

# Electronic Laboratory Reporting for the Infectious Diseases Physician and Clinical Microbiologist

Rebecca Wurtz<sup>1,2</sup> and Bruce J. Cameron<sup>2</sup>

<sup>1</sup>Northwestern University Feinberg School of Medicine, Department of Preventive Medicine, Chicago Illinois, and

<sup>2</sup>Scientific Technologies Corporation, Tucson, Arizona

**Background.** One important benefit of electronic health information is the improved interface between infectious diseases practice and public health. Electronic communicable disease reporting (CDR), given its legal mandate and clear public health importance, is a significant early step in the sifting and pooling of health data for purposes beyond patient care and billing. Over the next 5–10 years, almost all CDR will move to the internet.

**Methods.** This paper reviews the components of electronic laboratory reporting (ELR), including sifting through data in a laboratory information management system for reportable results, controlled “vocabularies” (e.g., LOINC, Logical Observation Identifiers Names and Codes [Regenstrief Institute], and SNOMED, Systematized Nomenclature of Medicine [College of American Pathologists]), the “syntax” of an electronic message (e.g., health level 7 [HL7]), the implications of the Health Insurance Portability and Accountability Act for ELR, and the obstacles to and potential benefits of ELR.

**Results.** There are several ways that infectious diseases physicians, infection control professionals, and microbiology laboratorians will participate in electronic CDR, including web-based case reporting and ELR, the direct, automated messaging of communicable disease reports from clinical lab information management systems to the appropriate public health jurisdiction’s information system.

**Conclusions.** ELR has the potential to make a large impact on the timeliness and the completeness of communicable disease reporting, but it does not replace the clinician’s responsibility to submit a case report with important demographic and epidemiologic information.

Increasingly, medical and health data is recorded, stored, analyzed, and communicated electronically. This has many benefits for infectious diseases physicians and clinical microbiologists. One important benefit is the improved interface between infectious diseases practice and public health. Some infectious diseases physicians already participate in public health electronic communications networks, including ProMED-mail, the Emerging Infectious Disease network, and local and state “health alert networks.” Electronic communicable disease reporting (CDR) is another facet of electronic health information management [1].

Several state and local health departments have al-

ready moved CDR on-line and have employed Web-enabled user interfaces that are backed by powerful relational databases. Over the next 5–10 years, almost all CDR will move to the internet. There are several ways that infectious diseases physicians, infection control professionals, and laboratorians will participate in this transition, including Web-based case reporting and electronic laboratory reporting (ELR). Web-based case reporting essentially replicates paper-based “yellow card” or morbidity card reporting. ELR is a less familiar concept, but, of the two, it has the greater potential to improve the timeliness and completeness of CDR. However, microbiology, with its ever-changing nomenclature and the emergence of new species and serotypes, creates special challenges to any attempt to systematize and automate electronic communication. This article summarizes the important principles of ELR for infectious diseases physicians and laboratory professionals. Because medicine, public health, and information technology are acronym-rich fields, a glossary is provided (table 1).

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Reprints or correspondence: Dr. Rebecca Wurtz, Feinberg School of Medicine, Dept. of Preventive Medicine, Ste. 1102, 680 N. Lake Shore Dr., Chicago, IL 60611 (rwurtz@northwestern.edu).

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**Table 1. Glossary of some acronyms used in public health and information technology.**

Acronym	Expansion
HL7	Health Level 7
LIMS	Laboratory information management system
LOINC	Logical Observation Identifiers Names and Codes
NCMT	Nationally Notifiable Conditions Mapping Tables
NEDSS	National Electronic Disease Surveillance System
OBR	Observation request
OBX	Observation result
PHIN	Public Health Information Network
PHIN MS	Public Health Information Network Messaging System
PHLIS	Public Health Laboratory Information System
SFTP	Secure File Transport Protocol
SNOMED	Systematized Nomenclature of Medicine

## ELECTRONIC LABORATORY REPORTING

Over the last decade, some laboratories, especially reference laboratories, have transmitted some high-volume laboratory results (e.g., sexually transmitted infection test results) in an electronic file format, via the internet or on a disk sent by regular mail. When the file arrives at the health department, it must be opened and the data must be distributed to the appropriate programs and databases, either electronically or on paper. The Public Health Lab Information System (PHLIS) of the Centers for Disease Control and Prevention (CDC) is a nationwide MS-DOS (Microsoft Disk Operating System)-based laboratory surveillance system; state health departments input laboratory data on reportable laboratory isolates [2].

ELR is the direct, automated messaging of reportable disease laboratory information from clinical laboratory information management systems (LIMS) directly to the appropriate public health jurisdiction's CDR system. When the report arrives, a case report is created by the CDR system, and a communicable disease investigator is alerted.

ELR is particularly useful for conditions where the diagnosis can be based solely on positive results from laboratory testing (e.g., *Chlamydia* and *Salmonella* infection and gonorrhea, among others). Toxic shock syndrome, Lyme disease, and the various categories of syphilis (e.g., congenital, primary, and secondary) require clinical input for diagnosis.

ELR can be used for other communicable disease public health surveillance purposes, including tracking the volume of test ordering (e.g., the number of influenza cultures ordered) to detect outbreaks at the earliest possible moment [3], and tracking the reporting of other laboratory-diagnosed noncommunicable disease public health problems, such as lead [4], mercury, and carbon monoxide poisoning; animal disease reporting; and food, drug, and dairy surveillance.

The goal of ELR is to minimize the human effort required

to report cases and to improve the speed and completeness of reporting. "Completeness" refers to both the information provided in the report and the proportion of diagnosed cases reported. Far fewer cases of communicable disease are reported than are diagnosed in the microbiology laboratory [5–7]. Several studies have documented that CDR is faster [8, 9] and more complete with ELR [10]. In Hawaii, electronic reporting of 5 conditions resulted in a 2.3-fold increase in the number of reports, which arrived at the public health jurisdiction an average of 3.8 days earlier than conventional reports [10]. In some studies, electronic reports were likely to have more fields completed than did paper-based reports [10].

## STANDARDS AND ELECTRONIC LABORATORY REPORTING

Virtually all success in electronic data transmission depends on "interoperability," universally shared definitions and methods of transmitting information. This is not a foreign concept for infectious diseases physicians, who understand the elemental importance of case definitions. The most important components of interoperability—vocabulary (the words), syntax (the "sentence" structure), and messaging protocols (the method of delivery) [11]—are especially critical for automated electronic data transmission. The CDC has been at the forefront of proposing frameworks and standards for the collection, maintenance, analysis, and dissemination of electronic data of public health importance [12, 13]. The CDC's effort toward the National Electronic Disease Surveillance System (NEDSS)—now more broadly referred to as the Public Health Information Network (PHIN) initiative—has focused on CDR, providing a model for database architecture, messaging and vocabulary standards, and the development of a reporting system. Professional organizations with an interest in improving the interface between electronic health information and public health, including the National Association of City and County Health Organizations, the Council of State and Territorial Epidemiologists, the American Public Health Laboratory Association, the Public Health Informatics Institute, the National Association for Public Health Information Technology, and the National Association for Public Health Statistics and Information Systems, have also been instrumental in the progress of ELR.

## VOCABULARY

The definition of "vocabulary" in this context does not differ from its definition in Webster's dictionary: a group of terms arranged and defined. Two health care vocabularies—LOINC (Logical Observation Identifiers Names and Codes; Regenstrief Institute) and SNOMED (Systematized Nomenclature of Medicine; College of American Pathologists)—have been endorsed by the US Department of Health and Human Services and the

CDC in their efforts to promote interoperable health and public health information systems. LOINC [14] is an exhaustive catalogue of all diagnostic tests (including chemistry, hematology, and microbiology), as well as other diagnostic observations (e.g., electrocardiography reports). Each test has been distinguished by source (e.g., serum, sputum, or stool), method (e.g., ELISA, culture, or DNA amplification), and the format in which the result is represented (ordinal [e.g., positive or negative, or present or absent], nominal [the name of an organism], titer [e.g., 1:8], or quantitative [e.g., 15 mg/dL]). The LOINC number describes a test, but does not provide the result of a specific test.

Pathologists were among the first doctors to recognize the need for a standardized way to name the results of tests. In the mid-1960s, pathologists began to systematize diagnostic concepts. SNOMED (<http://www.snomed.org>) [15] has gone through several versions and subset versions (e.g., SNOMED-CT or SNOMED-Clinical Terminology). SNOMED distinguishes concepts for the condition (e.g., pertussis) and the causative organism (*Bordetella pertussis*).

LOINC and SNOMED complement each other; the LOINC number describes the test performed, and the SNOMED code names the result. Thus, simplistically, the LOINC/SNOMED combination is the same as “order/result.” For example, LOINC number 600–7 describes a blood culture. SNOMED concept identifier 17872004 describes a result: *Neisseria meningitidis*. Together, they describe a blood culture positive for *N. meningitidis*. The same LOINC number might describe a blood culture with a different result, *Brucella melitensis*, for example, and a different SNOMED concept identifier, 72829003. A LOINC number can describe an organism-specific test, such as a test for a specific antigen. The result is reported as “detected” or “not detected,” for which there is no SNOMED concept. The SNOMED concept identifier would not be necessary, however, because the word “detected” reflexively names the condition on the basis of the LOINC number. For example, LOINC number 13956–8 describes a test to detect *Mycobacterium tuberculosis* DNA in the sputum, and it is performed by probing a PCR-amplified target. “Positive,” “present,” or “detected” might appear in the “result” portion of a message.

Although LOINC and SNOMED are the accepted vocabularies for clinical test ordering and reporting in the United States (and in other parts of the world), they are far from ideal for public health and ELR purposes. Both were developed initially for billing and patient care purposes, there is redundancy in LOINC numbers (because of individual laboratory’s desires to maintain “separate but equal” codes), few LIMSs have actually incorporated LOINC and SNOMED, and new diseases (e.g., severe acute respiratory syndrome or infection due to a new salmonella serotype) cannot be added rapidly. Efforts are underway to modify both LOINC and SNOMED to improve their

public health applicability [16] and to encourage LIMS vendors to use them.

## **“MAPPING” TO LOINC AND SNOMED: NATIONALLY NOTIFIABLE CONDITIONS MAPPING TABLES**

As noted above, at the present time, few LIMSs use LOINC and SNOMED. Many LIMSs record the order for and the result of a laboratory test using local alphanumeric codes specific to that laboratory or to a particular vendor’s LIMS. Mapping—determining which of the thousands of LOINC/SNOMED code combinations match a laboratory’s local test and result—is a surprisingly complex and tedious job. The CDC recently (May 2004) published the “Nationally Notifiable Conditions Mapping Tables” (NCMT) [17]. These tables, successors to the Dwyer Tables, exhaustively “map,” or associate, LOINC numbers to nationally notifiable (and some state notifiable) diseases or conditions. In separate tables, SNOMED concepts are mapped to the same notifiable diseases and conditions. These tables serve as the basis for mapping local LIMS codes to standard codes.

In theory, each possible routine microbiologic culture described by a LOINC number (in a format that includes the source of the specimen, the methodology used, and the result achieved) would need to be coupled with each possible reportable outcome (e.g., for *Salmonella*, this exceeds 2300 serotypes). In practice, however, many combinations are not possible (e.g., blood culture and *Treponema pallidum*) or likely (e.g., burn-wound culture and *N. gonorrhoeae*). When only the possible and likely (and reportable) combinations are included, the number of NCMT entries decreases from >25,000 to ~3400.

## **SYNTAX**

In addition to agreeing on the meanings of terms and order/result pairings in an electronic message, the sender (usually the LIMS) and the receiver (usually the public health database) must agree on the order—the “sentence” structure or syntax—in which those terms are transmitted. A human can interpret the meaning of a Yoda-like disordered sentence (e.g., “walk in park I will”), but a machine cannot. The Health Level 7 (HL7) [18] organization provides the most widely accepted rules for the syntax of health-related messages. A number of organizations and documents specify how HL7 is to be used in public health ELR [19, 20].

Although complex, HL7 rules are straightforward. HL7 messages are divided into “segments,” and each segment is divided into “elements.” Each segment in an ELR contains different portions of the message, which include the demographic characteristics of the patient, information identifying the laboratory, and the ordering health care provider. There are 2 places that a LOINC number may appear in an HL7 message. The OBR (observation request) segment is analogous to a labora-

tory request form: “here is the specimen, please do this test (LOINC number).” The OBX (observation result) segment reports the test results. The LOINC number may be found again, in the OBX-3 element, to let the receiver know which test was done. The actual result of the test is indicated in OBX-5 by a SNOMED identifier, a result value (e.g., “positive” or “31 mg/dL”), or the name of an organism written (and potentially misspelled) in any of a number of ways (e.g., “*Staphylococcus aureus*,” “*Staph aureus*,” or “*S. aureus*”).

## MESSAGING PROTOCOLS AND SECURITY

Once the meaning and the structure in the message have been standardized, the sending and receiving parties have to agree on the manner in which the message will be sent (i.e., the “messaging protocol” or “transport protocol”). If the receiver is standing at the fax machine and the sender transmits the message via a carrier pigeon, the 2 parties will not communicate. In addition, the message must be encoded or encrypted, in case it is intercepted by an inappropriate party. The file transport protocol is usually selected on the basis of the type of sending and receiving information systems and the level of security that is desired. Security options for ELR range from the secure file transport protocol (SFTP) to the CDC’s proposed Public Health Information Network Messaging System (PHIN MS).

From low-volume sources of data, daily results may be batched and transported at night. From high-volume sources (large hospital or referral laboratories or the state public health laboratories), ELRs may be transmitted in the form of nearly continuous, discrete “messages” as laboratory result reports are completed, then formatted into HL7 and transmitted to the public health jurisdiction’s CDR system.

## THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT AND ELR

CDR is a legally authorized and required activity in all states and territories. The Health Insurance Portability and Accountability Act (HIPAA) permits a provider and/or the provider’s medical records department or staff to report a patient’s medical information pertaining to a communicable disease, without the patient’s authorization, to the appropriate public health jurisdiction, in accordance with state laws and rules regarding communicable disease reporting. The HIPAA exemption is not affected by the manner in which the information is transferred or maintained (e.g., electronically or on paper, automated transmission or manual).

Although HIPAA requires that a covered entity, such as a provider, must account for each disclosure of protected health information without the patient’s authorization, simplified accounting is explicitly allowed for multiple disclosures for the same purpose [21]. According to the CDC and the Department of Health and Human Services, “where the covered identity

has, during the accounting period, made multiple disclosures to the same recipient for the same purpose, the Privacy Rule provides for a simplified means of accounting. In such cases, the covered entity need only identify the recipient of such repetitive disclosures, the purpose of the disclosure, and describe the PHI routinely disclosed” [22]. A LIMS that is programmed to automatically transmit reportable results to a specified public health jurisdiction can generate a daily or weekly list of reports for accounting purposes.

## OBSTACLES TO ELR AND SOME SOLUTIONS

Many obstacles exist for effective ELR. These include, first and foremost, the fact that many clinical laboratories do not have an electronic LIMS. Of those that do, most LIMSs do not use LOINC, SNOMED, and HL7; instead, they use “local codes” (or worse, a combination of local codes and free text) to indicate the test ordered and its result. In such situations, local LIMS codes must be “mapped” to standard codes. When ELR is initiated in a public health jurisdiction, infectious diseases physicians and clinical microbiologists and immunologists may participate in correlating local LIMS codes with LOINC and SNOMED standards.

Ideally, ELR includes the automated and continuous “sifting” of all laboratories results for reportable results. One approach to incorporating automated sifting into a LIMS is to create a reflex “test” record for every test that yields a reportable result. Rules must be written to identify a positive result for a notifiable disease. What counts as a positive result will vary, depending on the nature of the test. For example, a positive blood culture result is reportable if the isolate is *Neisseria meningitidis*, but not if the isolate is *Enterobacter*. An individual laboratory may define a local threshold for positive results of serologic testing. When a reportable result is identified, a new record—the reportable test:reflex—is created. All reportable test:reflex records are sent to the public health jurisdiction’s information system, and a copy is created for facility record-keeping purposes (if desired), but the reflex record is not sent to the hospital or health care information system.

Many LIMSs do not include extensive information on the source-patient’s demographic characteristics, lacking basic information such as the patient’s address, which is available in the associated health care information system but not necessarily in the LIMS. Although some studies have shown that ELR increases the number of fields that have data [10], some have found that fewer fields are completed [23]. Information can be gathered from the health care information system to include in the ELR, but this requires more programming; hence, it is more expensive. Thus ELR may shift some of the work of obtaining basic demographic and epidemiologic information from the laboratory and infection control professionals to health department personnel.

When new test methodologies (e.g., susceptibility testing by molecular probe) and diseases (e.g., severe acute respiratory syndrome) emerge, coding and rules for the appropriate diagnostic tests must be added to the LIMS and the CDR system. Thus, mapping is an ongoing task.

Many conditions require more than laboratory data to meet a case definition. However, an electronic laboratory report sent to the public health jurisdiction's CDR system will alert a communicable disease investigator, who will initiate an investigation to see if the case meets the definition.

## BENEFITS TO HEALTH CARE PROVIDERS

Although health care providers have been slow to embrace the use of electronic health records, ELR will ultimately decrease the paperwork burden on providers and improve reporting. However, ELR may require the laboratory and infection control professionals to interact in new and different ways to fulfill communicable disease reporting responsibilities. ELR will decrease the laboratory's, and perhaps the infection control professionals', paperwork for the submission of laboratory information about reportable diseases. It will provide documentation of reports for internal records, and, if desired, for compliance with HIPAA rules.

Although the sending laboratory can share the report generated by its LIMS with appropriate infection control professionals and health care providers, the laboratory and providers cannot retrieve data—other than the data they have entered—from the CDR system. This would be analogous to the microbiologist and the provider going to the health department and opening its file drawers. The information gathered in a communicable disease investigation is not a clinical record and does not belong to the clinician or the case. Many CDR systems “give back” by providing real-time or close to real-time aggregated and geographically mapped data (e.g., data collected on the West Nile virus infection or influenza) to clinicians.

## CONCLUSION

Many people see profound and beneficial changes occurring as a result of electronic health data [24]. Electronic CDR, because of its legal mandate and clear importance for public health, is a significant first step in the sifting and pooling of health data for purposes beyond patient care and billing. Although developing a controlled vocabulary for automated CDR is challenging because of the dynamic nature of microbiology, it will pave the way for gathering other information critical to improving health care.

ELR does not replace the astute clinician or the public health epidemiologist and does not replace the direct, immediate communication from clinician to the health department in situations involving a serious concern. It does not replace the cli-

nician's responsibility to submit a case report with important demographic and epidemiologic information. However, ELR will improve the completeness and timeliness of reporting for conditions that depend on laboratory results for reporting, such as foodborne disease, invasive bacterial diseases, and sexually transmitted infections.

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