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DEVELOPING A PROCESS FRAMEWORK TO CREATE REPORTING CRITERIA FOR CONDITIONS EXTENDING BEYOND THE 2015 NATIONALLY NOTIFIABLE CONDITIONS LIST

BY

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Degree to be awarded: M.P.H.
Executive MPH

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An abstract of
A Thesis submitted to the Faculty of the
Rollins School of Public Health of Emory University
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2016

Abstract

DEVELOPING A PROCESS FRAMEWORK TO CREATE REPORTING CRITERIA FOR CONDITIONS EXTENDING BEYOND THE 2015 NATIONALLY NOTIFIABLE CONDITIONS LIST

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The reporting of disease cases is the foundation of public health surveillance. In order to better facilitate public health surveillance for conditions of interest to Public Health, the Council of State and Territorial Epidemiologists (CSTE) is responsible for the creation and implementation of position statements. These documents provide standard agreed-upon criteria for case classification and case reporting to help epidemiologists conduct disease investigations. The Reportable Conditions Knowledge Management System (RCKMS) project previously established a process for developing reporting criteria of reportable conditions that have a corresponding CSTE position statement; however, no such process exists for conditions that do not have a CSTE position statement. This study will develop a process framework to be used by the RCKMS team to develop reporting specifications for conditions that are reportable to local or state public health, but are not nationally notifiable.

Methods: This thesis work reviewed data from a 2012 State Reportable Condition Assessment (SRCA) and the current Reportable Conditions Mapping Table (RCMT) to identify reportable conditions that are not nationally notifiable. Each condition was analyzed based on the following criteria: availability of a CSTE position statement, availability of other related CSTE position statement, exists in RCMT, and whether or not the condition has laboratory criteria.

Results: Total of 190 conditions were analyzed and divided into 7 groups based off the criteria outlined above. These groups were then prioritized for development of reporting criteria to be pre-populated in the RCKMS tool. Within each group, the conditions were further prioritized based on the number of jurisdictions requiring the condition to be reported. A process framework was developed that recommended prioritization of the condition groups, and methods for deriving reporting criteria for each group.

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CHAPTER 1: INTRODUCTION

Introduction and rationale

The reporting of infectious disease cases is the foundation of public health surveillance. "In the United States, the authority to require notification of cases of disease resides in the respective state legislatures." [1] Typically done through the use of paper forms, this process allows public health authorities to monitor, control, and prevent the spread of infectious diseases [1]. Public health case reporting has since expanded from just infectious diseases to include other non-infectious reportable conditions. The primary source of data used to lie solely in the hands of health care professionals such as nurses and physicians, but more recently laboratories have also become a critical source of information for public health surveillance [2]. These sources of data will hereafter be referred to as public health reporters.

In order to better facilitate public health surveillance for conditions of interest to public health, the Council of State and Territorial Epidemiologists (CSTE) is responsible for the creation and publication of position statements. "CSTE position statements represent the documentation and analysis of policy issues affecting public health and can cover any issue of importance to CSTE members" [3]. The position statements of particular interest for this work are those which "call for placing health conditions under standardized surveillance" [3]. CSTE provides a template when establishing a new position statement for a disease or condition of interest for public health surveillance. Specifically within that template there is a section VI titled "Criteria for case identification" where the author lays out

particular criteria to determine when a case report should be sent to public health [3]. These documents are voted on and approved by the CSTE membership, which consists of states and territories through their public health epidemiologists [4]. While these position statements are not a pre-requisite for mandating reporting of a new condition by public health reporters, they do provide standard agreed-upon criteria for reporting and classifying cases.

Stimulated by the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 [5], more and more health care settings are adopting Health Information Technology systems, such as Electronic Health Records (EHRs). According to data briefs from the Office of the National Coordinator for Health IT (ONC) and the National Center for Health Statistics (NCHS), "[i]n 2014, 3 out of 4 (76%) hospitals had adopted at least a Basic EHR system" and "[u]se of any type of EHR system by office-based physicians is expected to reach 78% by 2013" [6, 7]. Within these systems lie a wealth of data useful to public health surveillance efforts and a tremendous opportunity to transform outdated paper-based case reporting into an electronic and automated process. "EMR-based reporting has the potential to provide active notifiable disease surveillance that is more timely, complete, and clinically detailed" [8]. Recently there has been a big push in the public health community to establish an infrastructure to support this transformation.

"Upon a foundation of work supported by the Centers for Disease Control and Prevention (CDC) and [ONC], the public health community is advancing toward a nationwide vision, infrastructure, and standards for [Electronic Case Reporting (eCR)]" [9]. Projects such as the Reportable Conditions Knowledge Management

System (RCKMS), the Public Health Community Platform (PHCP), and Structured Data Capture (SDC) highlight public health's focus on building the needed infrastructure [9]. Additionally, a new initiative, led by Robert Woodruff Johnson Foundation (RWJF), the Public Health Informatics Institute (PHII) and Deloitte, entitled the Digital Bridge has emerged as a forum for discussion between public health, healthcare, and healthcare IT vendors to discuss and collaborate on improving information exchange between healthcare and public health. "The initial focus of Digital Bridge activities is on electronic case reporting (eCR), and participating representatives are working together to develop an interoperable, multi-jurisdictional approach to eCR that will be available this fall." [10] The Digital Bridge has also taken on a governance role for eCR, previously lead by ASTHO and their work with the PHCP.

Particularly of interest is the RCKMS project, a collaborative project between the CDC and CSTE, "envisioned to be an authoritative, real-time portal to enhance disease surveillance by providing comprehensive information to public health reporters about the 'who, what, when, where, and how' of reporting" [11]. In an attempt to support reporters at different levels of automation, this information will be provided in both human-readable and machine-processable public health case reporting.

Problem statement

The RCKMS project previously established a process for developing reporting criteria of reportable conditions that have a corresponding CSTE position statement; however, no such process exists for conditions that do not have a CSTE position

statement.

Currently there are conditions deemed reportable by public health agencies that do not have a corresponding CSTE position statement [12-14]. These conditions, therefore, lack the standard agreed-upon reporting criteria, as described previously, to assist public health reporters in knowing when they are required to send a case report to public health. Without this starting guidance from a CSTE position statement, it may be more challenging to define clear reporting criteria to provide to public health reporters. This could result in under-reporting for these conditions, or even worse, case reports not being sent at all.

Purpose statement

This study will develop a process framework to be used by the RCKMS team to develop reporting specifications for conditions that do not have a CSTE position statement, hereafter referred to as "Round 2 conditions". It will do so by evaluating previous processes used for defining reporting specifications for reportable conditions. It will compare similarities and differences in reporting criteria of conditions for which a CSTE position statement exists. This analysis will culminate in a recommended process framework to be implemented by the RCKMS project for reportable conditions that have no CSTE position statement.

Research question

This study aims to address the following questions:

- What processes already exist for developing reporting criteria for conditions that have CSTE position statements? This question will focus on the work previously completed by the RCKMS project.

- What processes already exist for developing reporting criteria for conditions for which there is no CSTE position statement? Specifically, this question will focus on other projects outside of RCKMS such as NCD, ESP, SRCA, and RCMT.
    - What types of patterns exist in reportable conditions with CSTE position statements both by jurisdiction and condition category?
    - What types of similarities in reporting criteria exist with conditions for which there is a CSTE position statement? What types of differences exist?

Significance statement

Electronic Case Reporting (eCR) will benefit by having all conditions included in an automated process, and the only way to include those conditions with no CSTE position statement is to define a standard and repeatable process framework. This process framework and evaluation will enable the creation of machine-processable reporting criteria for approximately an additional 190 reportable conditions using a standardized process. With these newly created reporting criteria, public health agencies can help automate reporting and create a more complete picture of public health surveillance in the United States.

Definition of Terms

Term	Definition
Association of Public Health Laboratories (APHL)	"The Association of Public Health Laboratories (APHL) represents state and local governmental health laboratories in the United States. Its members, known as "public health laboratories," monitor and detect health threats

	to protect the health and safety of Americans. Founded over 50 years ago as a forum for state public health laboratory directors, APHL brings together laboratories and staff from multiple disciplines, including public health, environmental, agricultural and food safety laboratories." [15]
Association of State and Territorial Health Officials (ASTHO)	"ASTHO is the national nonprofit organization representing public health agencies in the United States, the U.S. Territories, and the District of Columbia, and over 100,000 public health professionals these agencies employ." [16]
Centers for Disease Control and Prevention (CDC)	CDC is a federal agency under Health and Human Services (HHS) responsible for "protect[ing] America from health, safety and security threats, both foreign and in the U.S." [17] Related to this research, CDC is the funder of RCKMS and other efforts to advance eCR.
Council of State and Territorial Epidemiologists (CSTE)	"CSTE is an organization of member states and territories representing public health epidemiologists. CSTE works to establish more effective relationships among state and other

	health agencies. It also provides technical advice and assistance to partner organizations and to federal public health agencies such as the Centers for Disease Control and Prevention (CDC)." [4]
CSTE position statement	"CSTE position statements represent the documentation and analysis of policy issues affecting public health and can cover any issue of importance to CSTE members." [3]
Electronic Health Record or Electronic Medical Record (EHR or EMR)	An EHR is a digital representation of a patient's traditional paper chart and all associated clinical data. EHRs contain a patient's medical history and are used to automate and streamline healthcare provider workflow. They also use evidence-based tools that providers can use to make decisions about a patient's care. [18]
Electronic Medical Record Support for Public Health (ESP)	"The Electronic medical record Support for Public health (ESP) project is an automated software application that analyzes electronic health record (EHR) data to identify and report conditions of interest to public health." [19] This project currently is implemented to support eCR

	solution in Massachusetts. "ESP extracts details of every patient encounter every 24 hours from the primary care physician's EHR."[19]
Logic Set	Logic sets are groupings or combinations of criteria which indicate which criteria need to be met in order for a report to be sent to public health.
Logical Observation Identifiers Names and Codes (LOINC®)	"LOINC is a common language (set of identifiers, names, and codes) for clinical and laboratory observations." [20]
Machine-processable	"The characteristic required of data so that it can be successfully processed by a particular technology." [21] In this research it refers to turning human-readable reporting specifications into those, which can be consumed and automatically processed by the RCKMS Decision Support.
National Association of County & City Health Officials (NACCHO)	A non-profit association "comprised of over 2,800 Local Health Departments across the United States. Together, we form an organization focused on being a leader, partner, catalyst, and

	voice for change for local health departments around the nation." [22]
Nationally Notifiable Condition (NNC)	"CDC receives case notifications from 57 reporting jurisdictions. Each state has laws requiring certain diseases be reported at the state level, but it is voluntary for states to provide information or notifications to CDC at the federal level." [23] Those conditions requested by the CDC are considered Nationally Notifiable Conditions (NNC).
Notifiable Condition Detector (NCD)	"The NCD is open-source technology that leverages messaging and terminology standards such as HL7 and LOINC. It uses the rich inflow of clinical results into an operational regional health information exchange, the Indiana Network for Patient Care (INPC), to process over 300,000 messages daily from hundreds of sources and report 105 notifiable conditions to public health and other health care department" [24] It is currently being used in Indiana in support of eCR.

Public Health Community Platform (PHCP)	"With the goal of providing a forum for common information exchange and development of innovative and interoperable systems, ASTHO is leading the joint development of a CDC-funded initiative: the Public Health Community Platform (PHCP). A platform is a common architecture that is a base upon which other synergistic applications, processes, or technologies are developed." [25] PHCP will host services such as RCKMS and will be used as a nationwide model for Electronic Case Reporting (eCR).
Public Health Electronic Case Reporting (eCR)	"A fundamental building block of disease surveillance is accurate and timely diagnosis. Different state and local jurisdictions define in their local law or policy the set of "reportable conditions" that providers need to submit to public health, in some cases when they are even suspected let alone confirmed, in a process known as Electronic Case Reporting (eCR) when the submission is done in an automated manner." [26]

Public Health Informatics Institute (PHII)	"PHII is a program of the Task Force for Global Health, a 501(c)(3) nonprofit organization that was founded as the Task Force for Child Survival in 1984. The Task Force is affiliated with Emory University. Since 1992, PHII has led the charge in establishing informatics as a recognized discipline critical to the field of public health with our mission to transform health practitioners' ability to use information effectively." [27]
Public Health Reporters	A term used to group any facility, organization, or individual who is responsible for sending cases of reportable conditions to a public health agency. Examples relevant to this research are healthcare provider (clinician or hospital) or laboratory. Future states of eCR could also include vital statistics or birth registries.
Public Health Reporting Criteria	Public Health Reporting Criteria refers to the a single clinical, laboratory, epidemiologic, etc. criterion. One criteria alone could be sufficient to trigger a report to public health, or a combination of criterion is needed to trigger a report.

Public Health Reporting Specifications	Public Health Reporting Specifications refers to the full set of public health reporting criteria that make up the information needed to know when a given condition should be reported to public health. For the purposes of RCKMS this also includes the value sets and rules logic.
Public Health Surveillance	"…is the ongoing and systematic collection, analysis, and interpretation of outcome-specific data for use in the planning, implementation, and evaluation of public health practice." [2]
Reportable Condition Mapping Table (RCMT)	"The RCMT provides mappings between reportable conditions and their associated LOINC laboratory tests and SNOMED results." [28]
Reportable Conditions Knowledge Management System (RCKMS)	RCKMS is "an authoritative, real-time portal to enhance disease surveillance by providing comprehensive information to public health reporters about the 'who, what, when, where, and how' of reporting." The RCKMS will provide a "centralized public health decision support shared service that can return a Notice of Reportability of whether a case is reportable and to which jurisdiction." [11]

Reportable Condition Trigger Code (RCTC)	"Value sets for initiating case reports for electronic transmission from clinical care systems." [14] These are meant to cast a broad net coarse filter for all reportable conditions and all jurisdictions.
Rules Logic	These machine-executable logic statements consist of IF, THEN statements which are processed by the decision support service and produce a decision of reportability in the RCKMS system.
State Reportable Conditions Assessment (SRCA)	"The State Reportable Conditions Assessment (SRCA) is an annual assessment of reporting requirements for conditions that must be reported by clinicians, laboratories, hospitals, and others to public health according to jurisdictional laws." [13]
Structured Data Capture (SDC)	"Established as a Standards Initiative in 2013, SDC is focused on the identification, testing and validation of standards necessary to enable an electronic health record (EHR) system to retrieve, display, and fill a structured form or

	template, and store/submit the completed form to an external system and/or repository." [29]
Subject Matter Expert (SME)	A Subject Matter Expert is someone who specializes in a particular field of study. For the purposes of RCKMS, SMEs typically fill a role such as Vocabularist SME, Clinical Epidemiologist SME, etc.
Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT)	SNOMED CT "is the most comprehensive, multilingual clinical healthcare terminology in the world. It enables consistent, processable representation of clinical content in electronic health records. SNOMED CT supports the development of comprehensive high-quality clinical content in health records. It provides a standardized way to represent clinical phrases captured by the clinician and enables automatic interpretation of these." [30]
Value Set	"Value sets are lists of specific values (terms and their codes) that define clinical concepts derived from standard vocabularies to support effective health information exchange." [31]

Table 1 Definition of Terms used in Thesis

CHAPTER 2: REVIEW OF LITERATURE

Introduction

This literature review was conducted through electronic searches in PubMed, Google Scholar, materials from relevant projects, conversations held with professionals in the field, and previous public health conference presentations (e.g., CSTE Annual Conference, Public Health Informatics Conference, and American Medical Informatics Association Conference). The specific focus of the literature review is to examine publications around systems that address Electronic Case Reporting (eCR), Decision Support Services, previous efforts to document reportable conditions and the process used to create reporting specifications for conditions without CSTE position statements.

Review of literature

Established eCR projects – experiences defining reporting specifications

Notifiable Condition Detector (NCD)

The Regenstrief Institute, in Indianapolis, Indiana, has been experimenting and has successfully implemented a system to help automate the detection of reportable conditions. Their project is called the Notifiable Condition Detector (NCD). "The NCD is open-source technology that leverages messaging and terminology standards such as HL7 and LOINC […] to process over 300,000 messages daily from hundreds of sources and report 105 notifiable conditions to public health and other health care departments" [24].

Their model is built using a Health Information Exchange (HIE), in their case the Indiana Network for Patient Care (INPC), to gather the clinical data. They

examine the messages for any LOINC code that matches a reportable condition; this serves as their first layer of filtering and the message is deemed potentially reportable. Next, the message "is processed by a complex set of algorithms that first identify the result as numeric, discrete or free-text type and then determine whether the message is reportable. Key in this determination is an NLP rule-based system called REX15 (Regenstrief Extraction tool) that uses regular expressions to detect the presence and context of keywords" [24]. Their work on this project shows that their algorithms can help better detect and support the sending of reportable conditions by showing "a greater than four-fold detection rate over traditional physician-based reporting methods" [32].

Of particular interest to this research are the 105 reportable conditions in Indiana, as mentioned above, the NCD is able to detect and send to the health department. In an in-person informal interview with Dr. Shaun Grannis [33], he explained how the team is able to develop the algorithms for conditions for which there is no CSTE position statement. Indiana Department of Health publishes all of their reportable conditions on their website and provides "quick facts" for each condition such as: what is it, how is it spread, how do I know if I have it, what are the symptoms, etc. [34]. The Regenstrief team takes this information, and works with the health department epidemiologists to turn these data into executable algorithms, which enable automated detection of the reportable conditions [33].

NCD's model of examining a state health department website for reporting criteria is limited in scope to Indiana. Additionally, the NCD works with only one

HIE to analyze patient information thus eliminating the need to accommodate implementation variability across multiple systems.

Electronic Medical Record Support for Public Health (ESP)

Another successful project in support of eCR is the work being conducted in Massachusetts with a system called Electronic Medical Record Support for Public health (ESP). Instead of using data from an HIE as the NCD project does, ESP deploys software within a clinical setting. "ESP consists of a database and analytical software placed within a medical practice. The database is regularly populated with specific data elements extracted from each encounter recorded in the practice's EMR system" [35]. These data elements are laid out in the data model tables. "The ESP data model contains tables for patient demographics, vital signs, diagnosis codes, test orders, test results, medication prescriptions, allergies, social history, and provider contact details" [19]. A more complete view of the system architecture is shown below in Figure 1 [36].

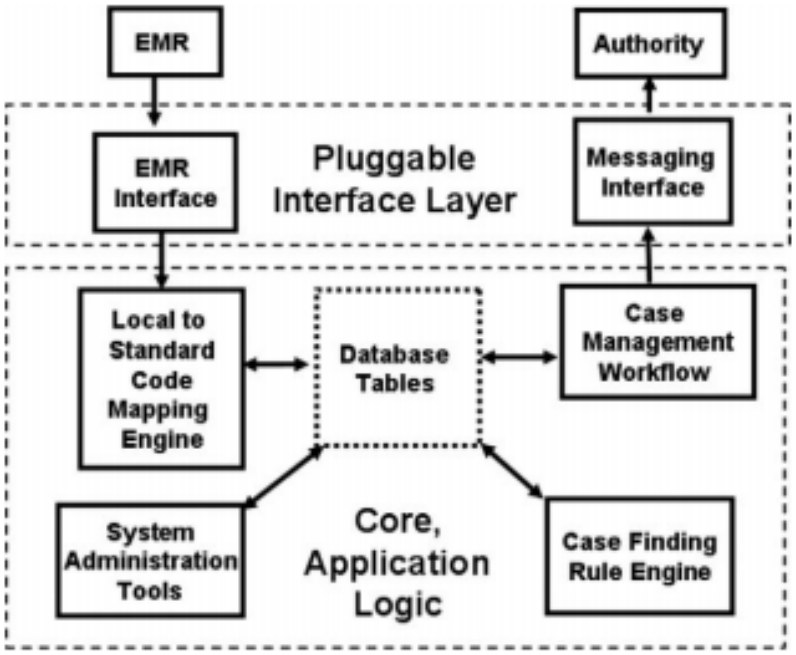


Figure 1 - ESP System Architecture [36]

ESP utilizes CDC case definitions but allows for localization and then "[c]ases are identified by analyzing diagnostic codes, laboratory tests and results, and medication prescriptions" [35]. From an in-person conversation with Bob Zambarano from Commonwealth Informatics Inc. [37], the case definitions are refined through efforts led by Dr. Michael Klompas from Harvard Medical School and Harvard Pilgrim Health Care. Dr. Klompas develops the case identification algorithms and works with epidemiologists to ensure they meet the needs of public health. These algorithms are then "validated by applying each algorithm to a five-year span of historical data from [Harvard Vanguard Medical Associates][…] a multipractice physician group serving 350,000 patients in Eastern Massachusetts" [35].

According to the Massachusetts eHealth Institute [19], algorithms exist for the following conditions: acute hepatitis A, B, and C, active tuberculosis, chlamydia,

diabetes type I and II (currently being validated), giardiasis, gonorrhea, influenza like illness, Lyme disease, pelvic inflammatory disease, pertussis, and syphilis. Out of these conditions, only pelvic inflammatory disease does not currently have a CSTE position statement.

Existing sources - Identifying and categorizing conditions

Cataloguing reportable conditions is not a new topic of interest. There have been previous attempts to capture pieces of this information in the past. Most notably are the State Reportable Condition Assessment (SRCA) and the Reportable Conditions Mapping Table (RCMT). Each project focuses on different aspects of reportable conditions and was designed with a specific purpose. The following is a review of each of these projects and their capabilities.

State Reportable Condition Assessment (SRCA)

Recommendations stemming from the Population Health and Clinical Care Connections Workgroup of the American Health Information Community (AHIC) back in 2007 set forth "to implement the informational tools and business operation to support real-time nationwide public health event monitoring and rapid response management" [38]. More specifically, the SRCA was created to fulfill the AHIC recommendation that "CSTE, in collaboration with CDC, should define an ongoing process to be used in establishing a common list of nationally notifiable conditions to be reported to all levels of public health" [38]. "As a result, the SRCA has gathered more complete data about public health reporting requirements than those data gathered independently by the CSTE or the CDC" [39].

"The [SRCA] is an annual assessment of reporting requirements for conditions that must be reported by clinicians, laboratories, hospitals, and others to public health according to jurisdictional laws" [13]. Perhaps the most important aspect of the SRCA is that the assessment is conducted retrospectively; it captures those conditions that were reportable in the previous year for a specific jurisdiction, therefore not providing an accurate current picture of surveillance conducted in the United States. Inclusion criteria for conditions were "if it was nationally notifiable during the previous year, if it was reportable by most jurisdictions (as determined by CDC and CSTE SRCA teams), or if it was thought to be of special interest to CSTE or CDC for initiatives or surveillance efforts" [39].

The first data for the SRCA was collected in 2008 and "had 270 conditions organized into 3 categories: 181 infectious, 64 noninfectious, and 25 crosscutting ("general") conditions" [39]. Limited information was collected about each reportable condition, but included types of reporters required to report and the legal authority to collect data on a condition. Reporter types included "clinicians, laboratories, hospitals, and 'other' public health reporters" [39]. Choices for legal authority included "explicitly reportable, implicitly reportable, and not reportable" defined as the following:

> Explicitly reportable was defined as a condition listed specifically as a disease (eg, Ebola virus disease) or category of diseases (eg, viral hemorrhagic fever) on reportable disease lists (Table 1). Implicitly reportable was defined as a condition, such as Ebola virus disease, which, instead of being listed explicitly on a reportable disease, was considered by

> the respondent state epidemiologist to be reportable under a broad nonspecific category such as “rare diseases of public health importance” (Table 1). A condition was defined as not reportable if it was not designated as reportable in the explicit or implicit categories. [39]

While the SRCA was a good first attempt to capture state reporting requirements, it proved to be more difficult than simply sending out a survey for states to enter in their reportable conditions. One big limitation survey data collection is there are “no assurances that all respondents in each state understood the instructions for the assessment and completed the assessment in a consistent manner” [39]. This is evidenced by the lack of standard names of diseases for states to choose from allowed them to enter free-text for the condition names. “States develop their reportable condition lists and the terminology to describe what is reportable differently, and each state may make different subsets of a specific condition reportable” [39]. This created a lot of variation in the naming of diseases when states tried to qualify the reporting of a reportable condition by adding an age, threshold level, or situational condition (e.g., outbreak, acute, invasive, in a particular occupation). This makes the data difficult to analyze at a national level. Again, this data was collected retrospectively “typically during the fourth quarter, and does not reflect changes made to a state’s reportable condition list after midyear” and therefore does not represent truly up-to-date information that reporters can use to know what conditions are reportable in their state [39].

There was a lot of important information on reportable conditions the SRCA lacked. It did not capture disease-specific criteria to help public health reporters

know if they had a case that needed to be sent to public health. It did not include information on where and how reporters should send in the report. It did not contain the underlying value sets of codes; thus the data is not machine-processable for use in automating of case reporting.

SRCA did contain some data elements that are extremely useful. One of those important elements was timeframe for reporting. According to the 2013 User Instruction guide, timeframe for reporting a condition is a data element captured for implicitly reportable conditions [40]. It also specified if a condition was implicitly or explicitly reportable for each reporter type: hospital, healthcare provider - laboratory, or other. Explicitly reportable was defined as "condition is mentioned by name in the jurisdiction's laws or reportable condition list" while implicitly reportable is defined as "condition is not specifically listed as reportable but would be considered reportable under general language in the jurisdiction's laws, such as calling for reporting of 'any condition of public health importance' or other similar terms" [13].

As limited this effort may seem, it was the first attempt to electronically capture all reportable conditions in all jurisdictions. The data captured can be used as a starting point for any future projects dealing with disease reporting, such as the RCKMS, who want to ensure all reportable conditions in each jurisdiction are captured. For this research, the data contained in SRCA for any participating jurisdiction, can be used to help identify and categorize reportable conditions that do not have a CSTE position statement for NNCs.

Reportable Condition Mapping Table (RCMT)

The next significant project around reportable conditions occurred in 2011 when CDC/CSTE published the Reportable Condition Mapping Table (RCMT). Led by the Standards Workgroup as part of the CDC/CSTE Electronic Laboratory Reporting (ELR) Task Force and previously referred to as the "Dwyer tables", "Sable tables", or Notifiable Condition Mapping Tables (NCMTs), RCMT "provides mappings between reportable conditions and their associated LOINC laboratory tests and SNOMED results […] us[ing] standards suggested for the meaningful use measure "reportable lab result reporting to public health" [28]. First published on the PHIN VADS website on June 30, 2011, the RCMT included content for 109 reportable conditions to be regularly updated as laboratory tests and standard codes change over time [28].

The codes in RCMT help provide a filter, particularly for electronic laboratory reporting, to know which conditions should be reported to public health. However, one possible downfall is, "if local laboratory test codes are not mapped to LOINC, then they cannot easily be automatically reported to or interpreted by the public health agency" [41]. Another issue with RCMT is it is only relevant for conditions with associated laboratory tests and results. Clinical criteria, such as the diagnosis of a condition, are not included since the original intent of these tables was to support ELR.

For purposes of this research, this agreed upon list of reportable conditions can be used to help identify reportable conditions lacking a CSTE position statement with section 6 and table 6b. The associated laboratory tests for those conditions,

can also be useful to suggest reporting criteria and draft supporting value sets for the criteria.

Conditions with CSTE position statements – Process to define reporting criteria

Reportable Conditions Knowledge Management System (RCKMS)

The most notable and relevant project related to improving eCR and documentation of reportable conditions is the RCKMS. Kicked off in 2012, the RCKMS completed a feasibility pilot phase in August 2015 aimed "to demonstrate the feasibility of using RCKMS for the authoring and management of reporting criteria and automated determination of whether a potential case is reportable" [11].

During the more recent phase of the RCKMS project there were two main focus areas: content development and technical development. Briefly, the technical development focused on building out the technical infrastructure for the authoring tool used by jurisdictions to manage their reporting criteria and the decision support tool. Meanwhile, the content development effort focused on establishing default reporting criteria for 74 reportable conditions, which are also nationally notifiable and therefore have a corresponding CSTE position statement containing the necessary section 6 and table 6b. These conditions will be pre-populated into the RCKMS authoring tool for jurisdictions to adopt or adapt depending on their jurisdictional reporting needs. This development of the content is most notable for this study as the RCKMS team developed a standard process to guide this work.

Created and lead by the project's Knowledge Engineer, Dr. Catherine Staes, the process started with a standardized Microsoft word template called "Process Criterion Valueset Rule STANDARDIZED" [42] (included in Appendix A1). The first step was to create a copy of this file and rename it with the condition it will represent. Next, within the document, a simple search and replace was conducted to populate the word document with the appropriate condition and organism name. This step would populate the standardized naming conventions for reporting criteria found in the template. Once the Word template was populated with the all the potential standardized criteria, the team started a separate Microsoft Excel document for the same condition using the template "Process Condition Template" (Appendix A2). The criteria from the CSTE position statement section 6 and table 6b were copied into the "Specifications" tab in the Excel template to represent the "National Criteria". Next, the criteria were standardized using the matching criteria in the previously created word template. If new criteria were discovered, the team used the "rules of thumb for creating new criteria" to guide the creation of proposed criteria, which was discussed with the team for a final solution [42]. Criteria were located down the first column in groups such as laboratory, clinical, and epidemiologic. Across the columns were groupings of criteria called "logic sets" which indicate the criteria necessary in order for a report to be sent to public health. These concepts can be seen in an example spreadsheet shown in Figure 2 below.

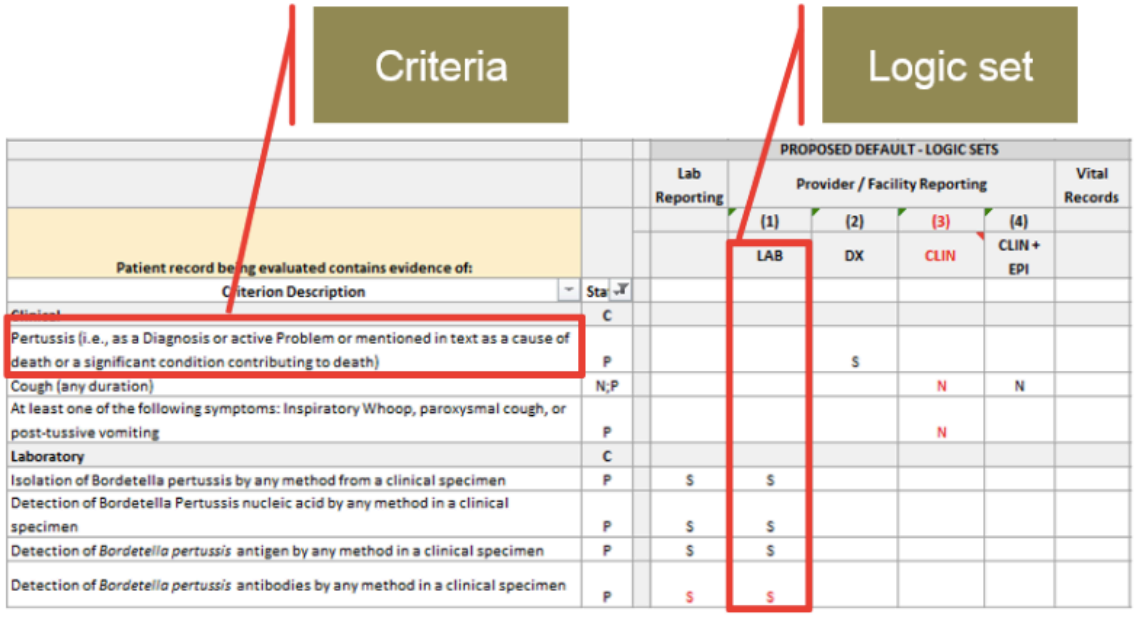


Figure 2 - Example Spreadsheet Indicating Criteria and Logic Set

The sufficient, necessary, optional notation from the CSTE position statements was followed. S for sufficient meant that the criteria on its own was enough to trigger a report. N (necessary) and O (optional) were often in combination where all Ns must be present plus at least one O in order for a report to be triggered. Optional criteria had variances where at times two or more optional criteria were needed to trigger a report and other instances when an optional criterion from each criteria category (clinical, laboratory, epidemiologic) was required.

This document became known as the "consolidated spreadsheet" to reflect combination of CSTE position statement criteria and newly drafted "proposed" criteria. Any remaining questions were documented the consolidated spreadsheet was ready to be vetted with the CSTE Content Vetting Workgroup [43]. This workgroup met weekly from October 2015 to June 2016 to vet the proposed criteria that the internal RCKMS Content Development Team drafted using this process.

The feedback from the CSTE Content Vetting Workgroup was logged and changes were incorporated to the consolidated spreadsheet in a new tab to preserve version history and show decisions. Once approved with final reporting criteria, the condition was ready for development of clinical rules logic and value sets. The clinical rules logic statements had templates in the same Word document that started the process for the condition. Necessary value sets were identified in the "Value Sets Needed" table of the document (Appendix A1). Applicable clinical rules logic statements were kept and made to match the logic sets laid out in the consolidated spreadsheet, while unnecessary statements were deleted. Finally the Clinical Vocabulary SME and Laboratory Vocabulary SME created the underlying clinical and laboratory value sets of codes in the Value Set Authority Center (VSAC) [44] to support the criteria for the condition. According to personal communication with the Project Manager and input from the Vocabulary SMEs [45], it takes approximately 1-2 days of work to create the clinical value sets and 2-3 days for the laboratory value sets per condition.

A high-level depiction of the steps of this process is shown in Figure 3 below. As noted in the diagram, as the process moves from left to right there is an increasing level of structure and computability to the content.

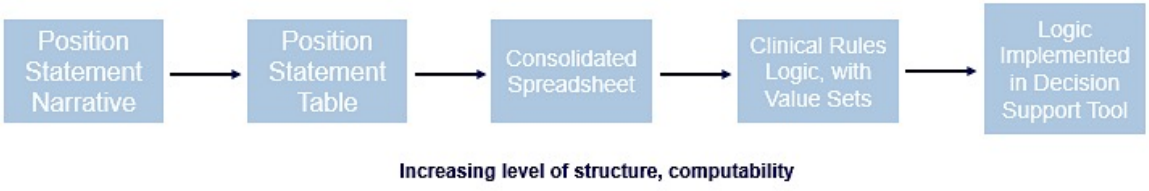


Figure 3 - RCKMS Content Development High-level Process

Overall, this process allowed for rapid development of reporting criteria in a standardized manner. It enabled team members without particular clinical, laboratory, or epidemiology knowledge or expertise to assist in the drafting and editing of condition artifacts such as the consolidated spreadsheet and word template containing clinical rules logic statements.

During this process the RCKMS team also found patterns amongst similar conditions, particularly in two instances when conditions fell into groupings such as Viral Hemorrhagic Fever and Arboviral diseases. It became easy to clarify reporting criteria across these different conditions when analyzed together. An example of this was discovered with Arboviral diseases when it was discovered that reporting criteria had varied between some of the conditions. When shown the Figure 4 below during a follow-up content vetting meeting the jurisdictions verified and corrected the missing criteria and harmonized laboratory testing across all Arboviral diseases.

	Culture		Antigen	Antigen (NS1)	NAT	Single IgM	Fourfold Rise (IgG/Total)	Seroconversion (IgG/Total)	Single IgG
	No Prelim. Results	Prelim. Results							optional
Arboviral Disease	X		X		X	X	X	X	X
West Nile Virus	X		X		X	X	X	X	X
St. Louis Encephalitis Virus Disease	X		X		X	X	X	X	X
Yellow Fever	X		X		X	X	X	X	?
Dengue		X*	X*	X*	X*	X*	X*	?	?
* Orders of lab test also requested									

Comparison of WG Requested Reporting Criteria for Arbovirals

- Are preliminary results only wanted for Dengue? Are lab orders only wanted for Dengue? Uncommon to do cultures, but if they existed, sure
- Are seroconversion results wanted for Dengue? (Convert from - to +) don't always have paired sera; not sure a lab could tell us this;
- Are single IgG's wanted for Dengue as a jurisdictional option? WI – Yes; LA – does want single IgG
- Are single IgG's wanted for Yellow Fever as a jurisdictional option? Let's go with yes?

Council of State and Territorial Epidemiologists

Figure 4 - Comparison of Criteria Across Arboviral Diseases

Ultimately the red question marks for Dengue and Yellow Fever were resolved when the Content Vetting Workgroup clarified that they indeed would want those tests to trigger a report to public health.

Summary of current problem and study relevance

Much of case reporting has historically been conducted using a paper-based system of faxing in cases of reportable disease, creating a lag in timeliness and typically missing pertinent information. Recent efforts show a push towards transforming this outdated process to be more electronic, complete, and even automated.

While ESP and NCD move towards more electronic methods their processes for developing reporting criteria are not standardized, repeatable, or extensible like the RCKMS process was for dealing with conditions that had a CSTE position

statement with section 6 and table 6b. SRCA and RCMT help inform the list of conditions that need to be considered when developing a solution that will encompass all disease reporting.

CSTE position statements containing section 6 and table 6b provide a standard baseline for deriving reporting criteria for certain reportable conditions. Reporting criteria for conditions that have a CSTE position statement with section 6 and table 6b can be transformed into machine-processable criteria, as demonstrated in the Phase I work of the RCKMS project. Conditions lacking a CSTE position statement do not have this baseline of reporting criteria making it more challenging to establish standard reporting criteria. If these conditions are to be included in systems that support eCR, such as the RCKMS, they will need reporting specifications to be defined.

CHAPTER 3: METHODS

Introduction

This thesis study utilized a four-step process: (1) an analysis of previous processes used to define jurisdictional reporting criteria for reportable conditions with or without a CSTE position statement, (2) a systematic review of previous efforts to document or gather jurisdictional reporting specifications, (3) identification of reportable conditions lacking a CSTE position statement, and (4) development of a recommended process framework for deriving jurisdictional reporting criteria for conditions that do not have a corresponding CSTE position statement.

Population and sample

This study is conducted based on all reportable conditions and emerging conditions of interest to public health in the United States. More specifically this study will focus on the conditions found in the State Reportable Conditions Assessment (SRCA) [13] and Reportable Conditions Mapping Tables (RCMT) [14] which were not covered by the first phase of the Reportable Conditions Knowledge Management System (RCKMS) content development effort [43]. This list consists of reportable conditions that are not nationally notifiable to the CDC and do not have a corresponding CSTE position statement. It is also important to include in this list conditions that are new or emerging (e.g., Zika Virus which emerged in an outbreak during 2016).

Research Design

This study utilized both comparative and descriptive methodologies. The comparative research method was applied to existing eCR processes that had experience in defining reporting specifications. These processes were examined for their reusability and extensibility.

Additionally, comparative and descriptive methods were applied to the analysis of conditions in order to identify and categorize into prioritization groupings.

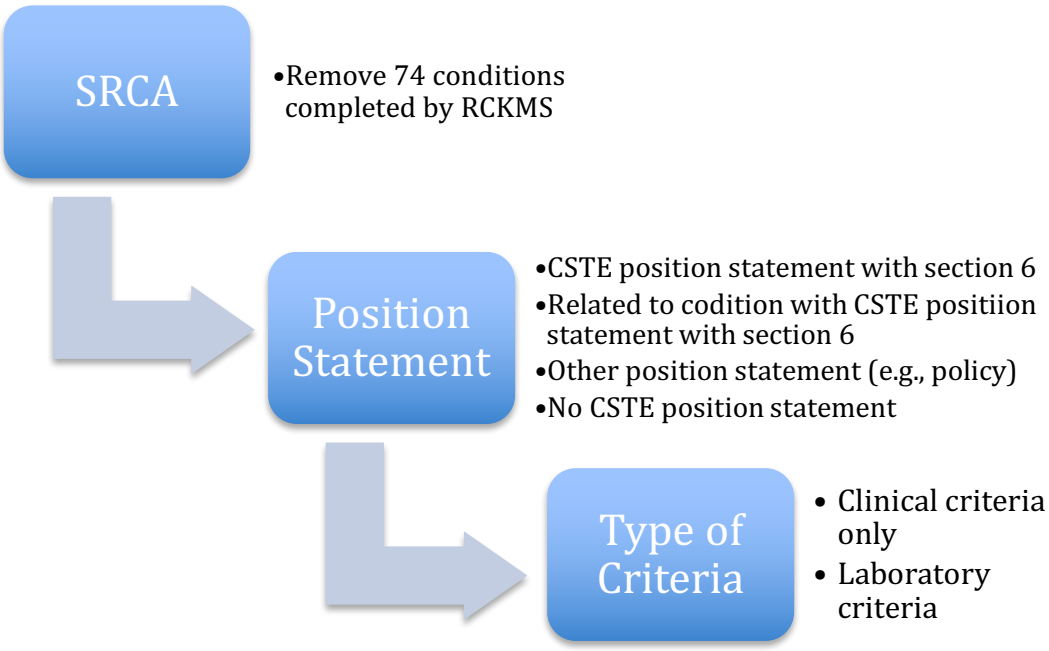


Figure 5 - Research Steps with Comparative Steps

Procedures

The first step of this research was to analyze the processes for existing systems that successfully support electronic case reporting. In these processes it was important to note how the projects derived algorithms to determine reportability for reportable conditions. Specifically, this analysis was interested in reportable conditions that did not have a CSTE position statement and the process

used to define their reporting criteria. Information about these systems was gathered through peer-reviewed articles about each system and informal in-person discussions with those who are intricately involved with the system.

Next this research examined previous efforts to gather and document reporting specifications. Three previous projects were examined: RCMT, SRCA, and RCKMS.

The third step of the research was to determine a comprehensive list of reportable conditions. Specifically, this list needed to indicate those reportable conditions that did not have a corresponding CSTE position statement. Data from RCMT and SRCA were analyzed by first removing those conditions completed by the RCKMS Phase I project. This included 74 reportable conditions, which were also nationally notifiable, and had a CSTE position statement. Once the 74 were removed the remaining conditions in SRCA were scrubbed for errors. Some errors found included conditions being incorrectly grouped with another condition such as Rift Valley Fever being included as a Rickettsial disease and therefore not originally included in final condition count. Next each condition was given a status to indicate one of the 5 categories: 1) Covered by RCKMS round 1 to include 74 reportable conditions that were also nationally notifiable and had a CSTE position statement, 2) Reportable and has a CSTE position statement that includes section 6 and table 6b, 3) No CSTE position statement, 4) Included in another condition's CSTE position statement containing section 6 and table 6band possibly has related condition, 5) Has a related CSTE position statement but does not include section 6 (e.g., policy related). Using the CSTE position statement archive search tool [12], conditions

were entered to determine if a matching position statement existed. Only those CSTE position statements containing the necessary section 6 and table 6b were included; other position statements, with a topic such as policy, did not satisfy a condition as having a position statement (e.g., for poisoning, the position statement "Inclusion of Poisoning Mortality and Morbidity in the National Public Health Surveillance System (NPHSS)" should not be considered a valid position statement for this research). The conditions from SRCA came grouped into condition categories found in Table 2 below and the analysis needed to ensure these categories remained intact.

SRCA CONDITION CATEGORY
Birth Defects and Congenital Anomalies
Bloodborne Diseases
Enteric Diseases
Healthcare-Associated Events
Infectious Disease Not Otherwise Specified
Injuries
Neurologic and Toxin-Mediated Conditions
Respiratory Conditions (Infectious)
Selected Non-Infectious Diseases
Sexually Transmitted Diseases
Systemic Conditions
Toxic Effects of Non-Medicinal Substances
Vaccine-Preventable Conditions
Zoonotic and Vectorborne Diseases

Table 2 - SRCA Condition Categories

Next a crosswalk analysis was conducted comparing remaining conditions found in RCMT to those remaining conditions found in SRCA. Duplicate conditions were removed only if the naming of the condition was an identical match. Those conditions that seemed similar but had different names were kept as two separate

conditions but only counted once in the total count.

Finally, the remaining conditions in SRCA were analyzed to determine the number of jurisdiction who indicated a given disease was reportable. For SRCA there are a total of 56 jurisdictions: 50 states, 5 territories (America Samoa, District of Columbia, Federated Regions of Micronesia, Guam, and Puerto Rico) and 1 city (New York City). The following were used as inclusion criteria for a condition to be considered reportable for a given jurisdiction:

- In the "response" field of SRCA, if a condition had a timeframe indicated
- Only one reporter type needed to be marked with a timeframe
- Additional qualifying criteria for a condition (e.g., age criteria, outbreak status) as long as a timeframe was indicated

If a jurisdiction marked a condition as "implicit" this was tracked separately to indicate they are able to collect data on this condition but it is not specifically called out in the state regulations [40]. For the purposes of this research only those explicitly listed as reportable were included in final evaluation criteria. If the response was left blank or marked as "not reportable" it was excluded from the final count.

Each aforementioned step was used as evaluation criteria to inform the final recommended process for moving forward with content development in the next phase of the RCKMS project. Therefore, three evaluation criteria were considered:

- Does it have a CSTE position statement with section 6 and table 6b, or another related position statement?
- How many states want it reported?

- What type of condition is it? (e.g., Does it contain any laboratory criteria?

Instruments

Data were recorded in Microsoft Excel spreadsheets for comparison and analysis. Exports from both the SRCA and the RCMT were obtained in Microsoft Excel file formats. These files were combined into one Microsoft Excel file for analysis by the author. Additionally the CSTE position statement archive query website [12] was utilized to help assess which conditions did not have an existing approved CSTE position statement.

Information and documentation about previous work completed by the RCKMS project were obtained from the project's restricted Microsoft SharePoint webpage supported by the Association of Public Health Laboratories (APHL). This included document templates and project documentation held in Microsoft Word and Microsoft Excel documents (Appendix A).

Data analysis methodology

CHAPTER 4: RESULTS

Introduction

The results of this thesis are broken into 3 sections: 1) usability of existing frameworks for developing national default reporting criteria for conditions without CSTE position statements, 2) identification and analysis of reportable conditions in SRCA and RCMT that are reportable but not notifiable, and 3) recommended process for deriving reporting specifications for these remaining reportable conditions.

Key findings

Previous projects

The processes in place used by the NCD and ESP projects to identify reporting specifications for reportable conditions without a CSTE Position statement would not work for the future processes of the RCKMS project. However, the process used by the previous phase of the RCKMS project has the most potential for reuse moving forward.

First, the ESP project in Massachusetts is limited in scope to conditions reportable inside of their own state. This eliminates the need to account for variability in reporting specifications across jurisdictions; they only need to work with Massachusetts Department of Public Health to meet their requirements for reporting. Additionally, they are working with a limited set of conditions (acute hepatitis A, B, and C, active tuberculosis, chlamydia, diabetes type I and II, giardiasis, gonorrhea, influenza like illness, Lyme disease, pelvic inflammatory disease, pertussis, and syphilis). Given this limited scope of diseases within one jurisdiction

it is feasible for one person (Dr. Michael Klompas) to be defining the case identification algorithms needed. It would be worthwhile to take the defined specifications for these conditions, and their associated algorithms into consideration, the process itself is extensible to a national level.

Second for NCD, the project is limited in scope to conditions reportable in Indiana, and like ESP, does not have to consider jurisdictional variations in reporting criteria. They do cover more conditions than the ESP project; and their reporting specification could be useful for defining national default reporting specifications for process framework described in this study. The information about each reportable condition is made available on their website, and should be used to inform the national default reporting criteria.

The RCKMS process showed the most potential for reusability. This process was created for use by a team and not just work done by one person. The process was systematic and applied across 9 categories of conditions (Bloodborne, Enteric, Neurologic, Respiratory, Systemic, Sexually Transmitted Infections, Toxic, Vaccine Preventable, and Zoonotic and Vectorborne). It applied multiple levels of validation through both vetting and quality assurance checks. It was designed to create a set of national default content using harmonized criteria with standardized naming conventions. Lastly, it was built with consideration and support for jurisdictional variations in reporting criteria. It ensured the feedback from public health was incorporated and the final product met their needs. The public health community is now familiar with the templates used in this process and understands the concept of grouping reporting criteria into logic sets.

Condition analysis

The first set of results presented below indicates whether or not the condition has a CSTE position statement with section 6 and table 6b, or other related position statement. In total there are 252 conditions in SRCA. For all SRCA conditions the breakdown of available position statements is shown in Table 3.

Completed by RCKMS	Reportable and has CSTE PS with section 6	No CSTE PS exist	Has other Condition-specific related CSTE PS with section 6	Has related CSTE PS (e.g., policy)
74	19	109	18	32

Table 3 - Summary of SRCA Condition Analysis

The next set of results helps identify which conditions may not contain laboratory criteria or already have laboratory criteria partially defined thanks to the efforts of RCMT, another evaluation criterion to help determine condition prioritization and process.

After removing the conditions completed in the first round of the RCKMS content vetting, there are 178 conditions remaining in SRCA and an additional 12 in RCMT (not in SRCA) totaling 190 conditions to be considered for the next round of the RCKMS.

For SRCA these 178 conditions break out into the following condition categories as shown in Table 4.

Condition Category	Number of conditions
Birth Defects and Congenital Anomalies	31
Bloodborne Diseases	1
Enteric Diseases	12
Healthcare-Associated Events	9
Infectious Disease Not Otherwise Specified	5
Injuries	21

Neurologic and Toxin-Mediated Conditions	14
Respiratory Conditions (Infectious)	6
Selected Non-Infectious Diseases	15
Sexually Transmitted Diseases	8
Systemic Conditions	9
Toxic Effects of Non-Medicinal Substances	8
Vaccine-Preventable Conditions	3
Zoonotic and Vectorborne Diseases	36
Total	**178**

Table 4 - SRCA Condition Category Breakdown

RCMT currently contains 259 value sets. There are 8 value sets (7 for NHSN and 1 for cancer) which were added to RCMT later and extend beyond the original intent of RCMT. Removing these 8 value sets, the remaining 251 value sets represent a total of 129 conditions and 8 organisms. After eliminating the conditions previously completed by the RCKMS project and the 8 organisms, there are 64 reportable conditions remaining in RCMT. The crosswalk between SRCA and RCMT conditions can be summarized in Table 5 below.

	SRCA ONLY	RCMT ONLY	BOTH
Number of Conditions	132	12	46

Table 5 - SRCA and RCMT Crosswalk Analysis Summary

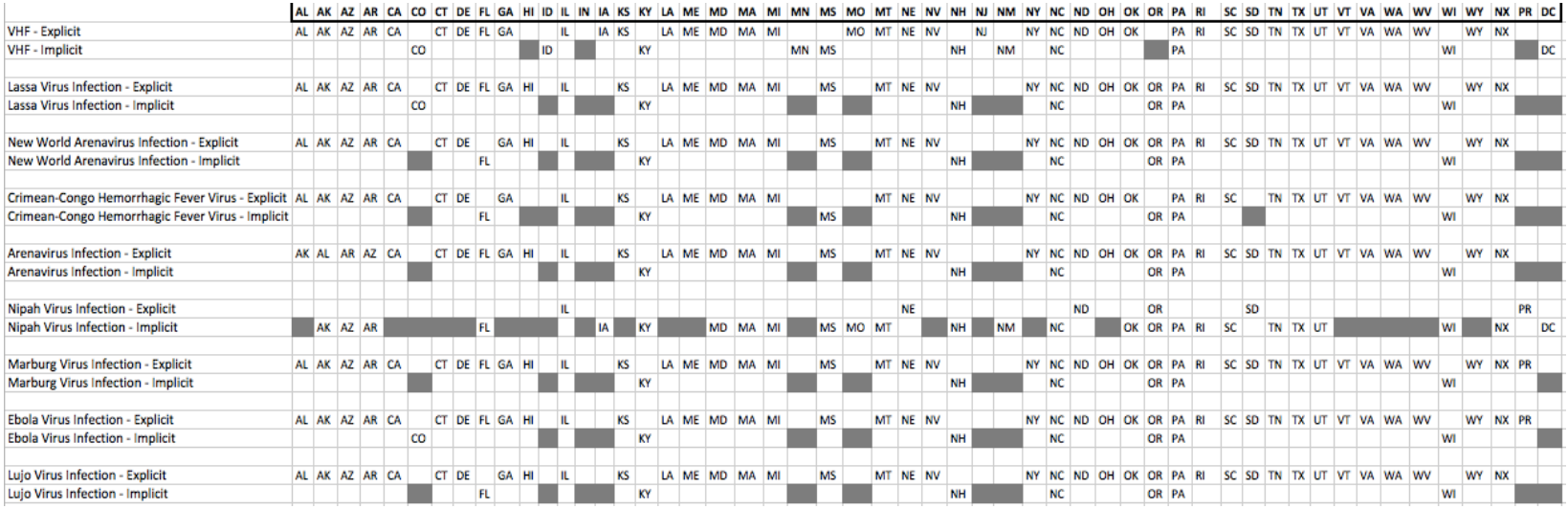
Finally, the last evaluation criterion is the number of states for whom the condition is reportable. This is shown in the following section with the recommended process and grouping of conditions. The condition groupings include the number of jurisdictions that want a condition reported to them. Additionally, a table of all conditions in SRCA ordered by number of jurisdictions that want a condition reported to them is included in Appendix B.

Recommended process

This process recommendation focuses mainly on the order of conditions to be tackled in the next phase of the RCKMS project. It also includes recommendations in how the project team should conduct this process.

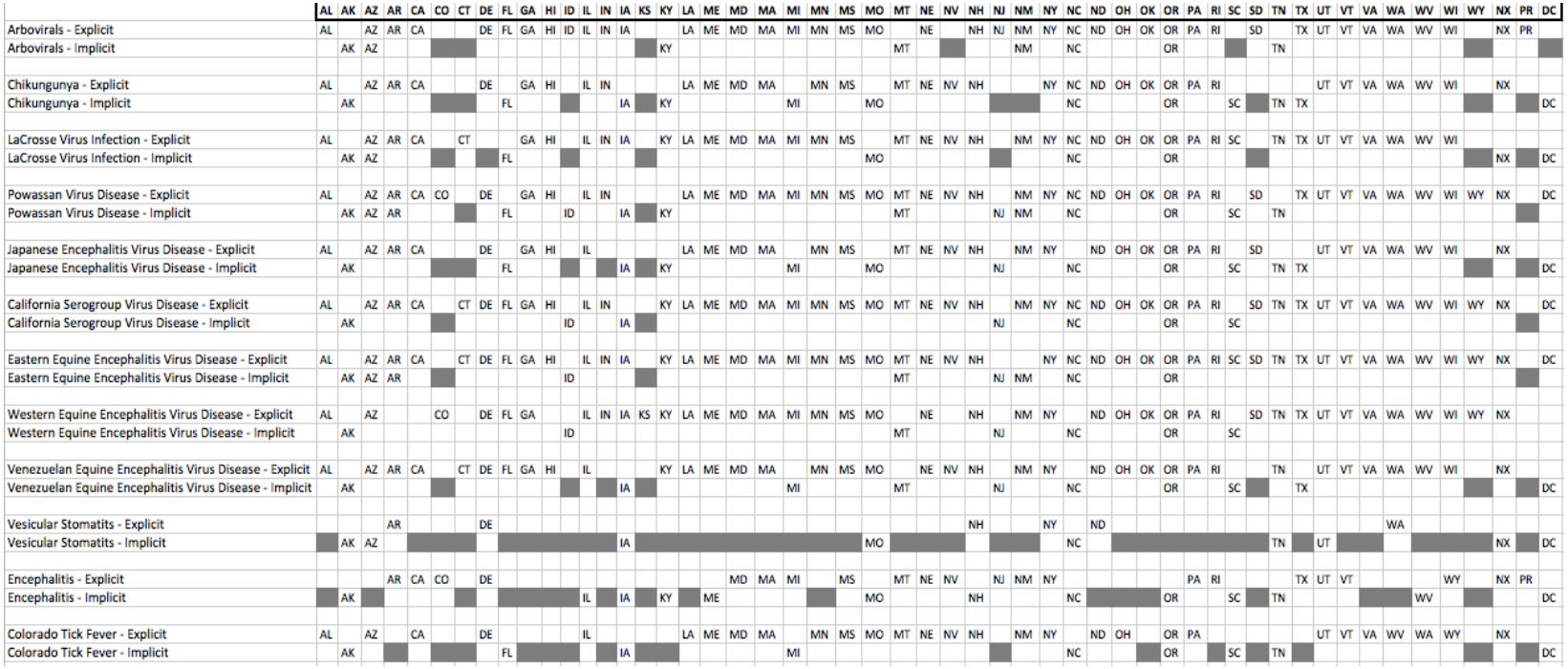
First and foremost, when completing new conditions, it is recommended to continue using the RCKMS standardized templates. Starting with the Microsoft Word template "Process Criterion Valueset Rule STANDARDIZED" to help name the reporting criteria in a standardized format. These standardized criteria should then be used to populate the Microsoft Excel template "Process Condition Template" with the relevant reporting criteria. Ultimately each condition completed will have an excel file populated with the reporting criteria and appropriate logic sets to then be accompanied by a word document naming the necessary value sets and clinical rules logic statements for implementation into the Decision Support tool.

The first conditions to be completed are those conditions that fall into a smaller group within a condition category (e.g., Arbovirals, Viral Hemorrhagic Fevers). The first phase of the RCKMS project grouped these into the respective category, but each condition should be broken out so jurisdictions can select individual conditions reportable in their jurisdiction. Analyses were conducted to show the differences between jurisdictions when it comes to wanting these conditions reportable (Figures 6 and 7 below).



	AL	AK	AZ	AR	CA	CO	CT	DE	FL	GA	HI	ID	IL	IN	IA	KS	KY	LA	ME	MD	MA	MI	MN	MS	MO	MT	NE	NV	NH	NJ	NM	NY	NC	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV	WI	WY	NX	PR	DC
VHF - Explicit	AL	AK	AZ	AR	CA		CT	DE	FL	GA			IL		IA	KS		LA	ME	MD	MA	MI			MO	MT	NE	NV		NJ		NY	NC	ND	OH	OK		PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV		WY	NX		
VHF - Implicit						CO						ID					KY							MS					NH		NM		NC					PA											WI				DC
Lassa Virus Infection - Explicit	AL	AK	AZ	AR	CA		CT	DE	FL	GA	HI		IL			KS		LA	ME	MD	MA	MI		MS		MT	NE	NV				NY	NC	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV		WY	NX		
Lassa Virus Infection - Implicit						CO											KY												NH				NC					OR	PA											WI					
New World Arenavirus Infection - Explicit	AL	AK	AZ	AR	CA		CT	DE		GA	HI		IL			KS		LA	ME	MD	MA	MI		MS		MT	NE	NV				NY	NC	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV		WY	NX		
New World Arenavirus Infection - Implicit									FL								KY												NH				NC					OR	PA											WI					
Crimean-Congo Hemorrhagic Fever Virus - Explicit	AL	AK	AZ	AR	CA		CT	DE		GA			IL			KS		LA	ME	MD	MA	MI				MT	NE	NV				NY	NC	ND	OH	OK		PA	RI	SC		TN	TX	UT	VT	VA	WA	WV		WY	NX		
Crimean-Congo Hemorrhagic Fever Virus - Implicit									FL								KY							MS					NH				NC					OR	PA											WI					
Arenavirus Infection - Explicit	AK	AL	AR	AZ	CA		CT	DE	FL	GA	HI		IL			KS		LA	ME	MD	MA	MI		MS		MT	NE	NV				NY	NC	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV		WY	NX		
Arenavirus Infection - Implicit																	KY												NH				NC					OR	PA											WI					
Nipah Virus Infection - Explicit													IL														NE						ND			OR				SD											PR		
Nipah Virus Infection - Implicit		AK	AZ	AR					FL						IA		KY			MD	MA	MI		MS	MO	MT			NH		NM		NC			OK	OR	PA	RI	SC		TN	TX	UT					WI		NX		DC
Marburg Virus Infection - Explicit	AL	AK	AZ	AR	CA		CT	DE	FL	GA	HI		IL			KS		LA	ME	MD	MA	MI		MS		MT	NE	NV				NY	NC	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV		WY	NX	PR	
Marburg Virus Infection - Implicit																	KY												NH				NC					OR	PA											WI					
Ebola Virus Infection - Explicit	AL	AK	AZ	AR	CA		CT	DE	FL	GA	HI		IL			KS		LA	ME	MD	MA	MI		MS		MT	NE	NV				NY	NC	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV		WY	NX	PR	
Ebola Virus Infection - Implicit						CO											KY												NH				NC					OR	PA											WI					
Lujo Virus Infection - Explicit	AL	AK	AZ	AR	CA		CT	DE		GA	HI		IL			KS		LA	ME	MD	MA	MI		MS		MT	NE	NV				NY	NC	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV		WY	NX		
Lujo Virus Infection - Implicit									FL								KY												NH				NC					OR	PA											WI					

Figure 6 - Viral Hemorrhagic Fever Comparison Across Jurisdictions



	AL	AK	AZ	AR	CA	CO	CT	DE	FL	GA	HI	ID	IL	IN	IA	KS	KY	LA	ME	MD	MA	MI	MN	MS	MO	MT	NE	NV	NH	NJ	NM	NY	NC	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV	WI	WY	NX	PR	DC
Arbovirals - Explicit	AL		AZ	AR	CA			DE	FL	GA	HI	ID	IL	IN	IA			LA	ME	MD	MA	MI	MN	MS	MO		NE		NH	NJ	NM	NY	NC	ND	OH	OK	OR	PA	RI		SD		TX	UT	VT	VA	WA	WV	WI		NX	PR	
Arbovirals - Implicit		AK	AZ														KY									MT					NM		NC				OR					TN												
Chikungunya - Explicit	AL		AZ	AR	CA			DE		GA	HI		IL	IN				LA	ME	MD	MA		MN	MS		MT	NE	NV	NH			NY	NC	ND	OH	OK	OR	PA	RI					UT	VT	VA	WA	WV	WI		NX		
Chikungunya - Implicit		AK							FL						IA		KY					MI			MO								NC				OR			SC		TN	TX												
LaCrosse Virus Infection - Explicit	AL		AZ	AR	CA		CT			GA	HI		IL	IN	IA		KY	LA	ME	MD	MA	MI	MN	MS		MT	NE	NV	NH		NM	NY	NC	ND	OH	OK	OR	PA	RI	SC		TN	TX	UT	VT	VA	WA	WV	WI				
LaCrosse Virus Infection - Implicit		AK	AZ						FL																MO								NC				OR														NX		DC
Powassan Virus Disease - Explicit	AL		AZ	AR	CA	CO		DE		GA	HI		IL	IN				LA	ME	MD	MA	MI	MN	MS	MO	MT	NE	NV	NH		NM	NY	NC	ND	OH	OK	OR	PA	RI		SD		TX	UT	VT	VA	WA	WV	WI	WY	NX		DC
Powassan Virus Disease - Implicit		AK	AZ	AR				FL				ID			IA		KY									MT				NJ	NM		NC				OR			SC		TN											
Japanese Encephalitis Virus Disease - Explicit	AL		AZ	AR	CA			DE		GA	HI		IL					LA	ME	MD	MA		MN	MS		MT	NE	NV	NH		NM	NY		ND	OH	OK	OR	PA	RI		SD			UT	VT	VA	WA	WV	WI		NX		
Japanese Encephalitis Virus Disease - Implicit		AK							FL						IA		KY					MI			MO					NJ			NC				OR			SC		TN	TX											
California Serogroup Virus Disease - Explicit	AL		AZ	AR	CA		CT	DE	FL	GA	HI		IL	IN			KY	LA	ME	MD	MA	MI	MN	MS	MO	MT	NE	NV	NH		NM	NY	NC	ND	OH	OK	OR	PA	RI		SD	TN	TX	UT	VT	VA	WA	WV	WI	WY	NX		DC
California Serogroup Virus Disease - Implicit		AK										ID			IA															NJ			NC				OR			SC													
Eastern Equine Encephalitis Virus Disease - Explicit	AL		AZ	AR	CA		CT	DE	FL	GA	HI		IL	IN	IA		KY	LA	ME	MD	MA	MI	MN	MS	MO	MT	NE	NV	NH			NY	NC	ND	OH	OK	OR	PA	RI	SC	SD	TN	TX	UT	VT	VA	WA	WV	WI	WY	NX		DC
Eastern Equine Encephalitis Virus Disease - Implicit		AK	AZ	AR								ID														MT				NJ	NM		NC				OR																
Western Equine Encephalitis Virus Disease - Explicit	AL		AZ			CO		DE	FL	GA			IL	IN	IA	KS	KY	LA	ME	MD	MA	MI	MN	MS	MO		NE		NH		NM	NY		ND	OH	OK	OR	PA	RI		SD	TN	TX	UT	VT	VA	WA	WV	WI	WY	NX		
Western Equine Encephalitis Virus Disease - Implicit		AK										ID														MT				NJ			NC				OR			SC													
Venezuelan Equine Encephalitis Virus Disease - Explicit	AL		AZ	AR	CA		CT	DE	FL	GA	HI		IL				KY	LA	ME	MD	MA		MN	MS	MO		NE	NV	NH		NM	NY		ND	OH	OK	OR	PA	RI			TN		UT	VT	VA	WA	WV	WI		NX		
Venezuelan Equine Encephalitis Virus Disease - Implicit		AK													IA							MI				MT				NJ			NC				OR			SC			TX											
Vesicular Stomatits - Explicit				AR				DE																					NH			NY		ND														WA					
Vesicular Stomatits - Implicit		AK	AZ												IA										MO								NC									TN		UT									NX		DC
Encephalitis - Explicit				AR	CA	CO		DE												MD	MA	MI		MS		MT	NE	NV		NJ	NM	NY						PA	RI				TX	UT	VT					WY		NX	PR	
Encephalitis - Implicit		AK											IL		IA		KY		ME						MO				NH				NC				OR			SC		TN							WV				DC
Colorado Tick Fever - Explicit	AL		AZ		CA			DE					IL					LA	ME	MD	MA		MN	MS	MO	MT	NE	NV	NH		NM	NY		ND	OH		OR	PA						UT	VT	VA	WV	WA	WY		NX		
Colorado Tick Fever - Implicit		AK							FL						IA							MI											NC				OR			SC		TN												

Figure 7 - Arbovrial Conditions Comparison Across Jurisdictions

Figures 6 and 7 demonstrate the differences in reportability between the different types of Viral Hemorrhagic Fevers and Arboviral Diseases. Each figure shows the over category of VHF and Arboviral along with the specific conditions under each of these category and which states said the condition was explicitly or implicitly reportable. The grey boxes indicate when a state indicated it was not reportable at all. These figures can show the importance of needing to separate out these conditions so that jurisdictions can individually select them. For example, Connecticut indicated that LaCrosse Virus infection, California Serogroup Virus disease, Easter Equine Encephalitis Virus Disease, and Venezuelan Equine Encephalitis Virus Disease were explicitly reportable but the other Arboviral conditions, including Arbovirals as a category, were not reportable.

These conditions are expected to have similar reporting criteria as shown in the Arboviral disease grouping in Figure 4 previously mentioned in Chapter 2, harmonized and verified by the CSTE Content Vetting Workgroup. Thus, it should be easy to reuse the reporting criteria associated with the group and efficiently vet them with the public health community. The conditions which fall into these groupings are shown in Tables 6 and 7 below resulting in 8 new Viral Hemorrhagic Fever conditions and 11 new Arboviral conditions.

VHFs	**# of Jurisdictions**
Lassa Virus Infection	40
New World Arenavirus Infection	39
Crimean-Congo Hemorrhagic Fever Virus Infection	35
Arenavirus Infection	40
Nipah Virus Infection	6
Marburg Virus Infection	41

Ebola Virus Infection	41
Lujo Virus Infection	39
Total New = 8	

Table 6 - Viral Hemorrhagic Fever Conditions in SRCA

Arbovirals	**# of Jurisdictions**
Chikungunya	34
LaCrosse Virus Infection	40
Powassan Virus Disease	42
Japanese Encephalitis Virus Disease	34
California Serogroup Virus Disease	45
Eastern Equine Encephalitis Virus Disease	46
Western Equine Encephalitis Virus Disease	40
Venezuelan Equine Encephalitis Virus Disease	37
Vesicular Stomatits	6
Encephalitis	22
Colorado Tick Fever	29
Total New = 11	

Table 7 - Arboviral Conditions in SRCA

The next conditions to tackle should be the 19 conditions from Table 3 above that have a CSTE position statement with section 6 and table 6b. The content development of these conditions should follow the previous RCKMS process for content development, which uses the position statement as a starting point for the reporting criteria. Some of these conditions may be covered by the first step. The conditions included in this grouping are show in Table 8 below, those which are covered from previous groupings are crossed out and not included in total count resulting in 13 new conditions.

CSTE position statement with section 6	**# of Jurisdictions**
Cancer	48
(outbreak-associated) Foodborne Disease	48
(outbreak-associated) Waterborne Disease	42
~~Eastern Equine Encephalitis Virus Disease~~	
~~Western Equine Encephalitis Virus Disease~~	
~~Powassan Virus Disease~~	
Smoke Inhalation	5

~~Marburg Virus Infection~~	
~~Ebola Virus Infection~~	
Acanthamoeba Disease (excluding keratitis)	1
Asthma	15
Balamuthia mandrillaris Disease	1
Enterobacteriaceae Infection	5
Histoplasmosis	17
Melioidosis	21
Primary Amebic Meningoencephalitis	13
Staphylococcus aureus Infection	40
Streptococcal Disease	41
~~California Serogroup Virus Disease~~	
Total New = 13	

Table 8 - Conditions with CSTE position statement with section 6 in SRCA

Next the conditions that have are related to another condition where there is a CSTE position statement with section 6 and table 6b, should be tackled. Any information about the related condition that could be reused should be considered in developing the reporting specifications. If the position statement does not supply all of the information, then it should be supplemented with information from the following websites: state health department website, CDC, or World Health Organization (WHO). Based off a cursory search of state health department websites, Indiana had a website that was most comprehensive and helpful but other state websites may be useful. Additionally, a search should be conducted in LOINC to identify any potential laboratory testing for a given condition, this can help inform the laboratory reporting criteria. The conditions that fall into this grouping can be found in Table 9 below resulting in 10 new conditions.

Related CSTE position statement	# of Jurisdictions
Coal workers' pneumoconiosis	10
~~New World Arenavirus Infection~~	
~~Crimean-Congo Hemorrhagic Fever Virus Infection~~	

~~Encephalitis~~	
~~Arenavirus Infection~~	
Acute Flaccid Paralysis	1
Acute Upper Respiratory Illness	0*
~~Chikungunya~~	
~~LaCrosse Virus Infection~~	
Streptococcus pneumoniae Infection	48
Vancomycin-Resistant Enterococci (VRE) Infection	18
~~Japanese Encephalitis Virus Disease~~	
Meningitis	18
Pneumoconiosis	9
Hospital-acquired Infection	13
Influenza	18
Influenza-like Illness	10
Total New = 10	

Table 9 - Conditions with Related CSTE position statement in SRCA

The next grouping of conditions is those which have a policy-related CSTE position statement. These position statements may not detail exact criteria but there may be useful information related to symptoms or laboratory testing that can be used to help determine the criteria that should be included. Table 10 depicts the conditions which fall into this grouping, resulting in 32 new conditions.

Policy-related Position Statement	# of Jurisdictions
Ventilator-associated Pneumonia	5
Variant Creutzfeldt-Jakob Disease	35
Pneumonia	4
Arsenic Poisoning	19
Cadmium Poisoning	16
Catheter-associated Urinary Tract Infection (UTI)	7
Central-line associated Bloodstream Infection	22
Disaster Casualty	8
Domoic Acid Poisoning	12
Fish and Shellfish Poisoning	13
Hazardous Substances Emergency Event	15

Healthcare-associated Adverse Event	9
Healthcare-associated Infection	13
Immunization-related Adverse Reaction	10
Intimate Partner Violence	10
Mercury Poisoning	23
Motor Vehicle Injury	9
Mushroom Poisoning	7
Nosocomial Infection	12
Respiratory Syncytial Virus (RSV) Infection	7
Ricin Poisoning	20
Septicemia	1
Traumatic Fatalities	16
Traumatic Injuries	13
Filariasis	2
Clostridium difficile Infection	8
Creutzfeldt-Jakob Disease	43
Diabetes	2
Drownings and Submersions	9
Herpes Genitalis	6
Suicide	14
Surgical Site Infection	18
Total = 32	

Table 10 - Conditions with Policy-related Position Statement in SRCA

Once conditions that have any type of CSTE position statement are completed, the project should move onto the 109 conditions from Table 3 and remaining conditions in RCMT. For this group of conditions, the recommendation is to start with conditions that do not have laboratory criteria, specifically injuries and birth defects. As learned from the previous phase of the RCKMS content development, creation of value sets for laboratory criteria took much longer than the clinical diagnosis value sets. Therefore, it is believed that conditions lacking laboratory criteria can be completed at a much faster rate. The list of conditions that fall into the category of birth defects or injuries are shown in Tables 11 and 12 below.

BIRTH DEFECTS	# of Jurisdictions
Other Specified Developmental Deformity	26
Other Specified Genetic Disorder	30
Other Specified Metabolic Disorder	32
Abdominal Wall Defects	34
Alcohol-related Birth Defects	26
Anencephaly	27
Autism	11
Autism Spectrum Disorders	12
Biotinidase Deficiency	32
Cardiac Defect	32
Cleft Lip	34
Cleft Lip/Palate	33
Cleft Palate	34
Congenital Hyperthyroidism	23
Down's Syndrome (Trisomy 21)	35
Epispadia	28
Fetal Alcohol Spectrum Disorders (FASD)	20
Fetal Alcohol Syndrome (FAS)	27
Galactosemia	35
Gastroschisis	28
Hypospadia	32
Inborn Errors of Metabolism	29
Infant Hearing Loss	33
Limb Reduction	33
Maple Syrup Urine Disease	34
Neural Tube Defect	32
Omphalocele	30
Phenylketonuria	36
Primary Congenital hypothyroidism	34
Spina Bifida	26
Sudden Infant Death Syndrome (SIDS)	20
Total New = 31	

Table 11 - Conditions in Birth Defects Category in SRCA

INJURIES	# of Jurisdictions
Animal Bites	26
Burns	11
Contaminated Sharps Injury	4
~~Disaster Casualty~~	
Drug (Controlled Substance) Overdose	7

Farm-related	8
Gunshot Wounds	15
~~Hazardous Substances Emergency Event~~	
Head Injury	16
Hyperthermia	5
Hypothermia	5
~~Intimate Partner Violence~~	
~~Motor Vehicle Injury~~	
Noise-induced Hearing Loss	3
Spinal Cord Injury	17
~~Traumatic Fatalities~~	
~~Traumatic Injuries~~	
Violent Injuries	7
~~Smoke Inhalation~~	
~~Drownings and Submersions~~	
~~Suicide~~	
Total New = 12	

Table 12 - Conditions in Injuries Category in SRCA

After those with no laboratory criteria are completed the next grouping of conditions are those that are in both RCMT and SRCA and do not have any type of CSTE position statement (shown in Table 13 below). Therefore, RCMT will provide starting information on laboratory criteria for these conditions. The codes associated with these conditions in RCMT should be checked to ensure only the necessary codes of interest to public health are included. There are 25 conditions that fall into this grouping that were not previously covered in a grouping.

Conditions in both RCMT and SRCA	# of Jurisdictions
Amebiasis	29
~~Arenaviral hemorrhagic fever (disorder)~~	
Asbestosis	17
Bartonellosis	2
Berylliosis	9
Blastomycosis	7
~~Cadmium Poisoning~~	

~~California Serogroup Virus Disease~~	
~~Chikungunya~~	
~~Colorado Tick Fever~~	
~~Crimean-Congo hemorrhagic fever~~	
Cryptococcosis	8
Cysticercosis	7
~~Ebola virus disease (disorder)~~	
Glanders	22
Granuloma Inguinale	16
Hepatitis D	37
Hepatitis E	38
~~Herpes Genitalis~~	
~~Histoplasmosis~~	
~~Lassa fever~~	
~~Lujo Virus Infection~~	
Lymphogranuloma Venereum	45
~~Marburg fever~~	
~~Melioidosis~~	
Monkeypox	14
Nongonococcal Urethritis (NGU)	4
Norovirus Infections	14
~~Powassan Virus Disease~~	
~~Respiratory Syncytial Virus (RSV) Infection~~	
~~Ricin Poisoning~~	
Rickettsial Disease	14
Rift Valley Fever	34
Rotavirus Infections	4
Staphylococcal Enterotoxin B Pulmonary Poisoning	15
~~Staphylococcus aureus Infection~~	
Toxic Effects of Chemicals	9
Toxic Effects of Heavy Metals	18
Toxoplasmosis	14
Typhus Fever	27
Vaccinia Disease	18
~~Vancomycin-Resistant Enterococci (VRE) Infection~~	
~~Vesicular Stomatitis~~	
~~Western Equine Encephalitis Virus Disease~~	

Yersiniosis	38
Total New = 25	

Table 13 - Conditions in Both RCMT and SRCA

The next group of conditions will be those remaining only in RCMT. These conditions already have associated codes defined, which can help inform the necessary reporting criteria. These codes should be reviewed for relevance to insure they meet the needs of public health. RCMT has previously included codes for research purposes and may not be relevant for the purposes of eCR. Table 14 below lists the 12 conditions remaining in RCMT.

RCMT
Anaplasma phagocytophilum
Guanarito hemorrhagic fever
Infection caused by Trypanosoma cruzi (disorder)
Jamestown Canyon virus disease (disorder)
Junín hemorrhagic fever
Machupo hemorrhagic fever
Malignant neoplastic disease (disorder)
Prion disease (disorder)
Relapsing fever (disorder)
Sabia-associated hemorrhagic fever
Methicillin resistant Staphylococcus aureus infection (disorder)
Streptococcus pyogenes infection (disorder)
Total = 12

Table 14 - Conditions Remaining in RCMT

Finally, the remaining conditions, which have no CSTE position statement and are likely to have laboratory criteria, should be tackled in order according to the number of jurisdictions who require the disease to be reported to them. This process should utilize the analysis from the Table in Appendix B and work down

through the conditions, which have not already been covered by a previously mentioned grouping in this process. Table 15 shows the conditions that apply to this group, 36 in total arranged in order of number of jurisdictions requesting the condition to be reported.

CONDITION	# of Jurisdictions
Mesothelioma	40
Staphylococcal Disease	28
Trachoma	26
Paralytic Shellfish Poisoning	17
Pelvic Inflammatory Disease (PID)	17
Rash Outbreak	17
Hepatitis G	15
Rheumatic Fever	14
Tick-borne Relapsing Fever	14
Ciguatera	13
Kawasaki Disease	13
Louse-borne Relapsing Fever	12
Neurotoxic Shellfish Poisoning	12
Scombroid	12
Toxic Effects of Agricultural Chemicals	11
Chemical Pneumonitis	10
Reye's Syndrome	10
Cerebral Palsy	9
Byssinosis	7
Farmers' Lung	7
Hypersensitivity Pneumonitis	7
Ophthalmia Neonatorum	7
Orthopox	7
Scabies	7
Conjunctivitis	6
Guillain-Barre Syndrome	6
Taeniasis	6
Chagas Disease	5
Enterovirus Infections	4
Pneumonitis	4
Parkinson's Disease	3
Genital Warts	2
Leishmaniasis	2

Angiostrongyliasis	1
Chronic Fatigue Syndrome	0
Mucopurulent Cervicitis (MPC)	0
Total New = 36	

Table 15 - Remaining Conditions in SRCA

As a starting point for developing the reporting criteria, again it is recommended to conduct a search across websites using the acceptable websites listed previously. These websites will provide symptoms and hopefully laboratory testing information. However, the better source for laboratory tests is LOINC. Therefore, a search should be conducted in LOINC for relevant laboratory testing in order to help populate the laboratory criteria for a given condition. These conditions will require more review with the RCKMS Clinical Epidemiology SME before being vetted with the broader community to ensure accuracy.

Pilot condition

In order to test the feasibility and accuracy of this process it is necessary to pilot a condition. Since a more standardized process already exists for any condition with a CSTE position statement, it is more important to choose a condition with no preexisting supporting documentation. Therefore, a condition was selected from the final grouping of conditions laid out in the recommended process above. The condition had to have the following criteria:

1. Not related to another condition (e.g., does not fall into Arboviral or Viral Hemorrhagic Fever grouping)
2. Does not have a CSTE position statement
3. Does not have any other related position statement

4. Is not in RCMT
5. Is reportable and has both clinical and laboratory criteria

One condition that meets all of these criteria is Chagas Disease.

The first place to start identifying criteria is Indiana Health Department website where they have information on their reportable conditions, while Chagas Disease is not actually reportable in Indiana they do have information about the condition. Below in a screenshot of the website, there is not only a "Chagas Quick Fact" document but also links to CDC and WHO websites containing information on Chagas.

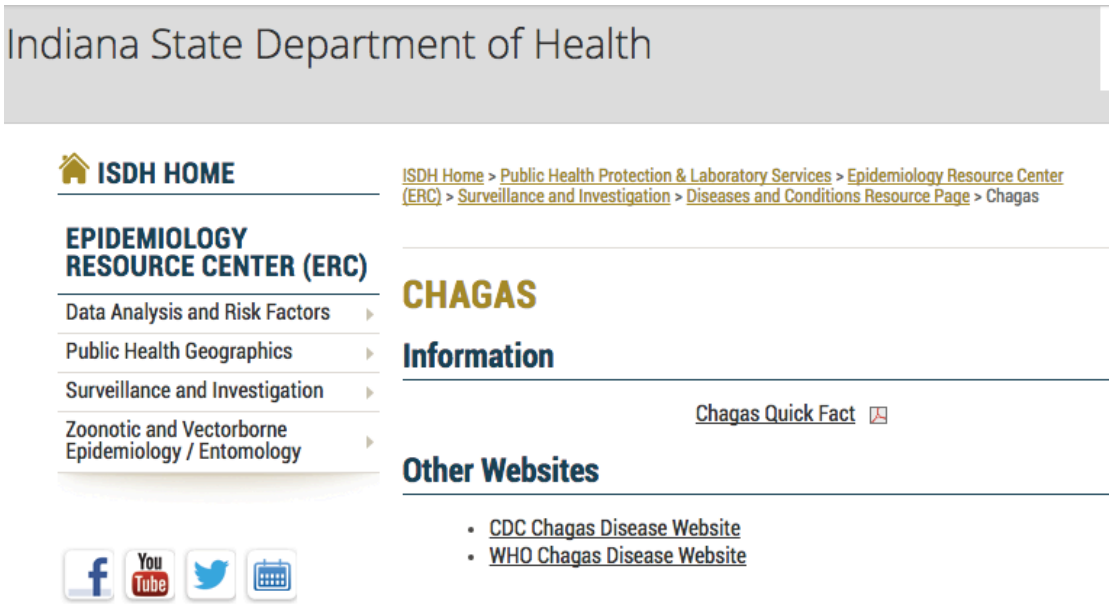


Figure 8 - Screen Capture of Chagas disease information from Indiana State Department of Health website [34]

There is a lot of usable information in the Chagas Quick Fact document. It states that Chagas is a parasitic infection of the blood spread by insect vectors mainly in the Americas and there are two phases: acute and chronic. [46]

- Acute phase:

    - May show no symptoms
    - Swelling where the parasite entered your body (Chagoma)
    - Romana's Sign, which is swelling of the eyelids on the same side of the face as where the bug bite occurred
    - Patient may also have mild flu like illness:
        - Fever
        - Fatigue
        - Body aches
        - Headache
        - Rash
        - Loss of appetite
        - Diarrhea
        - Vomiting
- Chronic Phase
    - One third of people who get Chagas disease will develop severe illness later in life, such as:
        - Heart problems; or
        - Intestinal problems.

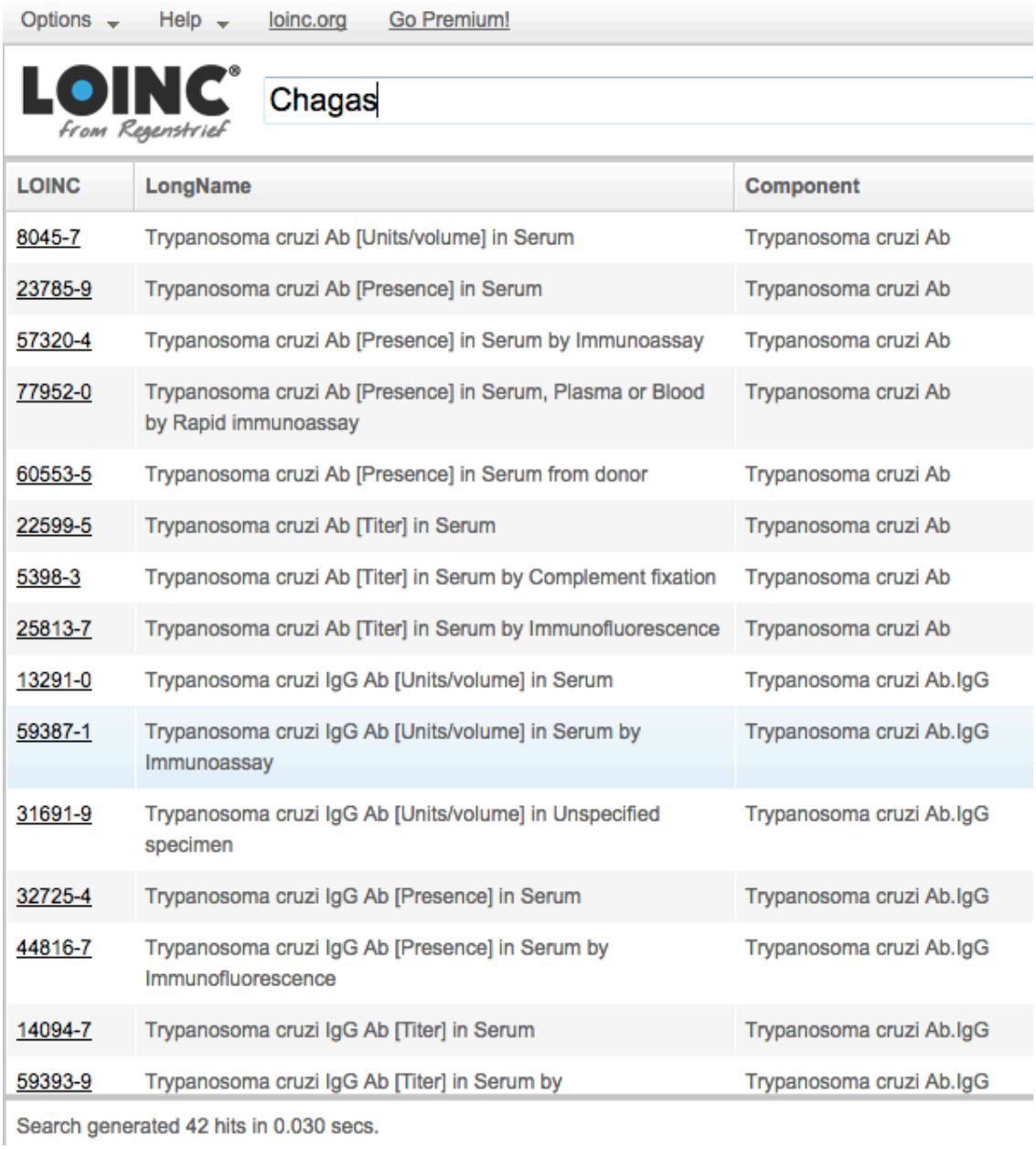
There is also some additional information that may help provide some epidemiologic criteria:

People can also get Chagas by:

- Eating uncooked meat that has the parasite in it
- From pregnant mother to her unborn baby

- Blood transfusion from a donor who has Chagas
- Organ transplantation from a donor who has Chagas
- Exposure in a lab

Next it is necessary to conduct a search in LOINC to find any relevant laboratory tests related to Chagas. Below is a screenshot of the search results from the LOINC website [47].



LOINC	LongName	Component
8045-7	Trypanosoma cruzi Ab [Units/volume] in Serum	Trypanosoma cruzi Ab
23785-9	Trypanosoma cruzi Ab [Presence] in Serum	Trypanosoma cruzi Ab
57320-4	Trypanosoma cruzi Ab [Presence] in Serum by Immunoassay	Trypanosoma cruzi Ab
77952-0	Trypanosoma cruzi Ab [Presence] in Serum, Plasma or Blood by Rapid immunoassay	Trypanosoma cruzi Ab
60553-5	Trypanosoma cruzi Ab [Presence] in Serum from donor	Trypanosoma cruzi Ab
22599-5	Trypanosoma cruzi Ab [Titer] in Serum	Trypanosoma cruzi Ab
5398-3	Trypanosoma cruzi Ab [Titer] in Serum by Complement fixation	Trypanosoma cruzi Ab
25813-7	Trypanosoma cruzi Ab [Titer] in Serum by Immunofluorescence	Trypanosoma cruzi Ab
13291-0	Trypanosoma cruzi IgG Ab [Units/volume] in Serum	Trypanosoma cruzi Ab.IgG
59387-1	Trypanosoma cruzi IgG Ab [Units/volume] in Serum by Immunoassay	Trypanosoma cruzi Ab.IgG
31691-9	Trypanosoma cruzi IgG Ab [Units/volume] in Unspecified specimen	Trypanosoma cruzi Ab.IgG
32725-4	Trypanosoma cruzi IgG Ab [Presence] in Serum	Trypanosoma cruzi Ab.IgG
44816-7	Trypanosoma cruzi IgG Ab [Presence] in Serum by Immunofluorescence	Trypanosoma cruzi Ab.IgG
14094-7	Trypanosoma cruzi IgG Ab [Titer] in Serum	Trypanosoma cruzi Ab.IgG
59393-9	Trypanosoma cruzi IgG Ab [Titer] in Serum by	Trypanosoma cruzi Ab.IgG

Search generated 42 hits in 0.030 secs.

Figure 9 - Chagas Disease Search Results in LOINC

From this search result information about the laboratory tests can be derived. The organism related to Chagas is known as Trypanosoma with a specific species of cruzi. There are 42 related tests including antibody tests, IgG antibody tests. Other tests not shown in the image above include: IgM antibody tests, culture tests, and nucleic acid tests. The species information will have to be verified by the Content

Vetting Workgroup to see if they are only interested in the cruzi species or any species.

Now that the necessary information has been collected on Chagas disease the next step would be to take the Word document (Appendix A1) and do a search and replace for the following terms:

Terms to use throughout using 'Search and Replace'

- Use [C*ondition] for condition name = Chagas disease
- Use [O*rganism] for organism name = Trypanosoma cruzi

This will populate the standardized criteria to be used to populate the excel template. Once the reporting criteria is in the excel spreadsheet the logic must be applied to show the groupings of criteria needed in order to be deemed reportable. The end result is a spreadsheet that looks like this:

		PROPOSED DEFAULT - LOGIC SET					
		Lab Reporting	Provider / Facility Reporting				Vital Records
			(1)	(2)	(3)	(4)	
The patient record being evaluated contains evidence of:			LAB	DX	CLIN + EPI 1	Congenital	
Criterion Description	Stat						
Clinical	**C**						
Chagas disease (i.e., as a Diagnosis or active Problem or mentioned in text as a cause of death or a significant condition contributing to death)	P			S			
Chagoma (defined as: swelling where the parasite entered body)	P				N		
Romana's Sign (swelling of the eyelids on the same side of the face as where the bug bite occurred)	P				N	N	
mild flu like illness (to include: Fever, Fatigue, Body aches, Headache, Rash, Loss of appetite, Diarrhea, Vomiting)	P				N	N	
Laboratory	**C**						
Isolation of any Trypanosoma species by culture method in a clinical specimen	P	S	S				
Detection of Trypanosoma nucleic acid by any method in a clinical specimen	P	S	S				
Detection of Trypanosoma IgG or IgM antibody by any method in a clinical specimen	P	S	S				
Demographic	**C**						
Age < 1 year old						N	
Immunization	**C**						
Epidemiologic	**C**						
Ingestion of uncooked meat containing Trypanosoma cruzi	P				O		
Eating uncooked meat that has the parasite in it							
Mother infected with Chagas during pregnancy	P					O	
Blood transfusion within 30 days of symptom onset	P				O		
Organ transplant recipient from a donor who has Chagas	P				O		
Exposure to Chagas in a lab	P				O		
Vital Records	**C**						
Death certificate lists [condition] as a cause of death or a significant condition contributing to death							S

Figure 10 - Proposed Reporting Criteria for Chagas Disease

This spreadsheet indicates that any of the laboratory tests on their own are sufficient to trigger a report to public health as well as a diagnosis of Chagas. Also the information from the Indiana website was used to show the "CLIN + EPI" logic set where all 3 clinical criteria must be present along with at least one of the epidemiologic criteria in order to trigger a report. Additionally, the congenital infection is broken out with potential age criteria required. Questions for the CSTE Content Vetting Workgroup will be laid out in preparation for the vetting of Chagas. Questions such as:

- Is it ok to generalize “by any method” in a “clinical specimen” for the lab tests or jurisdictions want to limit the testing methodology or specimen type?
- Does the acute versus chronic need to be separated?
- Are there any lab tests missing?
- Would they want all the clinical symptom criteria to be (N)ecessary or is there one that is more critical?
- For congenital logic set is the age criteria of <1 correct? Or should it be a different age range? Are there other symptoms associated with a congenital case that are not captured here?
- Does there need to be an Epidemiologic criterion for travel to an area infected with Chagas?

This spreadsheet will now be used to vet the proposed default criteria for Chagas disease. The CSTE Content Vetting Workgroup will provide feedback on the reporting criteria to ensure it meets their needs. It will be extremely important to ensure that the 5 jurisdictions (Arizona, Massachusetts, Mississippi, Oregon, and Tennessee) who indicated that Chagas is reportable are in attendance on the Content Vetting Workgroup call. Additionally, it will be helpful if any CDC SMEs are available to provide input as well. After the workgroup, feedback will be incorporated and then the clinical rules logic statements and value sets can be defined to complete the necessary artifacts for Chagas to be included into the RCKMS tool.

Other findings

In order to determine associations among conditions, particularly in a group as large as this research discovered, it is necessary to rely on the input from other SMEs who have medical or epidemiological knowledge about conditions and how they relate to each other. Additionally, this level of knowledge needs to be applied to the original group of 74 conditions completed by the RCKMS project in their previous phase of work.

This research uncovered an unexpected amount of reportable conditions between the two sources of data examined (SRCA and RCMT). The original expectation for number of additional reportable conditions, outside the original 74, was thought to be about 50. However, a total of 190 conditions were discovered.

In gathering data from RCMT, it uncovered conditions that were not reportable and thus outside the scope of this research. When the RCMT team was approached it was discovered that the original intent and focus of RCMT had shifted since its original inception. Some examples of these out-of-scope value sets were those labeled with "NHSN Lab ID Event" and the Cancer value set which was added to support cancer surveillance.

Resources needed to find all reportable conditions and reporting specifications on websites of all jurisdictions (state and local health departments) who have a condition reportable would be prohibitive. More information about this is discussed below in the limitations section of Chapter 5.

While this recommended prioritization of conditions was the scope and feasibility in this research study, there are other factors that should be considered.

One of those factors is the path of reporting: does the condition get reported through another avenue? One example where this scenario might apply is injury-related conditions, healthcare-associated infections, and cancer data, which all already have their own reporting mechanisms. When considering prioritization of conditions, these examples may determine another needed evaluation criterion of what would be captured with eCR via conditions that fall into other reporting.

Summary

By applying defined evaluation criteria for reportable conditions without CSTE position statements it is possible to establish a process framework for deriving nation default reporting specifications for any reportable condition. These evaluation criteria consist of:

- Is it related to another condition (e.g., does not fall into Arboviral or Viral Hemorrhagic Fever grouping)?
- Does not have a CSTE position statement with section 6 and table 6b?
- Does not have any other related CSTE position statement?
- Is it in RCMT?
- How many jurisdictions indicate it is reportable?

Using this analysis, the RCKMS project now has a recommended process to follow in order to continue their development of defining national default reporting specifications for inclusion in the Decision Support tool, which will support a national eCR initiative.

CHAPTER 5: CONCLUSIONS

Introduction

Reportable conditions without a CSTE position statement lack pre-defined criteria to serve as a starting point for deriving national default machine-processable reporting specifications in order to move towards automation of reporting of reportable diseases. The RCKMS project must define a new standardized process for creating reporting specifications without the assistance of a CSTE position statement.

Summary of study

In examining previous works such as NCD, ESP, SRCA, RCMT, and RCKMS, this research study was able to determine a process which includes a prioritization of reportable conditions to be completed in the next phase of the RCKMS project as well as a repeatable and extensible framework in which to tackle these conditions. Conditions were grouped by available existing resources such as the CSTE position statements, relation to similar conditions (e.g., Arboviral and Viral Hemorrhagic Fever), and number of jurisdictions who list a condition as reportable. Existing resources such as CSTE position statements should be used first to derive reporting criteria, and, where applicable, follow previous RCKMS processes. Where these materials are lacking other sources such as LOINC, Indiana State Health Department condition list (or other state health department website), CDC surveillance definitions, WHO website, or other reliable sources should be examined for relevant reporting criteria.

Limitations

The analysis completed on the conditions found in the SRCA and the RCMT should not be considered a fully completed list of all reportable conditions for all jurisdictions. In order to ensure every single condition is represented this research would have needed to include a detailed dive into each jurisdiction's website where they publish their list of reportable conditions, or a request by CSTE for them to provide that listing. Due to time and resource constraints it was not feasible to complete this task for this study. This limitation was discovered while piloting Chagas by examining the state websites. This search uncovered two (Massachusetts and Oregon) out of the five jurisdictions who indicated in 2012 SRCA that Chagas was reportable did not list the condition as reportable on their current website. There are conditions listed on their website which were not found in either the RCMT or SRCA datasets. While these additional conditions are not marked as reportable in Indiana, it does introduce the possibility of reportable conditions not captured in SRCA or RCMT. This could potentially be due to the use of an old dataset for SRCA, data from 2012. This is the last year that CSTE publically published SRCA data. There is updated data from 2015, however it was not used in this study as it has yet to be publically released.

Additionally, there was a lack of access to SMEs in order to determine relation of conditions to each other and how some of these conditions might be able to be combined or eliminated. Conditions that have slightly different naming conventions may be able to be combined. One example of this was also discovered during the Chagas pilot. Table 14 shows conditions only in RCMT but has a disorder

named infection caused by Trypanosoma cruzi which was the organism name found for Chagas in LOINC. Furthermore, information regarding history of nationally notifiable conditions, such as Rickettsial diseases, that have changed over time is crucial in understanding condition relationships.

Along with relationships between conditions, SME input was lacking to indicate conditions which may be reportable by other reporting mechanisms (e.g., Healthcare-associated Infections, Injuries, Birth Defects). These SMEs are needed to make determinations on how these conditions should be captured in the RCKMS system.

These limitations call into question the total number of conditions the for which RCKMS project will be responsible for developing reporting criteria. The outcome of these decisions, and additional available data, have an impact on the total number of conditions for which content needs to be developed.

Implications

This research will benefit the public health community by providing a standardized agreed-upon set of reporting specifications for reportable conditions without CSTE position statements. These national default reporting specifications can then be used to help harmonize reporting criteria across jurisdictions and also be translated into machine-processable information to enable automated electronic case reporting of these conditions thus improving timeliness, completeness, and accuracy of public health surveillance.

Recommendations

The first step that should occur next is a comprehensive review of the list of reportable conditions from SRCA with a SMEs and jurisdictions to eliminate the outstanding questions about inclusion or exclusion of certain conditions, as mentioned previously in the limitations. Some conditions seem to be duplicated due to naming conventions or perhaps it's a specific situation of a given disease. For example, there are a couple different ways that shellfish poisoning is represented (Neurotoxic Shellfish Poisoning versus Paralytic Shellfish Poisoning). Potentially these could be combined into one condition. Additionally, understanding relationships of conditions caused by the same organism may help reduce the total number of conditions. These discussions have already proved fruitful and have uncovered three relationships between similar conditions: (1) conditions caused by different organisms, which can be categorized into general categories (e.g., STIs) and are not on the notifiable list at this time, but may be reportable in some states (e.g., Genital Warts, Herpes, Granuloma Inguinale), (2) clinical conditions caused by a currently Notifiable condition but not currently included in Table 6b of position statement (e.g., lymphogranuloma venereum. trachoma), and (3) clinical conditions caused by more than one currently Notifiable condition, but not included in Table 6b of position statement (e.g., Mucopurulent Cervicitis [MPC], Opthalmia Neonatorum, Pelvic Inflammatory Disease [PID]). This comprehensive review needs to include input from the jurisdictions who indicated these conditions are reportable to them and perhaps provide some history as to why they are reportable (e.g., previously notifiable or condition changed over time). Other SMEs who can assist in this task

are those at the CDC who have worked extensively with nationally notifiable conditions and have an understanding of their history.

As mentioned previously, there is updated SRCA data from 2015, but it is not publically available. It is highly recommended that this new SRCA dataset be compared with the analysis done in this research to ensure newly-captured conditions are included. After ensuring any newly-available data from SRCA are included, each jurisdiction needs to review the list of reportable conditions and inform of any missing conditions relevant to their jurisdiction-specific need. This will help ensure the list of reportable conditions is as comprehensive as possible. It will also ensure the RCKMS project develops content for all necessary conditions reportable to public health agencies.

Finally, the recommended process and evaluation criteria must be reviewed with subject matter experts (RCKMS Knowledge Engineer) to verify that the prioritization and process is valid. Additional buy-in on this process will help ensure team members agree and are clear on their role in the process as the project moves forward.

Conclusion

Now, more than ever before, eCR is a real possibility. Collaboration between many public health partners (CDC, CSTE, ASTHO, APHL, NACCHO, and PHII) recently "identified the important technical elements needed for the first phase of eCR implementation, including initial standards, platform structure, tools, and guides" [48]. One of these technical elements includes the work being done by the RCKMS project to define machine-processable reporting specifications. The work

completed in this research will help advance eCR for reportable conditions beyond those that are nationally notifiable. This recommended process will help fill the void previously held by a CSTE position statement when defining a set of national default reporting specifications for all reportable conditions to be incorporated into RCKMS.

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Appendix A: RCKMS Project Documents

Appendix A1 Process Criterion Valueset Rule STANDARDIZED (MS Word)

Contents

Terms to use throughout using 'Search and Replace'

- (HINT: remove spaces before or after the text)
- Use [C*ondition] for condition name
- Use [O*rganism] for organism name
- NOTE: when there is a subset of the species that needs to be handled differently, you may need to address this in the naming. Example is Salmonella sp and all subtypes, except subtype of typhi. O*rganism = salmonella sp and subtype (not typhi) nucleic acid Test

Purpose

This document provides a template and instructions to create clinical rules logic and define associated value sets for reportable conditions for RCKMS. In addition, this document will contain updated examples of standardized criterion so they can be used in the clinical rules and inform the earlier task of drafting criterion to develop proposed reporting specifications within the Excel file.

Revision History

Version #	Implemented By	Revision Date	Reason
1.0	Catherine	2/23/2016	Drafted this file for use
1.1	Catherine staes	2/24/2016	• Added rules for symptom and epi logic • Added the Decisions/Issues table and removed the comments from within the document • Updated the instructions to point to the companion file for addressing issues: **Topic 2: Process_criterion_valueset_rule NEED REVIEW.docx**
1.2	Catherine staes	2/25/2016	• Updated the text for sterile sites to the following: "…in a specimen from a normally sterile site" • Updated the list of sites by adding peritoneal fluid, so now the standard question to ask is: Do you agree: Normally sterile site = cerebrospinal fluid [CSF], blood, joint fluid, pleural fluid, pericardial fluid, peritoneal fluid? NOTE: this changes evolved from WG feedback about invasive pneumococcal disease
1.3	Catherine Staes	3/13/2016	Per input from Rob McClure: Updated the name of the lab tests to include the term 'detection' in the antigen, antibody, nucleic acid etc tests. Added the additional note about the naming of the organism if need to exlude a child tree – salmonella vs typhi

			Also added an encounter criteria
1.4	Catherine	3/15/2016	Updated the normally sterile fluid info based on input from the epidemiologist in Texas. Added standard valueset names and criterion for lab orders
1.5	Catherine	3/22/16	Added 'death'
1.6	Catherine	3/25/16	Added criteria for seroconversion – qualititative
1.7	catherine	4/7/2016	Changed 'death' to 'documentation of death'. Added 'and' to the encounter logic. Updated the seroconversion and titre paired testing to more clearly indicate that we are looking at timing between specimens that makes sense to operationalize, not the actual recommended timing between specimens. Updated the examples of logic to show examples of epi+clinical logic
1.8	catherine	4/21/2016	• Added sample clinical rules when specific specimen types are included in a rule. For now, we are documenting the requirement, but not finalizing the syntax to address specimens. • Revised the example for clinical rules for lab test orders to use value sets created for lab test results. This should simplify the valueset management and harmonize the sets of labs relevant for orders and results. • added paired serum clinical rules logic for the common criteria – no threshold, but 1 to 180 days apart) • corrected paired serum clinical rules logic for the criteria that includes a threshold.
1.9	catherine	4/22/2016	Moved lab orders clinical rules to follow lab test results so the word doc is created automatically in the correct order
2.0	catherine	4/26/2016	Fixed the clinical rules for symptoms and body temperature to the following. ~~• Patient has clinical observation of ([VS: *[symptom]*)~~ ~~OR~~ ~~• Patient has body temperature > ##° F (##° C)~~ ~~Changed the default valueset info to the following:~~ ~~• [Symptom]: Codes for [Symptom] as a clinical observation~~ ~~• body temperature: Codes for body temperature as an observation name~~ Added clinical rules for medications
2.1	catherine	4/29/2016 – 5/3/2016	Updated description for the symptom-related valueset: • Codes for [Symptom] as a diagnosis, problem, symptom, or some other clinical observation • Removed the body temperature valueset since that would be a valueset for the field, not the values expected to be sent from the EHR Updated symptom-related clinical rules to make it more generic:

			• Patient has ([VS: *[symptom]*) (e.g., as diagnosis, problem, symptom or some other clinical observation) Updated the instructions to be consistent with current practices Updated the clinical rules and criteria for medications
2.2	catherine	5/17/2016	In clinical criteria, • changed 'antibodies' to 'antibody'. Now all are singular. • Updated the criteria for 4-fold rise criteria from "?1 day" to "1 day". In clinical rules, • added seroconversion clinical rules
2.2	catherine	5/19/2016	• Added question about how to handle criteria for 'placental or fetal tissue' NEED FOLLOWUP • Added example criteria for cultures and nucleic acid tests when the condition is caused by a species and it's subspecies, but there is a single subspecies that concerns another condition: salmonellosis/Typhi, Vibriosis/cholera • Added example criteria and rules and valuesets for 'IgG and total antibody tests' • Fixed the criteria text for 4-fold rise when have a threshold to meet • Lots of edits to clean up text (proper capitalization etc) so the template info is formatted properly.
2.3	Catherine	5/24/16	• Added criteria for 'negative results': "Absence of detection of [Hepatitis C Virus antibody] by any method specific for detecting [hepatitis C virus antibody] in a clinical specimen." This is more explicit for criteria that will actually be implemented. • This clarification is needed because previously we were stating that pos and neg results meant that all organism specific tests would be included, but that was missing the general tests with positive results. By modularizing, then we are including a criteria for the positives (using both organism-specific and general tests) and a criteria for the negatives (using organism-specific tests only). The advantage is: We are clear that we are not including general tests with negative results. Also, by phrasing as the 'absense of….' then we can use NOT operator and ensure that all values are captured. In addition, this modularizes the logic so the one criteria can be turned on or off. • **Need to remove the 'pos and neg' result value criteria from all the current clinical rules files. NEED TO SEARCH AND FIX**

			• Refined the valuesets and clinical rules for 4-fold rise of serology titers.
2.4	catherine	6/1/2016	• **Changed "reportable flag" to "Abnormal interpretation"** • **Changed "Qual Lab Result Positive (Reportable conditions)" to "*Positive Qualitative Lab Result*"** • ~~**NEED TO SEARCH AND REPLACE**~~
2.5	catherine	6/1/2016	Added the laboratory assumptions section. Added criteria for radiology reports and histopathology reports
2.6	Denisha	6/7/2016	Updated logic to reflect new lab value set names • Lab result → **Lab result value** • Reportable flag → **Abnormal interpretation** • Qual Lab Result Positive (Reportable conditions) → **Positive qualitative lab result**
2.7	Denisha	6/14/2016	Updated Step 7 – added auto date to document header • Remove highlighting from document
2.8	Catherine	7/7/2016	Added symptom clinical rules
2.9	Catherine	7/12/2016	Fixed second part of the base rule for general micro tests to say "Status includes…", not "Status of…" Now it reads: Patient has lab results with (test name of [VS: Lab Test Name (Bacteria)]) and (lab result value of ([VS:Lab result value ([C*ondition])) and (Status **includes** [VS:Preliminary Status])) TEAM WILL NEED TO CHECK THIS IN THE CURRENT RULES AND MAKE SURE HLN MADE IT THIS WAY.
3.0	Catherine	7/12/2016	• Added second set of logic for microscopic observation tests to account for possibility of organism-specific tests • Also, changed the text from "microscopy observation" to "microscopic observation" • Added: [organism] immune stain test criteria
3.1	catherine	7/15/2016	• Added specimen criteria and clinical rules example for lead testing. • Added valueset labels for lead tests showing the adition of quanitative tests for tests with a venous or unknown specimen type. Also, added the corresponding rules related to this. • Added measurement example of criteria and valueset name and clinical rules. – derived from the carbon monoxide rules.
3.2	Catherine	7/19/2016	Added clinical rules for radiology reports and histopathology/biopsy reports Added question about the fever clinical rules.

			NEED TO INVESTIGATE HOW REPRESENTED IN THE eicr: radiology pathology, fever observations, vital signs.
3.3	Catherine	7/20/2016	Removed the text"(i.e., diagnostic orders)" after the criteria for lab orders. I was always removing it in the word files.
3.4	catherine	8/9/2016	• Added criteria: Detection of a negative treponemal or non-treponemal antibody by any method in a clinical specimen following a positive syphilis-specific antibody test (i.e., assess specimens no more than 30 days apart.) • Added the clinical rules for the above new criteria • For the value set names, I capitalized each word per the VSAC guidance. • Added clinical rules for "Example of immunization history"
3.5	catherine	8/10/2016	• Updated the medication ordered(prescribed) clinical rules. Previously, it was meds administered or ordered. I added "(presecribed)" after the ordered.
3.6	Catherine	8/12/2016	Added criteria and clinical rules for TB skin tests: Detection of a 'positive' tuberculosis tuberculin skin test (NOTE: 'positive is based on guidance for interpretting wheal size and risk level)
3.7	Catherine	8/28/2016	Added draft rules for immunization history information. We need to check the eICR and understand how immunization history information is documented to finalize this.

Decisions/Issues

Item #	By	Issue	Decision	Who made decision
1	Catherine staes	Should we use RCMT for the organism valuesets?	No. looking at RCMT, but created new valuesets for RCKMS for each of the set of organism codes.	Jerry
2	Catherine staes	Should we use RCMT for the general culture tests?	No. looking at RCMT, but created new valuesets for RCKMS. We are creating one valueset each for general tests for bacteria, virus, fungus, and parasites.	Catherine and Jerry

3	Catherine staes	A valueset for a test names for detecting a component (ie for antibody) may have test results that are reported as a titer or presence. We are grouping them all into one valueset based on the component detected, not the value of the result.	I am not creating separate value sets for test that look for titre vs presence of the component. We will deal with that in the clinical rules, and expect that the CDS system can determine which set of LOINC codes in the value set concern tests witih quantitative vs ordinal values. WE NEED TO INVESTIGATE THIS FURTHER	catherine
4	Catherine staes	Lab Test status – I am assuming system default is to restrict results to only process those with final or corrected results, unless the user specifies to include preliminary results as well. Need to clarify whether preliminary or only final/corrected will be used to create an eicr. This is an implementation guide issue.		
5	Catherine staes	Lab test status – need to verify the fields used for status in the ORB and OBX segments- Maiko TO FU: The current result status field is for the order status and does not include 'preliminary' so wondering if the current valueset is intending to meet the need or this is a mistake.		
6	Catherine staes	How would Conversion from negative to positive Coccidioidal skin-test be documented in the EHR?		
7	Catherine staes	For antibody tests, we need to address titres outside a normal range. Can one rely on the abnormal flag? Need lab SME / HL7 ELR input According to Rita Altamore, this is a requirement in the MU ELR implementation guide therefore we should expect that quantitative results include an interpretation flag. THIS may not be a requirement for the eICR though.		
8	Catherine staes	In the rules, do we need to make a distinction between any organism in the species vs a single organism? I don't think so because it is defined by the valueset but not sure if the text needs to be different if you want salmonella and all its subtypes vs wanting bordetella pertussis organism. See the first 2 examples for isolation tests.	No- see decision we make concerning salmonella and typhi	Catherine

9	staes	The valueset descriptions in this document are useful for drafting the rules, but are not as explicit as the definitions documented in VSAC	Leave as is. Will update if needed after completing this work. It may be addressed by using output from HLN where the specifications will get 'published'.	
10	staes	FOLLOW-UP: Need to allow the jurisdiction to set a timeframe for which to specify an active problem. Is an active problem only those with a start date in the past XXX days, or is it only problems with a start date after admission to the hospital, or what? This may be important to specify a default 'lookback' duration in a jurisdiction set-up but allow the jurisdiction to change it for an individual condition. (see hep C as example)		
11	staes	• In LOINC, "XXX Ab" is referring to Total Antibody tests. These should not be included in valuesets for IgG or IgM test. • We should not assume they want total antibody when they say they want IGG.	As we review each of the specifications, we should confirm this decision is followed.	Jerry
12	staes	what is the general solution for handling restricting test results to specific specimens. Issue: currently the eICR does not include a specimen field so we can not restrict using tests with XXX system and use the specimen type for the specimen information. we could add: For tests with system = xxx, then • Patient has lab results with (test name of [VS: Microscopic observation of specimens from urethra or cervix]) and (lab result value of [VS:Lab result value (Gonorrhea)) and specimen = (vs: vaginal, urethral etc)		
13	staes	**Detection of a 'positive' tuberculosis tuberculin skin test (NOTE: 'positive' is based on guidance for interpretting wheal size and risk level)** **IF** • Patient has lab result with (test name of [VS: TB Skin Test]) and ((lab result		

		value of ([VS:Positive qualitative lab result]) or (Interpretation of [VS:Abnormal interpretation])) **OR** • **NEED TO UNDERSTAND HOW ELSE SKIN TESTS MAY BE DOCUMENTED. NEED VENDOR INPUT.** Patient has (Clinical observation of [VS: TB skin test]) and (observation value of ([VS:Positive qualitative lab result]) **THEN** report		
14	staes	What do titers look like in the eICR for use by the logic requiring a 4-fold rise? NEED PHER INPUT		
15	staes	How is immunization info documented? And how do we write a rule for the absence of a particular vaccine?		

Laboratory-related logic and assumptions

The laboratory related clinical rules are based on the following patterns we expect to see in the content used to evaluate reportability:

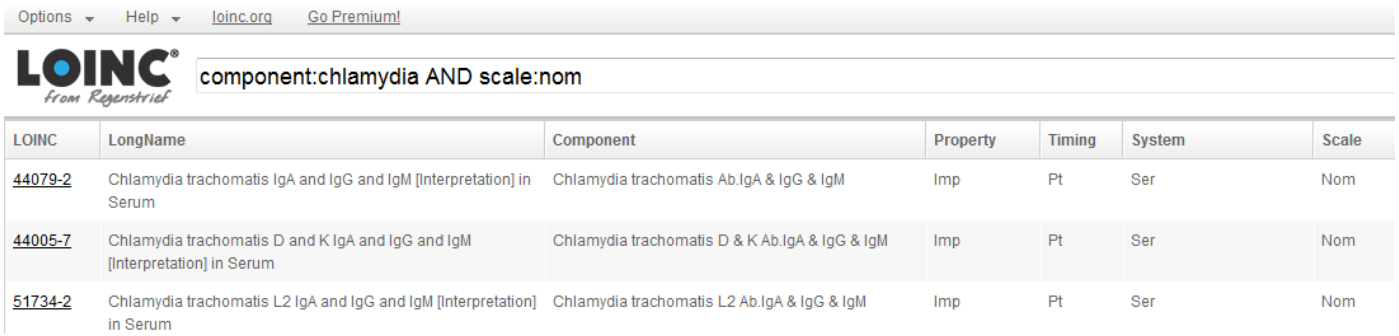
Test name (LN)	Property	Scale	Result value	Interp / Flag	Rule
VZV IgM		Ord	*Positive Qualitative Lab Result // Positive*		
VZV IgM		Nom	Lab Result (Varicella zoster) // VZV		
VZV IgM		Qn	Numeric	VS:*Reportable Flag*	
VZV IgG	Titer		Numeric		4x increase

Assumptions:

- Titer tests are correctly mapped to a Titer-related LOINC code.
- Abnormal flag / Interpretation code (OBX.8) is used for quantitative results.
- lab tests mapped to trigger codes and output from the EHR are FDA approved.
- when we say "Detection of Hepatitis C Virus antibody by any method in a clinical specimen" we mean "Detection of a 'positive' level (according to the test kit) of Hepatitis C Virus antibody by any method in a clinical specimen

Regarding the general tests:
Upon review of the general lab tests, we determined that most general lab tests are for cultures, and a few are for PCR panels or antigen tests to be applied to isolates. These tests are usually all appropriate for case detection because cultures and nucleic acid tests are usually both acceptable for every condition. Therefore, we will use a single valueset for the non organism-specific tests and add a criteria that looks for nominal lab result values for the organism of interest. We are creating one valueset each for general tests for bacteria, virus, fungus, and parasites.

Note that if we only use the lab result value to determine reportability, then we will be including all Nominal result values that often include organism-specific tests that may or may not be desired. For example, if we send reports based on nominal values, there we would include reports for chlamydia-specific antibody tests with nominal values that are not requested for identifying cases. See below:



LOINC	LongName	Component	Property	Timing	System	Scale
44079-2	Chlamydia trachomatis IgA and IgG and IgM [Interpretation] in Serum	Chlamydia trachomatis Ab.IgA & IgG & IgM	Imp	Pt	Ser	Nom
44005-7	Chlamydia trachomatis D and K IgA and IgG and IgM [Interpretation] in Serum	Chlamydia trachomatis D & K Ab.IgA & IgG & IgM	Imp	Pt	Ser	Nom
51734-2	Chlamydia trachomatis L2 IgA and IgG and IgM [Interpretation] in Serum	Chlamydia trachomatis L2 Ab.IgA & IgG & IgM	Imp	Pt	Ser	Nom

RECOMMENDATION:
recommend ONC standardize reporting of results, requiring abnormal flag/interpretation according to the test kit. present the reference range, but do not require the receiver to interpret the value based on the reported reference range.

Regarding organism codes found in result values:

- We are using codes from the snomed (organism) context, not the substance context. While there may be some substance codes currently in RCMT, Jerry plans to remove these as they are not used by labs.

Instructions

Step 1. Name file and add standard text

- Open this standardized document as you start defining proposed criteria for a condition in the Excel file
- Save this document to match the name of the Excel file for the condition
- Add the condition name in the header
- Search and replace the text for the *condition* and the *organism* to be applied throughout this document.

Step 2. Use document to create proposed criterion

- Use the standard criterion in Table 1 to add proposed criteria to the Excel file
- If you notice patterns not previously used, then use the rules of thumb to create a new criterion pattern and indicate it in the LOG tab of the excel file. We will discuss as a team & update this template if needed.
- Scan the criterion-specifc questions shown in Table 1 and transfer any questions relevant to the LOG tab in the excel file. (Note: Adding the questions will enhance feedback, verify our assumptions, and ensure that issue gets addressed.)

Table 1. Standardized examples of criterion and questions to be asked during vetting

Date added	General category	Examples of Standard text for the criterion	Questions to add to the LOG file so they get asked during the vetting call
2/23	Diagnosis/ Problem	[C*ondition] (i.e., as a Diagnosis or active Problem or mentioned in text as a cause of death or a significant condition contributing to death)	
2/23	Diagnosis/ Problem	[C*ondition] suspected (i.e., documented as a 'reason for study')	Do you want a report if the [C*ondition] is mentioned in a 'reason for study' for a lab or procedure order? Also ask: Do you want a report if condition-specific lab tests or procedures are ordered?

			Note this will require that this information is included in the record evaluated by the system.
3/22	Clinical	Documentation of death	
2/23	Symptoms:	[Symptom]	
8/16/16	Symptom and duration	[Symptom] with duration of [operator] [number] [units]	
7/16/2016	Measurement	Measurement of [component] level >= #% by [pulse CO-oximeter]	
5/2	Vital signs	Fever (temperature ≥ 38.9°C [102.0°F])	
5/2	Vital signs	Hypotension (systolic blood pressure ≤ 90 mm Hg for adults or less than fifth percentile by age for children aged less than 16 years)	
2/23	Maternal history	Maternal history of [C*ondition] during pregnancy documented in the health care record	
2/23	Lab orders	Lab test ordered for Isolation of [O*rganism] by any method in a clinical specimen	
2/23	Lab orders	Lab test ordered for Detection of [O*rganism] [add components here] by any method in a clinical specimen	Do you want tests for anything, or a subset?
2/23	Lab orders	Lab test ordered for detection of [O*rganism] IgG antibody by any method in an acute or convalescent clinical specimen (i.e., order indicates it is a first or second specimen for a pair)	
2/23	Culture – for species and subspecies	Isolation of any [O*rganism] *species* by culture method in a clinical specimen	Do you want to receive 'preliminary' results as well as the final and corrected results? If yes, append "-include preliminary results"

2/23	Culture - for specific sub-species	Isolation of [O*rganism] by culture method in a clinical specimen	Do you want to receive 'preliminary' results as well as the final and corrected results? If yes, append "-include preliminary results"
5/19	Species with sub-species that is a different condition	Isolation of *Vibrio species* and subtypes (except cholera) by culture methods in a clinical specimen	Second example: Isolation of *Salmonella species and subtypes (except typhi)* by culture method in a clinical specimen
2/23	Culture	Isolation of [O*rganism] by culture method in a clinical specimen – include preliminary results	
2/23	Microscopic observation	Microscopic observation of any [O*rganism] *species* by any method in a clinical specimen	
2/23	Microscopic observation	Microscopic observation of [O*rganism] by any method in a clinical specimen	
2/23	Nucleic Acid	Detection of *[O*rganism]* nucleic acid by any method in a clinical specimen	
5/19	Nucleic acid – when a species (except subspecies)	Detection of *Vibrio species and subtypes (except cholera)* nucleic acid by any method in a clinical specimen	
2/23	Antigen	Detection of *[O*rganism]* antigen by any method in a clinical specimen	
3/25	Antibody	Detection of *[O*rganism]* antibody titers above ### by **XXXX** method in a clinical specimen	
2/23	Antibody	Detection of *[O*rganism]* IgG or IgM antibody by any method in a clinical specimen	

2/23	Antibody - IgM	Detection of *[O*rganism]* IgM antibody by any method in a clinical specimen	
2/23	Antibody- IgG	Detection of *[O*rganism]* IgG antibody by any method in a clinical specimen	
5/19	Antibody – IgG or total	Detection of *[O*rganism]* IgG or total antibody by any method in a clinical specimen	RARE event wanting this
6/1	Antibody – IgM or total	Detection of *[O*rganism]* IgM or total antibody by any method in a clinical specimen	
4/7	Persistenly elevated antibody titers	Detection of a titer > ### for IgG antibody against *[O*rganism]* by any method between two serum specimens (i.e., assess specimens at least 1 day apart but no more than 180 days apart.) (i.e. persistently elevated)	Need to confirm the lower end of the timing between specimens to be used when logic is operationalized
5/19	Any antibody Seroconversion – (4-fold rise) quantitative	Detection of a fourfold or greater increase in antibody titer against [O*rganism] by any method between paired acute- and convalescent-phase serum specimens (i.e., assess specimens at least 1 day apart but no more than 180 days apart.)	Need to confirm the lower end of the timing between specimens to be used when logic is operationalized
		Detection of a fourfold or greater increase in IgG or total antibody titer against [O*rganism] by any method between paired acute- and convalescent-phase serum specimens (i.e., assess specimens at least 1 day apart but no more than 180 days apart.)	
4/7 updated 5/19	IgG Seroconversion – (4-fold rise) quantitative	Detection of a fourfold or greater increase in IgG antibody titer against [O*rganism] by any method between paired acute- and convalescent-phase serum specimens (i.e., assess specimens at least 1 day apart but no more than 180 days apart.)	Need to confirm the lower end of the timing between specimens to be used when logic is operationalized

4/7 updated 5/19	IgG Seroconversion –(4-fold rise with absolute value) quantitative	Detection of a fourfold or greater increase in IgG antibody titer against [O*rganism] by [complement fixation (CF)] to a titer of at least 1:32 between paired acute- and convalescent-phase serum specimens (i.e., assess specimens at least 1 day apart but no more than 180 days apart.)	Example #2: Using a specific lab test method Use when there is a specific titre that must be met in addition to the 4-fold rise.
4/7	Seroconversion - qualitative	Conversion from 'negative' to 'positive' IgG antibody against [O*rganism] by any method between paired acute- and convalescent-phase serum specimens (i.e., assess specimens at least 1 day apart but no more than 180 days apart.)	
2/23	~~Pos and neg results~~	~~All result values for laboratory tests specific for detecting [O*rganism] organisms, nucleic acid, antigen, or antibody by any method in a clinical specimen (i.e., 'negative' and 'positive' results)~~	removed this because it is missing the general tests that have a positive result. NEED TO MAKE SURE THIS IS NOT BEING USED.
5/24	'negative results'	Absence of detection of [Hepatitis C Virus antibody] by any method specific for detecting [hepatitis C virus antibody] in a clinical specimen (i.e., negative results)	Use this, particularly when jurisdictions may want flexibility to turn this off or on as an option.
8/9/16	Negative after a positive	Detection of a negative treponemal or non-treponemal antibody by any method in a clinical specimen following a positive syphilis-specific antibody test (i.e., assess specimens no more than 30 days apart.)	Required for management of serologies for detection.

2/23	Lab specimen detail	…..in a specimen from a normally sterile site	Do you agree: Specimen from a normally sterile site = cerebrospinal fluid [CSF], blood (excluding cord blood), pleural fluid, pericardial fluid, peritoneal fluid, bone and bone marrow. The following are also considered sterile sites when certain other criteria are met: • Internal body sites (brain, heart, liver, spleen, vitreous fluid, kidney, pancreas, lymph node or ovary) when the specimen is collected aseptically during a surgical procedure • Joint fluid when the joint surface is intact (no abscess or significant break in the skin)
2/23	Lab specimen detail	….in any respiratory specimen	Do you agree: Respiratory specimens = bronchial, nose, sputum, throat?
5/19	Lab specimen detail	… in placenta or fetal tissue	? need to determine if this can go in normally sterile fluid or should be a separate valueset
6/1	Pathology reports-interpretation	Histopathology of lung tissue with interpretation: consistent with silicosis or pneumoconiosis due to dust containing silica	
8/12	Skin tests	Detection of a 'positive' tuberculosis tuberculin skin test (NOTE: 'positive is based on guidance for interpretting wheal size and risk level)	
2/23	Sex	Male	
2/23	Sex	Female	

2/23	Age	Age [operator] [number][units]	i.e., Age < 5 years
5/2	Medication	[medication name] administered or ordered	Do you want to send a report based on orders or administration or both?
2/23	Immunization history	Oral polio vaccine administered within 30 days prior to [date of clinical encounter]	Is timeframe appropriate? Should a different date be used? Date of clinical encounter = Date of outpatient encounter or Date admitted
2/23	Immunization history	No documentation of receiving [vaccine]	
2/23	Epidemiologic	Contact of a person with [C*ondition]	
2/23	Epidemiologic	Member of a risk group defined by public health authorities during an outbreak	
2/23	Epidemiologic	Epidemiologically linked to a confirmed case of [C*ondition]	
2/23	Epidemiologic	Contact of a person with laboratory-confirmed [C*ondition]	
3/13	Encounter	Hospitalized within 3 days prior to and 14 days following specimen collection date for positive influenza laboratory test	
5/31	Radiography	Radiographic image of the chest with interpretation: consistent with silicosis or pneumoconiosis due to dust containing silica (includes radigraph (x-ray), computed tomography (CT), and other image modalities)	
2/23	Vital Records	Death certificate lists [C*ondition] as a cause of death or a significant condition contributing to death	

Table 2. Rules of Thumb to use when creating new criterion if examples don't meet the need

• Do not create criterion that are currently not being used. Consider future, but anticipating needs may waste time and effort.
• Point out new criterion in the LOG tab of the Excel file so the issue can be discussed with the team in the context of a specific condition.
• We will update this guidance document as new requirements are understood.
• Spell out the organism name, such as Bordetella pertussis, not B. pertussis.
• Lab criterion are structured using the following pattern: (Component/Method/System). For example, "Isolation of M. tuberculosis *(component)* from a culture *(method)* of a clinical specimen *(system)"*. This structure matches the way LOINC codes are designed so we can create the valuesets from the vetted criterion.
• Comments can be added after the criterion using parentheses "(i.e., ...)" for usability and to inform usage but the information in the parentheses would not be used to create or limit the valueset. It is descriptive in nature.
• Keep the criterion descriptions general unless there is a specific reason to restrict and further clarify.
• If lab tests should be limited by method, then specify specific methods
• If lab tests should be limited by specimen, then specify specimens (such as sterile sites)
• If Preliminary microbiology results should be reported as well as final results, then add a flag to the information: "Isolation of [O*rganism] .....– include preliminary results"
• Document the reason to restrict the criterion so it can be incorporated into the documentation about the project.

Step 3. Hold until vetting complete

- **Save to Sharepoint in Topic: Working Draft of Rules Logic** to be completed after content vetting and provisioning of the feedback.

Step 4. Review vetted criterion

- **Once feedback is provisioned,** review the criterion and save the criterion used by the specifications.
- Highlight any non-standardized criterion you drafted so they can be reviewed and potentially be added to this standard template.
- Log any additional issues in the Excel file you uncover that need to be addressed by the team.

Step 5. Define clinical rules

- Identify the clinical rules applicable to the criterion used.
- Note: the clinical rules are prefaced by the statement: "The patient record being evaluated contains evidence of….
- Remove unused clinical rules.
- Log any issues and highlight any non-standardized clinical rules you drafted so they can be reviewed and potentially be added to this standard template.

Step 6. Define Value Sets

- Save the rows in Value set Table that are applicable to the clinical rules.
- If the value set may be used for different conditions, indicate "*common*"
- If default text and options do not meet the needs, use naming conventions promoted in VSAC or add a comment for it to be reviewed.
- Remove unused rows of value sets
- Note: we are not creating valuesets for epi criteria at this time
- Note: Do not change columns in the table.

Step 7. Finalize documentation

- Create an updated snapshot of the proposed logic represented in the Excel file to add to the Summary below. The image should show just the proposed logic – i.e., info for only the columns relevant for lab and provider. In other words, crop the vital records rows and column and the national criteria.
- Log any issues in the Excel file you uncovered as a part of this process that may require SME input or review by the internal team.
- Delete everything before the Summary Title
- Remove highlighting from document
- Update the header with "Last updated" date (should automatically update to current date)
- **Save to Sharepoint in Topic: Internal Review of Rules Logic**

Summary of proposed specifications, value sets, and clinical rules

Terms to use throughout using 'Search and Replace'

- Use [C*ondition] for condition name
- Use [O*rganism] for organism name

Revision History

Version #	Implemented By	Revision Date	Reason
1.0			

Snapshot of logic: ADD HERE WHEN DONE

Valuesets required: REMOVE UNUSED VALUE SETS WHEN DONE

Comment	Value Set Name	OID	Description (informational for drafting rules, but not as explicit as documented in VSAC)	Include in Trigger set
Category	**Clinical (Diagnosis, Problems, Literals, or Symptoms)**			
New	[C*Ondition]		Codes for [C*ondition] as a diagnosis, problem, or cause of death.	Yes
New	[C*Ondition] Literal		Text strings and synonyms for detecting [C*ondition] in text-based entries. Would be used by lab or healthcare system to identify potentially relevant terms in text.	Yes
Common	[Symptom]		Codes for [Symptom] as a diagnosis, problem, symptom, or some other clinical observation	??
Common	Pregnant		Codes for pregnant as a diagnosis, problem, symptom, or some other clinical observation	No
New	[Component] Level By Pulse Oximeter	This will be a LOINC measurement, not a lab test	Set of measurements that may be 'observed' for detecting [component] levels by pulse oximetry	
Category	**Laboratory Test Names**			
New	[O*Rganism] Organism Identification Test		Set of lab tests that may be performed for isolating [O*rganism] by culture methods	Yes
New	[O*Rganism] Nucleic Acid Detection Test		Set of lab test names that may be ordered or 'observed' for detecting [O*rganism] nucleic acid by any method	Yes
New	[O*Rganism] Antigen Detection Test		Set of lab test names that may be ordered or 'observed' for detecting [O*rganism] antigen by any method	Yes
New	[O*Rganism] Igg Antibody Detection Test		Set of lab test names that may be ordered or 'observed' for detecting [O*rganism] IgG antibody by any method	Yes

New	[O*Rganism] Igg Or Total Antibody Detection Test		Set of lab test names that may be ordered or 'observed' for detecting [O*rganism] IgG or total antibody by any method	Yes
New	[O*Rganism] Igm Antibody Detection Test		Set of lab test names that may be ordered or 'observed' for detecting [O*rganism] IgM antibody by any method	Yes
New	[O*Rganism] Igg Antibody Titer Test		Set of lab test names that may be ordered or 'observed' for measuring [O*rganism] IgG or total antibody titer by any method	Yes
Common	Lab Test Name (Bacteria)		Lab tests for the presence of bacteria in a clinical specimen	No
Common	Lab Test Name (Fungus)		Lab tests for the presence of fungus in a clinical specimen	No
Common	Lab Test Name (Virus)		Lab tests for the presence of virus in a clinical specimen	No
Common	Lab Test Name (Parasite)		Lab tests for the presence of parasite in a clinical specimen	No
Common	Microscopic Observation Test		Set of microscopic observation lab tests that may be performed	No
Common	[Organism] Microscopic Observation Test		Set of [organism]-specific microscopic observation lab tests that may be performed	No
New	[Organism] Immune Stain Test		Set of ehrlichia-specific immune stain lab tests that may be performed	Yes
New	Lead Detection Quantitative Test	NOTE – include all tests	Set of lab test names that may be ordered or 'observed' for detecting Lead in any specimen by any method	Yes
New	Lead Detection Quantitative Test In Venous Blood		Set of lab test names that may be ordered or 'observed' for detecting Lead in venous blood by any method	Yes
New	Lead Detection Quantitative Test In Unknown Specimen		Set of lab test names that may be ordered or 'observed' for detecting Lead in an unknown specimen type by any method	Yes
Category	**Laboratory (Result Values, Abnormal Interpretation, Specimen Type, or Status)**			
New	Lab Result Value ([C*Ondition])		Organisms detected in laboratory results associated with [C*ondition]	

Common	Positive Qualitative Lab Result	2.16.840.1.113762.1.4.1146.272	Coded values for positive test results in the OBX-5 field, such as Detected, Positive, Reactive, etc.	
Common	Abnormal Interpretation	2.16.840.1.113762.1.4.1146.295	Set of HL7 Observation Interpretation codes (OID: [2.16.840.1.113883.5.83) that are indicative of 'abnormal' or 'outside normal range', or intermediate or resistant microbiology susceptibility results, all of which may be reportable.	
Common	Preliminary Status		Coded values for Preliminary status of lab results	
specimen	Venous		Set of specimen types for representing venous blood	No
Category	**Demographic**			
Common	Male		Set of codes for male that can be used in data fields for administrative gender or biologic gender	
Common	Female		Set of codes for female that can be used in data fields for administrative gender or biologic gender	
Category	**Medications**			
	[Medication]		Set of medication names that may have been administered or ordered or prescribed	
Category	**Immunizations**			
New	[antigens included in the vaccine]		Set of vaccines for an antigen that may be administered	
Category	**Other Categories**			

Clinical rules: REMOVE UNUSED CLINICAL RULES WHEN DONE

***The patient record being evaluated contains evidence of*:**

Standardized examples of clinical rules

CLINICAL-RELATED CLINICAL RULES:

Example of Diagnosis/problem:

[C*ondition] (i.e., as a Diagnosis or active Problem or mentioned in text as a cause of death or a significant condition contributing to death)

IF

- Patient has a diagnosis of [VS: [C*ondition]]

  OR

- Patient has an active problem list entry of [VS: [C*ondition]]

  OR

- Patient has a death recorded as [VS: [C*ondition]_Literals]

THEN report

Example of Diagnosis/problem suspected:

[C*ondition] suspected (i.e., documented as a 'reason for study')

IF

- Patient has lab result with (reason for study of [VS: [C*ondition]])

THEN report

Example of Measurement of carboxyhemoglobin (COHb) level >= 5% by pulse CO-oximeter

IF

- Patient has (measurement of [VS: Carboxyhemoglobin level by pulse oximeter]) and result value >=5%

THEN report

LAB-RELATED CLINICAL RULES:

Example of Culture for any bacterial species and any subspecies (i.e., any salmonella species and subspecies):

Isolation of any [O*rganism] species by culture methods in a clinical specimen

IF

- Patient has lab result with (test name of [VS: [O*rganism] organism identification test]) and ((lab result value of ([VS: Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))

  OR

- Patient has lab results with (test name of [VS: Lab test name (Bacteria)]) and (lab result value of [VS:Lab result value ([C*ondition]))

THEN report

- Patient has lab result value of [VS:Lab result value ([C*ondition])

THEN report

Example of Culture for a single bacterial organism (i.e., Bordetella Pertussis):

Isolation of [O*rganism] by culture methods in a clinical specimen

IF

- Patient has lab result with (test name of [VS: [O*rganism] organism identification test]) and ((lab result value of ([VS: Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))

  OR

- Patient has lab results with (test name of [VS: Lab test Name (Bacteria)]) and (lab result value of [VS:Lab result value ([C*ondition]))

THEN report

Example of Culture for any fungal species and any subspecies (i.e., any coccidioides species and subspecies):

Isolation of any [O*rganism] species by culture methods in a clinical specimen

IF

- Patient has lab result with (test name of [VS: [O*rganism] organism identification test] and ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation])

OR

- Patient has lab results with (test name of [VS: Lab test name (Fungus)]) and (lab result value of [VS:Lab result value ([C*ondition]))

THEN report

Example of Micro test AND wants preliminary results

Isolation of any [O*rganism] species by culture methods in a clinical specimen – include preliminary results

IF

- Patient has lab result with (test name of [VS: [O*rganism] organism identification test]) and ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))) and (Status includes [VS:Preliminary Status]

OR

- Patient has lab results with (test name of [VS: Lab Test Name (Bacteria)]) and (lab result value of ([VS:Lab result value ([C*ondition])) and (Status includes [VS:Preliminary Status]))

THEN report

Example of Microscopic observation for any organism within the species:

Microscopic observation of any [O*rganism] species by any method in a clinical specimen

IF

- Patient has lab result with (test name of [VS: [O*rganism] microscopic observation test]) and ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))

OR

- Patient has lab result with (test name of [VS: Microscopic observation test]) and (lab result value of ([VS:Lab result value ([C*ondition]))

THEN report

Example of Microscopic observation for single organism:

Microscopic observation of [O*rganism] by any method in a clinical specimen

IF

- Patient has lab result with (test name of [VS: [O*rganism] microscopic observation test]) and ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))

OR

- Patient has lab result with (test name of [VS: Microscopic observation test]) and (lab result value of ([VS:Lab result value ([C*ondition]))

THEN report

Example of detection of Nucleic Acid

Detection of [O*rganism] nucleic acid by any method in a clinical specimen

IF

- Patient has lab result with (test name of [VS: [O*rganism] nucleic acid detection test]) and ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))

THEN report

Example of detection of Antigen

Detection of [O*rganism] antigen by any method in a clinical specimen

IF

- Patient has lab result with (test name of [VS: [O*rganism] antigen detection test]) and ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))

THEN report

Example of detection of 'positive' IgM Antibody

Detection of [O*rganism] IgM antibody by any method in a clinical specimen

IF

- Patient has lab result with (test name of [VS: [O*rganism] IgM antibody detection test]) and ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))

THEN report

Example of detection of 'positive' IgG Antibody

Detection of [O*rganism] IgG antibody by any method in a clinical specimen

IF

- Patient has lab result with (test name of [VS: [O*rganism] IgG antibody detection test]) and ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))

THEN report

Example of detection of 'positive' IgG or total Antibody

Detection of [O*rganism] IgG or total antibody by any method in a clinical specimen

IF

- Patient has lab result with (test name of [VS: [O*rganism] IgG or total antibody detection test]) and ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))

THEN report

Example of criteria with specimen type requirements- for now, document the requirement until we clarify a general strategy for handling this.

Detection of Haemophilus Influenzae type B antigen by any method in cerebrospinal fluid

IF

- Patient has lab result with (test name of [VS: Haemophilus Influenzae antigen detection test]) and ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value (Invasive Haemophilus Influenza Disease)) or (Interpretation of [VS:Abnormal interpretation]))

- NEED TO OPERATIONALIZE 'in cerebrospinal fluid'

THEN report

Example of four-fold rise in antibody titres for a specific test method with a threshold

NOTE: SMEs indicated this it rare for paired sera to be performed and they want any single positive result reported. The health department will identify the pairs. In any case, here is potential required logic. Also note, there may be differing requirements for the timing between the 2 results. If so, then we would need to identify previous lab tests that meet the timing requirement and evaluate all of them. Here is some pseudocode, this this is just a start.

Detection of a fourfold or greater increase in IgG antibody against [O*rganism] by any method to a titer of at least 1:32 between paired acute- and convalescent-phase serum specimens. (i.e., assess specimens at least 1 days apart but no more than 180 days apart.)

Create a list of specimen collection dates, lab test name, lab test value, for tests of [VS: [O*rganism] IgG antibody detection test]

IF

- Patient has more than one lab test result with (test name of [VS: [O*rganism] IgG antibody detection test] in previous 180 days
  AND
- most recent lab test performed of [VS: [O*rganism] IgG antibody detection test] has result value (numeric and ≥ 1:32)
  - if yes, save the result value for a calculation and call it RESULT #1

  AND

(
- Compare earliest and most recent lab test performed of [VS: [O*rganism] IgG antibody detection test]
- If most recent result value ≥4 times earliest result value

)

THEN report

Example of four-fold rise in antibody titres for a specific test method requiring no threshold

Detection of a fourfold or greater increase in IgG antibody titer against [O*rganism] by any method between paired acute- and convalescent-phase serum specimens. (i.e., assess specimens at least 1 days apart but no more than 180 days apart).

Create a list of specimen collection dates, lab test name, lab test value, for tests of [VS: [O*rganism] IgG antibody titer test], selecting the highest value for a day.

IF

- Patient has more than one lab test result with (test name of [VS: [O*rganism] IgG antibody titer test] in previous 180 days

  AND

  (
  - Compare earliest and most recent lab test performed of [VS: [O*rganism] IgG antibody titer test]
  - If most recent result value ≥4 times earliest result value

)

THEN report

Example of seroconversion in antibody tests (i.e., for Conversion from 'negative' to 'positive' IgG antibody against [O*rganism] by any method between paired acute- and convalescent-phase serum specimens (i.e., assess specimens at least 1 day apart but no more than 180 days apart.))

Create a list of specimen collection dates, lab test name, lab test value, and interpretation for tests of [VS: [O*rganism] IgG antibody detection test] without quantitative results, selecting the highest value for a day. [Note, this will require that the CDS knows the subset of LOINC codes in the valueset that expect quantitiative or non–quantitative results.]

IF

- Patient has more than one lab test result in the list with (test name of [VS: [O*rganism] IgG antibody detection test] in previous 180 days
  AND
  (
  IF
  - Most recent lab result with (test name of [VS: [O*rganism] IgG antibody detection test]) and ((lab result value of [VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))

  AND
  - Earliest lab result with (test name of [VS: [O*rganism] IgG antibody detection test]) and NOT((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))

THEN report

Example of negative results associated with a previously positive test result

Detection of a negative treponemal or non-treponemal antibody by any method in a clinical specimen following a positive syphilis-specific antibody test (i.e., assess specimens no more than 30 days apart.)

NEED TO UNDERSTAND WHAT LABS ARE BEING INCLUDED IN THE EICR. CAN THEY SPECIFY TO INCLUDE ALL LAB TESTS IN THE PAST 60 DAYS SO THE PREVIOUS DATA IS AVAILABLE FOR THE LOGIC. COULD THE ADDITIONAL PREVIOUS LAB DATA BE LIMITED TO DATA FOR THE SAME CONDITION USED IN THE TRIGGER

Create a list of specimen collection dates, lab test name, lab test value, and interpretation for tests of [VS: treponemal or non-treponemal antibody detection test] in the past 60 days.

IF

- Patient has more than one lab test result in the list with (test name of [VS: treponemal or non-treponemal antibody detection test]
  AND
  (
  IF
  - Most recent lab result with (test name of [VS: treponemal or non-treponemal antibody detection test]) and NOT ((lab result value of [VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation])) → name this test "NEGATIVE TEST" AND GET THE SPECIMEN COLLECTION DATE

  AND
  {
  - Patient has (test name of [VS: treponemal or non-treponemal antibody detection test]) in the 30 prior to the specimen collection date of "NEGATIVE TEST"
    AND
  - ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))

  }
  THEN report

Example of negative results

Absence of detection of Hepatitis C Virus antibody **by any method specific for detecting hepatitis C virus antibody in a clinical specimen (i.e., negative results)**

IF

- Patient has lab result with (test name of [VS: [O*rganism] antibody detection test]) and (lab result value not missing) and NOT ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value ([C*ondition])) or (Interpretation of [VS:Abnormal interpretation]))
- **THEN** report

Example of lab test orders that are diagnostic

Lab test ordered for Isolation of [O*rganism] organism by any method in a clinical specimen

IF

- Patient has a lab test order for (test name of ([VS: [O*rganism] organism identification test]))

THEN report

Lab test ordered for Detection of [O*rganism] nucleic acid by any method in a clinical specimen

IF

- Patient has a lab test order for (test name of ([VS: [O*rganism] nucleic acid detection test]))

THEN report

Example of lab test orders for any test associated with the organism of interest

Lab test ordered for Detection of [O*rganism] IgG antibody by any method in a clinical specimen

IF

- Patient has a lab test order for (test name of ([VS: [O*rganism] organism identification test] or [VS: [O*rganism] nucleic acid detection Test] or etc…..))

THEN report

Example of Detection of lead concentraction ≥5 µg/dL (0.24 µmol/L) in a venous blood specimen AND Age ≥ 16 years

IF

- Patient has lab result with (test name of [VS: Lead detection quantitative test in venous blood]) and (lab result value of ≥5 µg/dL (0.24 µmol/L)
  OR
- Patient has lab result with (test name of [VS: Lead detection quantitative test]) and (specimen includes [VS:venous]) and (lab result value of ≥5 µg/dL (0.24 µmol/L)
  AND
- Patient age is **≥ 16 years**

THEN report

Example of pathology report interpretation Need to look at path report outputs and investigate how this would be represented in the eICR. This is preliminary. Currently I believe the lab results do not actually include free text interpretations, only the coded interpretation.

Histopathology of lung tissue with interpretation: consistent with silicosis or pneumoconiosis due to dust containing silica

IF

- Patient has lab result with (test name of [VS: biopsy]) and interpretation includes [VS: Condition_literal]

THEN report

Example of TB skin test

Detection of a 'positive' tuberculosis tuberculin skin test (NOTE: 'positive' is based on guidance for interpretting wheal size and risk level)

IF

- Patient has lab result with (test name of [VS: TB Skin Test]) and ((lab result value of ([VS:Positive qualitative lab result])) or (Interpretation of [VS:Abnormal interpretation]))

OR

- **NEED TO UNDERSTAND HOW ELSE SKIN TESTS MAY BE DOCUMENTED. NEED VENDOR INPUT.** Patient has (Clinical observation of [VS: TB skin test]) and (observation value of ([VS:Positive qualitative lab result])

THEN report

Example of symptom

IF

- Patient has ([VS: symptom]) (e.g., as diagnosis, problem, symptom)

THEN report

Example of [Symptom] with duration of [operator] [number] [units] NEED INPUT FROM VENDORS/eICR spec to complete this.

IF

(

- Patient has ([VS: symptom]) (e.g., as diagnosis, problem, symptom)

  Then gather relevant dates:

  Symptom start date – use start date. If not available, use documentation date.

  Symptom end date – if null, use today date

  Then calculate difference between the dates → 'difference' in days.
- If 'difference' is **[operator] [number] [units]**

)

THEN report

EXAMPLE of logic set that includes symptoms and epi criteria

Symptoms and epidemiologic criteria:

IF

(

- Patient has ([VS: symptom]) (e.g., as diagnosis, problem, symptom)

  OR
- Patient has body temperature > ##° F (##° C)

)

AND

(

- Contact of a person with [C*ondition]] is TRUE

  OR
- Member of a risk group as defined by public health authorities during an outbreak is TRUE

)

THEN report

1. **Symptom and Lab test ordered:**

   IF

- Patient has ([VS: Rash: generalized maculopapular]) (e.g., as diagnosis, problem, symptom)

AND

- Patient has a lab test order with (test name of [VS: Rubella virus IgM antibody detection test])

THEN report

2. **Symptoms and epidemiologic criteria:**

IF

- Patient has body temperature > 99.0° F (37.2° C)

AND

- Patient has ([VS: Rash: generalized maculopapular) (e.g., as diagnosis, problem, symptom)

AND

(

- Contact of a person with rubella is TRUE

OR

- Member of a risk group defined by public health authorities during an outbreak is TRUE

OR

- Residence in a geographic area of the US where an outbreak of rubella is occurring

OR

- Travel during the 21 days before illness onset to a geographic area where an outbreak of rubella is occurring

)

THEN report

QUESTION: NOT sure vital signs and observations of fever are included in the eICR. NEED MORE INPUT.

Should it be represented as:

- Patient has observation of (VS: fever) or body temperature > 100.4° F (38° C)

Example of Lab order and lots of clinical criteria:

Lab test ordered for detection of mumps IgM antibody by any method in a clinical specimen AND (Parotitis or Aseptic meningitis or Encephalitis or Hearing Loss or Orchitis or Oophoritis or Mastitis or Pancreatitis (i.e., as a Diagnosis or active Problem or mentioned in text as a cause of death or a significant condition contributing to death)

IF

Patient has lab test order for (test name of [VS: Mumps IgM Antibody Test])

AND

(

- Patient has a diagnosis of ([VS: Parotitis] or [VS: Aseptic meningitis] or [VS: Encephalitis] or [VS: Hearing Loss] or [VS: Orchitis] or [VS: Oophoritis] or [VS: Mastitis] or [VS: Pancreatitis])

  OR

- Patient has an active problem list entry of ([VS: Parotitis] or [VS: Aseptic meningitis] or [VS: Encephalitis] or [VS: Hearing Loss] or [VS: Orchitis] or [VS: Oophoritis] or [VS: Mastitis] or [VS: Pancreatitis])

  OR

- Patient has a death recorded as ([VS: Parotitis_Literals] or [VS: Aseptic meningitis_Literals] or [VS: Encephalitis_Literals] or [VS: Hearing Loss_Literals] or [VS: Orchitis_Literals] or [VS: Oophoritis_Literals] or [VS: Mastitis_Literals] or [VS: Pancreatitis_Literals])

)

THEN report

<u>Example of epidemiologic and lots of clinical criteria:</u>

Contact of a person with Mumps OR Member of a risk group defined by public health authorities during an outbreak AND (Parotitis or Aseptic meningitis or Encephalitis or Hearing Loss or Orchitis or Oophoritis or Mastitis or Pancreatitis (i.e., as a Diagnosis or active Problem or mentioned in text as a cause of death or a significant condition contributing to death)

IF

(

- Patient has contact of a person with Mumps

OR

- Patient is member of a risk group defined by public health authorities during an outbreak

)
AND
(

- Patient has a diagnosis of ([VS: Parotitis] or [VS: Aseptic meningitis] or [VS: Encephalitis] or [VS: Hearing Loss] or [VS: Orchitis] or [VS: Oophoritis] or [VS: Mastitis] or [VS: Pancreatitis])

OR

- Patient has an active problem list entry of ([VS: Parotitis] or [VS: Aseptic meningitis] or [VS: Encephalitis] or [VS: Hearing Loss] or [VS: Orchitis] or [VS: Oophoritis] or [VS: Mastitis] or [VS: Pancreatitis])

OR

- Patient has a death recorded as ([VS: Parotitis_Literals] or [VS: Aseptic meningitis_Literals] or [VS: Encephalitis_Literals] or [VS: Hearing Loss_Literals] or [VS: Orchitis_Literals] or [VS: Oophoritis_Literals] or [VS: Mastitis_Literals] or [VS: Pancreatitis_Literals])

)
THEN report

Example of medication adminstered

Patient had tetanus immune globlin administered

IF

- Patient had ([VS: Tetanus Immune Globulin]) medication administered

THEN report

Example of medication administered or ordered (prescribed)

1. **Patient had Bicilin administered or ordered (prescribed)**

IF

- Patient had ([VS: Bicilin]) medication administered

OR

- Patient had ([VS: Bicilin]) medication ordered (prescribed)

THEN report

Example of chest radiograph interpretation Need to look at radiography report outputs and investigate how this would be represented in the eICR. This is preliminary.

Radiographic image of the chest with interpretation: consistent with silicosis or pneumoconiosis due to dust containing silica (including radigraph (x-ray) or computed tomography (CT))

IF

- Patient has radiography with (radiograph name of [VS: Chest xray or CT]) and interpretation/summary/impression includes [VS: Condition_literal]

THEN report

Example of immunization history

NEED TO UNDERSTAND THE OPTIONS OF DATA AVAILABLE IN THE EICR for immunizations

Patient had [component] immunization in the past

IF

- Patient has documentation of (immunization name includes [VS: immunization]) administered [ever / within past ## [units]] with status of [???]

THEN report

Patient had no history of [component] immunization in the past ??? not sure if this is correct

IF

- Patient has no documentation of (immunization name includes [VS: immunization]) administered

THEN report

All result values for laboratory tests for isolation of Bordetella pertussis by any method in a clinical specimen (i.e., 'negative' and 'positive' results)

IF [**Isolation of Bordetella pertussis virus by culture methods in a clinical specimen]**

- Patient has lab result with (test name of [VS: Bordetella pertussis virus Organism Identification Test]) and ((lab result value of [VS:Positive qualitative lab result]or [VS:Lab result value (Pertussis)) or (Interpretation of [VS:Abnormal interpretation]))

OR

- Patient has lab results with (test name of [VS: Lab Test Name (Virus)]) and (lab result value of [VS:Lab result value (Pertussis))

OR

[Absence of isolation of Bordetella pertussis Virus by any method specific for detecting Bordetella pertussis virus in a clinical specimen (i.e., negative results)]

- Patient has lab result with (test name of [VS: Bordetella pertussis virus Organism Identification Test) and (lab result value not missing) and NOT ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value (Pertussis)) or (Interpretation of [VS:Abnormal interpretation]))

THEN report

All result values for laboratory tests for detecting Bordetella pertussis nucleic acid by any method in a clinical specimen (i.e., 'negative' and 'positive' results)

IF [**Detection of *Bordetella pertussis virus* nucleic acid by any method in a clinical specimen]**

- Patient has lab result with (test name of [VS: Bordetella pertussis virus nucleic acid Detection Test]) and ((lab result value of [VS:Positive qualitative lab result]or [VS:Lab result value (Pertussis)) or (Interpretation of [VS:Abnormal interpretation]))

OR

[Absence of detection of *Bordetella pertussis virus* nucleic acid by any method specific for detecting *Bordetella pertussis virus* nucleic acid in a clinical specimen (i.e., negative results)]

- Patient has lab result with (test name of [VS: Bordetella pertussis virus nucleic acid Detection Test) and (lab result value not missing) and NOT ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value (Pertussis)) or (Interpretation of [VS:Abnormal interpretation]))

THEN report

All result values for laboratory tests for detecting Bordetella pertussis antigen by any method in a clinical specimen (i.e., 'negative' and 'positive' results)

IF [Detection of *Bordetella pertussis virus* antigen by any method in a clinical specimen]

- Patient has lab result with (test name of [VS: Bordetella pertussis virus antigen Detection Test]) and ((lab result value of [VS:Positive qualitative lab result]or [VS:Lab result value (Pertussis)) or (Interpretation of [VS:Abnormal interpretation]))

OR

[Absence of detection of *Bordetella pertussis* virus antigen by any method specific for detecting *Bordetella pertussis* virus antigen in a clinical specimen (i.e., negative results)]

- Patient has lab result with (test name of [VS: Bordetella pertussis virus antigen Detection Test) and (lab result value not missing) and NOT ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value (Pertussis)) or (Interpretation of [VS:Abnormal interpretation]))

THEN report

An alternative, that I actually think is better, would be to create criteria for the negatives and let them select the positive and the negative, rather than grouping them as I did just above this. Please also create these so we can ask them which they prefer:

Absence of isolation of Bordetella pertussis Virus by any method specific for detecting Bordetella pertussis virus in a clinical specimen (i.e., negative results)

IF

- Patient has lab result with (test name of [VS: Bordetella pertussis virus Organism Identification Test) and (lab result value not missing) and NOT ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value (Pertussis)) or (Interpretation of [VS:Abnormal interpretation]))

THEN report

Absence of detection of *Bordetella pertussis virus* nucleic acid by any method specific for detecting *Bordetella pertussis virus* nucleic acid in a clinical specimen (i.e., negative results)

IF

- Patient has lab result with (test name of [VS: Bordetella pertussis virus nucleic acid Detection Test) and (lab result value not missing) and NOT ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value (Pertussis)) or (Interpretation of [VS:Abnormal interpretation]))

THEN report

Absence of detection of *Bordetella pertussis* virus antigen by any method specific for detecting *Bordetella pertussis* virus antigen in a clinical specimen (i.e., negative results)

IF

- Patient has lab result with (test name of [VS: Bordetella pertussis virus antigen Detection Test) and (lab result value not missing) and NOT ((lab result value of ([VS:Positive qualitative lab result] or [VS:Lab result value (Pertussis)) or (Interpretation of [VS:Abnormal interpretation]))

THEN report

Appendix A2: Process Condition Template (MS Excel)

		PROPOSED DEFAULT - LOGIC SET								NATIONAL (CSTE)		
		Lab Reporting	Provider / Facility Reporting			add if needed	add if needed	add if needed	Vital Records			
			(1)	(2)	(3)							
The patient record being evaluated contains evidence of:			LAB	DX	LAB + CLIN	CLIN + EPI 1	CLIN + EPI 2	DEM +....				
Criterion Description	Stat											
Clinical	C											
[Condition] (i.e., as a Diagnosis or active Problem or mentioned in text as a cause of death or a significant condition contributing to death)												
Laboratory	C											
Demographic	C											
age [operator] [number][units]												
Male												
Female												
Immunization	C											
Epidemiologic	C											
Vital Records	C											
Death certificate lists [condition] as a cause of death or a significant condition contributing to death												

Appendix B: SRCA Conditions by Number of Jurisdictions Where Reportable

CONDITION	#	CONDITION	#
Cancer	48	Hazardous Substances Emergency Event	15
Foodborne Disease	48	Hepatitis G	15
Streptococcus pneumoniae Infection	48	Staphylococcal Enterotoxin B Pulmonary Poisoning	15
Eastern Equine Encephalitis Virus Disease	46	Monkeypox	14
California Serogroup Virus Disease	45	Norovirus Infections	14
Lymphogranuloma Venereum	45	Rheumatic Fever	14
Creutzfeldt-Jakob Disease	43	Rickettsial Disease	14
Powassan Virus Disease	42	Suicide	14
Waterborne Disease	42	Tick-borne Relapsing Fever	14
Ebola Virus Infection	41	Toxoplasmosis	14
Marburg Virus Infection	41	Ciguatera	13
Streptococcal Disease	41	Fish and Shellfish Poisoning	13
Arenavirus Infection	40	Healthcare-associated Infection	13
LaCrosse Virus Infection	40	Hospital-acquired Infection	13
Lassa Virus Infection	40	Kawasaki Disease	13
Mesothelioma	40	Primary Amebic Meningoencephalitis	13
Staphylococcus aureus Infection	40	Traumatic Injuries	13
Western Equine Encephalitis Virus Disease	40	Autism Spectrum Disorders	12
Lujo Virus Infection	39	Domoic Acid Poisoning	12
New World Arenavirus Infection	39	Louse-borne Relapsing Fever	12
Hepatitis E	38	Neurotoxic Shellfish Poisoning	12
Yersiniosis	38	Nosocomial Infection	12
Hepatitis D	37	Scombroid	12
Venezuelan Equine Encephalitis Virus Disease	37	Autism	11
Phenylketonuria	36	Burns	11
Crimean-Congo Hemorrhagic Fever Virus Infection	35	Toxic Effects of Agricultural Chemicals	11

Down's Syndrome (Trisomy 21)	35	Chemical Pneumonitis	10
Galactosemia	35	Coal workers' pneumoconiosis	10
Variant Creutzfeldt-Jakob Disease	35	Immunization-related Adverse Reaction	10
Abdominal Wall Defects	34	Influenza-like Illness	10
Chikungunya	34	Intimate Partner Violence	10
Cleft Lip	34	Reye's Syndrome	10
Cleft Palate	34	Berylliosis	9
Japanese Encephalitis Virus Disease	34	Cerebral Palsy	9
Maple Syrup Urine Disease	34	Drownings and Submersions	9
Primary Congenital hypothyroidism	34	Healthcare-associated Adverse Event	9
Rift Valley Fever	34	Motor Vehicle Injury	9
Cleft Lip/Palate	33	Pneumoconiosis	9
Infant Hearing Loss	33	Toxic Effects of Chemicals	9
Limb Reduction	33	Clostridium difficile Infection	8
Biotinidase Deficiency	32	Cryptococcosis	8
Cardiac Defect	32	Disaster Casualty	8
Hypospadia	32	Farm-related	8
Neural Tube Defect	32	Blastomycosis	7
Other Specified Metabolic Disorder	32	Byssinosis	7
Omphalocele	30	Catheter-associated Urinary Tract Infection (UTI)	7
Other Specified Genetic Disorder	30	Cysticercosis	7
Amebiasis	29	Drug (Controlled Substance) Overdose	7
Colorado Tick Fever	29	Farmers' Lung	7
Inborn Errors of Metabolism	29	Hypersensitivity Pneumonitis	7
Epispadia	28	Mushroom Poisoning	7
Gastroschisis	28	Ophthalmia Neonatorum	7
Staphylococcal Disease	28	Orthopox	7
Anencephaly	27	Respiratory Syncytial Virus (RSV) Infection	7
Fetal Alcohol Syndrome (FAS)	27	Scabies	7

Typhus Fever	27	Violent Injuries	7
Alcohol-related Birth Defects	26	Conjunctivitis	6
Animal Bites	26	Guillain-Barre Syndrome	6
Other Specified Developmental Deformity	26	Herpes Genitalis	6
Spina Bifida	26	Nipah Virus Infection	6
Trachoma	26	Taeniasis	6
Congenital Hyperthyroidism	23	Vesicular Stomatitis	6
Mercury Poisoning	23	Chagas Disease	5
Central-line associated Bloodstream Infection	22	Enterobacteriaceae Infection	5
Encephalitis	22	Hyperthermia	5
Glanders	22	Hypothermia	5
Melioidosis	21	Smoke Inhalation	5
Fetal Alcohol Spectrum Disorders (FASD)	20	Ventilator-associated Pneumonia	5
Ricin Poisoning	20	Contaminated Sharps Injury	4
Sudden Infant Death Syndrome (SIDS)	20	Enterovirus Infections	4
Arsenic Poisoning	19	Nongonococcal Urethritis (NGU)	4
Influenza	18	Pneumonia	4
Meningitis	18	Pneumonitis	4
Surgical Site Infection	18	Rotavirus Infections	4
Toxic Effects of Heavy Metals	18	Noise-induced Hearing Loss	3
Vaccinia Disease	18	Parkinson's Disease	3
Vancomycin-Resistant Enterococci (VRE) Infection	18	Bartonellosis	2
Asbestosis	17	Diabetes	2
Histoplasmosis	17	Filariasis	2
Paralytic Shellfish Poisoning	17	Genital Warts	2
Pelvic Inflammatory Disease (PID)	17	Leishmaniasis	2
Rash Outbreak	17	Acanthamoeba Disease (excluding keratitis)	1
Spinal Cord Injury	17	Acute Flaccid Paralysis	1
Cadmium Poisoning	16	Angiostrongyliasis	1

Granuloma Inguinale	16	Balamuthia mandrillaris Disease	1
Head Injury	16	Septicemia	1
Traumatic Fatalities	16	Acute Upper Respiratory Illness*	0
Asthma	15	Chronic Fatigue Syndrome*	0
Gunshot Wounds	15	Mucopurulent Cervicitis (MPC)*	0

* Jurisdictions listed as implicitly reportable, therefore must be included