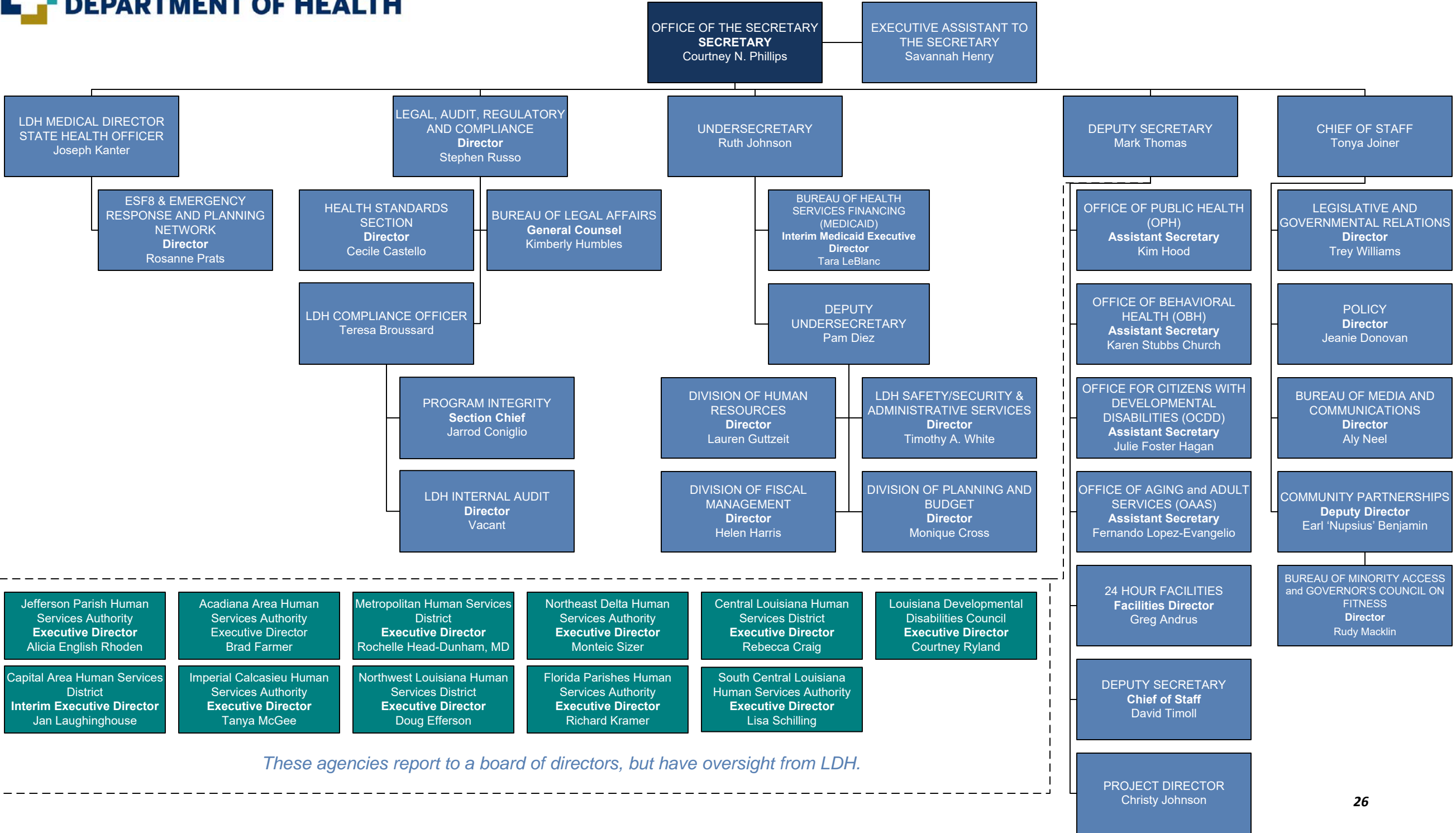


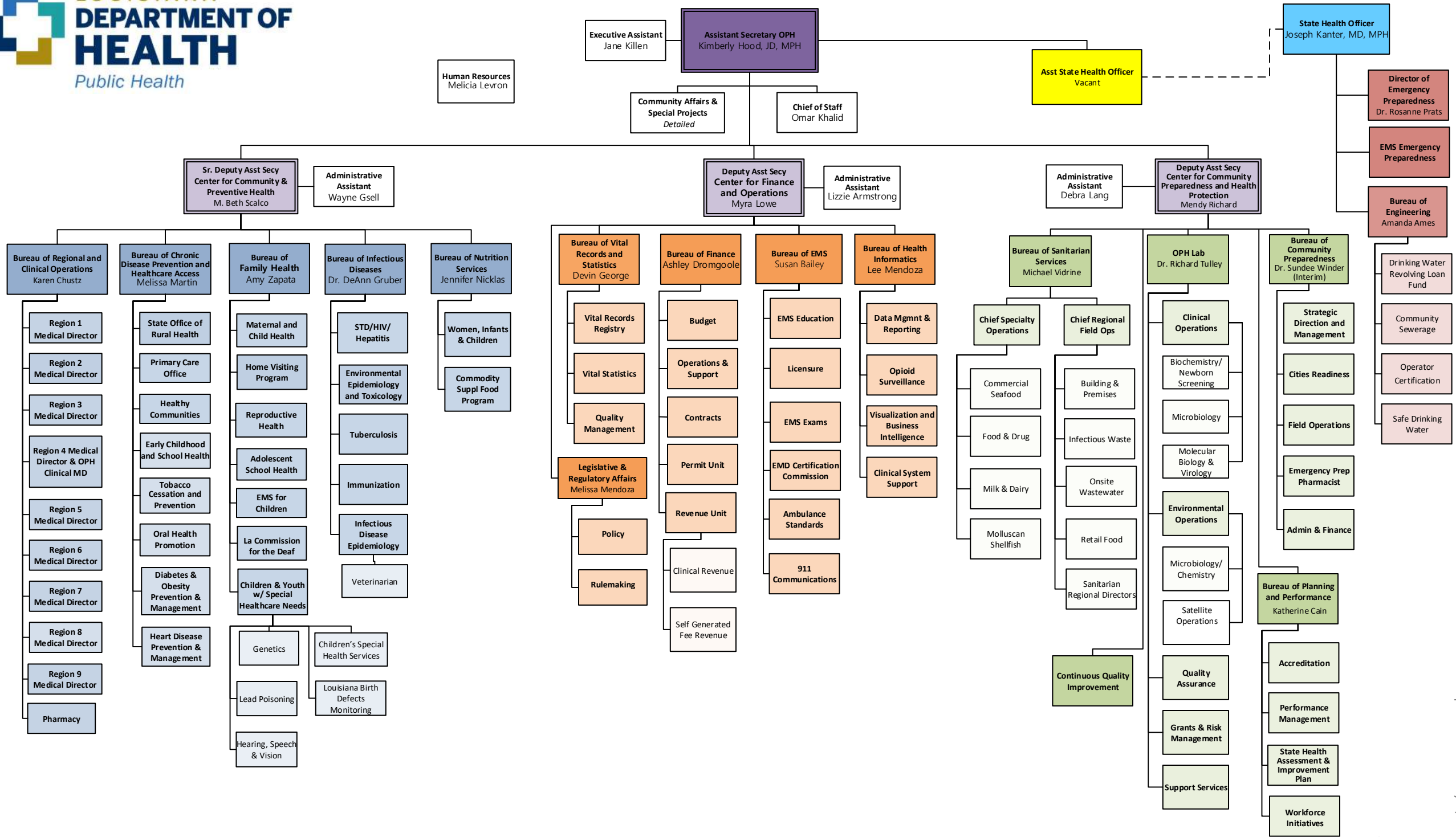
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Original	July 15, 2021

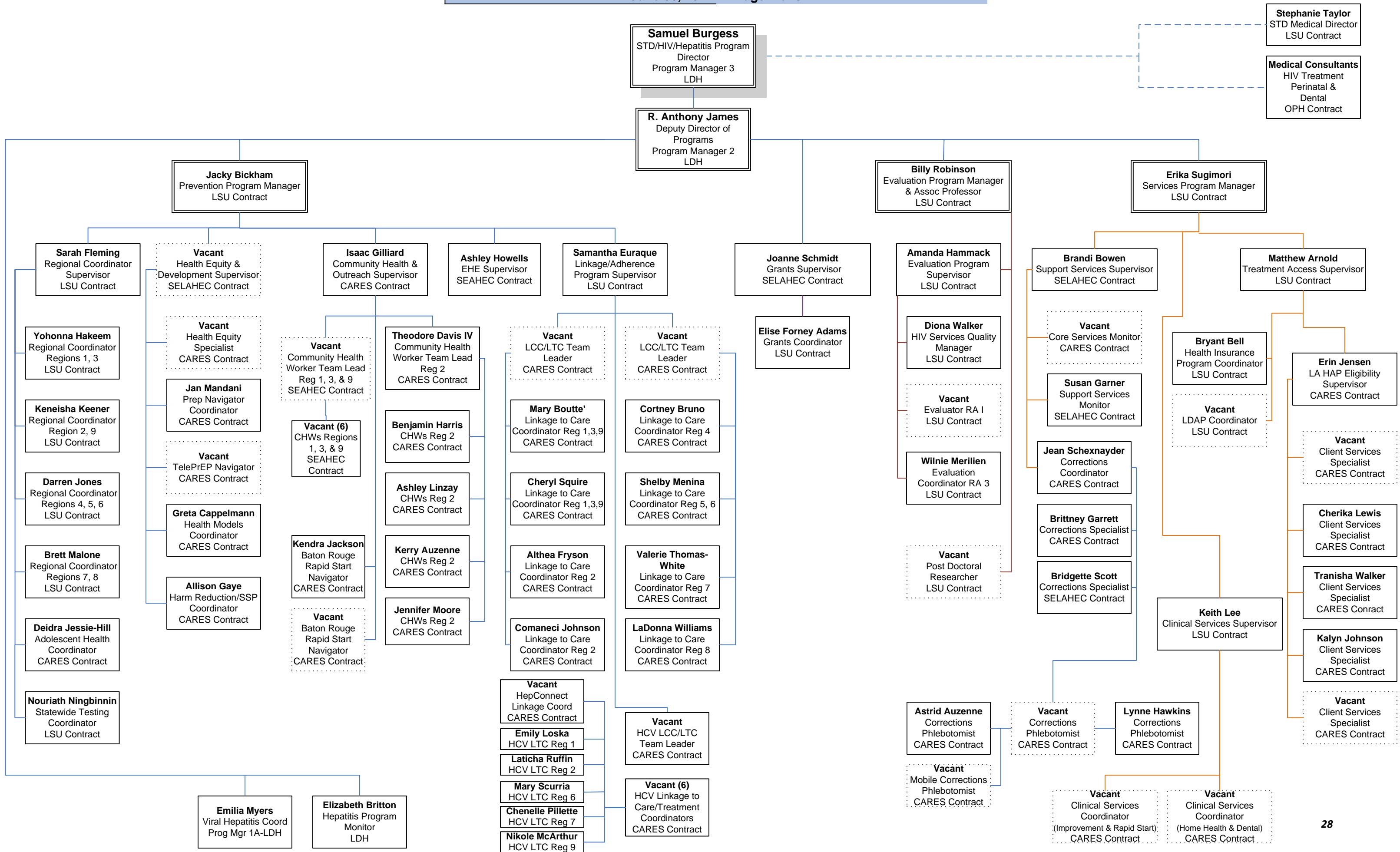
ORGANIZATIONAL CHART





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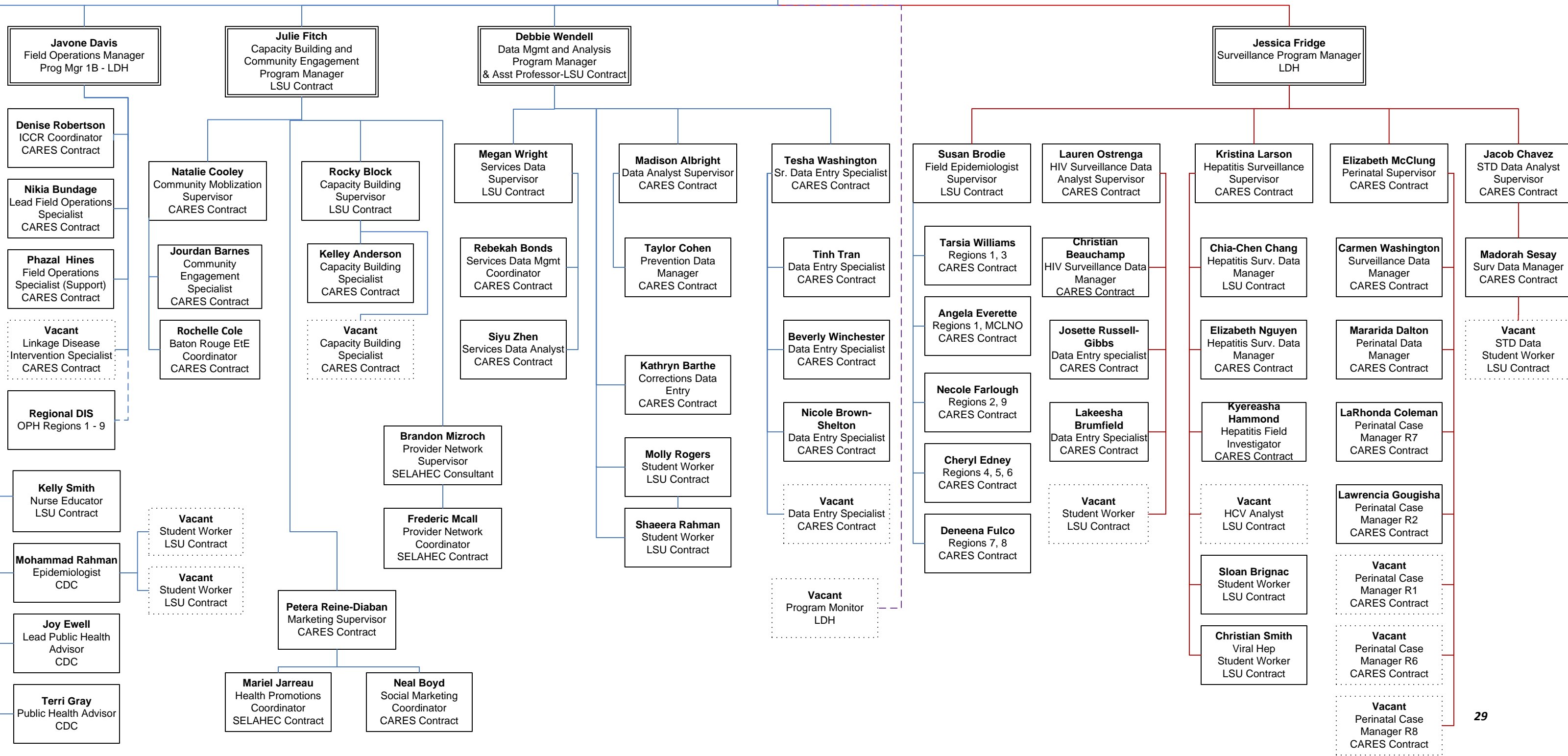


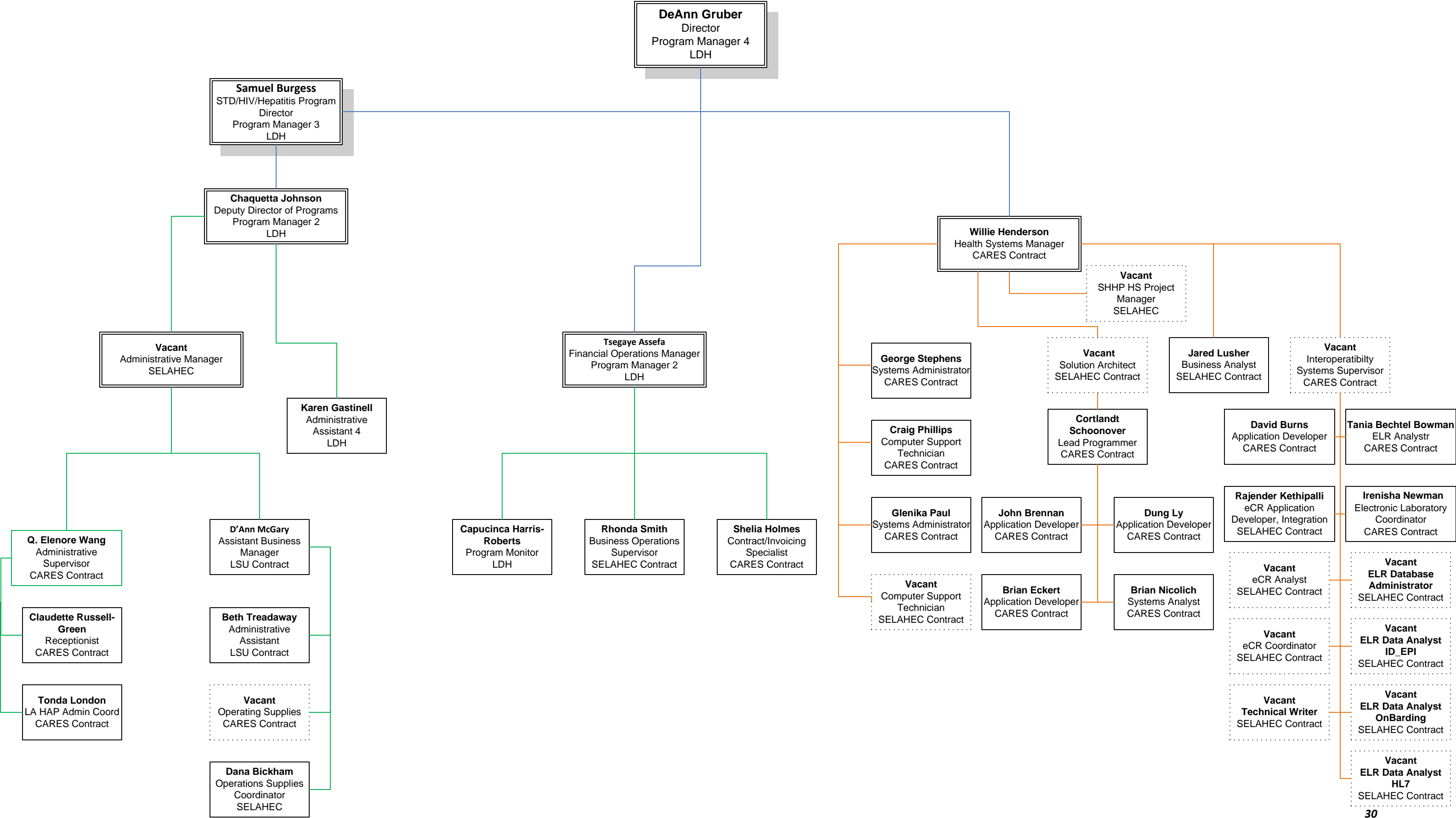
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Samuel Burgess
STD/HIV/Hepatitis Program
Director
Program Manager 3 LDH

Chaquetta Johnson
Deputy Director of
Operations
Program Manager 2
LDH





Appendix 4: Cluster Workgroup Members

NAME	TITLE
Samuel Burgess	Director, SHHP
Anthony James	Deputy Director
Chaquetta Johnson	Deputy Director
Jessica Fridge	Surveillance Manager
Jacky Bickham	Prevention Manager
Erika Sugimori	Services Manager
Julie Fitch	Capacity Building and Community Mobilization Manager
Javone Davis	Regional Operations Manager
Lauren Ostrenga	HIV Surveillance Supervisor – Data Analyst
Sarah Fleming	Regional Coordinator Supervisor
Susan Brodie	Field Epidemiologist Supervisor
Joy Ewell	CDC Public Health Advisor
Samantha Euraque	Linkage/Adherence Program Supervisor
Alison Gaye	Statewide Syringe Services Program Coordinator
Jimmy Gale	Community Mobilization Supervisor
Rocky Block	Capacity Building Supervisor
Position Currently Vacant	Hepatitis Program Coordinator
Position Currently Vacant	Outbreak Response Coordinator

Title 51

PUBLIC HEALTH—SANITARY CODE

Part II. The Control of Diseases

Chapter 1. Disease Reporting Requirements

§101. Definitions [formally paragraph 2:001]

A. Unless otherwise specifically provided herein, the following words and terms used in this Part and all other Parts which are adopted or may be adopted, are defined for the purposes thereof as follows.

Carbon Monoxide—carbon monoxide (CO) is a colorless, odorless, poisonous gas produced through incomplete combustion of carbon-based fuels, including gasoline, oil, and wood.

Carrier—a person, who without apparent symptoms of a communicable disease, harbors the specific infectious agent and may serve as a source of infection. The carrier state may occur with infections unapparent throughout their course, and also as a feature of incubation period, convalescence, and post-convalescence of a clinically recognizable disease.

Case—a particular instance of disease.

Case of Arsenic Exposure—any medical condition/visit resulting from arsenic exposure as determined from the exposure history or patient statement and/or injury resulting from inhalation, ingestion, dermal exposure or ocular contact with arsenic. Laboratory test results for arsenic: includes results of arsenic tests (blood, urine, or tissue samples), regardless of test result.

Case of Cadmium Exposure—any medical condition/visit resulting from cadmium exposure as determined from the exposure history or patient statement and/or injury resulting from inhalation, ingestion, dermal exposure or ocular contact with cadmium. Laboratory test results for cadmium: includes results of cadmium tests (blood, urine, or tissue samples), regardless of test result.

Case of Carbon Monoxide Exposure—any medical condition/visit resulting from carbon monoxide exposure as determined from the exposure history or patient statement and/or injury resulting from inhalation contact with carbon monoxide. Laboratory test results for carbon monoxide includes results of carboxyhemoglobin tests (blood samples), regardless of test result.

Case of Lead Exposure—any medical condition/visit resulting from lead exposure as determined from the exposure history or patient statement and/or injury resulting from inhalation, ingestion, dermal exposure or ocular contact with lead. Laboratory test results for lead: includes results of lead tests (blood, urine, or tissue samples), regardless of test result.

Case of Mercury Exposure—any medical condition/visit resulting from mercury exposure as determined from the exposure history or patient statement and/or injury resulting from inhalation, ingestion, dermal exposure or ocular contact with mercury. Laboratory test results for mercury: includes results of mercury tests (blood, urine, or tissue samples), regardless of test result.

Case of Perinatal Exposure to Human Immunodeficiency Virus (HIV)—any instance of a live birth to a woman in whom HIV infection was present prior to the birth (indicated by maternal or neonatal HIV testing). Laboratory test results for perinatal exposure to HIV include results of HIV-related tests for any child 0 to 6 years of age, regardless of test result.

Case of Perinatal Exposure to Treponema Pallidum—any instance of a live birth or stillbirth to a woman in whom syphilis infection was present prior to the birth (indicated by maternal or neonatal syphilis testing).

Case of Pesticide-Related Illness and Injury—any medical condition/visit resulting from pesticide exposure as determined from the exposure history or patient statement and/or acute, subacute, or chronic illness or injury resulting from inhalation, ingestion, dermal exposure or ocular contact with a pesticide. Laboratory test results for pesticide-related illness and injury includes results of cholinesterase tests (plasma and red blood cell), regardless of test results, for which the purpose of the test was possible pesticide exposure; and tests of pesticides or metabolites in blood, urine, or tissue samples, regardless of test results.

Communicable Disease—an illness due to a specific infectious agent or its toxic products, which arises through transmission of that agent or its products from a reservoir to susceptible host, either directly as from an infected person or animals, or indirectly through the agency of an intermediate plant or animal host, a vector or the inanimate environment.

Contact—any person who has been in such association with an infected person or animal or with a contaminated environment as to have had opportunity to acquire the infection.

Day Care Center—this term as defined in Part XXI.101.A of this code.

Isolation—the separation for the period of communicability of infected persons from other persons, in such places and under such conditions as will prevent the direct or indirect conveyance of the infectious agent from infected persons to persons who are susceptible or who may spread the agent to others.

Louisiana Immunization Network (“LINKS”)—the official *Louisiana* immunization information registry system, authorized by R.S. 40:31.13 and maintained by the Louisiana Department of Health, Office of Public Health (LDH-OPH).

Pesticide—any pesticide defined in the Louisiana Pesticide Law (Louisiana Revised Statutes Title 3, Chapter 20, 1999) as now stated and as may be amended in the future. Pesticides include but are not limited to insecticides, herbicides, rodenticides, repellants, fungicides, and wood treatment products.

Quarantine—the limitation of freedom of movement of such well persons or domestic animals as have been exposed to a communicable disease for a period of time equal to the longest usual incubation period of the disease, in such manner as to prevent effective contact with those not so exposed.

NOTE: In connection with the control of communicable diseases, the term *quarantine* is frequently used interchangeably with the term *isolation* as defined above in this Paragraph. At times, the two terms may be used together, as in an *isolation/quarantine order* pursuant to R.S. 40:4(A)(13), and further pursuant to §§117-121 in the body of this Part in this code pertaining to the Control of Diseases.

Reportable Disease—any disease or condition for which an official report is required by the state health officer.

AUTHORITY NOTE: The first source of authority for promulgation of the sanitary code is in R.S. 36:258(B), with more particular provisions found in Chapters 1 and 4 of Title 40 of the Louisiana Revised Statutes. This Part is promulgated in accordance with the specific provisions of R.S. 40:4(A)(2) and R.S. 40:5(1)(2) and (10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1212 (June 2002), amended LR 32:1050 (June 2006), LR 34:2173 (October 2008), repromulgated LR 34:2582 (December 2008), LR 36:1014 (May 2010), amended by the Department of Health, Office of Public Health, amended LR 45:667 (May 2019), LR 46:589 (April 2020).

§103. Public Notice of Reportable Diseases [formerly paragraph 2:002]

A. Those diseases to be reportable will be publicly declared by the state health officer and when any disease is so declared to be a reportable disease, the regulation herein provided shall apply thereto. The state health officer may, at his discretion, from time to time, by public notice, add to or delete from the list of reportable diseases. When a disease is added to the list, the regulations herein pertaining to the reporting of disease shall apply to said disease.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1212 (June 2002).

§105. Reportable Diseases and Conditions [formerly paragraph 2:003]

A. It is hereby made the duty of every physician practicing medicine in the state of Louisiana to report to the

state health officer, according to the requirements of this Section and utilizing the appropriate method(s) of reporting required under Subsection E of this Section, any case or suspected case of reportable disease or condition which he or she is attending, or has examined, or for which such physician has prescribed. The report shall be made promptly at the time the physician first visits, examines or prescribes for the patient, and such report shall state the name, age, sex, race, usual residence, place where the patient is to be found, the nature of the disease or condition and the date of onset, and the pregnancy status of the patient (if the pregnancy status is known and if it is clinically relevant to the disease or condition being reported). Reports of occupational disease/injury shall state contact information of the reporting person as well as the patient’s name, contact information, age (or date of birth), sex, race/ethnicity, usual residence, occupation, employer information, the nature of the disease or injury, and the date of diagnosis.

B. Any physician, whether Louisiana resident or non-resident, engaged in the practice of medicine at any federal installation or on any vessel, train or other common carrier, which enters any port, station or place in the state of Louisiana, is required to report as specified in Subsection A of this Section.

C. It shall be the duty of every osteopath, coroner, medical examiner, dentist, homeopath, infection control practitioner, laboratory director, medical records director, nurse, nurse midwife, nurse practitioner, pharmacist, physician assistant, podiatrist, poison control center, social worker, veterinarian, and any other health care professional to report a positive laboratory result or a confirmed or suspected case of any reportable disease or condition as required by this Section utilizing the appropriate method(s) of reporting required under Subsection E of this Section in which he or she has examined or evaluated, or for which he or she is attending or has knowledge. In the absence of a health care professional responsible for reporting as stated in the prior sentence (or a physician as referenced in Subsections A and B of this Section), it shall be the duty of the director, chief administrative officer, or other person in charge of any facility, program, or other entity that requires or conducts testing for reportable diseases or conditions, to report a positive laboratory result or a confirmed or suspected case of any reportable disease or condition as required by this Section utilizing the appropriate method(s) of reporting required under Subsection E of this Section.

D. The following diseases or conditions are hereby declared reportable with reporting requirements by class.

1. Class A Diseases or Conditions which Shall Require Reporting within 24 Hours

a. Class A diseases or conditions include diseases or conditions of major public health concern because of the severity of the disease or condition and the potential for epidemic spread. Class A diseases or conditions shall be reported to the Office of Public Health by telephone (or in another electronic format acceptable to the Office of Public Health) immediately upon recognition that a case, a

suspected case, or a positive laboratory result is known. In addition, all cases of rare or exotic communicable diseases, unexplained death, unusual clusters of disease and all outbreaks shall be reported. Any class A disease or condition, rare or exotic communicable disease, unexplained death, or unusual cluster of disease and any disease outbreak, shall be reported to the Office of Public Health as soon as possible but no later than 24 hours from recognition that a case, a suspected case, a positive laboratory result, an unexplained death, an unusual cluster of disease, or a disease outbreak is known. The following diseases or conditions shall be classified as class A for reporting requirements:

- i. *Acinetobacter* spp., carbapenem-resistant;
- ii. acute flaccid paralysis, including acute flaccid myelitis;
- iii. amoeba (free living) infection (including *Acanthamoeba*, *Naegleria*, *Balamuthia* and others);
- iv. anthrax;
- v. avian or novel strain influenza A (initial detection);
- vi. botulism;
- vii. brucellosis;
- viii. *Candida auris*, as well as common misidentifications of *C. auris* (e.g., *C. haemulonii*, *C. duobushaemulonii*, *C. famata*, *C. sake*, *C. lusitanae*, *C. parapsilosis*, *C. catenulata*, *C. guilliermondii*, and *Rhodotorula glutinis*);
- ix. cholera;
- x. *Clostridium perfringens* food-borne illness;
- xi. Coronavirus Disease 2019 (COVID-19)/Infections with SARS-CoV-2;
- xii. diphtheria;
- xiii. Enterobacteriaceae, carbapenem-resistant;
- xiv. fish or shellfish poisoning (domoic acid poisoning, neurotoxic shellfish poisoning, ciguatera, paralytic shellfish poisoning, scombroid);
- xv. food-borne illness;
- xvi. glanders (*Burkholderia mallei*);
- xvii. *Haemophilus influenzae* (invasive infection);
- xviii. influenza-associated mortality;
- xix. measles (rubeola, imported or indigenous);
- xx. melioidosis (*Burkholderia pseudomallei*);
- xxi. *Neisseria meningitidis* (invasive infection);
- xxii. outbreaks of any infectious diseases;
- xxiii. pertussis;
- xxiv. plague (*Yersinia pestis*);
- xxv. poliomyelitis (paralytic and non-paralytic);

- xxvi. *Pseudomonas aeruginosa*, carbapenem-resistant;
- xxvii. Q fever (*Coxiella burnetii*);
- xxviii. rabies (animal and human);
- xxiv. ricin poisoning;
- xxx. rubella (congenital syndrome);
- xxxi. rubella (German measles);
- xxxii. SARS (SARS-CoV-1 infection);
- xxxiii. *Staphylococcus aureus*, vancomycin intermediate or resistant (VISA.VRSA);
- xxxiv. staphylococcal enterotoxin B (SEB) pulmonary poisoning;
- xxxv. smallpox;
- xxxvi. tularemia (*Francisella tularensis*);
- xxxvii. viral hemorrhagic fever (Ebola, Lassa, Marburg, Crimean Congo, etc.); and
- xxxviii. yellow fever.

2. Class B Diseases or Conditions which Shall Require Reporting within One Business Day

a. Class B diseases or conditions include diseases or conditions of public health concern needing timely response because of potential for epidemic spread. The following class B diseases or conditions shall be reported to the Office of Public Health by the end of the next business day after the existence of a case, a suspected case, or a positive laboratory result is known:

- i. anaplasmosis;
- ii. arthropod-borne viral infections (including West Nile, Dengue, St. Louis, California, Eastern Equine, Western Equine, Chikungunya, Usutu, Zika, and others);
- iii. aseptic meningitis;
- iv. babesiosis;
- v. Chagas disease;
- vi. chancroid;
- vii. cryptosporidiosis;
- viii. cyclosporiasis;
- ix. *Escherichia coli*, Shiga-toxin producing (STEC), including *E. coli* O157:H7;
- x. granuloma inguinale;
- xi. hantavirus (infection or pulmonary syndrome);
- xii. hemolytic-uremic syndrome;
- xiii. hepatitis A (acute illness);
- xiv. hepatitis B (acute illness and carriage in pregnancy);
- xv. hepatitis B (perinatal infection);

- xvi. hepatitis C (acute illness);
- xvii. hepatitis C (perinatal infection);
- xviii. hepatitis E;
- xix. herpes (neonatal);
- xx. human immunodeficiency virus [(HIV), infection in pregnancy]^{2,6};
- xxi. human immunodeficiency virus [(HIV), perinatal exposure]^{2,6};
- xxii. legionellosis;
- xxiii. listeriosis;
- xxiv. malaria;
- xxv. mumps;
- xxvi. salmonellosis
- xxvii. shigellosis;
- xxviii. syphilis¹
- xxix. syphilis [(*Treponema pallidum*), infection in pregnancy]^{1,6}
- xxx. syphilis [(*Treponema pallidum*), perinatal exposure]^{1,6};
- xxxi. tetanus;
- xxxii. tuberculosis³ due to *Mycobacterium tuberculosis*, *bovis* or *africanum*;
- xxxiii. typhoid fever;
- xxxiv. *Vibrio* infections (other than cholera); and
- xxxv. Zika virus-associated birth defects.

3. Class C Diseases or Conditions which Shall Require Reporting within Five Business Days

a. Class C diseases or conditions shall include diseases or conditions of significant public health concern. The following class C diseases or conditions shall be reported to the Office of Public Health within five business days after the existence of a case, suspected case, or a positive laboratory result is known:

- i. acquired immune deficiency syndrome (AIDS)²;
- ii. aspergillosis;
- iii. blastomycosis;
- iv. campylobacteriosis;
- v. chlamydial infection¹;
- vi. coccidioidomycosis;
- vii. cryptococcosis (*Cryptococcus neoformans* and *C. gattii*);
- viii. ehrlichiosis (human granulocytic, human monocytic, *Ehrlichia chaffeensis* and *ewingii*);

- ix. *Enterococcus*, vancomycin resistant [(VRE), invasive disease];
- x. giardiasis;
- xi. gonorrhea¹ (genital, oral, ophthalmic, pelvic inflammatory disease, rectal);
- xii. Guillain-Barré syndrome;
- xiii. Hansen's disease (leprosy);
- xiv. hepatitis C (infection, other than as in Class B)²;
- xv. histoplasmosis;
- xvi. human immunodeficiency virus [(HIV) infection, other than as in class B]²;
- xvii. human T lymphocyte virus (HTLV I and II) infection;
- xviii. leptospirosis;
- xix. Lyme disease;
- xx. lymphogranuloma venereum¹;
- xxi. meningitis, eosinophilic (including those due to *Angiostrongylus* infection);
- xxii. Nipah virus infection;
- xxiii. non-gonococcal urethritis;
- xxiv. nontuberculous mycobacteria;
- xxv. ophthalmia neonatorum;
- xxvi. psittacosis;
- xxvii. spotted fever rickettsioses [*Rickettsia* species including Rocky Mountain spotted fever (RMSF)];
- xxviii. staphylococcal toxic shock syndrome;
- xxix. *Staphylococcus aureus*, methicillin/oxacillin-resistant [(MRSA), invasive infection];
- xxx. streptococcal disease, group A (invasive disease);
- xxxi. streptococcal disease, group B (invasive disease);
- xxxii. streptococcal toxic shock syndrome;
- xxxiii. *Streptococcus pneumoniae* invasive disease;
- xxxiv. transmissible spongiform encephalopathies (Creutzfeldt-Jakob disease and variants);
- xxxv. trichinosis;
- xxxvi. varicella (chickenpox); and;
- xxxvii. yersiniosis.

4. Class D Special Reportable Diseases or Conditions Shall Require Reporting within Five Business Days

a. Class D diseases or conditions shall include diseases or conditions of significant public health concern.

The following class D diseases or conditions shall be reported to the Office of Public Health within five business days after the existence of a case, suspected case, or a positive laboratory result is known:

- i. cancer;
- ii. carbon monoxide exposure and/or poisoning⁵;
- iii. complications of abortion;
- iv. congenital hypothyroidism⁴;
- v. galactosemia;
- vi. heavy metal (arsenic, cadmium, mercury) exposure and/or poisoning (all ages)⁵;
- vii. hemophilia;
- viii. lead exposure and/or poisoning (all ages)⁵;
- ix. pesticide-related illness or injury (all ages)⁵;
- x. phenylketonuria⁴;
- xi. pneumoconiosis (asbestosis, berylliosis, silicosis, byssinosis, etc.)⁵;
- xii. radiation exposure, over normal limits⁵;
- xiii. Reye's syndrome;
- xiv. severe traumatic head injury;
- xv. severe undernutrition (severe anemia, failure to thrive);
- xvi. sickle-cell disease (newborns);
- xvii. spinal cord injury; and
- xviii. sudden infant death syndrome (SIDS).

5. Class E Reportable Occupational Diseases or Conditions Shall Require Reporting within 10 Business Days⁵

a. Class E diseases or conditions shall include any occupationally-related diseases or conditions of significant public health concern. This includes cases where the work environment is suspected to be the cause of an illness or injury or cases where the work environment is thought to be the cause of an illness exacerbation. Class E diseases or conditions shall be reported to the Office of Public Health, Section of Environmental Epidemiology and Toxicology, Occupational Health and Injury Surveillance Program, within 10 business days after existence of the case, suspected case, or positive test result is known.

E. Case reports not requiring special reporting instructions (see below) can be reported by mail or facsimile [(504) 568-8290 (fax)] on confidential disease report forms, or by phone [call (800) 256-2748 for forms and instructions] or in an electronic format acceptable to the Office of Public Health. When selecting a method of notification, the person or entity submitting a report shall be respectful of the time limitations for the report to be received by the Office of Public Health in accordance with the particular time limitations specified under classes A-D above.

1. ¹Report on STD-43 Form. Report cases of syphilis with active lesions by telephone, within one business day, to (504) 568-7474.

2. ²Report to the Louisiana STD/HIV Program. Visit www.hiv.dhh.louisiana.gov or call (504) 568-7474 for regional contact information.

3. ³Report on CDC72.5 (f.5.2431) card.

4. ⁴Report to the Louisiana Genetic Diseases Program and Louisiana Childhood Lead Poisoning Prevention Programs, www.genetics.dhh.louisiana.gov, or facsimile [(504) 568-8253 (fax)], or call (504) 568-8254 or (800) 242-3112.

5. ⁵Report to the Section of Environmental Epidemiology and Toxicology, Occupational Health and Injury Surveillance Program, www.seet.dhh.louisiana.gov or call (504) 568-8150, toll free at (888) 293-7020, or by fax at (504) 568-8149.

6. ⁶Report to the Louisiana STD/HIV Program on HIV/Syphilis during Pregnancy Reporting Form. Visit www.hiv.ldh.louisiana.gov or by phone at (504) 568-7474.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5(2)(10)(11).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1212 (June 2002), amended LR 32:1050 (June 2006), LR 34:2173 (October 2008), repromulgated LR 34:2582 (December 2008), LR 36:1014 (May 2010), repromulgated LR 36:1253 (June 2010), amended LR 39:1053 (April 2013), LR 41:2653 (December 2015), amended by the Department of Health, Office of Public Health, amended LR 45:667 (May 2019), LR 47:51 (January 2021).

§107. Laboratory and Healthcare Facility Reporting Requirements (Formerly §113)

A. The director of every laboratory and the director of an applicable healthcare facility whether public, private, hospital or other, within or out of the state shall report to the state health officer the results of all tests that are in any way clinically relevant, suggestive or indicative of an individual having active disease, past or present exposure to, past or present contact with and/or past or present association with any of the disease/conditions listed in LAC 51 (Public Health—Sanitary Code), Part II, Chapter 1, §105. The results of the tests to be reported to the state health officer do not have to be conducted for diagnostic reasons, nor do the results have to be diagnostic or confirmatory. The report shall be received in a timely manner consistent with the requirements of the diseases/conditions by class for the diseases/conditions described in §105 of this Chapter and shall state the name, date of birth, sex, race, usual residence, pregnancy status of the individual (if the pregnancy status is known and if it is clinically relevant to the disease or condition being reported), specimen identification code/ID and test results of the tested individual as well as the name of the physician or person submitting the specimen. Contact information for the laboratory or an applicable healthcare facility performing the test(s) shall be provided. Laboratories or an applicable healthcare facility shall not defer their

public health reporting responsibilities to any other authorities within the institutions they serve. In addition, laboratories or an applicable healthcare facility performing tests on specimens received from other laboratories or an applicable healthcare facility shall report to the state health officer all results as prescribed above plus the contact information for the facility/laboratory or an applicable healthcare facility where the specimen originated. Moreover, no considerations, evaluations or concerns, regarding any test technology or test result by institutions and/or organizations whether federal, state or otherwise (e.g., FDA, CMS-CLIA, etc.) which may be overseeing, approving, evaluating or licensing laboratory testing, shall represent an *a priori* rationale for withholding laboratory reports from the state health officer.

B. All laboratory facilities shall, in addition to reporting tests indicative of conditions found in §105, report positive or suggestive results for additional conditions of public health interest. The following findings shall be reported as detected by laboratory facilities:

1. adenoviruses;
2. coronaviruses;
3. enteroviruses;
4. hepatitis B (carriage, other than in pregnancy);
5. hepatitis C (past or present infection), including genotype where available;
6. human metapneumovirus;
7. parainfluenza viruses;
8. respiratory syncytial virus; and
9. rhinoviruses.

C. A reference culture or culture-independent diagnostic test (CIDT) specimen is required to be sent to the Office of Public Health laboratory, or a specialized laboratory as indicated below, for the following microorganisms within five business days of the final identification of the microorganism:

1. *Acinetobacter* spp., pan-resistant; consult with the OPH's Infectious Disease Epidemiology for submission to the CDC's Antibiotic Resistance Laboratory Network (ARLN);

2. *Bacillus anthracis* (confirmed or suspected);
3. *Bordetella pertussis*;
4. *Brucella* spp.
5. *Burkholderia mallei*;
6. *Burkholderia pseudomallei*;
7. *Campylobacter* spp.;

8. *Candida auris* submitted to the CDC's ARLN; consult with the OPH's Infectious Disease Epidemiology for common misidentifications of *C. auris* (e.g., *C. haemulonii*, *C. duobushaemulonii*, *C. famata*, *C. sake*, *C. lusitaniae*, *C.*

parapsilosis, *C. catenulata*, *C. guilliermondii*, and *Rhodotorula glutinis*);

9. *Corynebacterium diphtheriae*;

10. *E. coli* O157:H7 or *E. coli* Shiga toxin producing;

11. Enterobacteriaceae, carbapenem-resistant (excluding *Klebsiella pneumoniae*, *K. oxytoca*, *E. coli*, and *Enterobacter* spp.); consult with OPH's Infectious Disease Epidemiology for submission to the CDC ARLN;

12. *Francisella* spp.;

13. *Klebsiella pneumoniae*, *K. oxytoca*, *E. coli*, and *Enterobacter* spp., carbapenem-resistant;

14. *Listeria* spp.;

15. *Mycobacterium tuberculosis*, *bovis* or *africanum*;

16. *Plesiomonas* spp.;

17. *Pseudomonas aeruginosa*, carbapenem-resistant;

18. *Salmonella* spp.;

19. *Shigella* spp.;

20. *Vibrio* spp.;

21. *Yersinia enterocolitica*; and

22. *Yersinia pestis*.

D. A reference culture or culture-independent diagnostic test (CIDT) specimen is required to be sent to the Office of Public Health laboratory for the following microorganisms if the original culture was from a sterile site (e.g., blood, spinal fluid, other internal fluid, tissue, etc.). Such reference culture shall be sent to the Office of Public Health laboratory within five business days of the final identification of the microorganism:

1. *Haemophilus influenzae* type b or untyped;
2. *Neisseria meningitidis*; and
3. *Streptococcus pneumoniae*.

E. Laboratory reports shall not be construed by the Office of Public Health as diagnosis. In the case of private patients, follow-up of laboratory reports shall be through the physician(s) submitting the specimen(s).

F. Electronic reporting by a laboratory/facility shall include any results, negative or positive, for all components of testing indicative of the following conditions:

1. Coronavirus Disease 2019 (COVID-19)/Infections with SARS-CoV-2;
2. hepatitis C virus;
3. human immunodeficiency virus (HIV), including nucleotide sequences; and
4. syphilis.

G. Laboratories and applicable healthcare facilities are encouraged to report results electronically using Health Level Seven (HL7)-compliant message structure and

appropriate standard Logical Observation Identifiers Names and Codes (LOINC) terminology designating the test(s) performed.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5(2)(10)(11).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1214 (June 2002), amended LR 32:1052 (June 2006), LR 39:1054 (April 2013), LR 41:2655 (December 2015), amended by Department of Health, Office of Public Health, LR 45:669 (May 2019), LR 47:52 (January 2021).

§109. Reports by Emergency Departments (Formerly §105.A.5)

A. Syndromic Surveillance: Reportable Conditions seen at Emergency Departments of Acute Care Hospitals which Shall Require Reporting Electronically within One Business Day of the Visit

1. Emergency department reporting shall include all conditions seen at emergency departments of acute care hospitals. The text content of the chief complaint for the visit or an international classification of disease code shall be reported to the Office of Public Health within one business day of the visit by electronic means as specified by the Office of Public Health.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5(2)(10)(11).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1213 (June 2002), amended LR 32:1051 (June 2006), LR 36:1015 (May 2010), LR 41:2656 (December 2015).

§111. Reports by Hospitals

A. It shall be the duty of all hospitals producing antibiograms detailing the antibiotic sensitivities and resistances of microorganisms in their facility to provide a report annually of antibiogram results to the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5(2)(10)(11).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 41:2656 (December 2015).

§113. Reports Required of Parents, Schools and Day Care Centers (Formerly §111)

A. It shall be the duty of every parent, guardian, householder, attendant or other person in charge, principal of a public or private school, operator of a day care center or residential facility (public or private) to report a case of reportable disease in his household or school to the state health officer [as required by Subsection 105.C of this Chapter utilizing the appropriate method(s) of reporting required under Subsection 105.E of this Chapter], when he or she knows or reasonably believes that the disease is one which legally must be reported, except when he or she knows or reasonably believes that a physician, presumed to have already reported the case, is in attendance.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5(2)(10)(11).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1213 (June 2002), amended LR 36:1015 (May 2010), LR 41:2656 (December 2015).

§115. Investigations [formerly paragraph 2:009]

A. The state health officer may immediately upon receiving notification of any communicable disease or reportable condition, investigate as the circumstances may require for the purpose of verification of the diagnosis, to ascertain the source of the causative agent, to disclose unreported cases and to reveal susceptible contacts if such information is required to prevent a serious health threat to the community. The decision of the state health officer as to the diagnosis shall be final, for administrative purposes.

B. [formerly paragraph 2:010] The state health officer is hereby empowered and it is made his or her duty whenever a case of communicable disease occurs, to obtain laboratory specimens of body tissues, fluids or discharges and of materials directly or indirectly associated with the case as may be necessary or desirable in confirmation of the diagnosis or for ascertaining the source of the infection, recency of onset, strain of organism, and/or medication resistance, when acceptable laboratory and medical reports are not available. Whenever laboratory tests are required for the release of cases or carriers or suspected cases or carriers, the state health officer shall be satisfied that a sufficient number of specimens are examined, that the specimens are authentic and are examined in an acceptable laboratory.

C. [formerly paragraph 2:013] No person shall interfere with or prevent the entrance to or examination of any house, building, trailer, camp, train, airplane, bus, steamship, or other water craft, or any abode, by the state health officer where a case of communicable disease is either suspected or reported to exist.

D. [formerly paragraph 2:009-1] The state health officer shall make a good faith effort to notify individuals who are spouses and/or sexual contacts to persons with Human Immunodeficiency Virus (HIV) infection of their exposure, offer them counseling about their risk of infection, and offer them testing for HIV infection. In performing this activity, the state health officer or his/her designee shall initially contact the primary medical provider of the person who has HIV infection, if such medical provider can be identified, and ask if the infected person or the medical provider intends to conduct this notification. If neither the infected person nor the medical provider intends to notify spouses or sexual partners of the exposure, the state health officer or his/her designee shall attempt to interview the infected person directly to identify these partners for counseling and testing. Notification of partners shall be conducted in such a manner as to maintain the confidentiality of the infected person.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1214 (June 2002), amended LR 32:1052 (June 2006), LR 36:1016 (May 2010).

§117. Disease Control Measures Including Isolation/Quarantine
[formerly paragraph 2:011]

A. Individuals suspected of being cases or carriers of a communicable disease, or who have been exposed to a communicable disease, and who in the opinion of the state health officer may cause serious threat to public health, shall either submit to examination by a physician and to the collection of appropriate specimens as may be necessary or desirable in ascertaining the infectious status of the individual, or be placed in isolation or under quarantine as long as his or her status remains undetermined. Specimens collected in compliance with this Section shall be examined either by a state laboratory free of charge or by a laboratory approved by the state health officer at the individual's own expense.

B. [formerly paragraph 2:014] It shall be the duty of the state health officer or his or her duly authorized representative to promptly institute necessary control measures whenever a case of communicable disease occurs.

C. [formerly paragraph 2:015] The state health officer or his or her duly authorized representative is hereby empowered and it is made his or her duty, whenever a case of communicable disease occurs in any household or place, and it is in his or her opinion, necessary or advisable that persons residing therein shall be kept from contact with the public, to declare the house, building, apartment, room, or place where the case occurs, a place of quarantine, and to require that only persons so authorized by the state health officer shall leave or enter said quarantined place during the period of quarantine.

D. [formerly paragraph 2:016] Whenever a disease of international or interstate epidemic significance occurs in any community within or outside the state of Louisiana, the state health officer shall, if in his or her opinion, it is necessary, proclaim and institute a quarantine of the locality in which the said disease prevails and shall formulate and publish rules and regulations to carry out such quarantine effectively; which rules and regulations shall have the same force and authority as this code and shall remain in force until rescinded by proclamation of the state health officer.

E. [formerly paragraph 2:017] It is a violation of this code for any person to enter or leave any quarantined area in the state of Louisiana, or to enter from any quarantined area without the state of Louisiana except by permission of the state health officer.

F. [formerly paragraph 2:018] No person shall interfere with, conceal, mutilate or tear down any notices or placard placed on any house, building, or premises by the state health officer. Such placards shall be removed only on authority of the state health officer.

G. [formerly paragraph 2:019] Whenever in the judgment of the state health officer, it is necessary to protect

the public health against a serious health hazard, the state health officer may take complete charge of any case of communicable disease occurring therein and may carry on such measures to prevent its spread as he or she may believe necessary and as are provided for by this Code.

H. If expedited partner therapy is chosen as an alternative by the before mentioned physician, advanced practice registered nurse or physician assistant, the patient with a case of gonorrhea or chlamydia will be given a written document that the patient agrees to give to his or her sexual contact. The document will contain, but will not be limited to the following information.

1. The sexual contact should be examined and treated by a physician, advanced practice registered nurse or physician assistant, if at all possible.

2. The medicine or prescription for medicine given to the sexual contact by the patient should not be taken by the contact if the contact has a history of allergy to the antibiotic or to the pharmaceutical class of antibiotic in which case the sexual contact should be examined and treated by a physician, advanced practice registered nurse or physician assistant and offered another type of antibiotic treatment.

3. The medicine or prescription for medicine given to the sexual contact by the patient should not be taken by the contact if the contact is pregnant, in which case the sexual contact should be examined by a prenatal care health care provider.

4. Additionally, any pharmacist licensed to practice pharmacy in this state may recognize a prescription authorized by this section as valid, notwithstanding any other provision of law or administrative rule to the contrary.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1214 (June 2002), amended LR 35:249 (February 2009).

§119. Duty of Custodians of Medical Records
[formerly paragraph 2:012]

A. Custodians of medical records on patients known or suspected of being cases or carriers of a communicable disease, shall make such records available for review by the state health officer.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5(10).

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1215 (June 2002).

§121. Special Tuberculosis Control Measures
[formerly paragraph 2:014-1 and Appendix A]

A. Louisiana is changing its method of treating tuberculosis due to recent recommendations of the federal Centers for Disease Control and Prevention as set forth in its Morbidity and Mortality Weekly Report, Volume 42, Issue RR-7, dated May 21, 1993. These new and revised recommendations have become necessary because the majority of tuberculosis patients on daily self-administered

medications do not comply with a full course of therapy which leads to drug resistance and secondary spread of the disease.

B. This Section contains a step-wise approach for encouraging compliance with treatment and for managing the non-compliant patient. The steps in the process begin with a voluntary patient compliance agreement, meant to spell out the time and place of directly-observed therapy negotiated between the healthcare provider and the patient and to inform the patient of the possible consequences of non-compliance with the course of therapy.

C. If the patient does not comply with the terms of this agreement, a quarantine order for directly-observed therapy follows. This order from the state health officer or his designee reinforces the need for compliance with therapy.

D. If the patient continues to be uncooperative, the state health officer or his designee may issue a formal quarantine order for hospitalization. This assigns the patient to a specific hospital facility for care of tuberculosis as an inpatient, with detailed warning of the consequences of non-compliance with therapy. It is to be noted that the patient must agree to be transported to the selected hospital facility, and to further comply with the quarantine order to remain in the hospital until his/her condition improves, and the patient may be discharged and placed under a new quarantine order for continued directly observed therapy treatment, as needed, outside of the hospital facility's restrictive environment.

E. In certain cases, where the OPH disease intervention specialist and supervisor anticipate that a given uncooperative patient will refuse to be voluntarily transported to a hospital facility under a formal quarantine order for hospitalization, the state health officer may authorize and instruct the OPH disease intervention specialist supervisor or other appropriate OPH official, to fill out a request for a court order for hospitalization, and present it to the district attorney in the parish wherein the patient is known to be situated. (In rare instances, the district attorney may see that criminal charges for violation(s) of the quarantine order for directly observed therapy are filed at this point, instead of the OPH requested civil court order).

F. It is hoped that in most instances of initial non-compliance with the required treatment, an uncooperative patient will agree to be transported to a specific hospital facility for inpatient care under a formal quarantine order issued by the state health officer or his designee, without court intervention.

G. In the event a patient under a formal quarantine order for hospital care becomes uncooperative within the hospital facility's restrictive environment, or a patient continues to be non-compliant with therapy after isolation/quarantine by a civil court order, the hospital facility or state health officer may seek to have criminal charges filed pursuant to R.S. 40:6.B, and upon conviction, the patient may be sentenced to the hospital unit of a state prison and placed in the custody of the Department of Corrections.

H. This Section contains suggested forms with instructions for the steps prior to the filing of criminal charges.

I. Louisiana is following the recommendations of the federal Centers for Disease Control and Prevention by placing all tuberculosis patients initially under a voluntary program of "Directly Observed Therapy" pursuant to a "Patient Compliance Agreement" signed by the patient. A sample "Patient Compliance Agreement" form follows:

J. Tuberculosis Control Sample Form 1

VOLUNTARY PATIENT COMPLIANCE AGREEMENT

Plan of therapy for _____
Full Name

Date of birth _____ Social Security # _____

Whose residence is _____

Parish _____ Date this regimen begins _____

For the Patient: NOTE: All statements are to be read to patient
(or patient may read).

1. You are being treated for suspected tuberculosis; therefore, it is essential that you take your medication.

2. To avoid long-term isolation or quarantine, you will be expected to follow your drug therapy schedule. No dose of medication is to be missed.

3. State law requires that the Office of Public Health assist you in controlling your disease. The only way to cure your disease is by regular use of drug therapy.

4. The following therapy schedule requires that you report to _____
on _____, at _____ o'clock to receive your medications under supervision. The staff will work with you in arranging special schedules for your therapy as necessary. You will be expected to call and report any difficulties in keeping your appointments.

5. Failure to comply with these guidelines may result in quarantine, involuntary confinement to a hospital or possible criminal charges for violations of quarantine.

(If patient states any barriers to compliance, list them here.)

I agree that I understand the above therapy schedule and will make every effort to comply with the full course of my therapy.

Patient's Signature _____

Date _____
Public Health Nurse or Disease Inter. Spec.

Copy received by patient _____
Patient Initials

SCHEDULE CHANGES

New schedule _____

Medical Reason/Other _____

Patient Signature _____ Date _____

Signature Public Health Nurse or Disease Intervention Specialist

Copy to patient _____
Patient Initials

K. In the event a particular tuberculosis patient fails to cooperate, as evidenced (for example) by failing to voluntarily appear timely at the place that was agreed upon in the patient compliance agreement to take the required drugs, or otherwise interrupts and/or stops taking the anti-tuberculosis medication as prescribed, it may become

necessary to issue a formal public health isolation or quarantine order to "Directly Observed Therapy" (DOT) means drugs taken in the presence of a designated health care provider at a specified place. In such cases, the patient is fully informed that a violation of the terms of the isolation or quarantine order to DOT may result in orders issued by the state health officer or his designee or agent, or by an order from a Louisiana court of competent jurisdiction, to a more restrictive environment for the management of uncooperative tuberculosis patients. A sample of a public health isolation or quarantine order to DOT follows:

L. TB Control Form 2 is a sample letter to hand deliver a quarantine order for directly observed therapy.

Date _____

_____, LA 70 ____

RE: Quarantine Order for Directly Observed Therapy

Dear _____:

This is to inform you that you are under quarantine to prevent the spread of your tuberculosis infection. The circumstances necessitating the specific terms of your quarantine are as follows:

1. You have been diagnosed as having active pulmonary tuberculosis, which could be spread to others when you cough.
2. You were diagnosed with pulmonary tuberculosis in _____, and had a positive sputum smear and culture for M. tuberculosis, which showed sensitivity to _____.
3. You have failed voluntary Directly Observed Therapy, as evidenced by _____.

In order to protect the public from further unwarranted exposure to your infection, you are required to fully comply with these terms of your quarantine:

1. You will be placed on mandatory Directly Observed Therapy by the regional chest clinician in _____. This regimen will require medications administered at the _____ Parish Health Unit. This therapy will continue until the state health officer determines that you are no longer likely to transmit your infection to others and have completed an adequate therapy regimen.
2. You will comply and cooperate fully with the treatment regimen prescribed for you.
3. Failure to comply with mandatory Directly Observed Therapy on an outpatient basis may require subsequent legal action. Failure for the purposes of this quarantine is defined as missing one or more doses of therapy during one month. This order will remain in force until the order is revoked or revised by the authority of the state health officer.

In view of the risk to the public health which would result from failure to keep your tuberculosis infection under control, any violation of the specified terms of your quarantine may force us to bring immediate action against you in court.

Please signify your intention to comply with the terms of this order by signing the Statement of Intention which is attached. Return the statement to me through the officer who delivers it to you.

I sincerely hope that you will have a rapid and uneventful recovery and that your tuberculosis can be classed as inactive before very long.

_____, M.D.
State Health Officer

M. Tuberculosis Control Form 3 is an attachment to Form 2 to be hand delivered to the patient.

STATEMENT OF INTENTION TO COMPLY

I, _____, have read the terms of my quarantine for control of tuberculosis, or have had them read to me. I have had a chance to ask questions about the terms of my quarantine and am satisfied that I understand them. For my own protection and the protection of the public, I agree to comply fully with the specified terms of my quarantine.

(Signature)	Date
WITNESSES: _____	_____
(Signature)	(Signature)
(Print Name)	(Print Name)

cc:
State Health Officer

EXECUTIVE OFFICER, ADMINISTRATION
DHH OFFICE OF PUBLIC HEALTH
TUBERCULOSIS CONTROL SECTION
DHH OFFICE OF PUBLIC HEALTH
BUREAU OF LEGAL SERVICES
DEPARTMENT OF HEALTH AND HOSPITALS
REGION ____ DIS SUPERVISOR 1
DHH OFFICE OF PUBLIC HEALTH
____ PARISH HEALTH UNIT
DISTRICT ATTORNEY _____ PARISH
SHERIFF _____ PARISH

N. A tuberculosis patient with a diagnosis of active tuberculosis who fails to comply with a public health isolation or quarantine order to directly observed therapy may be ordered to a more restrictive environment for the management of uncooperative tuberculosis patients, or by requesting a Louisiana court of competent jurisdiction for the issuance of an order placing the patient in a more restrictive environment. A sample of the state health officer's isolation or quarantine order to a more restrictive environment follows, along with a sample request for a court order.

O. TB Control Form 4 is a sample quarantine order (by the state health officer) for hospitalization

SAMPLE QUARANTINE ORDER FOR HOSPITALIZATION

Date _____

_____, LA 70 ____

RE: Quarantine Order for Directly Observed Therapy

Dear _____:

This is to inform you that you are under quarantine to prevent the spread of your tuberculosis infection. The circumstances necessitating the specific terms of your quarantine are as follows:

1. You have been diagnosed as having active pulmonary tuberculosis, which could be spread to others when you cough.
2. You were diagnosed with pulmonary tuberculosis on _____, and had a positive sputum smear and culture for M. tuberculosis, which showed resistance to _____.
3. You failed to comply with your prescribed therapy and failed mandatory Directly Observed Therapy under quarantine, as evidenced by _____.

In order to protect the public from further unwarranted exposure to your infection, you are required to fully comply with these terms of your quarantine for hospitalization:

1. You have been placed on treatment for tuberculosis and will remain hospitalized with subsequent transfer to Villa Feliciana Chronic Disease Hospital and Rehabilitation Center.
2. You will comply and cooperate fully with the treatment regimen prescribed for you.
3. Failure to comply with this order for you to remain hospitalized may result in CRIMINAL CHARGES filed against you and a warrant for your arrest. The CRIMINAL CHARGE would be a violation of your Tuberculosis Quarantine Order, R.S. 40:6.B. Upon trial, if convicted of this charge, you may be sentenced to the hospital unit of a state prison operated by the Department of Corrections. Please be guided accordingly.

This formal quarantine order will remain in force until the order is revoked or revised by the state health officer.

In view of the risk to the public health which would result from failure to keep your tuberculosis infection under control, any violation of the specified terms of your quarantine will force us to bring immediate action against you in court.

Please signify your intention to comply with terms of this order by signing the Statement of Intention which is attached. Return the Statement to me through the officer who delivers it to you.

I sincerely hope that you will have a rapid and uneventful recovery and that your tuberculosis can be classed as inactive before very long.

_____, M.D.
State Health Officer

P. TB Control Form 5 is a statement of intention to comply with the state health officer's quarantine order for hospitalization.

STATEMENT OF INTENTION TO COMPLY

I, _____, have read the terms of my quarantine for control of tuberculosis, or have had them read to me. I have had a chance to ask questions about the terms of my quarantine and am satisfied that I understand them. For my own protection and the protection of the public, I agree to comply fully with the specified terms of my quarantine. I also expressly understand that if I violate the terms of this quarantine order, I may be charged with a CRIME and can be SENTENCED TO PRISON.
(Signature) (Date)

_____ (Signature)	_____ Date
WITNESSES:	
_____ (Signature)	_____ (Signature)
_____ (Print Name)	_____ (Print Name)

cc:
state health officer

EXECUTIVE OFFICER, ADMINISTRATION
DHH OFFICE OF PUBLIC HEALTH

TUBERCULOSIS CONTROL SECTION
DHH OFFICE OF PUBLIC HEALTH

BUREAU OF LEGAL SERVICES
DEPARTMENT OF HEALTH AND HOSPITALS

REGION II DIS SUPERVISOR
DHH OFFICE OF PUBLIC HEALTH
DISTRICT ATTORNEY _____ PARISH

SHERIFF, _____ PARISH

L S U UNIT, EARL K. LONG HOSPITAL

_____ PARISH HEALTH UNIT

Q. The following "format" may be used by the district attorney when the state health officer or his designee or agent requests help in handling an uncooperative person known to have active, infectious tuberculosis. The district attorney may substitute any "format" of his/her preference, however. The general intent here is to provide the OPH disease intervention specialist supervisors (who will be the state health officer's designee in most cases) with an instrument to complete and submit to the district attorney when a particular TB patient shows no intent to cooperate. The "format" of the instrument itself may have to be altered so as to present the facts of a particular case accurately.

R. Tuberculosis Control Form 6

SAMPLE REQUEST FOR A COURT ORDER FOR HOSPITALIZATION

IN RE: 1 _____
NO. 2 _____
_____ 3 JUDICIAL DISTRICT COURT PARISH OF _____ 4
FILED: _____ 5 _____ 6

DEPUTY

REQUEST FOR AN EMERGENCY PUBLIC HEALTH ORDER TO ISOLATE/QUARANTINE A TUBERCULOSIS PATIENT TO PROTECT THE PUBLIC HEALTH AND THE PATIENT

ON THE MOTION OF _____, 7

a Disease Intervention Specialist Supervisor employed by the Office of Public Health of the Department of Health and Hospitals of the State of Louisiana and duly designated to act in these premises by the state health officer, appearing herein through the undersigned Assistant District Attorney, and moves pursuant to the provisions of LSA-R.S. 40:3, 40:4A(13), 40:4B(4), 40:5(1), 40:6.C and 40:17, and further pursuant to Sections 117- 119.F of Chapter 1 of Part II of the state sanitary code, and respectfully suggests to the Court that:

I.

_____, 1 to the best of my knowledge and belief is an imminent danger and/or threat to the health and/or lives of individuals in this parish and state and is now in need of immediate medical examination and treatment in a restricted environment in order to protect the individuals of this parish and state as well as the subject individual person from physical harm and/or from spreading active and infectious tuberculosis.

II.

_____ 1 is known to be located at _____, 8 and has been encouraged to voluntarily submit to necessary medical examination and to seek and receive necessary treatment, but is unwilling and uncooperative in these regards.

III.

Mover has contacted _____, 9 concerning the danger and/or imminent threat posed by the subject individual, _____ 1, and is informed that _____ 9 is prepared to receive the patient and provide housing in a restrictive environment allowing immediate examination and care for tuberculosis and the said facility is further prepared to provide any necessary anti-tuberculosis medication.

IV.

Mover asserts that the imminent danger and/or threat to the public health is based on mover's knowledge that _____ 1 is infected with active, infectious tuberculosis as evidenced by _____

_____, 10
WHEREFORE, mover prays that an emergency public health order be
issued to locate, detain and transport _____ 1
to _____ 9 without delay.

Respectfully submitted,
_____, 16
Assistant District Attorney
_____, 3 Judicial District

S. TB Control Form 6 (continued)

AFFIDAVIT

STATE OF LOUISIANA
PARISH OF _____ 4

BEFORE ME, the undersigned authority, personally came and appeared
_____, 7 who, being first duly sworn, deposed: That
_____, 11 is the Disease Intervention Specialist Supervisor employed by the
Office of Public Health of the Department of Health and Hospitals in the
regional area including _____, 4 and _____, 11 is the mover in
the above and foregoing motion, and that all of the allegations of fact made
therein are true and correct to the best of mover's knowledge, information
and belief.

_____, 12
SWORN TO AND SUBSCRIBED BEFORE ME
THIS _____, 13 DAY OF _____, 14 20____, 15
_____, 16
NOTARY PUBLIC

T. TB Control Form 6 (continued)

ORDER

IT IS ORDERED, ADJUDGED AND DECREED that _____, 1
be detained and placed in the protective custody of a law enforcement
officer and transported to the 9 for such medical examinations, testing and
treatment for active and infectious tuberculosis and be detained at that
facility until the existing imminent danger and/or threat to the public health
has subsided.

IT IS FURTHER ORDERED that any law enforcement officer may execute
this order by detaining and transporting _____, 1
to the designated treatment facility named above without delay.

JUDGEMENT read, rendered and signed this _____ day of _____, 20____, at
_____ o'clock, at _____, Louisiana.

_____,
JUDGE
_____, JUDICIAL DISTRICT COURT
PARISH OF _____

U. TB Control Form 6 Instructions

SUBSTITUTE FOR NUMBERS IN ABOVE FORM

1. Name of the person in need of treatment.
2. Court personnel will complete this item.
3. District Attorney's office will complete this item.
4. District Attorney's office will complete this item.
5. Court personnel will complete this item.
6. Court personnel will complete this item.
7. Insert the name of the Disease Intervention Specialist Supervisor who is submitting the matter to the District Attorney's office.
8. Insert the person in need of treatment's complete address (which may be in care of a relative's address, or even a "halfway house" or possibly the person may be a patient in a hospital refusing treatment and demanding discharge. Just try to insert sufficient information to enable the deputy

sheriff or other law enforcement officer to find and take the party into protective custody, etc.)

9. Insert the name of the physician or administrator and the name and address of the designated TB treatment facility.

10. Here it will be necessary for a concise statement of the problem presented by the TB patient whose condition is diagnosed as active and infectious TB.

11. Insert "he" or "she."

12. The Disease Intervention Specialist Supervisor must sign his or her name exactly as it appears in the form above, and this should be done in the presence of a Notary, who may also be the Assistant District Attorney who will handle the case in court.

13-16 will be completed by the District Attorney's office.

V. A tuberculosis patient who has been ordered to be isolated or quarantined to a more restrictive environment than directly observed therapy and who fails to comply with the express terms and provisions of the isolation/quarantine order to a more restrictive environment issued by the state health officer or his designee, or by the orders of a Louisiana court of competent jurisdiction, shall be considered as having violated the provisions of the state sanitary code and be subject to criminal prosecution pursuant to R.S. 40:6.B, and if so charged and convicted, further subject to being sentenced to the hospital unit of a state prison operated by the Department of Corrections, and to remain so confined so long as the prisoner's tuberculosis condition is active, in order to assure the public is protected from unwarranted exposure to the disease.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(c)(vii)(aa)-(cc), R.S. 40:5(1) and R.S. 40:1161.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1215 (June 2002).

§123. Ventilation Requirements for Housing TB Patients in Hospitals and Nursing Homes [formerly paragraph 2:014-2]

A. Persons with tuberculosis in a communicable state or suspected of having tuberculosis in a communicable state who are cared for in hospitals and nursing homes shall be cared for in rooms with negative air pressure and either:

1. at least six changes of room air per hour accomplished by exhaust ventilation; or
2. equivalent circulation and treatment by ultraviolet light treatment, "air scrubber," or equivalent. If the patient is not in a room with proper ventilation and is unable or unwilling to cover his/her cough, then exposed persons shall wear proper masks, which filter all particles larger than one micron, in order to prevent the spread of infectious respiratory droplets.

B. [formerly paragraph 2:014-3] Rooms used for aerosolized pentamidine treatments or for aerosol treatments designed to induce sputum shall have negative air pressure and at least six changes of room air per hour accomplished by exhaust ventilation.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2)(c)(ii),(iii) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1219 (June 2002).

Chapter 3. Testing of Newborn Infants

§301. Measures to Prevent Ophthalmia Neonatorum at Time of Birth of an Infant [formerly paragraph 2:020]

A. It shall be the duty of the attending physician, midwife, nurse or other person in attendance on a parturient person to use prophylactic measures at the time of delivery to prevent ophthalmia neonatorum, such as the instillation into both eyes of the newborn a 1 percent solution of nitrate of silver, a 1/2 percent erythromycin ophthalmic ointment or drops, a 1 percent tetracycline ophthalmic ointment or drops, all in single dose or single use containers, or an equally efficient agent, as determined by the state health officer. This duty is waived if the newborn has no evidence of ophthalmia neonatorum and the mother of the newborn states in writing that she objects to the application of such prophylactic agent on religious ground.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2), R.S. 40:5 and R.S. 40:1102-1106.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1219 (June 2002).

Chapter 5. Health Examinations for Employees, Volunteers and Patients at Certain Medical Facilities

§501. Employee Health [formerly paragraph 2:021]

A. The requirements of Part I, Chapter 1, §117 shall be met.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4, and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1219 (June 2002).

§503. Mandatory Tuberculosis Testing

A. [formerly paragraph 2:022] All persons, including employees, students or volunteers, having no history of latent tuberculosis infection or tuberculosis disease, prior to or at the time of employment, beginning clinical rotations in the healthcare profession, or volunteering at any hospital or nursing home (as defined in Parts XIX and XX of the Sanitary Code, respectively, herein, and including intermediate care facilities for the developmentally disabled) requiring licensing by the Louisiana Department of Health or at any Louisiana Department of Health, Office of Public Health (LDH-OPH) parish health unit or an LDH-OPH out-patient health care facility, whose duties include direct patient care, shall be free of tuberculosis in a communicable state as evidenced by either:

1. a negative purified protein derivative skin test for tuberculosis, 5 tuberculin unit strength, given by the Mantoux method or a blood assay for *Mycobacterium*

tuberculosis approved by the United States Food and Drug Administration;

2. a normal chest X-ray, if the skin test or a blood assay for *Mycobacterium tuberculosis* approved by the United States Food and Drug Administration is positive; or

3. a statement from a licensed physician certifying that the individual is non-infectious if the X-ray is other than normal. The individual shall not be denied access to work solely on the basis of being infected with tuberculosis, provided the infection is not communicable.

B. [formerly paragraph 2:023] Any employee, student or volunteer at any medical or 24-hour residential facility requiring licensing by the Louisiana Department of Health or at any LDH-OPH parish health unit or an LDH-OPH out-patient health care facility who has a positive purified protein derivative skin test for tuberculosis, 5 tuberculin unit strength, given by the Mantoux method, or a positive blood assay for *Mycobacterium tuberculosis* approved by the United States Food and Drug Administration; or a chest X-ray other than normal, in order to remain employed, remain in clinical rotations, or continue work as a volunteer, shall complete an adequate course of medical treatment for tuberculosis as prescribed by a Louisiana licensed physician, or shall present a signed statement from a Louisiana licensed physician stating that medical treatment for tuberculosis is not indicated.

C. [formerly paragraph 2:024] All persons with a history of latent tuberculosis infection or tuberculosis disease prior to or at the time of employment, including employment as a student in clinical rotations, or volunteering at any medical or 24-hour residential facility requiring licensing by the LDH, at any hospital or nursing home (as defined in Parts XIX and XX of the Sanitary Code, respectively, herein, and including intermediate care facilities for the developmentally disabled) requiring licensing by the LDH, at any LDH-OPH parish health unit, or at any LDH-OPH out-patient health care facility, whose duties include direct patient care, must present a statement from a Louisiana licensed physician that he or she has been satisfactorily treated for tuberculosis and is non-infectious or, for persons with a history of untreated latent tuberculosis infection, a statement that he or she is non-infectious.

1. Further, for persons with a history of untreated latent tuberculosis infection an annual symptom screen shall be done, including, but not limited to, the following questions.

- a. Do you have a productive cough that has lasted at least 3 weeks? (Yes or No)

- b. Are you coughing up blood (hemoptysis)? (Yes or No)

- c. Have you had unexplained weight loss recently? (Yes or No)

- d. Have you had fever, chills, or night sweats for 3 or more days? (Yes or No)

2. Any employee, student, or volunteer with a history of untreated latent tuberculosis infection giving a positive response to any one of the questions under Paragraph 1 of this Subsection shall be referred to a physician for medical evaluation as soon as possible.

3. All initial screening test results and all follow-up screening test results shall be kept in each employee's, student's, or volunteer's health record or facility's personnel record.

D. Annually, but no sooner than 6 months since last receiving tuberculosis educational information (more fully described at the end of this sentence) or symptom screening, all employees, students in the healthcare professions, or volunteers at any medical or 24-hour residential facility requiring licensing by LDH or at any hospital or nursing home (as defined in Parts XIX and XX of the Sanitary Code, respectively, herein, and including intermediate care facilities for the developmentally disabled) requiring licensing by the LDH or at any LDH-OPH parish health unit or and LDH-OPH out-patient health care facility shall receive, at a minimum, educational information explaining the health concerns, signs, symptoms, and risks of tuberculosis.

E. [formerly paragraph 2:033] All persons with acquired immunodeficiency syndrome (AIDS) or known to be infected with the human immunodeficiency virus (HIV), in the process of receiving medical treatment related to such condition, shall be screened for tuberculosis, with screening to include a chest X-ray. Sputum smear and culture shall be done if the chest X-ray is abnormal or if the patient exhibits symptoms of tuberculosis disease. Screening for tuberculosis shall be repeated as medically indicated.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1220 (June 2002), amended LR 32:98 (January 2006), LR 33:93 (January 2007), LR 37:598 (February 2011), LR 40:1942 (October 2014), amended by the Department of Health, Office of Public Health, LR 47:744 (June 2021).

**§505. Required Medical Examinations of
All Persons Admitted to Nursing Homes
and Residential Facilities
[formerly paragraph 2:026]**

A. Any person (adult or child) admitted to any nursing home or other residential facility shall have a complete history and physical examination, including symptoms and signs of pulmonary tuberculosis, by a licensed physician within 30 days prior to or up to 72 hours after admission, except that any resident/patient who has complied with this provision shall be exempt from re-examination if transferred to another residential facility provided the record of examination is transferred to the new facility. This examination shall include laboratory tests as indicated by the history and physical examination. A United States Food and Drug Administration approved screening test for tuberculosis, *i.e.*, a purified protein derivative skin test for tuberculosis, 5 tuberculin unit strength, given by the

Mantoux method or a blood assay for *Mycobacterium tuberculosis* shall be given to all residents/patients. A chest X-ray shall be given to all residents/patients whose screening test for tuberculosis is positive, or who have signs and/or symptoms of tuberculosis no more than 30 days prior to admission to any nursing home or other residential facility. If the skin test or a blood assay for *Mycobacterium tuberculosis* is not done prior to admission, it may be done within 72 hours after admission and interpreted at the appropriate time. A repeat skin test or a blood assay for *Mycobacterium tuberculosis* is not required if the resident/patient has a chest X-ray with no abnormalities indicative of tuberculosis and has had a negative skin test or a blood assay for *Mycobacterium tuberculosis* approved by the United States Food and Drug Administration, documented within 1 year of admission or if the resident/patient has a previously documented positive skin test or a positive result of a blood assay for *Mycobacterium tuberculosis* and had a chest X-ray with no abnormalities indicative of tuberculosis. A record of the admission history, physical examination, purified protein derivative skin test for tuberculosis, 5 tuberculin unit strength, given by the Mantoux method, or a blood assay for *Mycobacterium tuberculosis* approved by the United States Food and Drug Administration, chest X-ray, and any other laboratory tests shall be a part of the permanent record of each resident/patient. No resident/patient with evidence of active tuberculosis shall be admitted unless the examining physician states that the resident/patient is on an effective drug regimen, is responding to treatment, and presents no imminent danger to other residents/patients or employees, or unless the facility has been specifically approved by the LDH-OPH to house residents/patients with active tuberculosis. The approval by the LDH-OPH will include the provision that the nursing home or residential facility has a designated isolation (negative pressure) room.

B. [formerly paragraph 2:026-1] Any resident/patient who is a case or an asymptomatic carrier of a communicable disease which may pose a serious risk to other residents/patients or employees shall not be admitted except under the supervision of the state health officer or his agent.

C. [formerly paragraph 2:027] When a suspicious case or carrier of a communicable disease poses a serious public health risk, appropriate measures shall be taken to prevent the disease from spreading to other residents/patients.

D. [formerly paragraph 2:028] Any child under 18 years of age in any residential facility in the state shall have an annual examination by a licensed physician to determine the child's physical condition, mental condition and the presence of any indication of hereditary or other constitutional disease. Any deformity or abnormal condition found upon examination shall be entered by the physician on the medical record of the child.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1220 (June 2002), amended LR 33:94 (January 2007), LR 38:2928 (November

Chapter 7. Public Health Immunization Requirements

§701. Immunization Schedule [formerly paragraph 2:025]

A. The Office of Public Health (OPH) will determine the Louisiana immunization schedule, with appropriate immunizations for age using the current immunization schedule from the Advisory Committee for Immunization Practice (ACIP) of the United States Public Health Service (USPHS). Compliance for school and day care center entry will be based on the individual having received an appropriate number of immunizations for his/her age of the following types:

1. vaccines which contain tetanus and diphtheria toxoids, including Diphtheria and Tetanus (DT), Diphtheria/Tetanus/Acellular Pertussis (DTaP), Tetanus and Diphtheria (Tdap), Tetanus Toxoid (TT) or combinations which include these components;
2. polio vaccine, including Inactivated Polio Vaccine (IPV), or combinations which include this component;
3. vaccines which contain measles antigen, including Measles, Mumps, and Rubella (MMR) and combinations which include these components;
4. vaccines which contain hepatitis antigen, including Hepatitis B (HepB), Hepatitis A (HepA), and combinations which include these components;
5. vaccines which contain varicella antigen, including varicella and combinations which include this component.
6. vaccines which contain meningococcal antigen and combinations which include this component.

B. A one-month period will be allowed from the time the immunization is due until it is considered overdue. Medical, religious, and philosophic exemptions will be allowed for compliance with regulations concerning day care attendees and school enterers. Only medical and religious exemptions will be allowed for compliance with regulations concerning public assistance recipients. A copy of the current Office of Public Health immunization schedule can be obtained by writing to the Immunization Program, Office of Public Health, 1450 Poydras Street, Suite 1938, New Orleans, LA 70112 or by telephone (504)568-2600.

C. [formerly paragraph 2:025-1] Any person 18 years or under, admitted to any elementary and secondary school, kindergarten, college, university, proprietary school, vocational school, licensed day care center or residential facility shall have verification that the person has had all appropriate immunizations for age of the person according to the Louisiana immunization schedule unless presenting a written statement from a physician stating that the procedure is contraindicated for medical reasons, or a written dissent from parents. The operator of any elementary and secondary school, kindergarten, college, university, proprietary school,

vocational school, licensed day care center or residential facility shall report to the state health officer through the health unit of the parish or municipality where such facility is located any case or suspected case of reportable disease. Health records, including immunization records, shall be made available during normal operating hours for inspection when requested by the state health officer. When an outbreak of a communicable disease occurs in an elementary and secondary school, kindergarten, college, university, proprietary school, vocational school, licensed day care center or residential facility, the operator of said facility shall comply with outbreak control procedures as directed by the state health officer.

D. [formerly paragraph 2:025-2] On or before October 1 of each year, the operator of each elementary and secondary school, kindergarten, college, university, proprietary school, vocational school, licensed day care center or residential facility enrolling or housing any person 18 years or under, inclusive but not limited to these listed facilities shall submit a preliminary immunization status report of all persons 18 years or under enrolled or housed as of that date. This compliance report shall be submitted utilizing the official Louisiana Immunization Network (“LINKS”) and shall include identifying information for each person 18 years or under, and for each dose of vaccine received since birth. Any person 18 years or under exempt from the immunization requirement shall also be identified, and the reason for exemption given on the report. After review of the report(s) by the state health officer or his or her designee, the elementary and secondary school, kindergarten, college, university, proprietary school, vocational school, licensed day care center or residential facility operator shall notify, on or before December 31 of each year, the parent or guardian of all enrolled or housed persons 18 years or under who are not compliant of the immunization requirements of §701.A and C of this Part.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2), R.S. 40:5(A) and R.S. 40:31.15. Also see R.S. 17:170, R.S. 22:1030, and R.S. 44:17.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1221 (June 2002), amended LR 38:1252 (May 2012), amended by the Department of Health, Office of Public Health, LR 45:670 (May 2019), amended LR 46:590 (April 2020).

§703. Mandatory Immunization Reporting

A. All immunization providers in the state of Louisiana shall be licensed or credentialed by their respective boards (to administer vaccines) and shall register and enroll in the Louisiana Immunization Network (“LINKS”).

B. All licensed or credentialed immunization providers shall comply with the rules and regulations outlined in the LINKS site enrollment agreement.

C. All licensed and credentialed immunization providers in Louisiana shall report all immunizations administered, regardless of patient age, and update patient demographics at each patient encounter to LINKS within one week of vaccine administration to the patient.

D. Boards that license healthcare providers authorized to administer vaccines shall provide an updated listing of all such authorized providers every calendar year to the OPH's immunization program. The updated listings shall be received by the OPH's immunization program no later than January 31 annually.

E. All providers licensed/credentialed to administered vaccines shall report all specified immunizations, antivirals, and other medications administered for all ages (within seven days of administration) to the LINKS system in preparation for or in response to a declared public health disaster or emergency event.

F. When reporting to the LINKS system, several pieces of information will be needed including; site and individual user demographic information; and consent to privacy and confidentiality compliance.

G. All of the information reported under Subsection F of this Section may be found on the LDH-OPH Immunization Program webpage identified as "https://lalinks.org/linkswb/LINKS_ENROLL.html". All licensed or credentialed immunization providers shall comply with the rules, regulations and policies outlined within the LINKS information system.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2), R.S. 40:5(A) and R.S. 40:31.15. Also see R.S. 17:170, R.S. 22:1030 and R.S. 44:17.

HISTORICAL NOTE: Promulgated by the Department of Health, Office of Public Health, LR 46:590 (April 2020).

Chapter 9. Prevention and Control of Yellow Fever

§901. Definitions [formerly paragraph 2:029]

A. Unless otherwise specifically provided herein, the following words and terms used in this Chapter and all other Chapters which are adopted or may be adopted, are defined for the purposes thereof as follow.

Official Center—any nonfederal medical facility consisting of either a state, parish or municipal public health or a private clinic under full-time supervision of a physician licensed by the Louisiana Board of Medical Examiners.

Vaccination—the injection of immunizations required for international travel administered by approved centers medical personnel to an individual.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5(12), and further in full cooperation with the U. S. Public Health Service requirements for international travel.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1221 (June 2002).

§903. Background and Legal Authority [formerly paragraph 2:030]

A. The International Health Regulations (IHR), Chapter II, Article 66, World Health Organization (WHO), to which

the United States is signatory, require the health administration of each nation to designate centers where international travelers may be vaccinated against yellow fever. In this nation, the United States Public Health Service (USPHS) has this responsibility under Executive Order of the President. The vaccine must be approved by WHO, and the traveler's International Certificate of Vaccination or Revaccination against Yellow Fever must be properly validated.

B. [formerly paragraph 2:030-1] Since September 1, 1977, the USPHS has delegated to the State and Territorial Health Departments the responsibility of designating and supervising non-federal Yellow Fever Vaccination Centers within their respective jurisdictions. Criteria for categories of facilities to be designated are determined by the State and Territorial Health Departments. State and Territorial Health Departments issue and control the uniform stamps which may be used to validate International Certificates of Vaccination or Revaccination against Yellow Fever.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4 (A)(2) and R.S. 40:5 and further in full cooperation with the U. S. Public Health Service requirements for international travel.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1221 (June 2002).

§905. Yellow Fever Regulations [formerly paragraph 2:031]

A. The following is a list of regulations of the Louisiana Department of Health and Hospitals, developed by the Office of Public Health, in conjunction with the USPHS Centers for Disease Control, Quarantine Division for non-federal facilities given the responsibility for administering and validating International Certificates of Vaccination or Revaccination against Yellow Fever.

1. [formerly paragraph 2:031-1] Any facility designated as a Yellow Fever Vaccination Center and issued a uniform stamp to validate International Certification of Vaccination against yellow fever shall be either a state, parish or municipal public health or a private medical clinic under full time supervision of a physician licensed by the Louisiana Board of Medical Examiners. The supervising physician must be fully knowledgeable of the procedures necessary for issuing a valid document. Written instructions with illustrations are included in Health Information for International Travel issued annually as a supplement to the Morbidity and Mortality Weekly Report of the Centers for Disease Control. Possession of a current book is mandatory for all approved centers.

2. [formerly paragraph 2:031-2] The uniform stamp:

a. is the property of the Office of Public Health and must be returned upon request via registered mail within 30 days of notification of cancellation;

b. is to be used to validate only those certificates issued by the approved non-federal medical facility;

c. should be kept in a safe place when not in use and must not be loaned or reproduced.

3. [formerly paragraph 2:031-3] Loss or theft of a uniform stamp must be reported immediately to the Office of Public Health which in turn shall report to the Division of Quarantine, Center for Prevention Services, Centers for Disease Control, Atlanta, Georgia 30333.

4. [formerly paragraph 2:031-4] Approval of and continued possession of the uniform stamp will be based on justified need and maintenance of policies compatible with the Office of Public Health guidelines. Reevaluations will be conducted semi-annually.

5. [formerly paragraph 2:031-5] Improperly prepared certificates bearing the uniform stamp as reported by the CDC Division of Quarantine at ports of entry will be further investigated by personnel of the Office of Public Health.

6. [formerly paragraph 2:031-6] The Office of Public Health shall maintain a listing of uniform stamps with corresponding identification codes. A duplicate listing shall be filed with the CDC Division of Quarantine.

7. "The Center must maintain adequate refrigeration to assure that the yellow fever vaccine will be kept in a refrigerated state with temperatures as recommended by the vaccine manufacturer and included in the storage recommendations of the vaccine package insert. Once the vaccine has been removed from refrigeration and reconstituted, it must be administered within 60 minutes. Any remaining unrefrigerated and unused vaccine must be destroyed."

8. [formerly paragraph 2:031-8] When a supervising physician named on the application is no longer associated with an approved center, the Office of Public Health shall be notified. Application procedures as stated below must be completed by the new replacement supervising physician.

9. [formerly paragraph 2:031-9] Approved centers are required to keep records of persons whose International Certificates of Vaccination or Revaccination against Yellow Fever are validated and to submit periodic (six months) reports covering operations to the Office of Public Health. All designated centers are required to report adverse reactions to yellow fever vaccine of sufficient severity to require medical attention.

a. Adverse reactions or other complications occurring within 30 days of the receipt of the vaccine shall be reported:

i. neurologic reactions—meningitis, encephalitis, polyneuropathy, guillain-barre syndrome, paralysis;

ii. allergic reactions—urticaria, asthma, angioneurotic edema, erythema multiforme, anaphylaxis, other;

iii. other post vaccination complications—acute febrile illness with headache, malaise, Barthralgia, or jaundice.

10. [formerly paragraph 2:031-10] International Certificates of Vaccination must conform to International Health Regulations, Chapter III, Article 79, World Health Organization.

11. [formerly paragraph 2:031-11] The approved center shall develop, implement and maintain a procedure for handling emergencies due to severe vaccine reactions such as anaphylaxis, including the maintenance of necessary supplies and medicine to provide life support until patient can be transferred safely to an acute care facility.

12. [formerly paragraph 2:031-12] The state health officer may order additional procedures to ensure compliance with the provision of these regulations and reserves the authority to enforce any regulation not so specified in this rule that is considered to be medically significant in the operation of such clinics.

13. [formerly paragraph 2:031-13] The supervising physician is responsible for his or her practices regarding administration of immunizations.

14. [formerly paragraph 2:031-14] Proper infectious waste handling and disposal shall be done in accordance with the Louisiana Sanitary Code, Part XXVII.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5. and further in full cooperation with the United States Public Health Service requirements for international travel.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1221 (June 2002), amended LR 34:444 (March 2008).

Editor's Note: The address, telephone and website listed in §907.A have changed to:
Office of Public Health
Yellow Fever Vaccination Center Certification Program
P.O. Box 60630
New Orleans, LA 70160
Telephone: (504) 568-5048
<http://www.ddh.louisiana.gov/offices/?IS=292>

§907. Application Procedures [formerly paragraph 2:032]

A. To request designation as an approved Yellow Fever Center call or write to the Office of Public Health, Epidemiology Section, P.O. Box 60630, New Orleans, LA 70160 (504-568-5005) and request an application form. After receipt of a completed application form, OPH personnel will conduct an on-site inspection of the clinic facilities utilizing an instrument developed by the Office of Public Health for this purpose. A report will then be forwarded along with the completed application to the state health officer for approval/disapproval. If approved, the designated center, the Division of Quarantine, Centers for Disease Control, and the vaccine manufacturer shall be notified in writing. The uniform stamp is then issued using the supervising physician's state medical license number for identification. Any facility whose request for approval is denied may appeal the denial after conditions which resulted in a denial of approval have been verifiably modified to bring the center into conformity with established regulations. The facility has 30 days after receipt of the denial in which

to appeal in writing to the state health officer, Office of Public Health, P.O. Box 60630, New Orleans, LA 70160.

AUTHORITY NOTE: Promulgated in accordance with the provisions of R.S. 40:4(A)(2) and R.S. 40:5. and further in full

cooperation with the U.S. Public Health Service requirements for international travel.

HISTORICAL NOTE: Promulgated by the Department of Health and Hospitals, Office of Public Health, LR 28:1222 (June 2002).

RS 40:1171.4**§1171.4. Confidentiality of HIV test result; disclosure**

A. Except as otherwise provided by law, no person who obtains, retains, or becomes the recipient of confidential HIV test results in the course of providing any health or social service or pursuant to a release of confidential HIV test results may disclose such information pursuant to a written authorization to release medical information when such authorization contains a refusal to release HIV test results.

B. Notwithstanding the provisions of Subsection A of this Section, HIV test results may be released to the following:

(1) Any person to whom disclosure of medical information is authorized by law without the consent of the patient.

(2) Any agent or employee of a health facility or health care provider if:

(a) The agent or employee is permitted access to medical records.

(b) The health facility or health care provider is authorized to obtain the HIV test results.

(c) The agent or employee provides health care to the patient or maintains or processes medical records for billing or reimbursement purposes.

(3) A health care provider or health facility, when knowledge of the HIV test results is necessary to provide appropriate care or treatment to the patient and afford the health care provider and the personnel of the health facility an opportunity to protect themselves from transmission of the virus.

(4) A health facility or health care provider, in relation to the procurement, processing, distributing, or use of a human body or a human body part, including organs, tissues, eyes, bones, arteries, blood, semen, or other body fluids, for use in medical education, research, therapy, or transplantation.

(5) Any health facility staff committees or accreditation or oversight review organizations authorized to access medical records, provided that the committee or organization shall only disclose confidential HIV test results:

(a) To the facility or provider of a health or social service.

(b) To a federal, state, or local government agency for the purposes of and subject to the conditions provided in Paragraph (6) of this Subsection.

(c) To carry out the monitoring evaluation, or service for which it was obtained.

(6) A federal, state, parish, or local health officer when the disclosure is mandated by federal or state law.

(7) An agency or individual in connection with the foster care programs of the Department of Children and Family Services or an agency or individual in connection with the adoption of a child.

(8) Any person to whom disclosure is ordered by a court of competent jurisdiction.

(9) An employee or agent of the committee on parole of the Department of Public Safety and Corrections to the extent that the employee or agent is authorized to access records containing HIV test results in order to implement the functions, powers, and duties with respect to the individual patient of the committee on parole, Department of Public Safety and Corrections.

(10) An employee or agent of the office of probation and parole of the Department of Public Safety and Corrections, division of correction services, to the extent the employee or agent is authorized to access records containing HIV test results in order to carry out the functions, powers, and duties, with respect to patient of the office.

(11) A medical director of a local correctional facility, to the extent the medical director is authorized to access records containing HIV test results in order to carry out the functions, powers, and duties with respect to the patient.

(12) An employee or agent of the Department of Public Safety and Corrections, to the extent the employee or agent is authorized to access records containing HIV test results in order to carry out the Department of Public Safety and Corrections functions, powers, and duties with respect to the patient.

(13) An employee or agent who is authorized by the Louisiana Workforce Commission to access

records containing HIV test results in order to carry out the Louisiana Workforce Commission's vocational rehabilitative services functions, powers, and duties with respect to the protected patient.

(14) An insurer, insurance administrator, self-insured employer, self-insurance trust, or other person or entity responsible for paying or determining payment for medical services to the extent necessary to secure payment for those services.

C. A state, parish, or local health officer may disclose confidential HIV test results when:

- (1) Disclosure is specifically authorized or required by federal or state law.
- (2) Disclosure is made pursuant to a release of confidential HIV test results.
- (3) Disclosure is requested by a physician pursuant to Subsection E of this Section.
- (4) Disclosure is authorized by court order.

D. No person to whom confidential HIV test results have been disclosed pursuant to this Subpart shall disclose the information to another person except as authorized by this Subpart, provided, however, that the provisions of this Subsection shall not apply to the individual or to a natural person who is authorized by law to consent to health care for the individual.

E.(1) A physician may disclose confidential HIV test results under all of the following conditions:

(a) Disclosure is made to a contact, or to a public health officer for the purpose of making the disclosure to said contact.

(b) The physician reasonably believes disclosure is medically appropriate, and there is a significant risk of infection to the contact.

(c) The physician has counseled the patient regarding the need to notify the contact, and the physician reasonably believes the patient will not inform the contact.

(d) The physician has informed the patient of his or her intent to make such disclosure to a contact and has given the patient the opportunity to express a preference as to whether disclosure should be made by the physician directly or to a public health officer for the purpose of said disclosure. If the patient expresses a preference for disclosure by a public health officer or by the physician the physician shall honor such preference.

(2) When making such disclosures to the contact, the physician or public health officer shall provide or make referrals for the provision of the appropriate medical advice and counseling for coping with the emotional consequences of the knowledge of the information and for alteration of behavior to prevent transmission or contraction of HIV infection. The physician or public health officer shall not disclose the identity of the patient or the identity of any other contact. A physician or public health officer making a notification pursuant to this Subsection shall make such disclosure in person, except where circumstances reasonably prevent doing so.

(3) A physician shall have no obligation to identify or locate any contact.

(4) A physician may, upon the consent of a parent or guardian, disclose confidential HIV test results to a state, parish, or local health officer for the purpose of reviewing the medical history of a child to determine the fitness of the child to attend school.

(5) A physician may disclose confidential HIV test results pertaining to a patient to a person authorized by law to consent to health care for the patient when the physician reasonably believes that disclosure is medically necessary in order to provide timely care and treatment for the patient and, after appropriate counseling as to the need for such disclosure, the patient has not and will not inform the person authorized by law to consent to health care. The physician shall not make such disclosure if, in the judgment of the physician, the disclosure would not be in the best interest of the patient or of the individual authorized by law to consent to such care and treatment. Any decision or action by a physician pursuant to this Paragraph and the basis thereof shall be recorded in the patient's medical record.

F. A physician may choose, notwithstanding any other provision of law to the contrary, not to disclose the results of a confidential HIV test to a person upon whom such a test has been performed when in the medical opinion of the physician the disclosure of such results would be medically contraindicated.

Acts 1991, No. 1054, §1; Acts 2010, No. 939, §7, eff. July 1, 2010; Redesignated from R.S. 40:1300.14 by HCR 84 of 2015 R.S.

RS 40:1171.5**§1171.5. Court authorization for disclosure of confidential HIV test results**

A. Notwithstanding any other provision of law, no court shall issue an order for the disclosure of confidential HIV test results except a court of record of competent jurisdiction in accordance with the provisions of this Subpart.

B. A court may grant an order for disclosure of confidential HIV test results upon an application showing:

(1) A compelling need for disclosure of the information for the adjudication of a criminal or civil proceeding.

(2) A clear and imminent danger to an individual whose life or health may unknowingly be at significant risk as a result of contact with the individual to whom the information pertains.

(3) Upon application of a state, parish, or local health officer, a clear and imminent danger to the public health.

(4) That the applicant is lawfully entitled to the disclosure and the disclosure is consistent with the provisions of this Subpart.

C. Upon receiving an application for an order authorizing disclosure pursuant to this Section, the court shall enter an order directing that all pleadings, papers, affidavits, judgments, orders of the court, briefs, and memoranda of law which are part of the application or the decision thereon, be sealed and not made available to any person, except to the extent necessary to conduct any proceedings in connection with the determination of whether to grant or deny the application, including any appeal. Such an order shall further direct that all subsequent proceedings in connection with the application, shall be conducted in camera, and, where appropriate to prevent the unauthorized disclosure of confidential HIV test results, that any pleadings, papers, affidavits, judgments, orders of the court, briefs, and memoranda of law which are part of the application or the decision thereon omit the name of the individual concerning whom confidential HIV test results are sought.

D.(1) The individual concerning whom confidential HIV test results are sought and any person holding records concerning confidential HIV test results from whom disclosure is sought shall be given adequate notice of such application in a manner that shall not disclose to any other person the identity of the individual, and shall be afforded an opportunity to file a written response to the application, or to appear in person for the limited purpose of providing evidence on the statutory criteria for the issuance of an order pursuant to this Section.

(2) The court may grant an order without such notice and opportunity to be heard, if an ex parte application by a public health officer shows a clear and imminent danger to an individual whose life or health may unknowingly be at risk.

(3) The service of a subpoena shall not be subject to this Subsection.

E. In assessing the compelling need and clear and imminent danger, the court shall provide written findings of fact, including scientific or medical findings, citing specific evidence in the record that supports each finding, and shall weigh the need for disclosure against the privacy interest of the protected individual and against the public interest that may not be served by disclosure which deters future testing or treatment or which may lead to discrimination.

F. An order authorizing disclosure of confidential HIV test results shall:

(1) Limit disclosure to that information necessary to fulfill the purpose for which the order is granted.

(2) Limit disclosure to those persons whose need for the information is the basis for the order, and specifically prohibit additional disclosure by such persons to any other persons, regardless of whether they are parties to the action.

(3) To the extent possible consistent with this Section, conform to the provisions of this Subpart.

(4) Include such other measures as the court deems necessary to limit any disclosures not

authorized by its order.

Acts 1991, No. 1054, §1; Redesignated from R.S. 40:1300.15 by HCR 84 of 2015 R.S.

Appendix 8: HIV/STI Testing and Prevention Services Directory

(Updated: May 2021)

Region 1—New Orleans Area

Access Health

Address: 234 Loyola Ave, Suite 300B, New Orleans, LA 70112

Office Phone Number: 504-226-2976

<https://accesshealthla.org/>

Brotherhood, Incorporated

Address: 2714 Canal Street Suite #503 A New Orleans, LA 70119

Office Phone Number: 504-309-3262

Hours of Operation: M-Sat 8AM-5PM

<http://brotherhoodinc.org/>

CrescentCare

Office Phone Number: 504-821-2601

Address: 1631 Elysian Fields Ave, New Orleans, Louisiana 70117

Hours of Operation: M-F 8:30am-5:00pm

www.crescentcare.org

Institute of Women and Ethnic Studies (IWES)

Office Phone Number: 504-599-7712

Physical Address: UNO Research and Technology Foundation, Inc. 2021 Lakeshore Dr. Suite 220, New Orleans, LA 70122

<https://www.iwesnola.org/>

Odyssey House New Orleans

Office Phone Number: 504-913-6776 Address:

1125 N. Tonti New Orleans, LA 70119

www.ohlinc.org

Priority Health Care

Office Phone Number: 504-309-3262

Address: 4700 Wichers Drive Suite #306 Marrero, Louisiana 70072

Hours of Operation: M-F 8:00am-4:30pm

www.priorityhealthcare.org

St.John #5 Baptist Church/Camp ACE

Office Phone Number: 504-283-7376

Physical Address: 3829 Hamburg St, New Orleans, LA 70122

Hours of Operation: M-F 9:30am-6:00pm

St. Thomas Community Health

Office Phone Number: 504-529-5558

Address: 1936 Magazine St. New Orleans, LA 70130

Hours of Operation: M-F 7:30AM-5:00pm

<https://www.stthomaschc.org/>

Trystero New Orleans Harm Reduction Network

Phone Number: 504-535-4766

Syringe Service Program

www.Trystereo.org

Tulane Total Health Clinic

Address: 711 N. Broad Ave. New Orleans, LA 70119

Office Phone Number: 504-988-3002/504-988-3262

Hours of Operation: M-F 8AM-5PM

<https://medicine.tulane.edu/tulane-doctors/total-health-clinic-ruth-fertel-tulane-communityhealth-center/contact-us>

Region 2—Baton Rouge Area

BRASS (Baton Rouge AIDS Society)

Office Phone Number: 225-923-AIDS (2437)

Physical Address: 646 North Foster Dr. Suite A Baton Rouge, LA 70806
www.batonrougeaidsociety.org

CARP (Capital Area Reentry Program)

Office Phone Number: 225-775-7988
Physical Address: 1364 Swan Ave. Baton Rouge, LA 70807 (Main Office)
Out of the Box Center: 9148 Scotland Ave. Baton Rouge, LA 70807
www.careentryprogram.com
www.carpbr.com

CareSouth

Office Phone Number: 225-560-2000
Physical Address: 3140 Florida St. Baton Rouge, La 70806
www.caresouth.org

FSGBR (Family Service of Greater Baton Rouge)

Office Phone Number: 225-927-9810
Physical Address: 4727 Revere Ave. Baton Rouge, LA 70808
www.fsgbr.org

HIV/AIDS Alliance Region Two (HAART)/Open Health Clinic

Office Phone Number: 225-424-1800
Physical Address: 4550 North Boulevard, Suite 250 Baton Rouge, La 70806
www.haartinc.org

Metro Health (Baton Rouge Black Alcoholism Council—BRBAC)

Office Phone Number: 225-338-9333
Physical Address: 950 East Washington St. Baton Rouge, La 70805
www.brmetrohealth.com

Region 3—Houma/Thibodaux Area

Start Corporation Office

Number: 985-333-2020

Address: 235 Civic Center Blvd, Houma, LA 70360

Hours of Operation: M-F 7:30am- 4:30pm

www.startcorp.org

Region 4—Lafayette Area

Acadiana Cares (CARES)

Office Phone Number: 337-233-2437

Physical Address: 809 Martin Luther King Drive Lafayette, La 70501

www.acadianacares.org

Region 5—Lake Charles Area

Odyssey House—Briscoe/Lake Charles

Office Phone Number: 337-433-3786

Physical Address: 4012 Ave. H. Lake Charles, LA 70615

<https://www.ohlinc.org/briscoe-lake-charles>

Southwest Louisiana AIDS Council (SLAC)/Common Street Clinic (CSC)

Office Numbers: 337-439-5861; 337-439-1386 (Clinic)

Physical Address: 425 Kingsley Street Lake Charles, LA 70601 (SLAC)

1715 Common Street Lake Charles, La. 70601 (CSC) www.slac.org

Southwest Louisiana Area Health Education Center (SWLAHEC)

Office Phone Number: 337-478-4822

Physical Address: 603 Pujo St. Lake Charles, LA 70601

Hours of Operation: M-F 8:30am-5pm

<https://www.swlahec.org/>

Region 6—Alexandria Area

CLASS (Central Louisiana AIDS Support Services, Inc.)

Office Phone Number: 318-442-1010

Physical Address: 1785 Jackson Street, Alexandria, LA 71301

Hours of Operation: M,W,TH, 8am - 4:30pm, Tues 8am - 6pm, Fri 8am - 4pm (Wellness clinic
1st and 3rd Thursday 6pm - 9pm) <https://www.class-cenla.org/>

Region 7—Shreveport Area

The Philadelphia Center

Office Phone Number: 318-222-6633

Physical Address: 2020 Centenary Blvd. – Shreveport, LA 71104

Hours of Operation: Monday - Friday: 8:30am - 5pm

<https://philadelphiacenter.org/>

Region 8—Monroe Area

GO CARE Community Health Center

Office Phone Number: 318-325-1092

Physical Address: 1801 North 7th Street | West Monroe, LA 71291

Hours of Operation: Monday 8 AM- 9PM, Tuesday-Thursday 8AM-4:30 PM, Friday 8AM-
2PM <https://www.go-care.org/>

Region 9—Hammond Area/Florida Parishes

Southeast Louisiana Area Health Education System (SELAHEC)*

Office Phone Number: (985) 345-1119

Physical Address: 1302 JW DAVIS Drive, Hammond, LA 70403

www.selahec.org

Prevention services expected to start 7/1/2021

Meeting Action Items/Minutes

Overview Of Outbreak Situation	
Outbreak Situation	
Overview Of Local Area & Systems	
Local patient population	
Locations where high-risk activity occurs	
Local CBOs that may be valuable partners	
Local surveillance and disease control procedures (surveillance data and case management, explanation/review of local casefinding mechanisms and resources, computer systems, and hard-copy record keeping)	
Listing of local health care provider resources, including local clinic and provider types, hours of operation and patient referral procedures	
Lines of communication with the local media per BMAC's recommendation	
Resource Assessment	
Available resources	
Needed resources	
Hours of operation, patient referral procedures of public clinics, and alternate health providers	
Surge capacity	
Mutual aid requests and anticipated requests for additional resources	
Case-Finding & Control Measures	
Testing Campaign (hours of operation, staff requirements, testing requirements, access to refrigerators or coolers, other resources that will be available, location, etc.)	
Immediate control measures	
Future control measures	
ORT Roles & Responsibilities	
ORT roles and responsibilities	
Assessment of whether other individuals other than the ORT will need to be involved in the response	
Partner Services	
Case, partner and cluster (i.e. nonsexual social contacts) interviewing	
Forms and procedures for documenting case, partner, and cluster information	
Diagnostic testing and phlebotomy	

Data entry and analysis (Including flow of data with sample algorithm)	
Timeline For The Completion Of Assigned ORT Tasks	
Modification appropriate timeline for the completion of assigned tasks for each team member	
Communication Plan (Per Communications Liaison)	
Implementation communication plan	
After-Action Report/Evaluation	
Plan for after-action report/evaluation	
Case Prioritization	
Established priority criteria for determining which order patients will be interviewed and counseled.	
Consideration of viral load, profile of partners (e.g., adolescent or female with a known or suspected pregnancy), pregnant females testing positive for HIV/STD, persons testing positive for an STD	
Confidentiality	
Review which ORT members have access to which data and how it will be securely shared between ORT partners	
Oath of Confidentiality Form	
Data Use Agreement Form to assure adherence to all local, state and federal regulations	
Review of confidentiality measures including only collecting identifying information that is essential.	
Use of the established system for secure transmission of data (i.e., DCH file transfer, shared server, fax, etc.)	

Materials for Time-Space Analysis located: I:\PUBLIC\Data Management\Time Space Analysis

Time-Space Analysis is run monthly at SHHP using a CDC-developed SAS Program. Each quarter a SHHP-developed SAS Program is run in addition to the CDC program.

CDC Provided SAS Program

Run the SAS program “STEP 01_LaSalle Parish Fix” located: I:\PUBLIC\Data Management\Time Space Analysis.

Spelling of LaSalle parish varies in eHARS. This very simple program standardizes the spelling so the Time-Space Program does not skip records due to different spellings of the parish name. CDC has fixed this at the parish-level by using fipsco instead of name, but the regions are still calculated using the parish name. Continue to run this program until the public health region section of the code has been updated.

Run the CDC Time-Space Alert SAS Program : *STEP 02_Time Space Alert__2021.02.03*

Refer to the Word doc protocol: *User Guide for Time-Space Analysis* for background and directions on how to run the CDC Time Space Alert SAS Program. Check Sharepoint to ensure the most recent version of the protocol is being referenced.

The CDC provided SAS programs creates an alert at the state, public health region, and parish levels if the number of cases in the past 12 months is greater than 2 standard deviations from the average of the previous 36 months. In addition, tabs for IDUs and MSM/IDUs are output at the aforementioned geographic levels to assess increases in HIV diagnoses related to needle sharing among people who inject drugs.

SHHP Developed SAS Program

An in-house, supplemental SAS Program was developed to monitor trends in HIV diagnoses among other geographic, demographic, and risk groups not assessed in the CDC provided program. They include:

- Baton Rouge MSA

- New Orleans MSA

- Gender (Male, Female, Transgender women)

- Race (Black, Hispanic/Latinx, White)

- Transmission Category (MSM, HRH)

- Age of HIV Diagnosis

The SAS Program is named: *MSA_Demographic_Time Space Alert_11.27.2018*. This program must be run after the CDC-provided program is run as it relies on a dataset produced from the SAS Program named: *HIVO_LA*.

Open the *MSA_Demographic_Time Space Alert_11.27.2018* after the CDC-Program has completed running, keeping the datasets output from the CDC-Program open.

Enter value in for the *%date* macro and run the program. An Excel file named: *RAWDATA_TimeSpace_Demo_MSA* will be output in the results folder created in the CDC program step.

Copy and paste the raw data output into the formatted Excel file: I:\PUBLIC\Data Management\Time Space Analysis\TEMPLATE_TimeSpace_Demo_MSA.xlsx

Save final spreadsheet in the results folder with date of analysis in file name (i.e. Timespace_Demo_MSA_11.27.2018).

Review output for Alerts=1, meeting CDC-defined criteria for a significant increase in number of new diagnoses.

Prioritizing Alerts

It is important to remember that the Time-Space program is analyzing real-time data which commonly results in inflated numbers of diagnoses in the most recent 6 months. Look into each Region or Parish with an alert:

- 1) If an alert is hovering around the +2 SD mark, I usually look back at previous month's Time-Space analysis to see if this is a sustained increase. If there has been at least a +2 SD increase in diagnoses for three consecutive months, I consider that a "sustained increase" in diagnoses and worth looking into and possibly convening a meeting with the Cluster Workgroup. Consult with Jessica on the response plan on a case by case basis.
- 2) In 2019, the Trump administration ramped up ICE raids, and Louisiana jails struck deals with select local jails to house the influx of ICE detainees. Louisiana is second only to Texas for number of ICE detainees housed. As of 7/20/2020 these were the new jails housing ICE detainees:

Catahoula Correctional Center (PP025)
Bossier Parish Jail, Plain Dealing (BMES/PP015)
Richwood Correctional Center (RICHWOOD)
Jackson Parish Correctional Center, Jonesboro (PP049)
Ferriday/River Correctional Center (PP029)
Natchitoches Parish Detention Center (DC069)
Oberlin (PP003)
South Louisiana Correctional Center, Basile (SLCC)
Winn Correctional Center (WIN)

The U.S. Customs and Immigration Enforcement website appears to update this page with the facilities housing detainees: <https://www.ice.gov/detention-facilities/facilities> The Freedom for Immigrants coalition has their own page and a helpful pdf from 2019:

<https://static1.squarespace.com/static/5a33042eb078691c386e7bce/t/5e021b602fb9601681036259/1577196395312/DIYD+LA+v2+Final.pdf>

<https://www.freedomforimmigrants.org/map>

Another website: <https://trac.syr.edu/immigration/detention/exit.shtml>

Sometimes it worth a quick Google search to see if anything has changed.

Existing ICE facilities are in Jena (LASALLE-ICE) and Pine Prairie (CFPINE, FCI). Abbreviations in “()” are the facility codes that will be entered into eHARS as facility of diagnosis. In 2019, a significant number of parish-level alerts were due to increases primarily in Hispanic/Latinx ICE detainees living with HIV housed at local jails. Be sure to review the facility of diagnosis among new diagnoses in the time-space results, particularly in parishes that have the jails and ICE Processing Centers listed above.

- 3) If an alert is generated that is significantly more than +2 SD greater than the previous 3-year average: review cases to see if they are previous OOS diagnoses who have not been updated, assess local trends in diagnoses, create an epidemiologic profile, review DIS PRISM interviews, and any other relevant information. Meet with Surveillance Manager - Jessica to plan next steps.

Secure HIV-TRACE: a guide for public health departments to constructing HIV-1 molecular transmission clusters

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INTRODUCTION

In their groundbreaking 1984 study supporting the then-unproven hypothesis that AIDS was an infectious disease, Auerbach et al. [*The American Journal of Medicine* (184) 76(3): 487-492] provided the first characterization of an HIV transmission cluster by tracing sexual contacts of a flight attendant who came to be known as “Patient 0”. To construct the cluster, they followed the traditional epidemiological approach: (i) start with an index case, Patient 0, (ii) connect sexual partners of the index case, (iii) connect sexual partners of these first-degree partners, and (iv) continue this process with available sexual contact data. Auerbach et al. were able to find AIDS cases up to six partners away from the index case and demonstrate that sexual partners in this cluster were more likely to have AIDS.

When we talk about HIV transmission clusters, these are the types of clusters we have in mind: everyone in the cluster shares a meaningful epidemiological connection to at least one other person in that cluster. The AIDS cluster described by Auerbach et al. was very unlikely to represent a true transmission cluster, since all of the individuals therein had been infected long enough to have progressed to AIDS. University of California, San Diego and Temple University built the HIV Transmission Cluster Engine (**HIV-TRACE**) to recapitulate this process of discovering clusters representing HIV transmission patterns, but with genetic sequence data.

HIV-TRACE differs from traditional shoe-leather epidemiology in one critical aspect. Instead of using epidemiologic, partner-tracing data to identify potential partners, **HIV-TRACE uses viral genetic sequence data—a genetic “partner-tracing”**. By comparing the viral sequence from every person in a surveillance cohort to every other sequence in the cohort, we can identify **potential transmission partners**: pairs of HIV-infected people whose viral genetic sequences are so similar as to imply a direct or indirect epidemiological link between them. To construct transmission clusters using a molecular dataset: for every person in a molecular dataset, we start with that person and follow the genetic links until they have been exhausted.

The HIV-TRACE approach can discover links in near real-time, as sequences become available, and reliably identify clusters of HIV transmission, although the clusters may not be completely characterized, depending on the fraction of people whose infection is diagnosed and who have sequence data available. Understanding the characteristics of these transmission clusters is of potential great importance to public health officials, because these clusters likely comprise individuals with higher risk of HIV transmission.

Here, we provide a walk-through for an exclusive version of this method, **Secure HIV-TRACE**, a secure and user-friendly online tool for constructing an HIV-1 molecular transmission network in a public health surveillance setting. We describe how to use **Secure HIV-TRACE** to construct HIV transmission clusters, detail how **Secure HIV-TRACE** is implemented, and address common questions about using genetic distances for reconstructing and interpreting HIV transmission clusters.

Overview of Secure HIV-TRACE

Secure HIV-TRACE is a web-based bioinformatics tool developed by researchers at the University of California, San Diego and Temple University to facilitate the construction and analysis of HIV-1 genetic transmission clusters. Molecular HIV Surveillance (MHS) is conducted by state and local health departments in collaboration with the HIV Incidence and Case Surveillance Branch (HICSB) at the Centers for Disease Control and Prevention (CDC), which conducts HIV-1 genetic transmission network analysis at the national level. **Secure HIV-TRACE** is available to CDC-funded state and local HIV surveillance programs to facilitate real-time analysis by local officials to better understand and respond to their HIV transmission clusters.

Terminology

As the first step, we introduce terminology necessary to understand HIV molecular transmission networks (**TABLE 1**). **Secure HIV-TRACE** constructs a molecular transmission network representing the inferred HIV-1 transmission patterns among a population of infected individuals from whom a viral genetic sequence was obtained. Each individual's HIV genetic sequence is represented by a node in the network. Individuals who are potential transmission partners (i.e., infected with unusually genetically similar viruses, as specified by the genetic distance) are connected by an edge. The connected group of nodes is called a cluster: this implies that every node in a cluster is connected to at least one other node in that cluster, that there exists a path (of edges) that connects every two nodes in the cluster. The number of edges connected to a node is termed its degree, and may be indicative of its importance in the cluster. By definition, each node in a cluster has a degree of at least one.

Table 1. Definitions of commonly used jargon and its meaning in Secure HIV-TRACE

Term	Technical definition ¹	Meaning in Secure HIV-TRACE
Node	A point (vertex) in the network	A person with diagnosed HIV infection, represented by their earliest reported viral sequence
Edge	A line connecting nodes	A connection denoting potential (but not necessarily direct) transmission partners
Cluster	A connected component in the network, i.e., there exists a path connecting any two nodes in a cluster	A connected group of potential transmission partners
Network	A collection of nodes, some of which are connected by edges	All persons in the molecular surveillance cohort connected to at least one potential transmission partner. A network will include multiple clusters and singletons.
Degree	The number of edges connecting to a node	The number of potential transmission partners for a given person

¹From M.E.J. Newman (2010) *Networks*, Oxford University Press.

If a node is clustered in a network, that means we were able to locate someone else in the dataset with a genetic connection to that node. **Importantly, these connections (edges) do**

NOT imply direct transmission! Using genetic surveillance data alone, we can never exclude the possibility of unsampled intermediate infections or shared sources of infection. Even an extraordinarily similar genetic sequence in a recently infected case cannot definitively identify true transmission partners. Furthermore, individuals can be connected to multiple potential transmission partners in the network, some of whom may also be connected to each other. This arrangement does not necessarily imply repeated transmission events from a single individual, but rather it indicates ambiguity possible routes of infection.

Classes of Secure HIV-TRACE Sites

Secure HIV-TRACE allows for two classes of sites. Each participating jurisdiction can decide which class of site they want to be. **Class I** sites can run stand-alone transmission network analysis, explore these clusters dynamically and downloading results. **Class II** sites will be able to perform all these actions, and they will also maintain an instance of their transmission network on the secure server (see section **WHAT MAKES Secure HIV-TRACE SECURE**). Maintaining the transmission network will allow any user from same institution to (i) revisit previous analyses and (ii) append new data to the network. By appending to the network, cluster IDs will remain consistent from run to run.

Participating site can change their Class status at any time (see **Role of MHS Contact Person**).

Institutions that choose Class II status WILL still be able to run stand-alone HIV-TRACE analyses in addition to their saved network. Stand-alone analyses WILL NOT be saved on the server for either Class I or Class II users. Class I sites will need to re-upload and rerun HIV-TRACE every time they wish to incorporate new data or visualize their results.

RUNNING Secure HIV-TRACE

Preparing Data for Analysis

To run **Secure HIV-TRACE**, the user needs to provide only a single file containing the relevant variables. HICSB has produced a SAS program (*SAS Program #1*) to facilitate the creation of these input files for Secure HIV-TRACE. This SAS program will compile the necessary variables from eHARS and properly format them for use in **Secure HIV-TRACE**. The output from the SAS program will be a comma separated value (CSV, extension .csv) file in which each row represents a single person with an associated HIV-1 *protease/reverse transcriptase (pro/RT)* sequence.

To run **Secure HIV-TRACE**, four variables for each person are required by the program: (1) the earliest sampled *pro/RT* HIV-1 genetic sequence for a given person, (2) the date of genotyping for this sequence, (3) date of HIV diagnosis, and (4) a unique ID for each person. The unique ID will be generated automatically based eHARS unique identifier and WILL NOT

contain or depend on any personally identifiable information (e.g., name, social security number, date of birth, address).

Table 2. Variable names and acceptable entries for use in Secure HIV-TRACE.

Variable	Variable name	Required ¹	Used in vizualization	Acceptable entries		
Unique ID	ehars_uid	Yes	Yes	eHARS Unique IDs		
Date of genotype	sample_dt	Yes	No	YYYYMMDD		
Date of diagnosis	hiv_aids_dx_dt	Yes	No	YYYYMMDD		
Genetic sequence	clean_seq	Yes	Yes	IUPAC codes		
Birth sex	birth_sex	No	Yes	Male	Female	Unknown
Current gender	current_gender	No	Yes	Male	Female	Unknown
				Transgender-Female to male	Transgender-Male to Female	Additional Gender Identity
Age	age_dx	No	No	<13	13-19	20-29
				30-39	40-49	50-59
				>=60		
Transmission risk category	sex_trans	No	Yes	Heterosexual Contact-Female	Heterosexual Contact-Male	IDU-Female
				IDU-Male	MSM-Male	MSM & IDU-Male
				Other/Unknown-Male	Other/Unknown-Female	Perinatal
Race/ethnicity	race_cat	No	No§	American Indian/Alaska Native	Asian	Black/African-American
				Hispanic/Latino	Native Hawaiian/Other Pacific Islander	White
				Multiple Races	Unknown	
Recent viral load	vl_recent_value	No	Yes	Positive integers		
Date of recent viral load	vl_recent_date	No	No	YYYYMMDD		
Stage 0 diagnosis	stage_zero_dx	No	Yes	Yes	No	
Vital status	vital_status	No	No§	Alive	Unknown	
				Dead		

¹Secure HIV-TRACE requires these variables to run and will not construct a transmission network if they are missing or improperly formatted.

Logging in to Secure HIV-TRACE

To log in to **Secure HIV-TRACE**, direct your web browser to *secure.hivtrace.org*, enter your username and password, and click “Sign in” (**FIGURE 1**). **Secure HIV-TRACE** uses modern web technologies and will not function unless your browser has JavaScript enabled. **Secure HIV-TRACE** supports all recent releases of major browsers (Chrome, Safari, Firefox, Internet Explorer). Each user of **Secure HIV-TRACE** will have a unique, registered username (i.e., email address) and password. Approved users at each health department (see **Role of MHS Contact Person**) will log on to their site’s account on *secure.hivtrace.org*. Users will be able to log in to Secure HIV-TRACE only from pre-approved locations (e.g., work stations within local public health department). If a problem is experienced with the login, please contact the administrators via email at hivtrace@ucsd.edu.

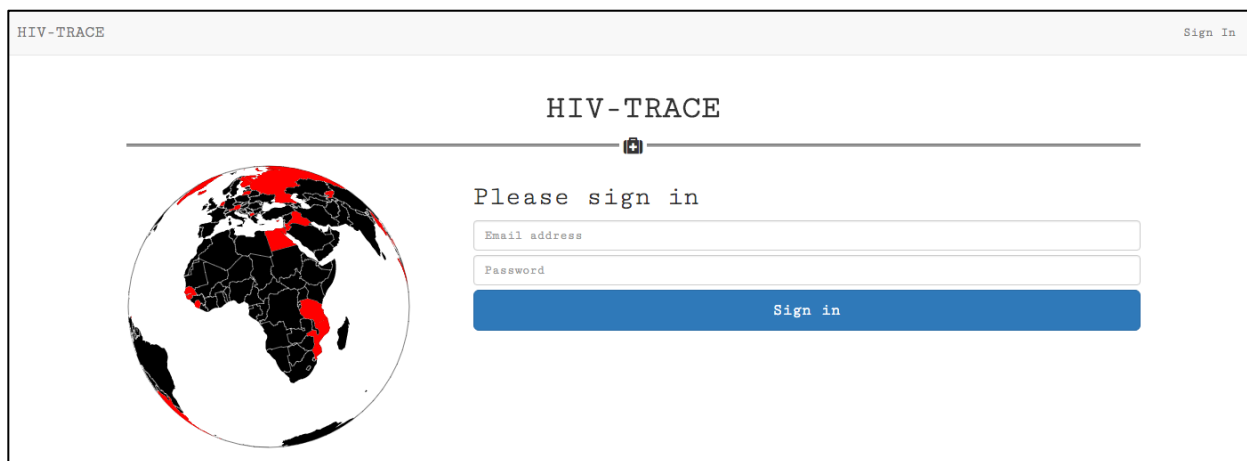


Figure 1. Login page for Secure HIV-TRACE.

Uploading the Data

All data for a **Secure HIV-TRACE** analysis must be uploaded as a single CSV file created by the SAS program. Once you have logged into Secure HIV-TRACE, you have the ability to upload the data file. To upload, simply select the “*Select Sequence File*” icon (**FIGURE 2**) and direct your web-browser to the location of the CSV file (**FIGURE 3**). Highlight the CSV file and select “*Open*” in the file browser window.

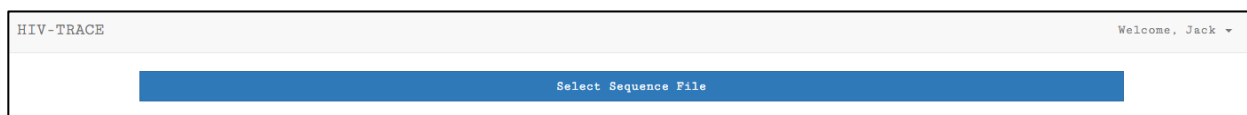


Figure 2. Data upload icon for Secure HIV-TRACE

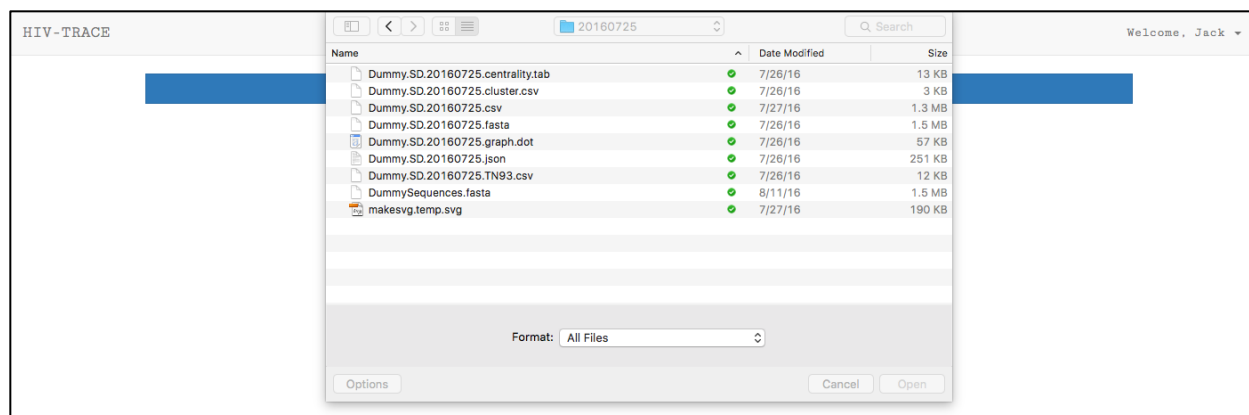


Figure 3. File browser dialog to select the CSV file created by SAS program.

Data Quality Control

Once the data file is selected, **Secure HIV-TRACE** will automatically perform a series of data quality checks locally (i.e., on the user's machine) to ensure that the data are properly formatted and that no detectable personally identifying information has been included. If improper formatting is detected, the problematic lines will be highlighted in the upload status page displayed in the browser in either orange or red (**FIGURE 4**).

- **Orange highlighting: a warning indicating that an entry is problematic, but that the variable is not necessary for running Secure HIV-TRACE.**
 - **What might produce an orange warning:**
 - a variable column is not on the approved variable list (see **TABLE 2**)
 - a variable is not properly formatted, e.g., if “Men who have sex with men” is provided instead of “MSM” under *sex-trans*
 - **What will happen as a result?**
 - non-conforming entries will be changed to ‘Missing’ for the *sex_trans* variable
 - Missing values will affect some visualization and analysis features.
 - **What to do about it:**
 - Select ‘Ignore and Continue’ to proceed to network construction.

<p>Warning</p> <p>There were issues with the comma-delimited file provided.</p> <p>Please review the rows that are highlighted in red and select the appropriate action.</p> <p>Please review the cells that are highlighted in yellow and select the appropriate action.</p> <p>Invalid Rows - Rows highlighted in red have a severe issue (invalid sequence or ehars_uid) and will be omitted.</p> <p>Invalid Attribute - Cells highlighted in yellow have invalid attributes and will be replaced with 'Missing'.</p>								
Ignore and Continue								
cur_city_name	cur_city_fips	cur_county_name	cur_county_fips	cur_state_cd	hiv_aids_dx_dt	vl_recent_value	vital_status	ehars_uid
					198808..		2-Dead	GA00HHARS002073*
					20120504		2-Dead	GA00S000159458-6
					20130505	500	2-Dead	GA00S000159577-0
ATLANTA	04000	DEKALB CO.	089	Georgia	20111224		1-Alive	GA00S000163009-7
ATLANTA	04000	DEKALB CO.	089	Georgia	20040101			GA00S000172660-0
ATLANTA	04000	FULTON CO.	121	Georgia	20040824		1-Alive	GA00S000178537-9
ATLANTA	04000	FULTON CO.	121	Georgia	20040824		1-Alive	GA00S000178537-9
					199211..		2-Dead	GA01HAGUS000080*
MACON	49000	BIBB CO.	021	Georgia	200201..		1-Alive	GA00HHARS000317*
		COLUMBIA CO.	073	Georgia	200108..		1-Alive	GA00HHARS000323*
ATLANTA	04000	FULTON CO.	121	Georgia	200101..		1-Alive	GA00HHARS000324*
ATLANTA	04000	FULTON CO.	121	Georgia	200104..	00003488	1-Alive	GA00HHARS000328*
COLUMBUS	19007	MUSCOGEE CO.	215	Georgia	200111..		1-Alive	GA00HHARS000356*
ATLANTA	04000	FULTON CO.	121	Georgia	200103..		1-Alive	GA00HHARS000485*

Figure 4. Quality control check displaying both red and orange warnings.

- **Red highlighting:** a warning indicating a problem in a necessary variable (i.e., unique ID, genetic sequence, or date of genotyping), e.g.
 - a non-IUPAC character (e.g., #, X, or ?) is found in the genetic sequence
 - the date of genotyping is improperly formatted (e.g., 08/22/2016 instead of 20162208)
 - the same individual is included more than once (i.e., duplicated unique ID).
- **What will happen as a result?**
 - Stand-alone analyses can still proceed if a red warning is issued; however, rows containing this warning will **NOT** be included in the analysis.
 - Datasets must be free of red warnings before a network can be stored for future analyses.

- **What to do about it:**
 - If a red warning persists using a file created by *SAS Program #1*, please contact us hivtrace@ucsd.edu.

Importantly, this quality check is run **locally** in the web-browser (i.e., on the user's computer), before the data are uploaded to the server for analysis. This security measure guards against personally identifiable information (e.g., names, address, social security numbers) accidentally being uploaded to the **Secure HIV-TRACE** server. Data cannot be uploaded if it fails the check against personally identifiable information (i.e., a red warning is provided). Once the quality check is completed, the user can proceed to upload the data to the secure server for analysis over an encrypted connection (see **johnsnow**).

CLASS I vs. CLASS II SITES

In order for jurisdiction to use the Secure HIV-TRACE web-application, each jurisdiction must first determine whether to have "Class I" or "Class II" access. All users at a given institution will have the same type of access.

- **Class I** access does not allow any of the users at the health department to save results on the University of California, San Diego secure server. The inability to save data has important implications:
 - The cluster names/numbers that are generated through the Secure HIV-TRACE analyses are not stored and will not be maintained across different analyses. Each time the analysis is run with new data, the cluster numbers will change.
 - Users cannot share their work with others. Although a user can download/export a static image snapshot of the network or clusters to send to others, the others would not be able to explore the interactive nature of the network and cluster visualizations offered by Secure HIV-Trace without re-running the analysis themselves. (When they re-run the analysis, the cluster names/numbers will differ from those obtained by the prior user.)
- **Class II** access allows all users within the jurisdiction to store the network results on the University of California, San Diego secure server for revisiting and sharing network results between users at the same health department. Cluster identifiers are maintained across analyses, allowing users to revert to previous versions of the network.

Table 3. Parameter options available for stand-alone Secure HIV-TRACE analysis.

Feature	Class I Sites	Class II Sites
Use default parameters	X	X
Personalize parameters	X	X
Multiple users per site	X	X
Store network on server		X
Revisit/append networks		X
Share work with others at site		X
Maintain cluster IDs		X
Network visualization	X	X
Save results locally	X	X
Contaminant screening	X	X
Security protocols	X	X

STAND-ALONE ANALYSIS

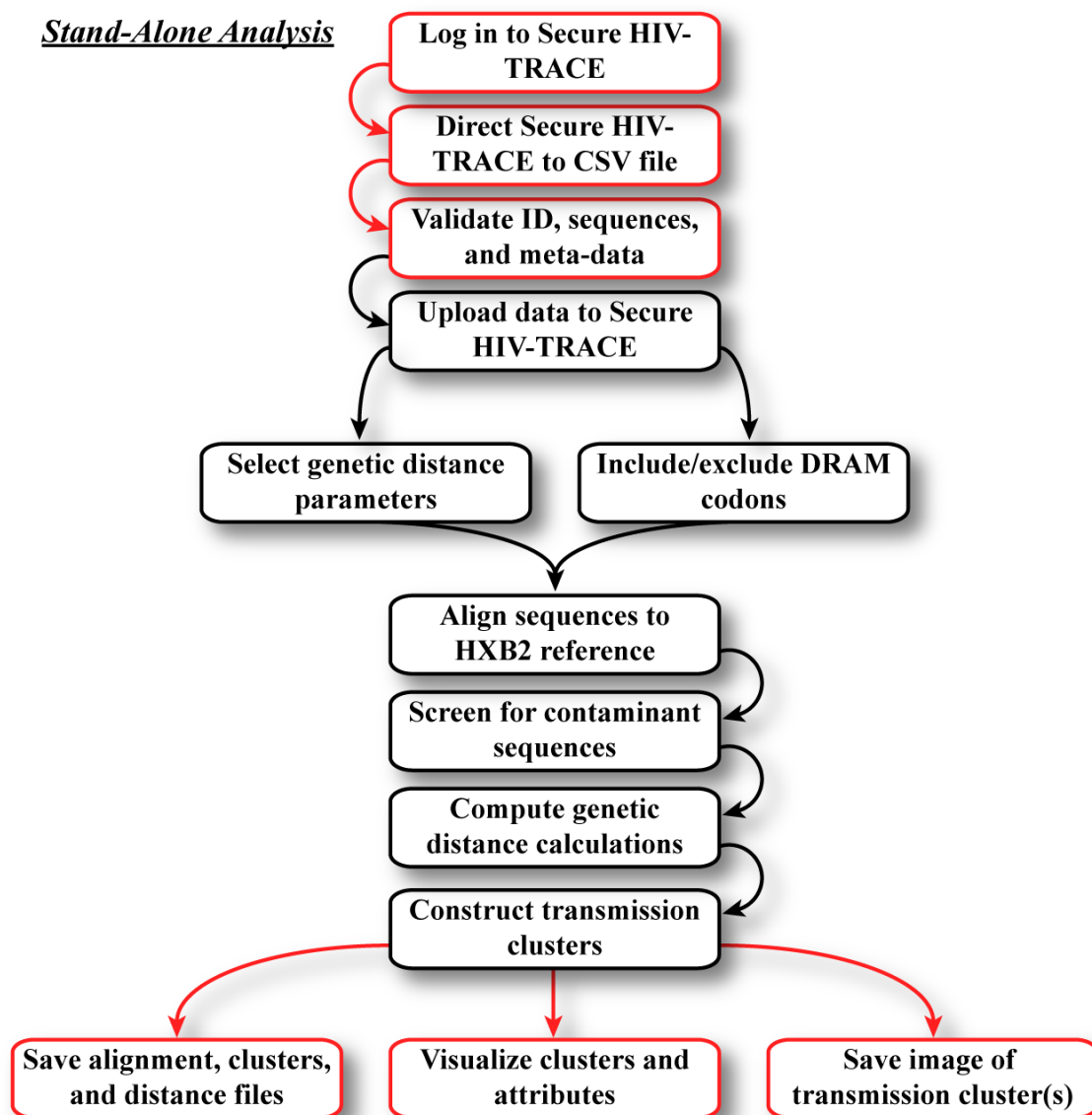
For sites that opt to **not** store their transmission network on the secure server, **Secure HIV-TRACE** provides the option for stand-alone transmission network analysis. (“Stand-alone” means that the analysis cannot be saved.)

Transmission Network Analyses for CLASS I Sites

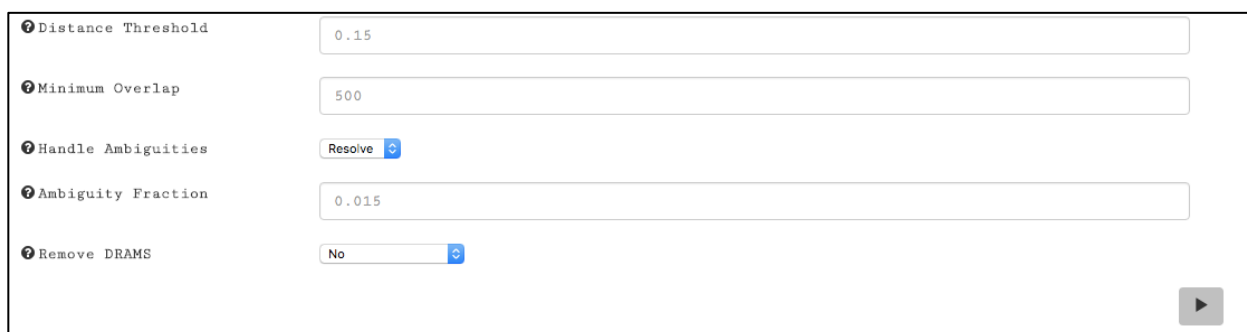
To run a transmission network analysis, CLASS I users can upload their dataset to the secure server. See **FIGURE 5** for an overview of the protocol. After **Uploading the Data**, the data are passed through **Data Quality Control**. Users will then be presented with the option to select the parameters that govern their stand-alone HIV-TRACE analysis (**FIGURE 6**). Enter (i) value for “*TN93 Genetic Distance Threshold*”, (ii) value for “*Minimum Overlap*”, (iii) type of “*Ambiguity Handling*”, (iv) value for “*Ambiguity Fraction*”, and (v) type of “*DRAM Handling*” (**TABLE 4**). The “*Ambiguity Fraction*” option is available only when “*Ambiguity Handling*” is set to “*Resolve*”. The default parameter values provided are the same parameter values that researchers at UCSD, Temple, and CDC routinely use in their own HIV-TRACE analyses. In general, we strongly recommend using the default parameter values, because they have been carefully chosen to produce the best results for a typical spectrum of analyses. However, different distance cutoffs or ambiguity/DRAM handling may be justified for specific use cases. For more information about these parameters and their value, see **FAQ**.

Table 4. Parameter options available for stand-alone Secure HIV-TRACE analysis.

Parameter	Purpose	Units	Default	Options
Distance Threshold	Define potential transmission partners	Substitutions/Site	0.015	0.0 to 0.02
Minimum Overlap	Prevent spurious links over short sequences	Nucleotides	500	0 to 1500
Handling Ambiguities	Penalize sequences with high proportions of ambiguous nucleotides	Categorical	Resolve	Resolve, Average
Ambiguity Fraction	Penalize sequences with high proportions of ambiguous nucleotides	Fraction	0.015	0.0 to 1.0
Remove DRAMs	Adjust for influence of drug resistance	Boolean	Include	Include or Exclude

Stand-Alone Analysis**Figure 5. Secure HIV-TRACE workflow for Stand-Alone analyses.**

Once all the parameter values have been selected, press “*Continue*”, and **Secure HIV-TRACE** will run automatically: (i) sequences are aligned against the reference strain, HXB2 *pro/rt*, (ii) sequences are screened for contamination (i.e., highly similar to the HXB2 reference strain) and region specificity, (iii) all pairwise genetic distances are calculated, and (iv) transmission clusters are assembled. A page showing the progress of this analysis will be displayed (**FIGURE 7**). The results page will be displayed once the analysis has been completed.



Distance Threshold	<input type="text" value="0.15"/>
Minimum Overlap	<input type="text" value="500"/>
Handle Ambiguities	<input type="button" value="Resolve"/>
Ambiguity Fraction	<input type="text" value="0.015"/>
Remove DRAMS	<input type="button" value="No"/>

Figure 6. Parameter selection options for stand-alone Secure HIV-TRACE analyses. Suggested default parameter options are shown in gray.

For CLASS I users, all uploaded data will be deleted from the secure server immediately following the analysis. Results will not be stored and will not be available once the user has logged out of Secure HIV-TRACE or closed the browser window.

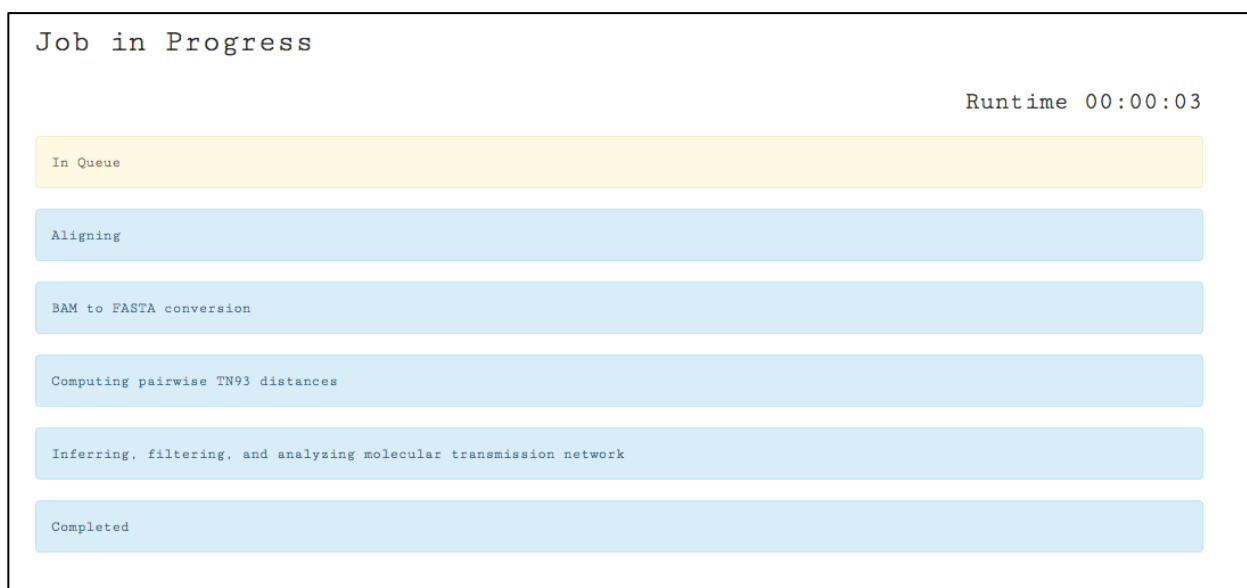


Figure 7. Job progress display indicating stage of analysis.

UPLOADING, REVISITING, AND APPENDING STORED NETWORKS FOR CLASS II SITES

Users at Class II Sites of **Secure HIV-TRACE** can upload and store their network on the secure server to be analyzed and viewed by all members of their institution. This network can be updated as new data become available which maintains the cluster names/numbers generated in the prior run. Stand-alone analyses (that will not be saved to the server) can also be run using these same data.

Beginning a Transmission Network Analysis for CLASS II Sites

After login, the user can initiate the process of network construction by indicating the option to 'Select Sequence File' (**FIGURE 2**) and the directing the browser to the most current version of the CSV dataset produced by the SAS program (see **Uploading the Data**). Once the data have passed through **Data Quality Control** the user can construct their transmission network by selecting "Continue". HIV-TRACE will then run automatically (**FIGURE 8**) on these data using the default parameters outlined in **TABLE 3**: (i) Sequences are aligned against HXB2 *pol*, (ii) sequences are screened for contamination and region specificity, (iii) all pairwise genetic distances are calculated, and (iv) transmission clusters are assembled. A page showing the progress of this analysis will be displayed (**FIGURE 7**). The results page will be displayed once the analysis has been completed.

If there are no red warnings (i.e., missing required fields, or duplicate IDs), the data and transmission network will then be stored on the secure server. If red warnings are issued, then the analysis will be performed, but the network WILL NOT be stored. A stored network can be accessed by all other users at the same institution and will still be available once the user has logged out or closed their browser window.

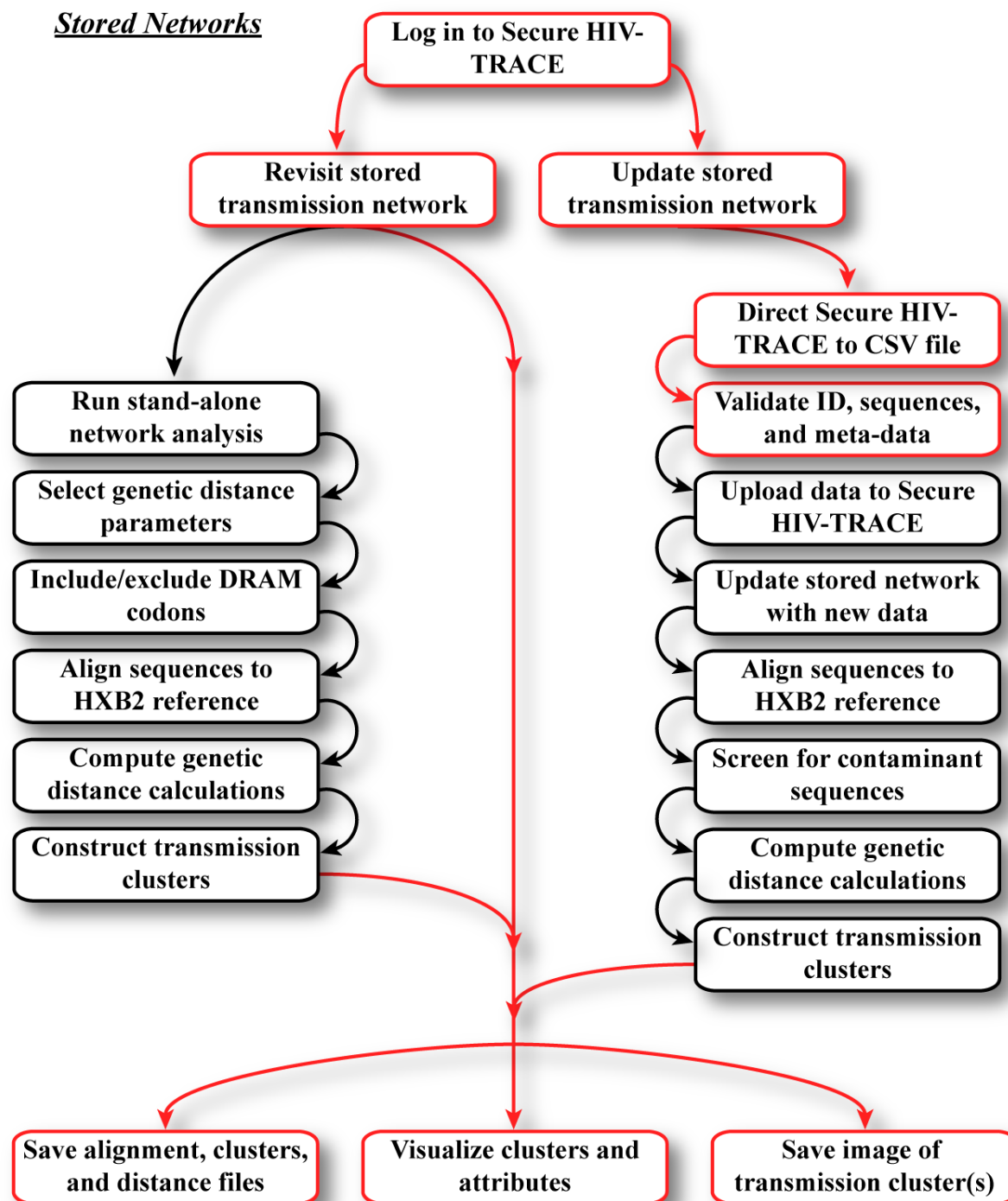


Figure 8. Secure HIV-TRACE workflow for CLASS II sites.



Figure 9. Landing page for CLASS II users with network already stored on Secure HIV-TRACE.

Revisiting a Stored Transmission Network for CLASS II Sites

Revisiting a stored transmission network can facilitate sharing of results within an institution without requiring re-analysis of the data (**FIGURE 8**). To access a stored network, log in to **Secure HIV-TRACE** and select “*Revisit Stored Network*”. The user now has the ability to visualize the transmission clusters and download the results from network analysis. Importantly, only one network per MHS site can be stored at a time.

Updating a Transmission Network Analysis for CLASS II Sites

As new data become available (i.e., new diagnoses, updated viral load, or other meta-data), these data can be incorporated into the existing transmission network, without requiring a complete re-analysis of the entire dataset. To update a transmission network, click the “*Append*” icon after logging in to **Secure HIV-TRACE** (**FIGURE 9**). The entire dataset must be re-uploaded to **Secure HIV-TRACE** every time a user wants to update their transmission network. To update the network, follow the same procedure as before when **Beginning a Transmission Network Analysis for CLASS II Users**. If there are no red warnings, click “*Continue*” and the network analysis will be automatically executed and the stored network updated. If there are red warnings, the user can choose to “*Continue*” to perform a standalone analysis. The network analysis will still be performed, but the stored network will not be updated. A page showing the progress of this analysis will be displayed (**FIGURE 7**). The results page will be displayed once the analysis has been completed. By appending new data to an existing network, the cluster naming scheme will remain consistent from analysis to analysis.

Stand-Alone Transmission Network Analyses for Class II Sites

Like Class I Sites, Class II Sites may also perform a stand-alone analysis that will not be stored on the server, if they so choose. Stand-alone analyses can be run using non-standard parameter settings or on sub-sets of the full dataset, comprising only certain individuals. Like Class I Sites, Class II Sites can also run **Secure HIV-TRACE** using an array of parameters that govern the genetic distance cutoff and the handling of DRAMs (**FIGURE 8**). To perform a stand-alone analysis, log in to **Secure HIV-TRACE** and select “*Revisit Stored Network*”. Then, select “*One-off*”.

To parameterize your stand-alone analysis, enter (i) value for “*TN93 Genetic Distance Threshold*”, (ii) type of “*Ambiguity Handling*”, (iii) value for “*Ambiguity Fraction*”, (iv) value for “*Minimum Overlap*”, and (v) type of “*DRAM Handling*” (**TABLE 2**). The “*Ambiguity Fraction*” option is available only when “*Ambiguity Handling*” is set “*Resolve*”. The default parameter values provided are the same parameter values that researchers at UCSD, Temple, and CDC routinely use in their HIV-TRACE analyses and the same values that **Secure HIV-TRACE** automatically runs for CLASS II users on their stored network. For more information about these parameters and their values, **see FAQs** or the HIV-TRACE publication [Kosakovsky Pond (2018) *Molecular Biology and Evolution*]. Once all the parameter values have been selected, press “*Continue*”, and Secure HIV-TRACE will run automatically. Again, (i) Sequences are aligned against HXB2 *pol*, (ii) sequences are screened for contamination and region specificity, (iii) all pairwise genetic distances are calculated, and (iv) transmission clusters are assembled. A page showing the progress of this analysis will be displayed (**FIGURE 7**). The results page will be displayed once the analysis has been completed; however, this version of the network will not be stored on the secure server and cluster naming will not be consistent with previous or subsequent versions of the network.

Deleting a Stored Transmission Network

To delete a stored network for any reason, click on the “*Delete*” icon (**FIGURE 9**) after logging in to **Secure HIV-TRACE**. The stored network will be removed from the secure server and a new network can be uploaded. Importantly, if a user at an MHS site deletes a stored network, no other user at that site will be able to access that network, and the network must be built anew. **Delete with caution.**

Executive (read-only) Users

Active users of **Secure HIV-TRACE** can modify, download, and delete the networks in any way. At Class II Sites, we permit another type of user: the Executive User. These Executive Users have ‘read-only’ access to the stored network on **Secure HIV-TRACE**. They can visualize and explore the network via the website, but they cannot download, modify, or delete the network in any way.

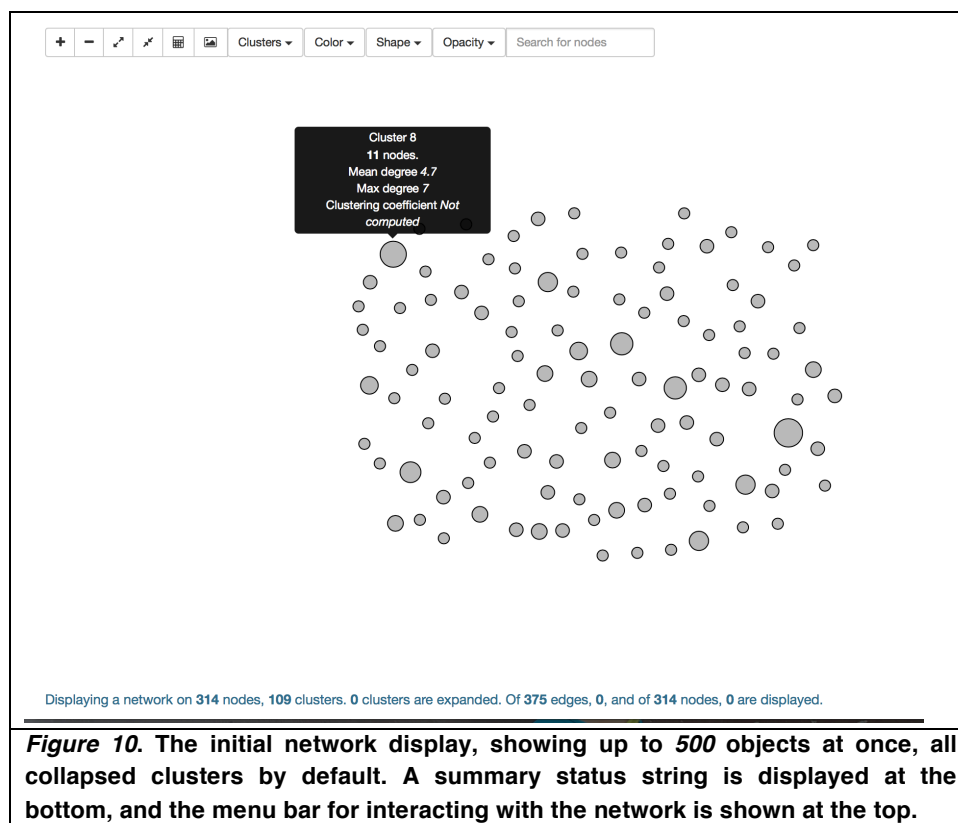
INTERPRETING THE RESULTS FROM **Secure HIV-TRACE**

The analytical **Secure HIV-TRACE** engine returns a rich description of the network, which can be explored, visualized, and exported by means of an interactive result viewing web application. The information is organized in five tabs: *Network*, *Graph*, *Clusters*, *Nodes*, and *Attributes*.

Network Tab

The structure of the inferred network is displayed in an interactive viewer within this tab. When the results are first presented to you, individual **clusters** will be displayed as circles with the area of the circle proportional to the number of nodes; this view is called **collapsed clusters** view. Holding a mouse pointer over a particular cluster will display a pop-over window with key

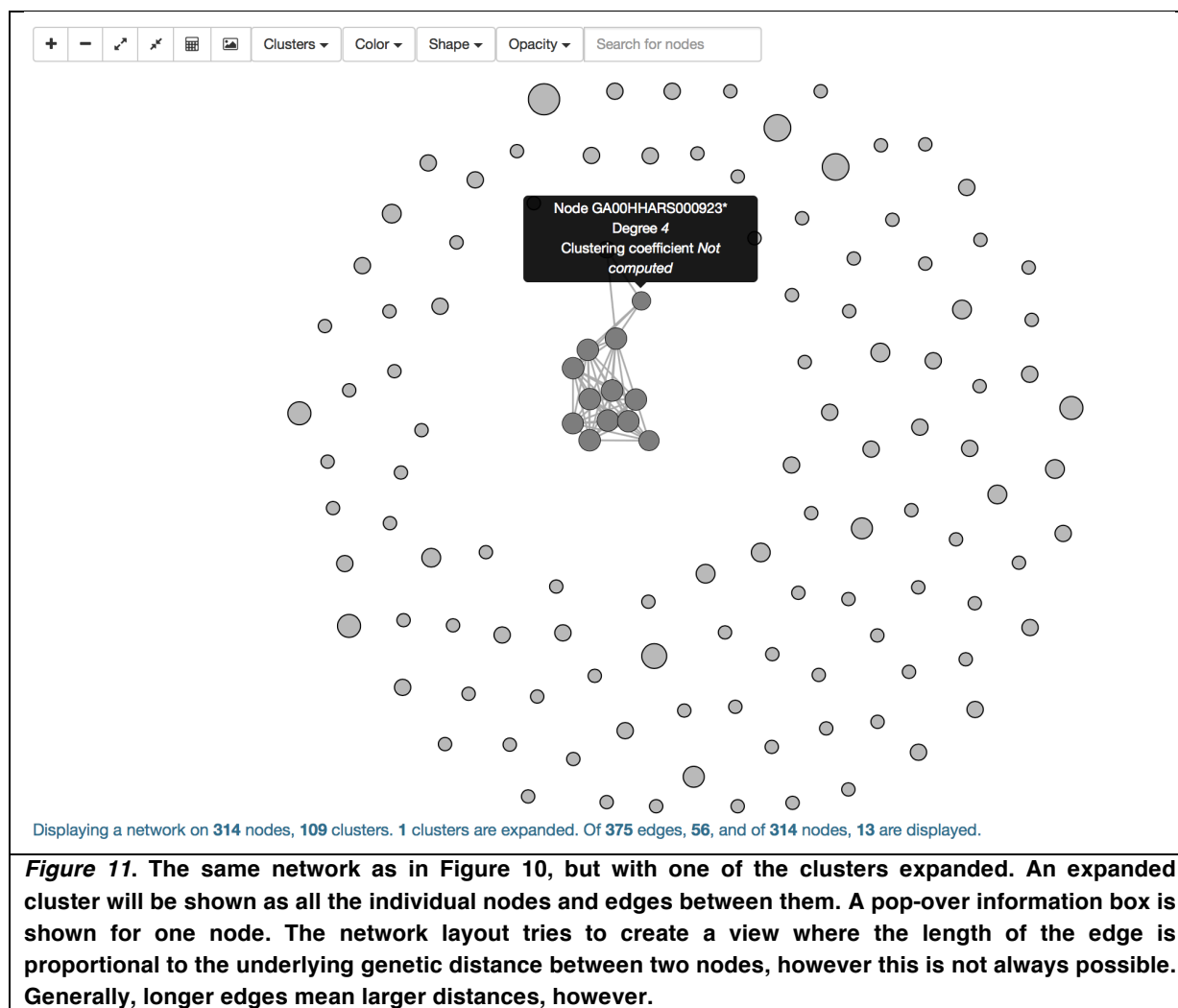
cluster metrics (see **FIGURE 10**). Clicking on a cluster and dragging the mouse pointer allows you to reposition the cluster. **Secure HIV-TRACE** implements a constantly updating network view, so you will see the clusters/nodes move about before settling into stable positions. Manipulating the network by moving objects around, resizing views, changing spacing options, and expanding/collapsing clusters will trigger new rounds of automatic network layout.



Clicking on a cluster will display a pop-up menu, which allows you to control the positioning for the cluster (*Center on screen* or *Fix in place*), and to “*Expand cluster*” (i.e., show its constituent nodes and edges; see **FIGURE 11**). You can interact with nodes the same way as with clusters. Node sizes (area) are proportional to the degree of the node, so that more connected/central nodes will be larger than nodes with only a few links. Below the network, you will find a status string showing (e.g., as in **FIGURE 11**) how many of the nodes and edges are shown and how many clusters are collapsed and expanded. Above the network, you will find the menu bar which gives you control over how the network is displayed. The first five buttons are discussed here, and the menus are explained in the next section.

1. **+** button **increases** the spacing between network objects: it pushes the nodes and clusters further apart. Note that the nodes cannot “escape” the network display pane: eventually they will bump against the edges and stay there (you can see some of that in effect in **FIGURE 14**)

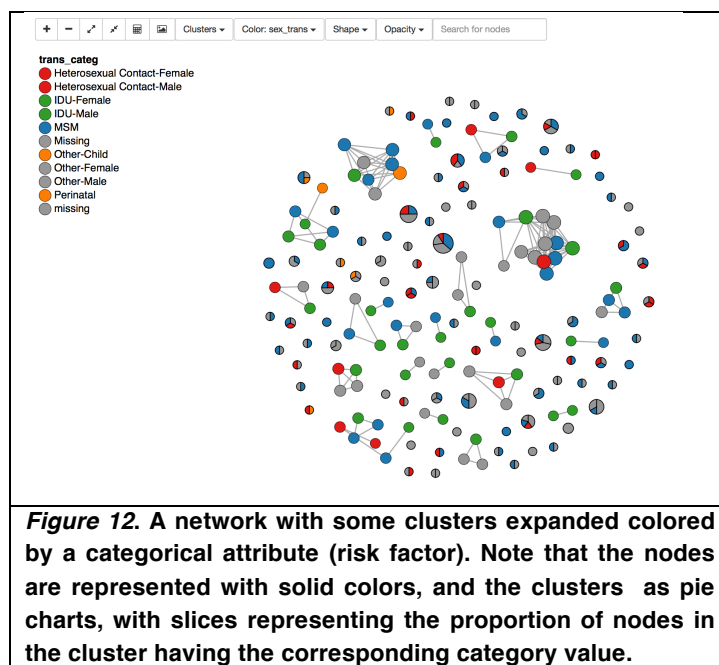
2. button **decreases** the spacing between network objects: it pulls the nodes and clusters closer together. At extreme settings, they will all clump together at the center of the pane.
3. button **expands** the size of the size of display on the screen (both width and height). Using it will trigger a network redraw.
4. button **shrinks** the size of the layout canvas (both width and height). Using it will trigger a network redraw.
5. button creates an image snapshot of the current view of the network, and, depending on the browser, will either download the result to a file, or open it in a separate browser tab/window (from which in can be saved or printed).



Interactive menus in the navigation bar allow you to select nodes and clusters, expand and collapse groups of nodes and clusters at once, and change how network objects are **colored**, **shaped**, and **how transparent** they are, thereby allowing you to visualize up to three different dimensions of the data at once. For the following discussion, the examples will assume that some of the clusters are collapsed and some are expanded. The easiest way to do this is to manually expand some clusters, by clicking on them and choosing the *Expand Cluster* option from the pop-up menu; you can also select and expand individual clusters from the **Clusters** tab (see below).

Clusters menu in the menu bar has five options.

1. *Expand All* will expand as many clusters as possible (starting with the largest ones), up to the total maximal number of objects.
2. *Collapse All* will collapse all expanded clusters.
3. *Expand Filtered* works in conjunction with the search box (discussed below) and expands all clusters having any nodes that match the search criteria.
4. *Collapse Filtered* works in conjunction with the search box (discussed below) and collapses all the clusters that any nodes matching the search criteria.



The **Color** menu will have a variable number of options, based on the node attributes (or variables, see **TABLE 2**) returned by the analysis. Selecting *None* in this menu will turn off coloring (revert to the default colors). **Secure HIV-TRACE** can color nodes and clusters either using variables with up to 10 categorical values, including the *missing* value, (like risk factor, or age, see **FIGURE 12**), or using variables with continuous ranges (like viral load, see **FIGURE 13**, left). Legends are automatically generated and positioned in the top left corner of the network display.

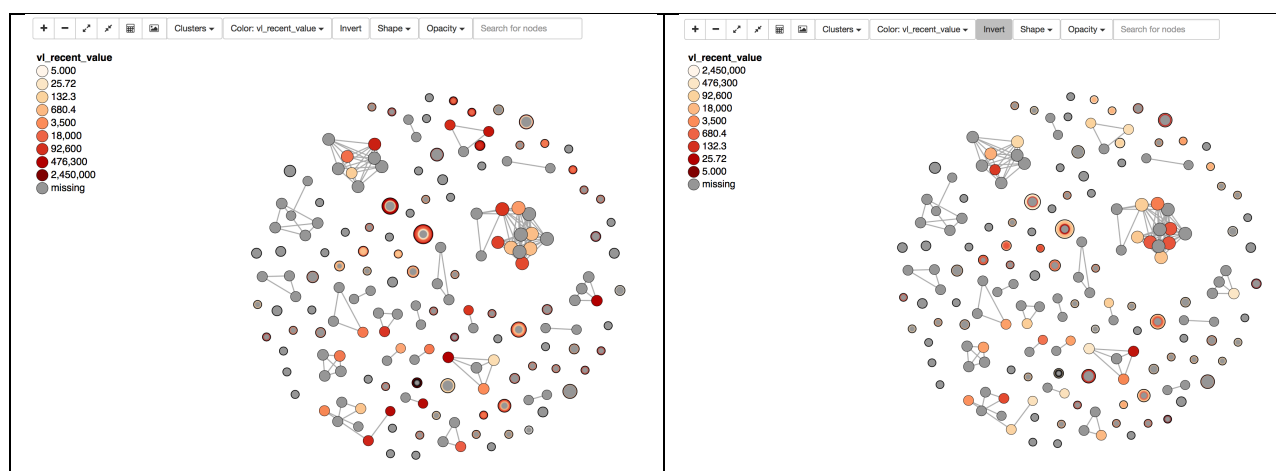


Figure 13. A network (with some clusters expanded) colored by a continuous attribute (viral load). Note that the nodes are represented with solid colors, and the clusters are shown as radial gradients, to indicate the distribution of attribute values for the nodes in the cluster, proportional to the number of nodes in that cluster that fall into that category. The color scale is low-to-high on the left, and it is flipped to high-to-low on the right by clicking the “invert” button. In other words, the left panel emphasizes high viral loads, while the right panel – low viral loads. Secure HIV-TRACE automatically determined that viral load is best displayed using a logarithmic scale, as reflected in the legend.

Categorical variables with more than 10 values are not included in the *Color* menu, because the human eye begins to have a difficult time parsing patterns with more than 10 colors. Some of the variables (e.g. risk factor) will have predefined color palettes, while other variables will be shaded with default color schemes [following the highly recommended work on cartographic coloring by Cynthia Brewer, see (colorbrewer2.org)].

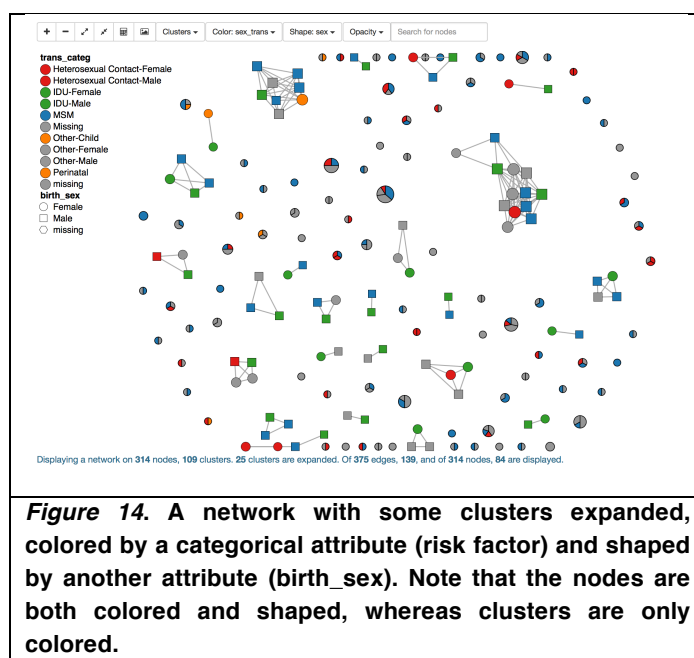
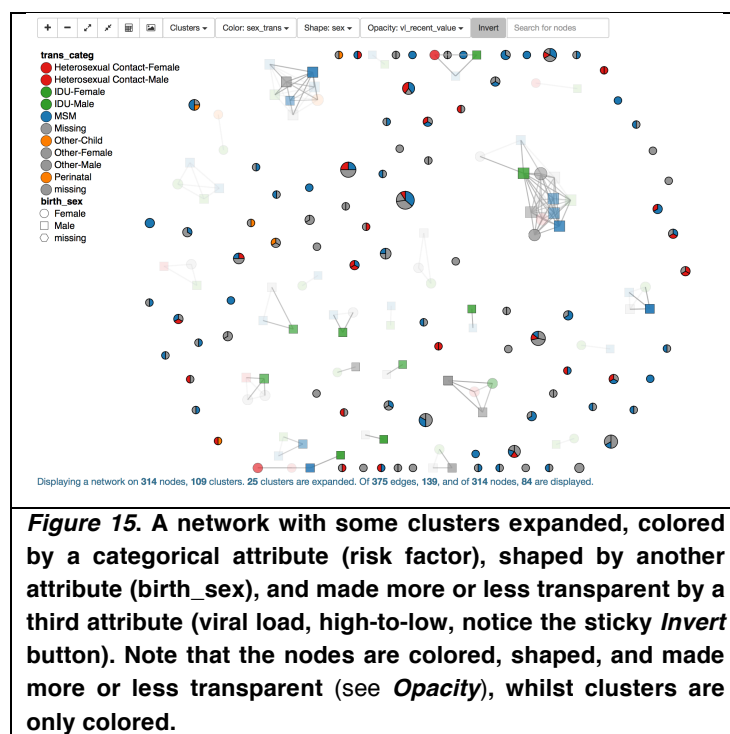


Figure 14. A network with some clusters expanded, colored by a categorical attribute (risk factor) and shaped by another attribute (birth_sex). Note that the nodes are both colored and shaped, whereas clusters are only colored.

For continuous valued variables, **Secure HIV-TRACE** will automatically consider several scales to best render the range. For example, with viral loads, which can range over several orders of magnitude, a logarithmic scale is frequently selected. If a continuous variable is used to color network objects, then an additional “sticky” button, titled **Invert**, is shown in the menu bar. Default color schemes show small values as light colors, and large values as dark (more visible) colors. If it is important to emphasize low values instead, the *Invert* button flips the scale (see **FIGURE 13**, right).

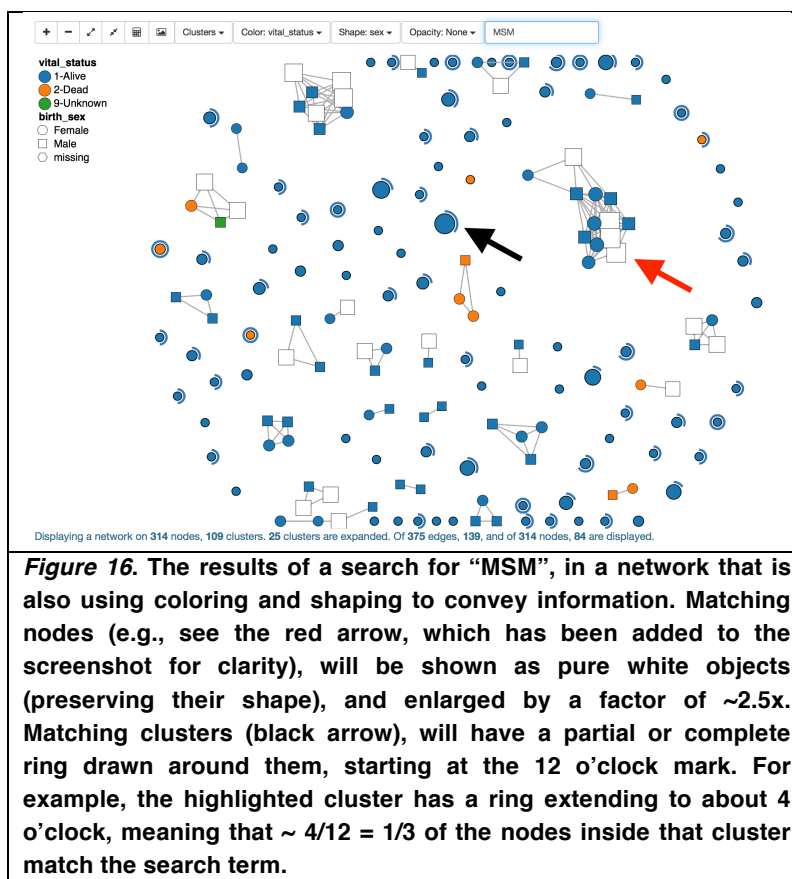
The **Shape** menu lists all categorical attributes with 6 or fewer values (e.g. *birth_sex*), including the *missing* value, to assign shapes to nodes (but not clusters) based on variable/attribute values. We limit the number of unique shapes to 6, because, once again, more than 6 will likely be too busy to convey useful information. Collapsed clusters will not be affected by changes in the shape menu, because currently we do not have a good visual metaphor for displaying collections of shapes, especially in conjunction with colors. Please see **FIGURE 14** for an example of two-variable display—*transmission risk factor* (color) and *sex* (shape). Of course, shapes can be used in isolation as well.



The **Opacity** menu lists all continuous variables, which can be used to make the nodes (but not clusters) more or less transparent. This menu allows you to emphasize (or deemphasize) nodes based on how large or small the variable value is. Nodes with missing values will receive the lowest (20%) value for opacity, while nodes with valid values will be assigned opacity in the 40-100% range. Each edge will also be more or less transparent, based on the opacity of the two nodes the edge connects. As with the Color menu, the sticky *Invert* button allows you to flip the

emphasis from large values (default) to small values. **FIGURE 15** shows a view where each node is visually annotated with three variables: *transmission risk factor* (color), *sex* (shape), and *viral load* (opacity, low values emphasized).

Search box is the rightmost item in the menu bar, and you can use it to select nodes and clusters that match a particular search term. The search is conducted within the node id and within any variable values associated with the node, and it is performed in real time as you type in the search box. The text entered in the box is interpreted as a regular expression, which in the simplest form (if you type in letters or numbers) is equivalent to text search. For example typing “Georgia” into the box is going to select all nodes which have the word “Georgia” in the ID of the node, or in any variable names. If you enter several space-separated terms into the search box (e.g., “MSM Georgia”), the matching is performed on “MSM” OR on “Georgia” (i.e., any node that matches either or the terms will be selected). Visual feedback on the search is immediate and different for nodes and clusters (see **FIGURE 16**). Any node matching the current search term will be displayed with pure white fill (regardless of other color

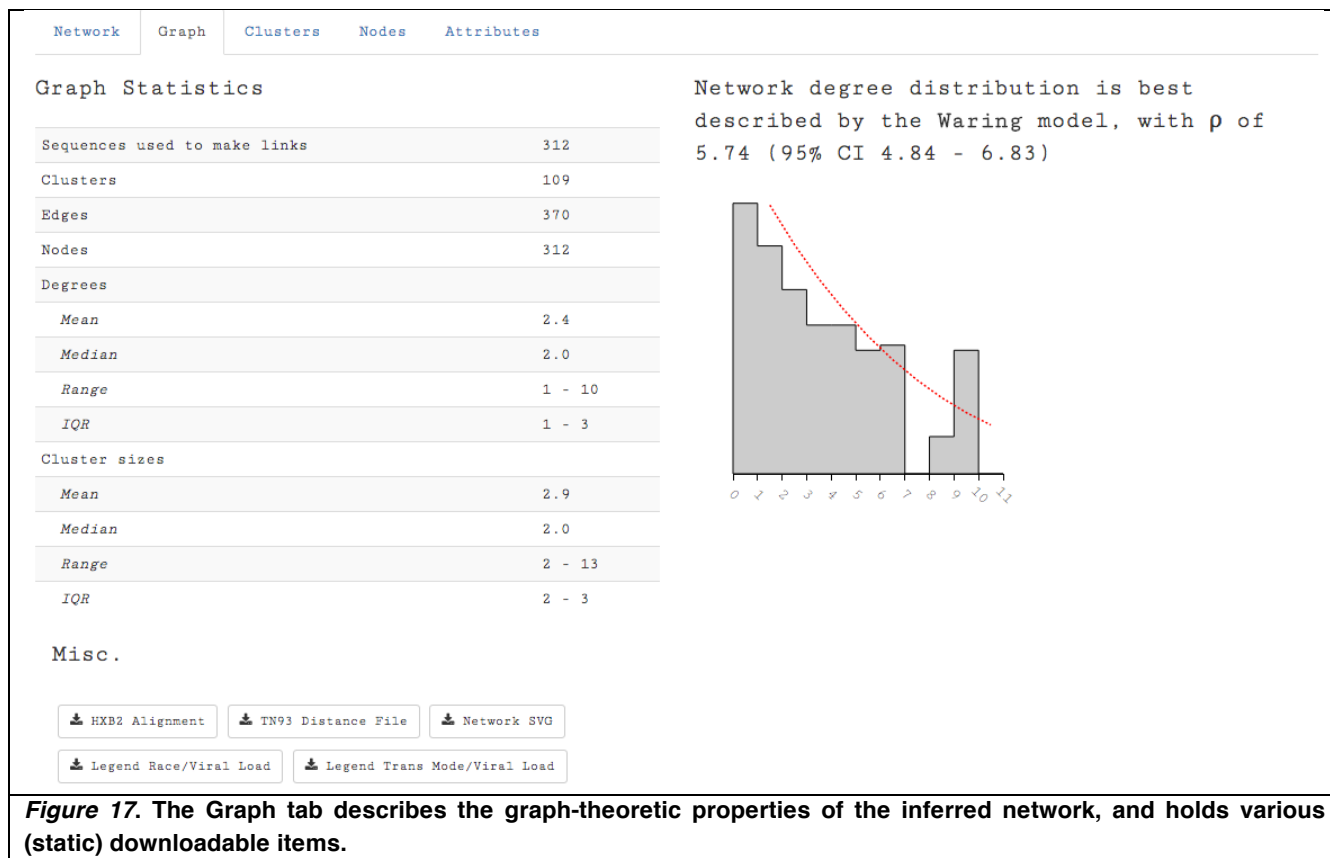


modifiers) and a larger size. Clusters will retain their coloring, but will be encircled by a partial ring, whose circumference indicates how many nodes in the cluster match the search term(s). Once you have selected some nodes and/or clusters, you can use the options in the **Clusters** menu to easily expand/collapse all of the clusters matching the current search term. Because

you have the option to enter regular expressions in the search box, it is possible to craft precise and complex queries.

Graph Tab

Under this tab, you will see a number of graph-theoretic properties that summarize the structure of the network in a way that enables comparison among networks, and inference about the network formation process that best fits the observed data. **Secure HIV-TRACE** reports the following network properties (**FIGURE 17**):



1. **Edges:** the total number of edges (links) in the inferred molecular transmission network.
2. **Nodes:** the total number of nodes (individuals) in the transmission networks. Note that this count only reflects nodes in the clusters (i.e., connected to at least one other node), and will generally be less than the number of individuals/sequences in the input file.
3. **Sequences used to make links:** when there is only one sequence per individual, this number will match the number of nodes. For analyses that permit multiple sequences from a single individual (e.g., sampled at different time points), this number of sequences can be greater than the number of nodes. (Note that currently, **Secure HIV-TRACE** accepts only the earliest genotype from each person. In the future, we are considering adding a feature that allows the analysis of multiple sequences per person.)
4. **Clusters:** the number of clusters in the transmission network.

5. **Degrees:** summary statistics (mean, median, full and interquartile ranges) of the degree distribution. A full distribution is also plotted on the right, together with the maximum likelihood fit of one of four generative distributions: negative binomial, Pareto, Yule, and Waring. The best distribution is selected by minimizing its small sample Akaike Information Score. For more information on the importance of this degree distribution, see **FAQ**.
6. **Cluster size:** summary statistics (mean, median, full and interquartile ranges) of the cluster size distribution.

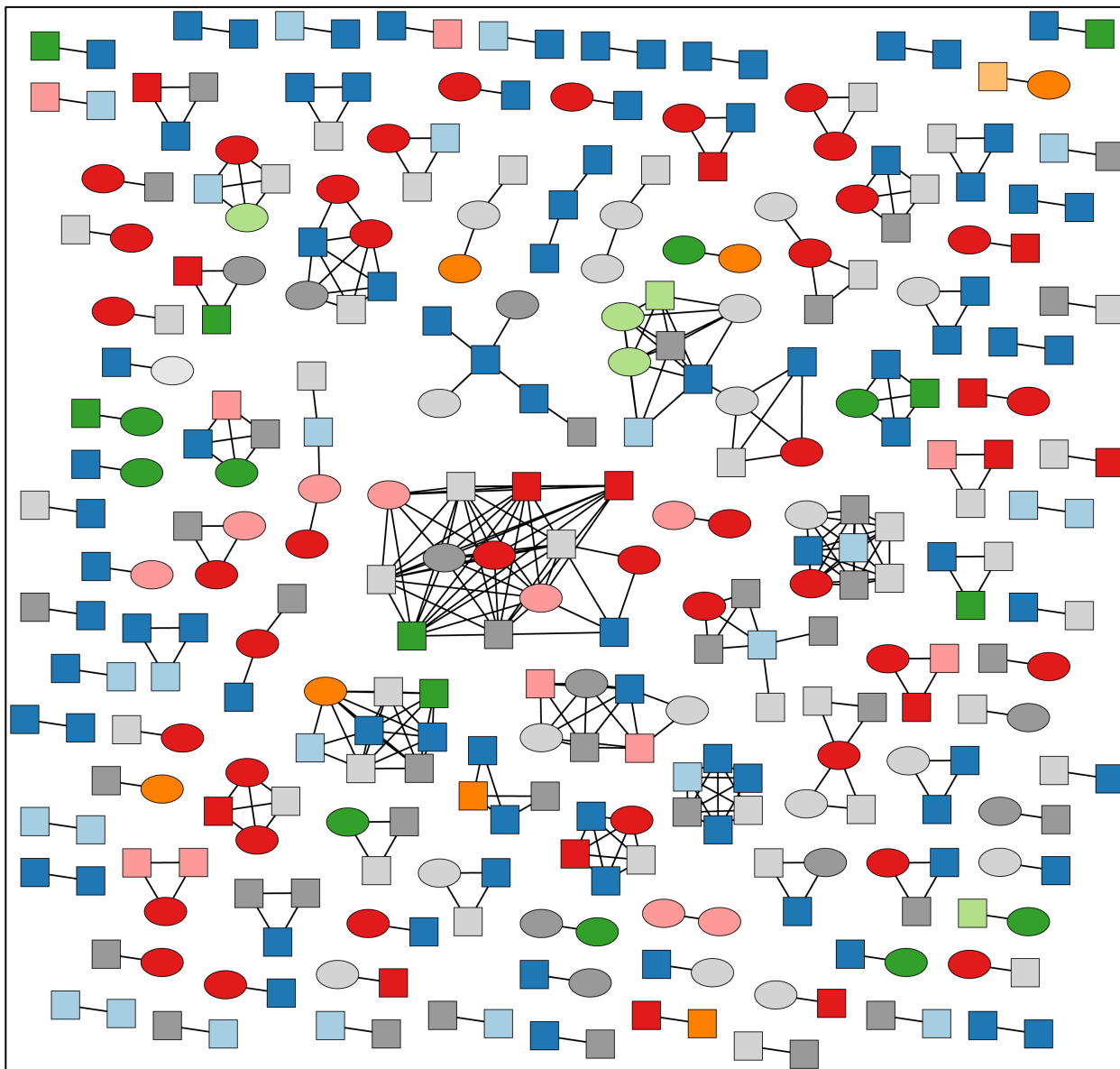


Figure 18. Example display of downloaded 'Network SVG file'. Color denotes transmission risk factor, shape denotes sex, and shading denotes viremia.

The Graph tab holds five buttons that allow you to download complete results of several analysis stages, and two types of standardized network displays.

1. **HXB2 alignment** links to a text file containing the alignment of all the uploaded sequences with HXB2. It can be used offline to build phylogenies, examine individual alignment positions, etc.
2. **TN93 Distance File** is a CSV file which contains all pairwise nucleotide distances that are 0.02 or less. Each row contains three columns: *sequence ID1*, *sequence ID2*, *distance (0-0.02)*.
3. **Network SVG** creates the image of the transmission network as displayed in the *Network* tab, as the Scalable Vector Graphics file. It can be printed, saved to disk, converted to PDF with standard tools, and otherwise used for data presentation. As a vector graphics file, SVG can be rescaled by arbitrary zoom factors without losing resolution (**FIGURE 18**).
4. **Legend Age/Race** links to a PDF file rendering the transmission network using a different tool (GraphViz) pre-annotated with Age/Race variables.
5. **Legend Trans Mode/Viral Load** links to a PDF file rendering the MTN using a different tool (GraphViz) pre-annotated with Transmission Mode (+Sex) /Viral Load variables (**FIGURE 19**).

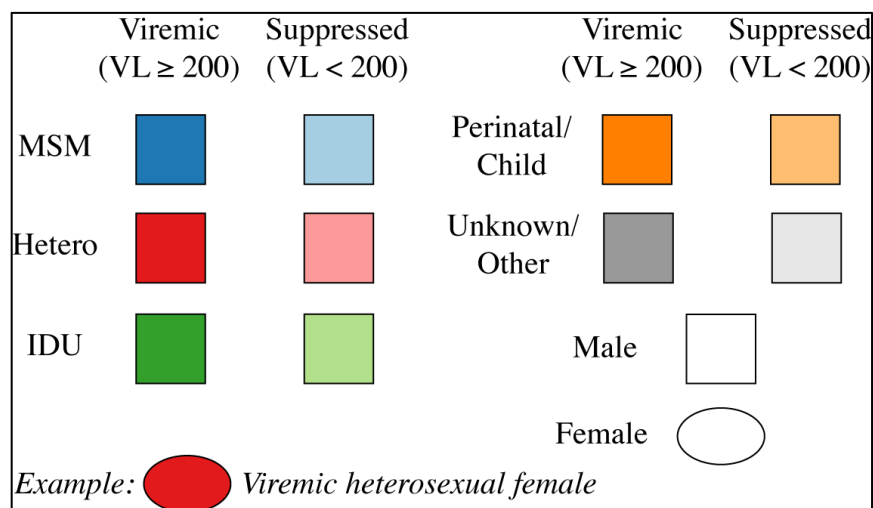
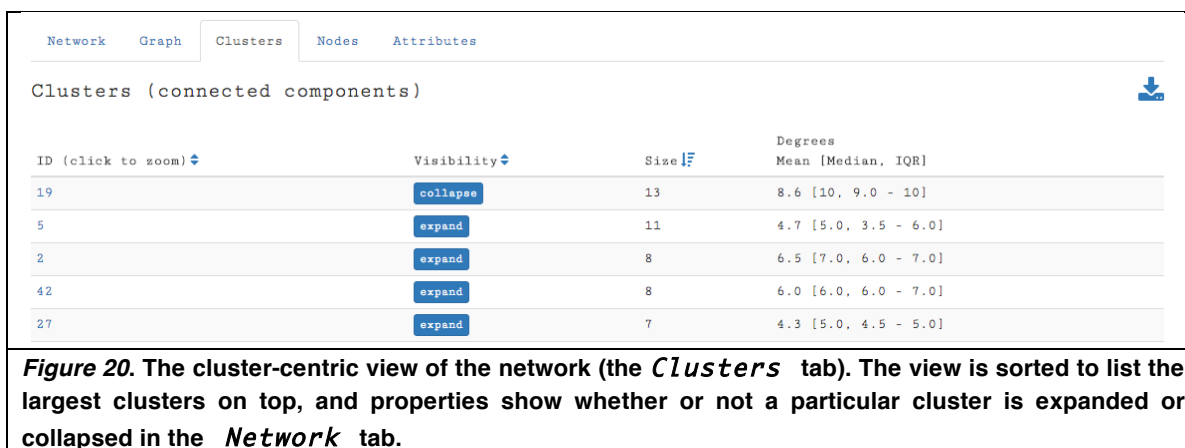


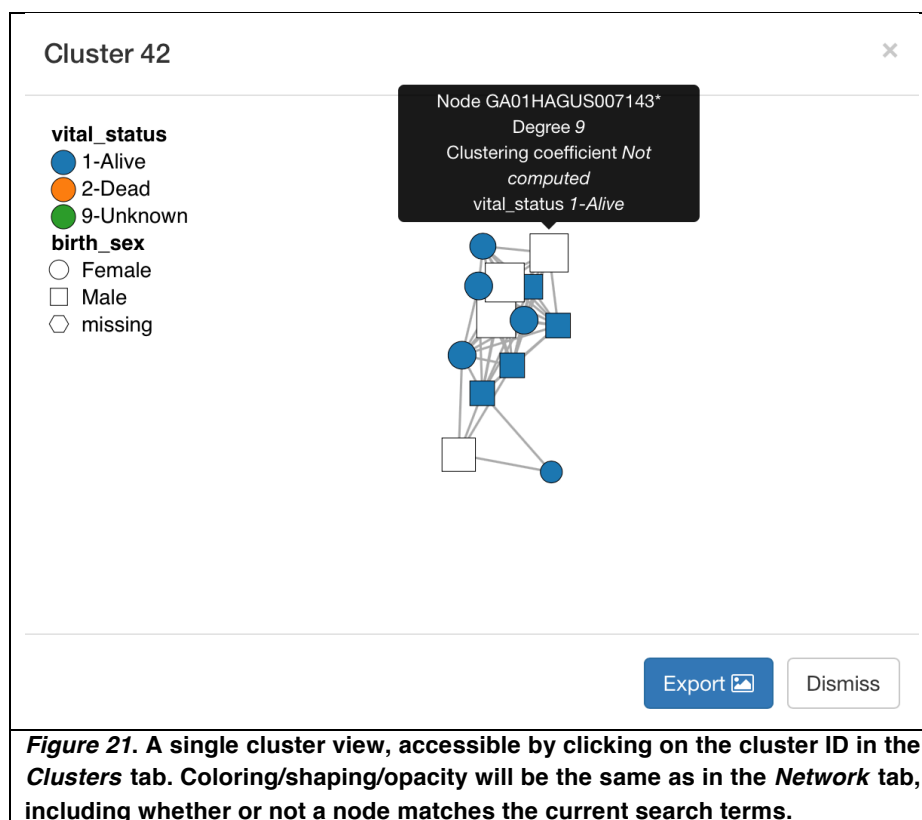
Figure 19. Legend for Network SVG File with transmission risk factor, sex, and viremia indicated.

Clusters Tab

This tab presents information about individual clusters and allows you to interact with one cluster at a time. The main component of this tab is a *sortable* table (e.g., in **FIGURE 20** it is sorted on cluster size in descending order); to sort by a column simply click on the icon next to the column name in the header row. Click again to reverse sort direction. The table contains the following columns:




1. **ID:** the unique ID of a cluster. For saved analyses, these IDs will persist between analyses (occasionally multiple clusters can merge with the addition of new sequences, so some IDs may disappear). Clicking on a specific cluster ID will display a separate window, which shows only the selected cluster, using the same rendering settings as what you currently have selected in the *Network* tab (see **FIGURE 21**, in which cluster 42 is shown). Both Classes of Sites can save individual clusters as images, by clicking on the *Export* button in the modal dialog. This view is fully interactive, just like the entire network view: nodes can be dragged around, moused over, etc.



2. **Properties:** shows attributes of individual clusters. Note that many labels in this column are clickable. For example if you click on a button that shows “collapsed”, the corresponding cluster will become “expanded”, and when you switch to the *Network* tab, you will see it expanded there. This is a convenient mechanism to select clusters to show by ID.
3. **Size:** the number of nodes in a given cluster
4. **Degrees:** displays summary statistics for the distribution of degrees for all nodes in a given cluster (compare with the **Graph** tab, where the network-wide distribution is shown)

This tab also includes a download icon (top right, **FIGURE 20**) for a text file (CSV) that contains a list of all clusters in the network, along with cluster size, and mean degree of the cluster.



ID	Visibility	Degree	Cluster
GA00HHARS000709*	show	1	93
GA00HHARS000822*	show	2	102
GA00HHARS000847*	show	1	101
GA00HHARS000923*	hide	4	19
GA00HHARS001583*	show	1	22
GA00HHARS001656*	show	1	56
GA00HHARS001668*	show	1	56
GA00HHARS001815*	show	2	15
GA00HHARS001836*	show	2	15

Figure 22. The cluster-centric view of the network (the *Nodes* tab). The view is sorted to list the nodes with the highest degrees on top, and properties show whether or not a particular node is shown or hidden in the *Network* tab.

Nodes Tab

This tab presents information about individual nodes and allows you to interact with one node at a time. The main component of this tab is a *sortable* table (e.g., in **FIGURE 22** it is sorted on node degree in descending order); to sort by a column simply click on the icon next to the column name in the header row. Click again to reverse sort direction. The table contains the following columns

1. **ID:** Unique node ID (same as in the upload CSV)
2. **Properties:** shows attributes of individual nodes. Note that many labels in this column are clickable. For example, if you click on a button that shows “hidden”, the corresponding node will become “shown”, and when you switch to the *Network* tab, you will see the cluster that contains it expanded there. This is a convenient mechanism to select nodes to show by ID.
3. **Degree:** the degree of a given node

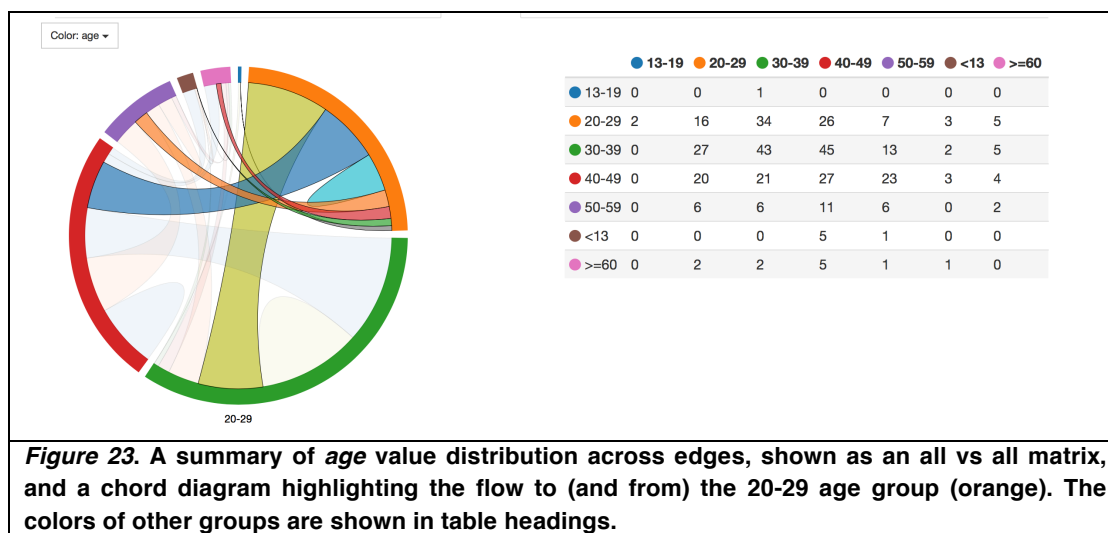
4. **Cluster:** the ID of the cluster that the node belongs to (sorting on this column allows you to quickly see all nodes that are in a given cluster)

This tab also includes a download icon (top right, **FIGURE 22**) for a text file (CSV) that contains a list of all IDs used in the analysis (excluding those IDs with red warnings or those with sequences linked to reference strain, HXB2). Also included in this file is whether or not this ID clustered in the network, which cluster they belonged to, their degree in the cluster, and all the original meta-data (variables) attached to this ID in the uploaded CSV file.

Attributes Tab

This tab presents information about the relationships between the values of a single variable that occurs along edges, e.g., how similar or dissimilar these values are for connected nodes. **Please note that the results on this tab are not directly comparable to previously published CDC analyses that may appear similar, as Secure HIV-TRACE does not apply weights to account for persons with multiple potential transmission partners.** This tab only has one menu, which contains the same entries as the Colors menu in the *Network* tab, namely categorical (up to 10 unique values) or continuous valued variables. The two menus are synchronized: changing one will automatically change the other. The tab will display two different views, based on whether the selected attribute is categorical or continuous.

For example, see **FIGURE 23**, by selecting *age* in the menu, you can display an NxN table (N=7, the number of values assumed by the *age* variable). For instance, the entry of 43 on the diagonal (i.e., in the row and column labeled 30-39) means that 43 of the edges in the network connected individuals that were **both** in the 30-39 age category. Off-diagonal entries are interpreted similarly, except in order to obtain the count of edges connecting, say ≥ 60 to 20-29, one would sum up the two corresponding entries (2+5=7). In the current implementation of **Secure HIV-TRACE**, there is no directionality to the edges, and whether or not an edge linking ≥ 60 to 20-29 will appear above or below the diagonal is almost arbitrary. With other information that might be available (e.g. estimated date of infection), it may be possible to resolve the direction of a link. The second view of the same information is through a chord diagram, which depicts the “flow” from one value of the variable to others. Mousing over the corresponding slice of the ring (see **FIGURE 23**, where 20-29 is selected), you can readily see how the connections to all 20-29 nodes are distributed across other categories.



Current support for continuous variables is rudimentary, and is limited to displaying a scatterplot of values where each (x,y) pair is defined based on the values labeling one edge in the network.

WHAT MAKES **Secure HIV-TRACE** SECURE?

Secure server at UC San Diego: johnsnow

Secure HIV-TRACE is hosted on a secure computer cluster: **johnsnow**. This computer cluster is named after the one of the founders of modern epidemiology John Snow, in honor of his work on tracing the origin of the Broad Street cholera outbreak in London. The **johnsnow** computer cluster is protected by a hardware (FortiNet) firewall that controls all aspects of access to the computer cluster.

Physical Security

The **johnsnow** computer cluster is housed in a locked rack in the San Diego Supercomputer Center (<http://www.sdsc.edu/>) on the main UCSD campus in La Jolla, CA. This building is kept under constant surveillance and employs biometric security to enter the facility. SDSC also provides back-up power, fire suppression, networking infrastructure, and other data-center level services.

Role of MHS Contact Person

The base of users allowed access to **Secure HIV-TRACE** is strictly limited to individuals in institutions (i.e., Public Health Departments) that CDC has given permission to use **Secure HIV-TRACE**. Currently, each site is encouraged to have no more than 3 active users with access to **Secure HIV-TRACE**. There is currently no limit to the number of Executive ('read-only') Users at a given site. It is up to the MHS Contact Person to determine who shall be granted access.

Each participating institution will have a point of contact designated by CDC whose responsibilities will include (i) requesting access for additional users at that institution and (ii) communicating to CDC the level at which that institution wishes to participate (**Class I** vs. **Class II**). To request or remove access for a user, the MHS Contact Person can email the **Secure HIV-TRACE** Administrators at hivtrace@ucsd.edu. To add a new user, please indicate “Add New User” and provide the new user’s (i) name, (ii) email address, (iii) job title, and (iv) phone number. To request the removal of user, please indicate “Remove Existing User” and supply the existing user’s (i) name and (ii) email address.

For other issues, the Secure HIV-TRACE administrators can be contact at hivtrace@ucsd.edu.

FAQS ABOUT GENETIC DISTANCE AND THE PARAMETERIZATION OF **Secure HIV-TRACE**

Why pairwise alignment?

Secure HIV-TRACE was designed to detect transmission clusters using the 1497 nucleotide region spanning the HIV-1 *pro/rt* region common in public health surveillance activities, drug resistance screening, and research studies. This genomic region is from a conserved genomic region with very limited length variation (unlike, say, *env*) across all major HIV-1 subtypes and circulating recombinant forms. The rarity of insertions and deletions permits robust pairwise alignment to a reference sequence. This approach is a timesaving measure compared with the more computational intensive approach of multiple sequence alignment, because it has linear complexity in the number of sequences; popular multiple sequence alignment algorithms all have superlinear complexity. **Secure HIV-TRACE** uses a modified version of the Smith-Waterman algorithm, which aligns nucleotide sequences by considering amino-acid translations of constituent codons; this approach allows us to make full use of amino-acid conservation to preserve alignment accuracy for divergent sequences (e.g., those from different subtypes).

Why genetic distance?

Genetic distance can be used as a proxy for epidemiological relatedness, because it increases as a function of time since transmission (in a linear fashion, as a first order approximation). This increase in genetic distance, due to an underlying molecular clock provides us with a proxy for the amount of time that has passed since two viral strains diverged from one another. The molecular clock in HIV, however, is highly imprecise because of factors like latency and natural selection due to immune escape and anti-retroviral treatment. Furthermore, the virus evolves in both the donor and recipient, so the distance between two strains is not simply a multiplier for the time since transmission. That being said, genetic distance serves as a useful proxy for epidemiological relatedness.

Why use a fixed distance cutoff?

Our recent work in named partners in New York City has demonstrated that genetic distance alone provides better insight into who are potential transmission partners than partner tracing alone. The distribution of pairwise distances among a population of named partners in New York City has the characteristic property of resembling a mixture of two distributions (see **FIGURE 24**): a component near 0 (i.e., closely/recently related sequences) and a component near 0.06 (i.e., two random sequences of the same subtype). Distance cutoffs of 0.01 to 0.02 segregate the two components nicely. See more below: **How do I select a genetic distance threshold?**. In a sense, using genetic distances allows one to perform something analogous to contact tracing among all persons in a surveillance cohort, asking each pair if they have genetic connection that can serve as a proxy for an epidemiologic connection.

What is TN93 genetic distance?

TN93 is the name of a nucleotide substitution model developed by Koichiro Tamura and Masatoshi Nei, published in 1993. Hence, TN93. Nucleotide substitution models are used in evolutionary analyses to correct for multiple substitutions (e.g., change from an A to a T then to C, before another genetic sequence has been sampled) and/or reversions (e.g., change from an A to a T back to an A, before another genetic sequence has been sampled) at a given site. Highly divergent sequences, with a greater number of substitutions separating them, are more likely to require complicated evolutionary models to properly estimate the level of divergence. The simplest evolutionary model, JC69, has a single parameter governing mutation rates among different nucleotides, and assumes equal frequencies for all nucleotides. In contrast, a more complex evolutionary model like general time reversible model with gamma rate variation (GTR+ Γ_4) allows all nucleotide substitutions to occur at a unique rate, unique equilibrium base frequencies, and rate variation across sites. Importantly, over relatively short evolutionary distances (i.e., <0.05 substitutions/site), GTR+ Γ_4 does not improve distance estimation accuracy for simpler models like JC69, because not enough time has elapsed for a substantial number of multiple substitutions and/or reversions. In basic calculus terms, most curves resemble straight lines if you zoom in closely enough.

For **Secure HIV-TRACE**, we wanted an evolutionary model that optimizes both realism and computational efficiency. Simple models like JC69 and K2P (Kimura 2-parameter) have obvious shortcomings when applied to HIV: these models do not permit unequal nucleotide base frequencies, and HIV has notorious high frequencies of adenine (A) and low frequencies of uracil/thymine (U/T). The TN93 substitution model allows for unequal base frequencies and three different rates of substitutions between nucleotide bases: transitions between purines (i.e., A and G), transitions between pyrimidines (i.e., C and U/T), and transversions between purines and pyrimidines (e.g., A or U/T to C or G). Furthermore, distances estimated under TN93 can be represented by a closed form solution (i.e., computed without numerical optimization, simply from pairwise differences in nucleotide counts), which permits rapid computation of pairwise distances. More complex models, which might be required for highly divergent sequences, require more computational time, which we want to avoid because distance calculation will have

to be done hundreds of millions or billions of times, to find all relevant distances. Importantly, over relatively short evolutionary distances (i.e., <0.05 substitutions/site), more complex models do not improve distance estimation accuracy. Therefore, when using genetic distances to identify potential HIV transmission partners, which are expected to be between 0.01 and 0.02 substitutions/site divergent, a substitution model more complicated than TN93 is not needed, and there are no appreciable computational savings to be had by using cruder models. As an example, our implementation can compute approximately 10 million TN93 distances per second on a single server node.

Why not phylogenetics?

Phylogenetics is an extraordinary powerful tool for understanding viral evolutionary history and dynamics. But phylogenetics says little about whether the relatedness of viruses A and B is epidemiologically meaningful. (For example, to say that two randomly selected subtype B sequences have a meaningful epidemiological linkage, would be saying that we care about events that had happened more than 50 years ago.) In fact, many HIV transmission network studies that used phylogenies **also needed a genetic distance** component.

A major problem with relying on phylogenetics to define what can be in a single cluster, is that they are highly contingent on the data, and change in counterintuitive ways. When the goal is tracking transmission network growth over time while adding more and more sequence data, this is a highly undesirable feature. Sequences that are clustered using **Secure HIV-TRACE** will always be clustered using **Secure HIV-TRACE**, if the analysis parameters stay the same. And adding more data can only increase the size of clusters, not break them apart.

Another issue with the phylogenetic approach is that it takes a lot of computational time, especially for big datasets with tens or hundreds of thousands of HIV sequences. Currently almost half a million sequences are contained in the U.S. National HIV Surveillance database. And unlike a phylogenetic approach which requires a complete re-analysis when a few new sequences are added, with our genetic distance approach, only the new sequences need to be considered, and all the previous computational work can be kept: like adding new pieces to a jigsaw puzzle.

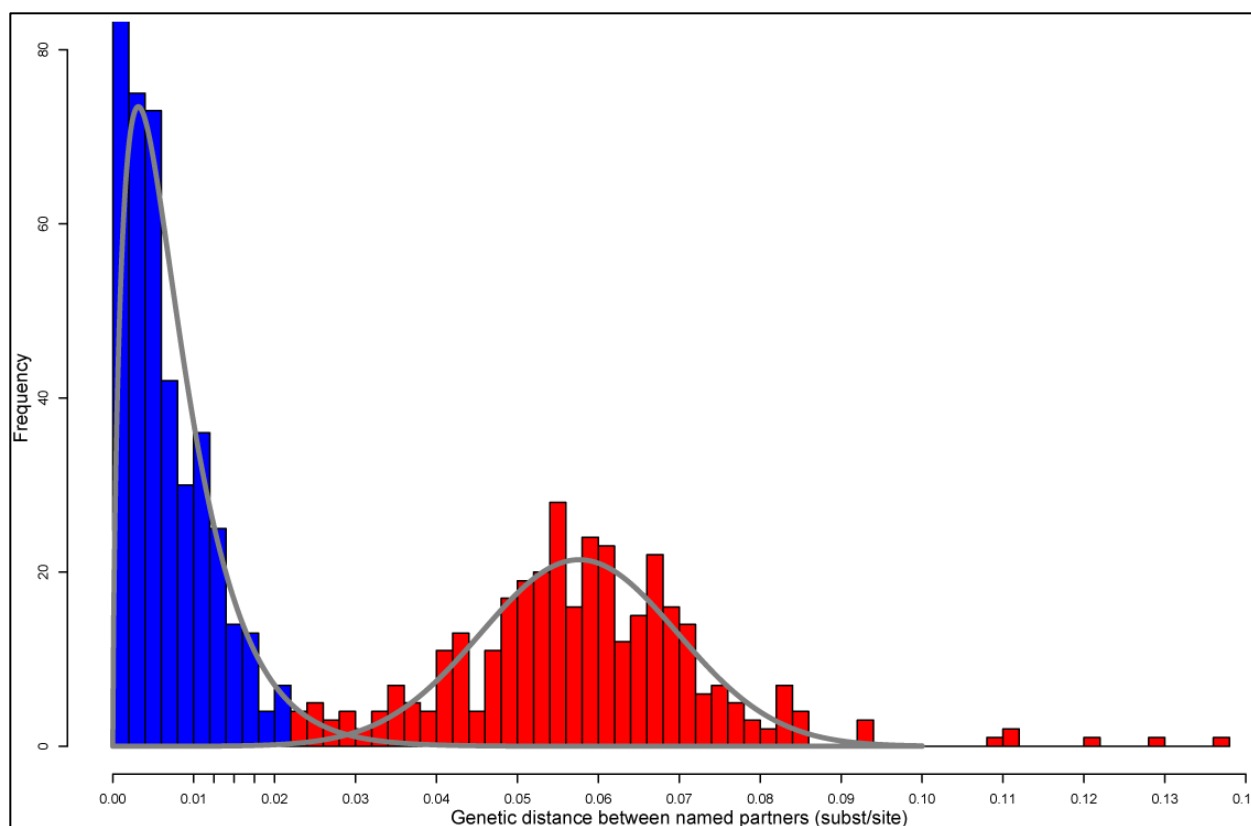


Figure 24. Distribution of genetic distances separating named partners in New York City. Potential transmission partners are shown in blue. Random within subtype variation is shown in red.

How do I select a genetic distance threshold?

An epidemiologically meaningful genetic distance threshold should link people who are potential transmission partners (i.e., close in the true transmission network) but not link people who are unlikely to have been involved in direct transmission. The best guide we have for determining a genetic distance threshold for identifying potential transmission partners in a U.S. surveillance setting comes from the analysis of 749 named partner pairs in New York City interviewed during 2006 through 2012. We analyzed the genetic distance separating baseline virus from named partners (reported sexual contact or shared injection drug use in the previous 12 months). When we plot these genetic distances, we observe two distinct modes: potential transmission partners (highlighted in blue) and partners who are HIV-infected, but have a genetic distance comparable to random within subtype variation (red). The potential transmission partners tend to have genetic distance ≤ 0.02 substitutions/site. To minimize the likelihood of spurious links in a surveillance cohort of thousands or tens of thousands of people, we recommend a slightly more conservative threshold: around 0.015 substitutions/site. More conservative genetic distance thresholds can also be applied to improve the probability that potential transmission partners share a meaningful epidemiological connection (i.e., 0.005 substitutions/site for identifying

clusters of particular public health concern), which is particularly helpful when considering all possible connections rather than just named partners.

What are ambiguous nucleotides? Or ambiguities?

When HIV infects an individual, it forms genetically diverse and potentially complex populations within that person. Currently, the sequence data reported to the National HIV Surveillance System are produced using bulk Sanger sequencing, which produces a single genetic sequence representing this circulating population. If, for example, a thymine (T) nucleotide is contained at a given sequence site in at least 80% of the intra-host population, Sanger sequencing typically identifies a T at that site. However, when some intermixing strains have one nucleotide at a position and others have a different nucleotide at the same position, Sanger sequencing typically reports diversity at that site by using common IUPAC ambiguity codes [e.g., R (representing a mix of A and G), Y (a mix of C or T), N (a mix of all nucleotides)]. In standard phylogenetic inference, nucleotide ambiguities are “partially missing data” (e.g., Y is either C or T, but not A or G). When using pairwise distances (as in **Secure HIV-TRACE**) to construct genetic transmission networks, these nucleotide ambiguities have the potential to greatly complicate inference (see **FIGURE 25A**). The most conservative approach is to average the distance between ambiguities and resolved bases (e.g., Y is 0.5 differences from either C or T. But averaging ambiguities in transmission network analysis decreases the probability that sequences from chronically infected individuals—who are likely to have a more diverse viral population—will cluster in the network. Therefore, **resolving ambiguities** (so that Y would be 0 differences from either C or T, and 1 difference from A or G) appears to be an attractive option. However, if we are too permissive in our tolerance of ambiguities, unrelated viruses can become connected in our network. Variable sites are not uniformly distributed across the HIV genome. As a result, if ambiguities are resolved in the genetic distance calculation for a highly polymorphic sequence, this highly polymorphic sequence is likely to link to many 'unrelated' viruses. The result is a large transmission cluster in which most sequences are connected to the high ambiguity sequence, but not to each other.

In an example from the San Diego Primary Infection Cohort (**FIGURE 25A**), the genetic transmission network is affected by handling of nucleotide ambiguities. When ambiguities are fully resolved, the largest cluster in this cohort contains 119 people. However, when this cluster was mapped onto a maximum likelihood phylogenetic tree, its members are dispersed across the tree, encompassing the genetic diversity of the entire city of San Diego. Furthermore, the majority of nodes in the cluster are connected via two nodes acting as hubs (highlighted in red in **FIGURE 25**) which have 5.8% and 7.6% ambiguities and represent the two highest degree nodes in the network. The nodes connected through the spokes on these hubs rarely share an edge with each other. This feature, along with the phylogenetic dispersion, suggests that this cluster is an artifact of nucleotide ambiguity resolution. When these two hubs are excluded from the analysis, the cluster breaks apart, resulting in several distinct clusters and unconnected nodes (**FIGURE 25B**).

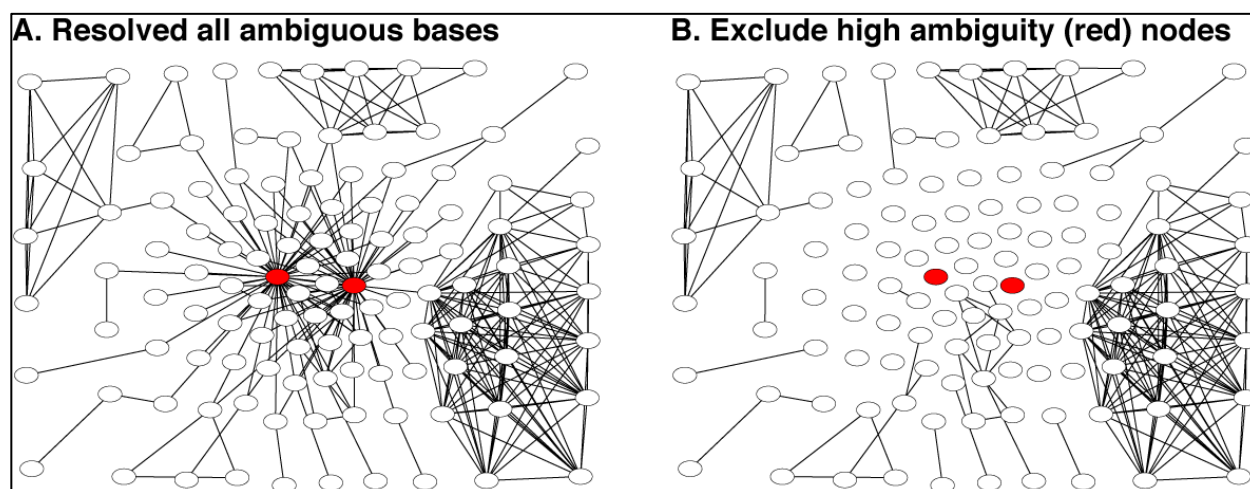


Figure 25. Example in which two contaminant sequences with high numbers of nucleotide ambiguities (shown in red) can create artificial clustering among unlinked singletons and unrelated clusters. (A) The inferred cluster resolving all ambiguous nucleotides. (B) The same cluster where the two hubs (shown in red) are excluded from the analysis.

Clusters that resemble **FIGURE 25A** should be interpreted with extreme caution. They are almost always spurious and the result of erroneous inference due to high levels of nucleotide ambiguities (or contamination with “reference” strains). **Secure HIV-TRACE** has been developed to minimize the chance of this artifact occurring.

How does Secure HIV-TRACE handle ambiguous bases?

We recommend that nucleotide ambiguities be fully resolved when calculating genetic distance only when (i) the sequences have a low proportion of ambiguities or (ii) if the size of the dataset is small. When constructing a transmission network for datasets of thousands or tens of thousands of sequences, we recommend penalizing sequences with high levels of ambiguities. The “**Ambiguity Fraction**” parameter (**TABLE 2**) governs this penalty. The default “Ambiguity Fraction” value of 0.015 resolves the genetic distance between ambiguous nucleotides when calculating the distance between sequences with $\leq 1.5\%$ ambiguities and averages the genetic distance between ambiguous nucleotides when calculating the distance between sequences with $>1.5\%$ ambiguities.

Although not currently implemented in **Secure HIV-TRACE**, future versions will identify sequences with $>5\%$ ambiguous nucleotides and flag them as problematic sequences and/or remove them from the analysis. This protocol follows the guide set forth by the Los Alamos National Laboratory (LANL) HIV Sequence Database (https://www.hiv.lanl.gov/components/sequence/HIV/search/help.html#bad_seq). Extremely high proportions of ambiguities can be the result of poor quality sequencing, contamination, or

dual infection. Including these sequences can adversely affect the performance of **Secure HIV-TRACE**.

Why should I screen for laboratory contaminants?

Although the protocols for generating HIV-1 *pro/rt* genetic sequences are well validated, occasionally laboratory contamination with other genetic material is known to occur. This contamination is most often with the lab strain HXB2, but it can happen with any strain of HIV. Importantly, this contamination often results in a mixed sample where the resulting sequence is a combination of the isolate and the laboratory contaminant. This mixed sample often has high levels of ambiguous nucleotides and could compromise HIV-TRACE analysis if it were to be included, especially because mixing two unrelated strains will create ambiguities at many sites that tend to vary between strains, thereby enabling a “connection” through this sequence if ambiguous nucleotides are resolved (see above). Furthermore, if multiple contaminant sequences are included in the same analysis, they will erroneously be inferred to be part of the same cluster. Therefore, we screen every run for HXB2 linked sequences. Any sequence that links to HXB2 will be identified after the alignment phrase and excluded from further analysis.

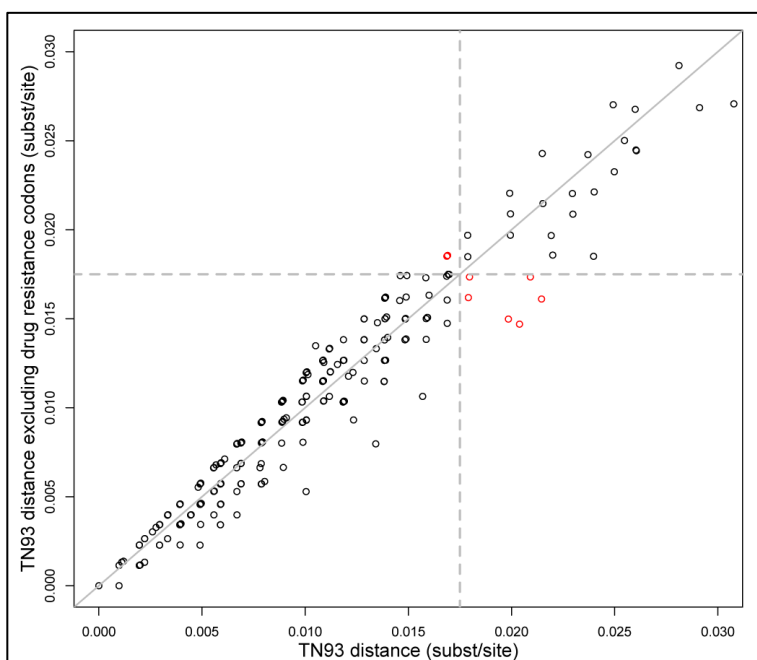


Figure 26. Genetic linkage including/excluding codons associated with drug resistance mutations in a New York City surveillance cohort. Nodes in red change linkage depending on inclusion/exclusion of DRAMs.

What about drug resistance associated mutations (DRAMs)?

DRAMs often arise in HIV found in people taking anti-retroviral therapy; they can be found in virus from both treatment-naïve and treatment-experienced people who were initially infected with a drug-resistant virus. DRAMs typically occur at a select set of sites that are not polymorphic in the absence of prior anti-viral therapy. This type of convergent evolution at the

amino acid-level has the potential to negatively affect phylogenetic inference. The genetic distance separating two viruses that have undergone convergent evolution will theoretically be lower than two viruses that have not experienced convergent evolution. In practice, however, we find little to no effect of excising DRAM sites from network inference. Specifically, transmission networks built at the city, national, global level are robust to inclusion of DRAM sites. For example, when analyzing a cohort of named partner pairs in New York City, only a small fraction of partners become either linked or unlinked when DRAMs are excluded (red in **FIGURE 25**). Therefore, we do not recommend excising DRAMs from transmission network analyses using HIV-TRACE. An exception to this recommendation is for studies focusing on the effect of DRAMs on network characteristics; in these instances, DRAM site should be excised prior to network construction.

Can Secure HIV-TRACE work with multiple sequences from the same person?

Not yet. Currently, **Secure HIV-TRACE** accepts only the earliest genotype from each person. In the future, we are considering adding a feature that allows the analysis of multiple sequences per person.

WHAT ARE THE PRACTICAL APPLICATIONS OF **Secure HIV-TRACE**?

“I stared at this for a long time, and I think it wouldn't look out of place on the walls of a modern art museum, but I was less clear about what it was telling me...” –Reviewer #1

Secure HIV-TRACE allows public health officials do to more than just produce “modern art”. We have used this approach to:

- Identify and characterize rapidly growing clusters.
-
- Determine whether a particular attribute (e.g., transmission risk category, age, etc.) is predictive of recent transmission.
- Determine whether named partners are potential transmission partners.
- Identify clusters of transmitted drug resistance.

CDC PUBLICATIONS USING HIV-TRACE

- Oster AM, Wertheim JO, Hernandez AL, Ocfemia MC, Saduvala N, Hall HI (2015) Using Molecular HIV Surveillance Data to Understand Transmission Between Subpopulations in the United States *J Acquir Immune Defic Syndr* 70(4): 444–451.

- Wertheim JO, Oster AM, Johnson JA, Switzer WM, Saduvala N, Hernandez AL, Hall HI, Heneine W (2017) Transmission fitness of drug-resistant HIV revealed in a surveillance system transmission network *Virus Evolution* 3(1): vex008.
- Whiteside YO, Song R, Wertheim JO, Oster AM (2015) Molecular analysis allows inference into HIV transmission among young men who have sex with men in the United States *AIDS* 29(18): 2517–2522.
- Wertheim JO, Oster AM, Hernandez AL, Saduvala N, Bañez Ocfemia MC, Hall HI (2016) The international dimension of the U.S. HIV transmission network and onward transmission of HIV recently imported into the United States. *AIDS Res Hum Retroviruses* 32(10-11): 1046-1053.

REFERENCE PUBLICATIONS FOR HIV-TRACE

- Kosakovsky Pond SL, Weaver S, Leigh Brown AJ, Wertheim JO (2018) HIV-TRACE (Transmission Cluster Engine): a tool for large scale molecular epidemiology of HIV-1 and other rapidly evolving pathogens *Mol Biol Evol*.
- Wertheim JO, Leigh Brown AJ, Hepler NL, Mehta SR, Richman DD, Smith DM, Kosakovsky Pond SL (2014) The global transmission network of HIV-1 *J Infect Dis* 209(2): 304–313.
- Wertheim JO, Kosakovsky Pond SL, Forgione LA, Mehta SR, Murrell B, Shah S, Smith DM, Scheffler K, Torian LV (2017) Social and genetic networks of HIV-1 transmission in New York City *PLOS Pathogens* 13(1): e1006000.
- Little SJ, Kosakovsky Pond SL, Anderson CM, Young JA, Wertheim JO, Mehta SR, May S, Smith DM (2014) Using HIV networks to inform real time prevention interventions *PLOS ONE* 9(6): e98443.

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Secure HIV-TRACE and Molecular HIV Surveillance Protocol

Secure HIV-TRACE is a web-based application developed by the CDC/Temple University/UC-Davis that allows jurisdictions to independently conduct molecular HIV surveillance activities. Secure HIV-TRACE should be run monthly to monitor cluster activity in the state. The steps below describe how to use Secure HIV-TRACE and process cluster data. All data related to MHS needs to be stored on the secure I-drive. Never store any personal health data on the desktop or a public drive.

Main data folder: I:\PUBLIC\Data Management\MHS

Secure HIV-TRACE output: I:\PUBLIC\Data Management\MHS\HIV-TRACE

EC-Code Fix

The CDC has developed a QC step in Secure HIV-TRACE to ensure genotypes uploaded for analyses are quality genotypes and correctly categorized. Run SAS Program #3 in the HIV-TRACE SAS Programs folder: *03_MHS_HIV_Trace_Data_Quality_prepare_data*.

After logging in to Secure HIV-TRACE, select “Sequence Analysis” in the upper left hand corner > Conduct New Sequence Analysis > Upload the Excel file that was output from SAS Program #3.

The output shows the records that may need to be fixed or removed. The primary report of interest in the last report “EC Code Report.” Download the report and upload to production eHARS. This text files fixes EC Codes on genotypes that had mis-assigned genotypes (e.g. RT change to IT).

Force update the Document dataset using the Admin tab > Dataset Maintenance in eHARS, so the O-drive datasets are updated with the new EC Codes.

Preparing eHARS Data for Secure HIV-TRACE

The CDC has developed SAS Programs to process genotypes uploaded to eHARS and format variables that can be used within Secure HIV-TRACE. Make sure the most up-to-date versions of the SAS programs and protocol have been downloaded from Sharepoint.

-Run *Step 01a_MHS_HIV_TRACE_prepare_data* located: I:\PUBLIC\Data Management\MHS\HIV-TRACE\SAS Programs. Enter filepaths and state abbreviation in the four macros > run the program. An Excel and SAS file will be output.

** Currently working on Step 01b. Issues with formatting once file is uploaded to Secure HIV-TRACE. Do not run step at this time. **

Processing Genotypes in Secure HIV-TRACE

-Login to Secure HIV-TRACE. To add new genotypes to the existing pool of genotypes, select the blue “Append” button at the top of the page in the Current Network box > Select Sequence File > Navigate to the Excel CSV file output in Step 01a.

-Secure HIV-TRACE runs QC checks on the dataset and displays errors for review. If cells are highlighted in red, the program will not include those records in the analysis. If cells are highlighted in orange, the field will be replaced with a missing value. Have not seen data highlighted in red in Secure HIV-TRACE since starting MHS activities. There are a few entries that routinely appear in orange – “multiple races”,

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VL values, and VL dates. These values have not been vital to work with Secure HIV-TRACE, so these errors have been ignored.

-Once review of the errors is complete, select “Ignore and Continue.” Secure HIV-TRACE immediately begins to process the new genotypes along with the existing genotypes. This step usually takes 3-5 minutes.

Reviewing Secure HIV-TRACE Results

Once complete, the screen will appear with dozens of different-sized gray circles. The majority of these clusters represent relatedness among people diagnosed many years ago and are not relevant to our current work trying to identify clusters of **recent and rapid transmission**.

In order to focus our efforts, the CDC developed a “Sub-Clusters” tab. On this page are clusters at the 0.5% threshold ordered by the number of diagnoses in the past 12 months (column on the far right). Clusters that meet the CDC priority criteria will have the number in the far right column highlighted in red. Clusters nearing the priority status (4-3 diagnoses in the past 12 months) are highlighted in orange.

CDC priority criteria: At the 0.5%, there has been 5 or more diagnoses within the cluster during the past 12 months.

The clusters meeting priority criteria or on the cusp of meeting priority criteria typically do not change much from run-to-run.

Use the most updated CDC developed protocol to understand how to navigate through Secure HIV-TRACE. Check Sharepoint to make sure you are using the most current file.

Secure HIV-TRACE protocol located: I:\PUBLIC\Data Management\MHS\HIV-TRACE

Exporting Cluster Data from Secure HIV-TRACE

-In Secure HIV-TRACE, select the “Nodes” tab > select “Export to CSV”

-Open the SAS Program *02_MHS_HIV_Trace_cluster_summary*. Enter the filepaths and required entry for the five macros. Run the program.

-Five Excel CSV files are output.

Variable list

Cluster line list at the 0.5%

Cluster line list at the 1.5%

Cluster summary list at the 0.5%

Cluster summary list at the 1.5%

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These lines lists can aid in the updating of the Excel sheets used to monitor priority clusters.

Monitoring Priority Cluster Activity

New Cluster Identification

-Once a priority cluster is identified, create a folder for the cluster here:

I:\PUBLIC\Data Management\MHS

-Name the folder: "Cluster_##"

-Create a cluster tracking spreadsheet using the following template:

I:\PUBLIC\Data Management\MHS\Cluster Tracking Template.xlsx

-In the tracking spreadsheet, complete the "Line List" tab with demographic data on each cluster case at the 0.5% threshold diagnosed in the past 36 months. Much of this information can be pulled from the CDC's cluster summary output Excel files.

-Next, complete the "Dx Timeline" tab. By tallying up the number of diagnoses per quarter, an epidemiologic curve is created for the cluster.

-Complete the "DIS_PRISM" tab. While, this step can be time consuming if there are many cases with detailed interview notes, it is crucial to thoroughly review each person's PRISM record and DIS HIV interview. In order to complete the CDC Cluster Report Form, details about the number of partners, common venues/behaviors, and aggregate statistics about partner's HIV testing status is needed. Information from the DIS interviews is essential in understanding the dynamics of the molecular cluster cases and greater transmission network. This data is valuable when presenting on the cluster and providing thorough details to the internal workgroup in order to inform response activities.

-Complete the "VL_Engagement" tab. Linkage to care and achieving viral suppression are key outcomes of interest for molecular cluster cases. This tab monitors those outcomes using LMS lab data. Make a copy of the *Cluster_##_Monitoring Health Outcomes* SAS Program in the cluster folder. Program located: I:\PUBLIC\Data Management\MHS. Enter the statenos of each cluster case and filepath for the output file. The output Excel file contains most recent viral load lab values for each case.

-Complete the "1.5% Threshold_or over36months" tab. While not essential to monitoring the 0.5% cluster cases, this tab is a holding spot for cases that are related at the more distance 1.5% threshold or who have aged out of the 0.5% cluster and no longer meet the "recent" criteria.

Updating an Existing Cluster's Excel File

-When monitoring an active cluster, update the Excel file as needed if new cases arise. Save the Excel file for each month as a new file with the current date. Keep a record of each month's tracking sheets so in the event we need to reference viral suppression or the size of the cluster at a certain point in

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time, we can refer to the old tracking sheet for that month. In each cluster folder, create a subfolder called: “Old Line Lists” and put the previous month’s tracking file there.

-Regardless of new cases, each month:

- Check if any cluster cases are now older than 36 months and move from the “Line List” to the “1.5% Threshold_or over36months” tab.

- Update the “Dx_Timeline” graph so the most recent quarter and numbers are reflected in the graph.

- Check if there are any cases who had yet to be located or interviewed by DIS. Look-up case in PRISM to see if there were any new notes or an interview entered.

- Run the *Cluster_##_Monitoring Health Outcomes* SAS program every month to monitor linkage to care, viral suppression, and engagement in care among cluster cases.

Closing a Molecular Cluster

If it has been 12 months since a new case was added to a cluster at the 0.5% genetic distance threshold, a cluster can be closed and monthly monitoring can end. The folder with all the data should remain as is in the event the cluster status changes in the future.