia.org/wiki/Clinical_laboratory

[2] Post, Preston and Sachs, "Redefining the Corporation," 2002, http://www.sup.org/book.cgi?book_id=4304%204310

1.1 Internal Stakeholders

Management and the employees are the primary internal stakeholders. Their focus is to provide excellent service to the customers, produce revenue and to be an active participant in developing processes that affect their workflow. Among the internal stakeholders are:

Medical Technologists are responsible for performing routine and highly specialized tests to diagnose disease and relay the results to the pathologist or treating physician. To achieve that, they need to have the appropriate tools to analyze specimens.

Laboratory Technicians perform routine tests and are responsible for entering data into the laboratory information system.

Pathologists want to make sure the information provided to him by the Medical Technologists is accurate so he/she could make the correct diagnosis.

Laboratory Medical Director expects that all clinical, technical and administrative functions of the lab are performed; expect the staff to comply with governmental standards to make sure the lab is accredited.

1.2 External Stakeholders

Any group or individual who could be affected by the laboratory's performance are considered external stakeholders. Among the external stakeholders are:

Patients and consumers who come in to the clinic with certain symptoms are referred for blood draws by their physicians in order to determine the exact cause and diagnosis for their symptoms. When going to the laboratory to have their blood drawn, patients have an expectation of a professional, efficient experience with the laboratory. They want to be treated with respect, have their time valued and to get accurate results back in a timely fashion.

Ordering Physicians order blood draws to help determine the correct diagnosis and appropriate treatment plan for their patients. When ordering blood draws, physicians expect their orders to be carried out effectively, to not have their patients inconvenienced, to be alerted when results are critical and to get accurate results back in a timely manner.

Stockholders own one or more shares of stocks in the corporation. They have the right to vote on certain company issues such as electing the board of directors and the right to share in the company's dividends. Stockholders expect the corporation they've invested their financial resources in, to be in the position to provide them with a steady income.

Government agencies are responsible for making sure that the laboratory is operating within the standards of agencies that inspect and accredit them. They expect to receive reports of infectious diseases and acquired hospital infections.

Competitors are interested in what services the other company is providing, what services are not available, and how much the other company is charging. By knowing what they have to compete against, the competitors could develop a strategy that would steer away some of the patients/physicians to their lab by offering better service.

Payors which include insurance companies, governmental agencies like Medicare and Medicaid, want to ensure that they are not paying for duplication of services. They also expect to pay at a contracted rate and expect the lab to write off some tests that did not have proper authorization.

Suppliers provide the materials needed to conduct the tests. To ensure profitability, suppliers want to be the exclusive provider for the laboratory.

Stakeholder engagement is essential in the success of the company. Stakeholders are grouped according to their level of power or influence as well as their level of interest. [3]

Keep Satisfied	Manage Closely
Patients	Stockholders
Ordering Physicians	Competitors
Medical Technologists	Government Agencies
Lab Technicians	Pathologists
Payors	Laboratory Medical Director
Monitor	Keep Informed
Suppliers	Community

Low   High

The Patients, Ordering Physicians, Payors, Lab Technicians and Medical Technologists have high level of power and low interest. This group warrants enough effort to keep them satisfied since they could always take their business to the competitors.

The Competitors, Stockholders and Government Agencies have high level of power and high interest. This group needs to be fully engaged along with making the greatest effort to keep them satisfied. They need to be managed closely as the Stockholders could easily withdraw their investment and the Government Agencies could deny the lab their accreditation necessary to keep it operational. The

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[3] Mindtools, "Stakeholders Analysis," n.d., http://www.mindtools.com/pages/article/newPPM_07.htm

Pathologists and Laboratory Medical Director want to make sure that they provide high quality service to keep the consumers they already have as well as attract new ones. They also want to make sure they maintain the standards to avoid losing their accreditation. The Competitors power and interest stems from their goal to lure away the Consumers.

The Suppliers has low level of power and low interest. They need to be monitored to make sure they are providing the correct supplies and not overcharging the lab.

The Community has a low level of power and high interest. They need to be informed about the services available at the lab thru web postings, marketing, advertisement and promotional materials as well as focus groups discussions and public meetings.

2.0 Business Needs

The business needs of the laboratory are largely determined by the interactions with other players in the continuum of care.

2.1 Patients

Expect to be able to schedule appointments quickly and to have those time estimates honored. Respecting the patient's time and anxiety will improve the patient's experience and likely their degree of satisfaction. Patients also want to have their results interpreted quickly and accurately to reduce the necessity of repeating tests. Knowing the results in a short time would reduce stress of the patient since their physician would be able to inform them of the current status of their health.

2.2 Hospitals

 Want to be able to submit and schedule their orders by phone, fax, and / or electronically. Hospitals that have invested in electronic medical records want a lab that is capable of adhering to the standards (e.g. HL7, LOINC) and providing secure communication of results. They also expect the reports to be accurate so that repeated tests are eliminated.

2.3 Clinicians

Those involved in the care of a patient would need the same basic requirements of the hospital regarding the ability to order tests and receive test results. They want to have access to tests that were ordered for their patient.

2.4 Payors

Expect the laboratories to submit the bill electronically and accurately. This expedites the payment process ensuring provider satisfaction.

2.5 Staff

The lab also has the need to attract and retain quality employees. In order to accomplish this business requirement, the lab must offer a work environment that provides employees with a modern laboratory information system (LIS).

2.6 Government and public health organizations

Want to be notified of lab results that could potentially spot an early outbreak of a contagious disease or bioterror event. They also have an expectation of being notified of certain diseases (sexually transmitted diseases, HIV) and to have that communication meet existing security requirements (HIPAA). The community expect the lab to remain open and accessible as well as provide employment to some of their residents.

2.7 Interface

The lab needs to be able to interface with outside systems. Accepting orders electronically, effective scheduling, reliability and interfacing with lab equipment are all factors that must be included in the LIS. One of the more important implications of this need is accurate billing for tests performed. The lab also needs its information system to be cost effective. The investment the lab makes in the LIS needs to show an increase in productivity, better utilization rates of equipment and increased accuracy in results reporting. In addition, the lab must comply with established standards regarding transfer of healthcare information and the HIPAA requirements.

3.0 Common Workflow Scenarios
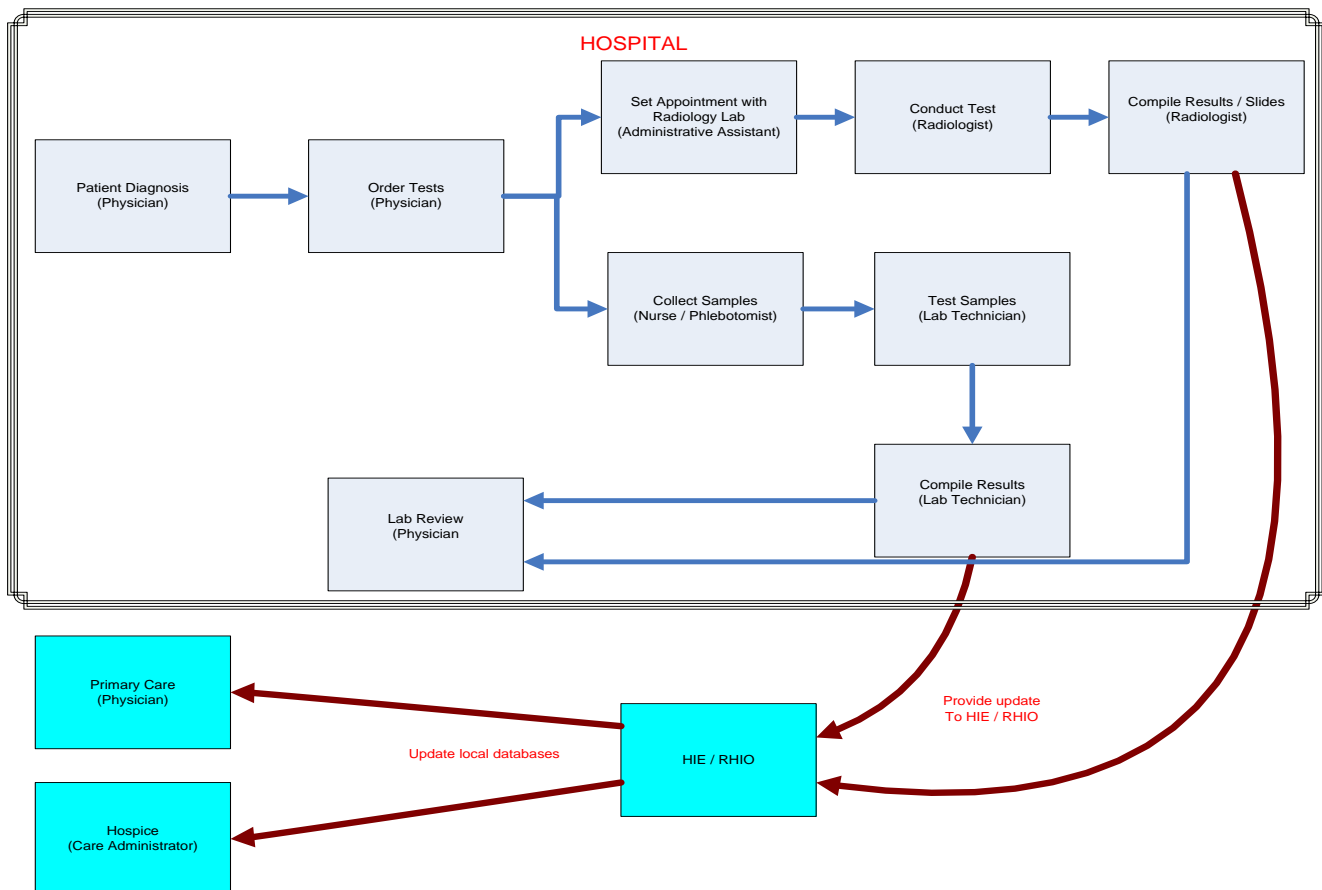
After Patient Diagnosis is completed, Physician orders tests.

Depending on the Radiology or other labs, a sample is collected or radiology lab appointment is done.

Radiologist test or Lab test is conducted.

The results are sent back electronically to the physician who ordered the tests. Critical results are flagged indicating that immediate attention is necessary.

For better continuity of care, the lab results could be sent to Health Information Exchange or RHIO

The results are reviewed by the primary care physician or specialists when patients come in for their appointment
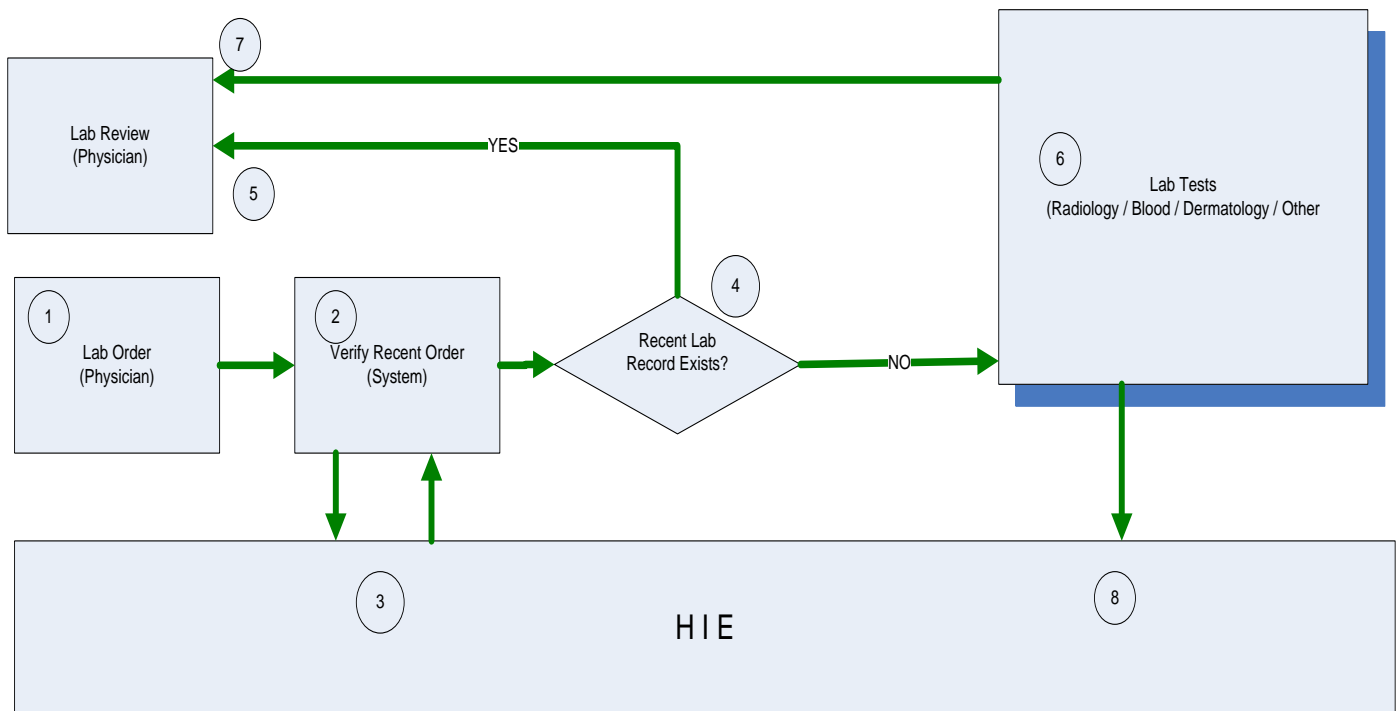
In this scenario, when the lab orders are submitted, the computer system will fetch recent lab test of the same patient from the Health Information Exchange (HIE). If the recent lab tests are same as requested test, the system will send the recent tests. If recent test results are not available, the orders will be processed. The results from the lab will be sent to the physician who ordered the tests and the HIE. This result will be used for future requests.

4.0 Standards

The laboratories' ability to integrate data within the lab and the ability to exchange data with external health entities such as hospitals, ambulatory clinicians, other labs, pharmacy department, radiology department, public health entities and payers depends on the harmonization of data standards. Among the standards involved in lab integration are:

4.1 HL7 V2.5

It is viewed by domain experts as the best available version of the laboratory profile and is the most widely implemented standard for health care information in the world. It is also the only available version that supports both specimen and container. HL7 V2.5 has several chapters that provide the general guidelines by which HL7 compliant applications should communicate. Among the chapters that apply to lab integration are:

2 - Control Message Definitions, Interchange Protocols.

3 - Patient Administration includes Admit, Discharge, Transfer, and Demographics.

4 - Order Entry involves orders for Clinical Services and Observations, Pharmacy, Dietary, and Supplies.

6 - Financial Management involves Patient Accounting and Charges.

7 - Observation Reporting includes Observation Report Messages.

10 - Scheduling Appointment involves Scheduling and Resources.

13 - Laboratory Automation includes equipment status, specimen status, equipment inventory, equipment comment, equipment response, equipment notification, equipment test code settings, equipment logs/service.

16 - Claims and Reimbursement involves submission of claims and receiving compensation for the services provided.

4.2 LOINC

According to the LOINC website, "In HL7 ORU messages, LOINC provides codes for the question (OBR-4, OBX-3) while SNOMED provides codes for the answers (OBX-5)." [4] A study reported in Clinical Chemistry clarifies the use of LOINC by stating: "The scope of the LOINC Committee includes the codes that identify the test observation per se, e.g., serum glucose or blood culture, not the codes that might be reported in the values of some test observations. If we consider the observation as a question and the observation values as answers, LOINC provides codes for the questions. Other code systems, e.g., International Classification of Diseases (ICD)-9 (11), International Classification of Diseases for Oncology (ICDO)-3 (12), Systemized Nomenclature in Medicine (SNOMED) (13), MEDCIN(14), and the Medical Dictionary for Regulatory Activities (MedDRA) (15), provide codes for the answers."

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[4] LOINC, "LOINC and other standards," 2008, http://loinc.org/faq/getting-started/loinc-and-other-standards/

The LOINC website asserts: "The basic use-case for the mapping is that LOINC codes would be used for ordering/reporting tests and observations, and the associated CPT codes would be used for billing. Thus, this is a unidirectional map from orderable LOINC codes to CPT billing codes."

4.3 ICD-9

Codes and classifies morbidity data from the inpatient and outpatient records, physician offices and National Center for Health Statistics surveys.[5]

4.4 XML

Extensible Markup language or XML provides data in a structured manner so that any system can understand the contents. It is derived from the ISO standard SGML. Almost all industries use XML to exchange data. HL7 data can be represented in XML format. This gives the flexibility for the users to use various tools to create the HL7 data and transport it.

```
Standard Hl7:
MSH|^~\&|LABLfoo^bar|767543|ADT|767543|19900314130405||ACK^|XX3657|P|2.3.1<CR>MSA|AA|ZZ9380<CR>


XML Representation:
<!DOCTYPE ACK SYSTEM "hl7_v231.dtd">
<ACK>
<MSH>
    <MSH.1>|</MSH.1>
    <MSH.2>^~\&amp;</MSH.2>
    <MSH.3>
            <HD.1>LAB</HD.1>
            <HD.2>foo</HD.2>
            <HD.3>bar</HD.3>
    </MSH.3>
    <MSH.4><HD.1>767543</HD.1></MSH.4>
    <MSH.5><HD.1>ADT</HD.1></MSH.5>
    <MSH.6><HD.1>767543</HD.1></MSH.6>
    <MSH.7>19900314130405</MSH.7>
    <MSH.9><CM_MSG_TYPE.1>ACK</CM_MSG_TYPE.1></MSH.9>
    <MSH.10>XX3657</MSH.10>
    <MSH.11><PT.1>P</PT.1></MSH.11>
    <MSH.12><VID.1>2.3.1</VID.1></MSH.12>
    </MSH>
<MSA>
    <MSA.1>AA</MSA.1>
    <MSA.2>ZZ9380</MSA.2>
</MSA>
</ACK>
```

This is a sample representation of HL7 data in XML. In the standard HL7 data, the information is continuously presented with the delimiters. The XML representation provides you further detail s of what the data is.

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[5] National Center for Health Statistics, "Classifications of Diseases and Functioning & Disability," 2008, http://www.cdc.gov/nchs/icd9.htm

4.5 HIPAA

HIPAA regulations dictate the content and format of the electronic transmission of healthcare information. HIPAA also establishes the criteria for evaluating the entity's security practices in the event of a breach of identifiable health information. Protected Health Information is allowed for Treatment, Payment and Healthcare Operations which covers the system requirements we are covering in this presentation.

5.0 System Requirements
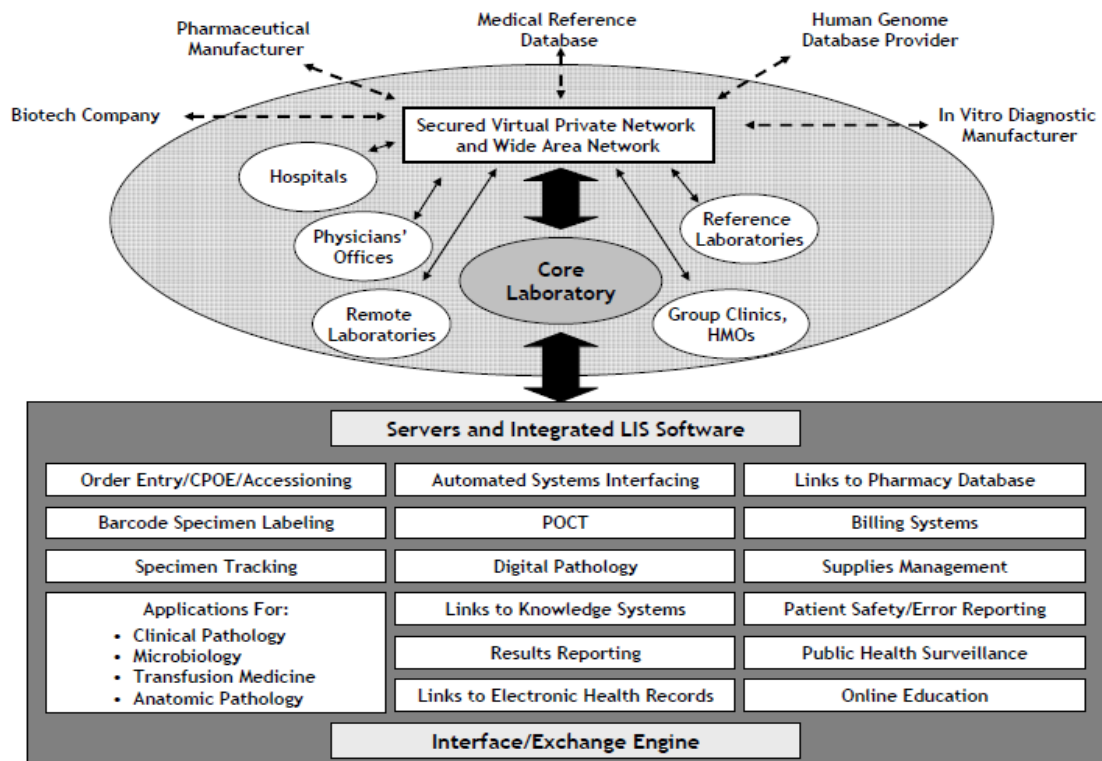
Adapted from: Cooper SD. The role of the laboratory information system in diagnostic services. In: Clinical diagnostic technology: the total testing process. Volume 1: the preanalytic phase. Ward-Cook KM, Lehmann CA, Schoeff LE, Williams RH, ed. Washington, DC: AACC Press, 2003.

This is an integrated laboratory information system which includes hospitals, outpatient clinics, ambulatory surgery centers, long term care facilities, physicians' offices, hospitals and reference laboratories. Depending on the integrated delivery system or IDS, they may operate across the network or group of networks. Some may even operate in a closed or proprietary environment. The core laboratory serves as the primary testing site for the network where they usually perform non-urgent and complex tests.[6]

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[6] Cooper, SD., "The role of laboratory information system in diagnostic services," Clinical diagnostic technology: the total testing process, 2003, https://www.future**lab**medicine.org/reports%5Cchapter_vi_-_lis.pdf

Order entry/CPOE/accessioning

The integrated systems provide built-in functions for test ordering. Information entered by clinicians into CPOE system will be automatically transferred to the LIS with any available information on laboratory location, time of day and priority status. To provide only the information that is appropriate to the parties, algorithms can be used between LIS and other systems integrated.

Bar Coding

After the specimen is prepared, the bar code is attached. The bar code information contains the necessary information that is fed through LIS. The information includes identification of the health care provider, the patient, the specimen container, what specimen to collect, and the order in which the specimens were drawn. Since the bar codes are unique identifiers, it can be tracked through automated systems when the specimen contained passes through them. Where ever automated scanning is not available, technician can manually enter the bar code information.

Application Systems

Clinical pathology modules including hematology, immunology and toxicology support the order entry, collection, tracking and automation of the processes. In Microbiology, the recorded observation, tests and algorithms can be transferred through the system. In Transfusion medicine, inventory, distribution, quality control and emergency release (with security) can be supported. With the integration systems, Anatomic pathology modules can provide access to patient clinical histories, correlation studies, and links gross and/or microscopic images to case worksheet and patient reports.

Automated systems interfacing

This includes the ability to manage and review large volumes of data, incorporate Quality Control functions to validate data from the workstations and verify the laboratory testing results are within acceptable levels. The system must be able to accommodate repeat testing using the same specimen for the same or different test with the same or different equipment. The system needs to allow manual entry of results and generate automated results and have some capacity to auto verify the reports. There should be a failsafe process to prevent release of potentially invalid data due to abnormal results.

Point of Care Testing

The LIS needs to accept connection to Point of Care testing devices. This includes creating, storing and generating results.

Digital pathology

The LIS needs to provide for the storage, retrieval and dissemination of images that could be generated. This transmission of data includes multimedia communication between laboratories, clinicians and telemedicine.

Links to knowledgebase systems

The system needs to provide laboratory personnel with the ability to access information from outside sources containing clinical, genetic and molecular information

Results reporting

The system must be able to format reports according to standards and communicate these results via fax, email or internet (usually vpn)

Links to EHR

In addition, the system needs to be capable of supporting transmission of data to EHR's both reporting of results and accepting orders for new tests.

Links to pharmacy database

Pharmacy database systems are linked to the lab information system for the selection and management of medications. This helps prevent medical errors. Links are usually from the pharmacy system to the lab information system and not the other way around.

Billing systems

Allows claims for services to be easily generated. Coding of tests are automated, generated from test orders. Billing systems also assist with management, receipt, collections, banking, and reporting of accounts receivable.

Supplies management

Responsible for the managing of the use, ordering and supply inventory in the lab. It helps track lot number, quantity, date received, opened, closed and expired for reagents and other lab supplies

Patient safety and error reporting

Lab personnel are alerted when critical value occurs. Protocols to be followed are provided. Contact info such as name and number of clinician, time the message was delivered and name of the person who received it is documented. Quality assurance functions such as documentation of abnormal results, turnaround time, and comparison to established standards are automated. Diagnostic errors in the lab are tracked thru links between laboratory information systems and laboratory error databases.

Public health surveillance

Incidents of infectious diseases and hospital acquired infections are reported for surveillance and management. Chemical or biological threats, emerging infectious diseases and natural disasters are relayed to the public health networks.

Online education

Knowledge and regulatory requirements are supported by online laboratory manuals and handbooks

6.0 Diagram of Information Architecture

7.0 Origin of Individual Data Elements

Demographics
Content: HL7 2.x for messaging, CCD for document summaries
Vocabulary: HITSP Harmonized codesets for gender, marital status

Problem List
Content: HL7 2.x for messaging, CCD for document summaries
Vocabulary: SNOMED-CT

Medications
Content: NCPDP script for messaging, CCD for document summaries
Vocabulary: RxNorm and Structured SIG

Allergies
Content: HL7 2.x for messaging, CCD for document summaries
Vocabulary: UNII for foods and substances, NDF-RT for medication class, RxNorm for Medications

Progress Notes and Other Narrative Documents (History and Physical, Operative Notes, Discharge Summary)
Content: HL7 2.x for messaging, CCD for document summaries
Vocabulary: CDA Templates

Departmental Reports (Pathology/Cytology, GI, Pulmonary, Cardiology etc.)
Content: HL7 2.x for messaging, CCD for document summaries
Vocabulary: SNOMED-CT

Laboratory Results
Content: HL7 2.x for messaging, CCD for document summaries

Vocabulary: LOINC for lab name, UCUM for units of measure, SNOMED-CT for test ordering reason

Microbiology
Content: HL7 2.x for messaging, CCD for document summaries
Vocabulary: LOINC for lab name/observation

Images
Content: DICOM

Administrative Transactions (Benefits/Eligibility, Referral/Authorization, Claims/Remittance)
Content: X12
Vocabulary: X12, CAQH CORE

Quality Measures
Content: Derived from all the data elements above
Vocabulary: Derived from all the data elements above

Privacy and Security
Transport: HTTPS, SOAP/REST
Transport Orchestration: WS*
Authorization/Access Control: XACML[7]

8.0 Flow of Data Sets between Systems

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[7] Halamka, J., "Data Elements of an EHR," 8 April 2009, http://geekdoctor.blogspot.com/2009/04/data-elements-of-ehr.html