Recommendations for State, Tribal, Local, and Territorial Health Agencies for Pregnancy Status Reporting

CSTE COVID-19 Pregnancy Status Reporting Workgroup

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Summary of Recommendations for Pregnancy Status Reporting for COVID-19

The Council of State and Territorial Epidemiologists (CSTE) COVID-19 Pregnancy Status Reporting Workgroup (PSRW) developed the following recommendations for the improvement of pregnancy status capture and reporting. Specific scenarios to which these recommendations apply include:

1) Identification of a reportable condition (infectious or non-infectious) where there is known potential impact on the pregnant person, fetus, or infant; or,
2) Reporting of an emerging or reemerging disease where the potential health impact on a pregnant person, fetus, or infant is unknown.

The workgroup formed recommendations for state, tribal, local, or territorial (STLT) administrative code or law language to support reporting of pregnancy status. The workgroup provided a framework for capturing pregnancy status through laboratory reporting where as appropriate. As eCR becomes more reliable and comprehensive, it may become a better source of pregnancy status information as a compliment to reportable condition data reported through other means. However, eCR is not yet fully implemented across the United States for all reportable conditions and does not yet consistently contain patient data regarding pregnancy. Lastly, multifaceted efforts are essential to continue the progress made in revising EHR certification standards, modernizing the U.S. public health infrastructure, and reinforcing the public health workforce. These recommendations are expected to evolve with the progression of public health data modernization initiatives.

Recommendation I: Inclusion of pregnancy status for reportable conditions in administrative code or law

The PSRW recommends jurisdictions adjust administrative code or laws to include pregnancy status as a required data element for reportable conditions where the health of a pregnant person, fetus, or infant may be affected. This includes adding specific language to require a pregnancy indicator for all emerging or reemerging conditions in addition to conditions with known maternal or perinatal impacts. Suggested language and examples of comprehensive state code or law are listed in the Recommendation I section of this document.

Recommendation II: Minimum standards for electronic laboratory reporting

The PSRW recommends minimum reporting standards for pregnancy status capture and reporting from laboratories. The PSRW recommends the use of the following HL7 segments and ontologies for laboratory reporting of pregnancy status with the response extracted from AOE:

OBX-3 (LOINC 82810-3)

AND

OBX-5 (77386006^Patient currently pregnant (finding)^SCT, 60001007^Not pregnant (finding)^SCT)

Additional specifications for using the minimum recommended OBX fields, other OBX fields, as well as alternatives to using OBX fields are located in the Recommendation II section of this document.

Recommendation III: Advancement and expansion of electronic case reporting (eCR)

The PSRW recommends that STLT jurisdictional public health agencies prioritize ingestion, extraction, and use of eCR for pregnancy status reporting. The pregnancy status observation is a defined component of eCR reporting and has the ability to provide thorough, adequate pregnancy data if the data are available in the electronic health record and included in the eCR message. However, changes to EHR configuration and eICR exchange requirements are needed to made eICRs a more valuable source of pregnancy data. Additional information is found in the Recommendation III section of this document.

Recommendation IV: Essential Supporting Activities

The PSRW recommends additional activities involving multiple stakeholders influential in improving pregnancy status reporting. Top priorities include:

A) *Promotion of the adoption of USCDI v3 through the ONC proposed CEHRT rule change* Including the Pregnancy Section capture in USCDI standards would create alignment with eCR reporting requirements and ensure clinicians can report pregnancy status within their EHR system.
B) *Provider reporting, education, and incentivization* Support for provider education around the importance of reporting of pregnancy status for relevant reportable conditions is essential. A multidisciplinary approach involving public health and professional organizations may be most efficacious in conducting education.
C) *Use of supplemental methods of reporting* Multiple supplemental methods (e.g., use of birth registries or hospital discharge data) for reporting pregnancy status are already in use in many jurisdictions. As states move toward standardized electronic laboratory reporting and expand eCR for reporting pregnancy status, retaining some supplemental data reporting methods may be needed for ELR and eICR validation.
D) *Policy development* National policies are essential to supporting jurisdictional efforts to improve pregnancy status reporting. The creation and codification of policies may help provide explicit guidance and enforcement ability at the jurisdiction level.
E) *Sustained funding support for STLT* As noted in the comprehensive assessment completed for this project with STLT agencies, progress is being made towards the modernization of public health reporting systems. However, substantial, sustained investments are required to fortify and continue the work underway. Data modernization funding must not be a one-time opportunity, but a longitudinal and reliable investment in public health infrastructure.

Additional details on these supporting activities are in the Recommendations IV section of this document.

Introduction

Overview

The Council of State and Territorial Epidemiologists (CSTE) COVID-19 Pregnancy Status Reporting Workgroup (PSRW) was formed in January 2022 to identify ways to improve the capture of pregnancy status for cases of COVID-19. The workgroup is comprised of representatives from federal, state, tribal, local, and territorial (STLT) public health agencies, laboratories, professional organizations, and CSTE. All members are experienced in identifying methods for capturing pregnancy status for various conditions of public health importance such as COVID-19, hepatitis B/C, Zika virus, HIV, and congenital syphilis.

Pregnancy presents a unique vulnerability to infectious diseases. Changes in the immune, respiratory, and cardiovascular systems during pregnancy result in pregnant people being more adversely impacted by certain infectious diseases including COVID-19.[1] Multiple infectious diseases may be transmitted perinatally or at birth, resulting in serious outcomes for the fetus or infant. [1-8] The ability to mitigate the impact of disease on pregnant people is dependent on the recognition and reporting of pregnancy status. For cases of certain infectious diseases, rapid, accurate, and early reporting of pregnancy status is essential.[9-11]

Ascertaining pregnancy status for emerging and some reemerging infectious conditions is critical as the potential impact of perinatal infection and transmission may not be known. Data obtained from public health investigations provides a foundation for the examination of new or reemerging diseases. This foundation is crucial to informing research, structuring public health interventions, and helping form clinical practice guidelines. The outcomes of these efforts improve pregnancy and birth outcomes, prevent health complications experienced by pregnant people, and prevent perinatal infections. The faster data are acquired and analyzed, the greater the potential protective effect.

Many infectious diseases have known consequences on pregnant people and/or their infants. Hepatitis B transmission risk from mother to infant is highest during delivery, and if the infection is acquired, the infant has a significant chance of experiencing chronic liver disease.[5,12] Timely and complete reporting of hepatitis B-positive pregnant persons to public health helps to ensure that these patients receive hepatitis B evaluation and treatment during pregnancy and that their infants are administered post-exposure prophylaxis within 12 hours following birth.[13] For diseases where prophylactic intervention is unavailable, targeted prevention measures can reduce the spread of disease. For example, when Zika virus reemerged in 2014 resulting in a Brazilian epidemic of microcephaly, prophylaxis was not available to prevent perinatal infections.[14,15] However, travel warnings, mosquito repellant use, and other prevention measures helped limit the majority of Zika cases to the countries initially affected.[15,16]

When SARS-CoV-2 emerged, the impact of this new pathogen on pregnant people or on the fetus/infant was unknown. Epidemiologists were tasked with capturing thorough case reports and clinical information on these cases to inform large-scale studies.[17,18] While it was several months into the pandemic before conclusions were realized, pregnant people were found to be at greater risk for serious illness and death due to COVID-19 compared to non-pregnant persons.[19-21] This finding helped equip clinicians and public health officials in educating

patients considering pregnancy or who were already pregnant, and later in prioritizing pregnant people for vaccination.

The keys to adequately assessing the impact of an emerging or reemerging disease on pregnant people are timeliness and completeness of data. Where possible, electronic means of data capture and reporting to public health should be used to rapidly identify pregnant people with high levels of certainty. There are multiple electronic modalities for capturing reportable condition case data including electronic laboratory reporting (ELR), electronic case reporting (eCR), and secure file exchange.[22] Currently, in public health, ELR is widely used for the electronic exchange of reportable condition data, though is rarely inclusive of pregnancy status. The utilization of eCR is ramping up quickly as public health agencies extract new conditions, parse new components of the eICR, and providers are added to exchange reportable condition data. Currently, agencies are only receiving eCR for COVID-19, mpox, and a subset of other reportable conditions. Agencies are not yet able to consistently capture pregnancy status outside of manual review of electronic initial case report (eICR) data.[23,24]

The COVID-19 pandemic resulted in improved information sharing across clinical and public health responses, yet more work remains. An electronic health record (EHR) may contain the ability for providers to indicate pregnancy status in a clinical record field, but the field may not be required for providers to complete nor is there a requirement for EHR vendors to include a pregnancy observation when sharing data with public health agencies. During the COVID-19 pandemic, the CARES Act required laboratories testing for SARS-CoV2 to capture and report pregnancy status to public health when available; most labs used the ask at order entry (AOE) field to capture pregnancy status. This practice was not widely used by providers and was discontinued with the end of the pandemic's public health emergency declaration.[25,26]

Public health jurisdictions may not have the ability to directly influence the configuration of EHRs or laboratory orders, but public health reporting laws can provide the framework for more consistent, standardized pregnancy data reporting. In order to be effective, such laws or administrative code must specify what data elements are required (e.g., pregnancy status), for which conditions (e.g., hepatitis B), and in what ways (e.g., ELR). Public health case investigation forms do not universally contain or require pregnancy status, even for emerging diseases.

To prevent a recurrence of the patterns of past public health emergencies and improve data capture for the most important perinatal diseases, a set of cohesive, practical recommendations is needed. The PSRW drafted this document to serve as a template for future policy, a roadmap for STLT advancement of pregnancy reporting, and a checklist for federal, clinical, and auxiliary agencies to ensure the right national constructs are in place. The precedence of decades of non-standard processes will be challenging to undo, but the result will fortify public health efforts to protect pregnant people and their fetus/infants for the foreseeable future.

Purpose statement

CSTE and the Centers for Disease Control and Prevention (CDC) convened this multidisciplinary workgroup of subject matter experts and public health partners to identify recommendations to improve pregnancy status reporting accuracy and completeness. The emphasis of this effort is on COVID-19 surveillance with applicability to other infectious disease threats to maternal and child health. Recommendations are centered on the following:

- Establishing a jurisdiction-specific framework for administrative code or law to require pregnancy status reporting
- Allowing for multiple approaches to capture and report pregnancy-related data elements by condition
- Utilization of existing clinical, technical, and public health systems and processes
- Refining standards for capturing and reporting pregnancy status through ELR
- Prioritization at the STLT public health agency level of eCR implementation and evaluation of the completeness of pregnancy content within eICR messages in production feeds
- Acknowledgement that multiple reporting approaches may be needed to ensure adequate identification of pregnancy status
- Critical national-level actions to augment STLT progress towards adoption and use of eCR

The adoption of these recommendations will provide an excellent basis for improving public health's ability to act and intervene for the benefit of maternal and child health.

Target audience

These recommendations are intended for use primarily by STLT public health agencies, with relevant guidance for all entities supporting pregnancy status identification and reporting including, but not limited to:

- Public health laboratories
- Commercial and private laboratories
- Clinicians and clinical administrators
- Federal health agencies (e.g., CDC, Office of the National Coordinator for Health Information Technology, Centers for Medicare and Medicaid Services)
- Health information exchanges
- Vendors of Clinical Information systems (Health Information Organization systems, EHR, and Laboratory Information Systems (LIS))
- Electronic data intermediary companies (e.g., ingestion, aggregation, processing services often referred to as middleware)
- Professional organizations
- Health IT professionals and consultants
- Administrative code, legislative or similar advocates and authors

Intended use

These recommendations are intended for assessing, strengthening, and advancing STLT capabilities in capturing, ingesting, and reporting pregnancy status for COVID-19. STLT agencies may use multiple recommendations to develop a roadmap for progressing to a faster, more comprehensive means of reporting, or identify opportunities for improvement in their current reporting process. Federal agencies may use these recommendations to prioritize funding, support efforts for STLT implementation of the recommendations, or to advocate for policies that would facilitate improved pregnancy reporting.

This document provides varying options of pregnancy status reporting from manual effort to automated capture using eCR or similar EHR-origin reporting. Recommendations include specific fields, codes, text, and other suggestions for reducing variability and manual efforts to extract pregnancy status from clinical information systems. The document also provides sample administrative language for codifying pregnancy status reporting requirements. The reference section of the document contains dozens of articles, sites, and other resources for public use.

Contributors/workgroup overview

This report was prepared by Meghan Schaeffer, MPH, MPA, EdD, of Aperio Statistical Consulting. The following is a comprehensive list of workgroup participants. Workgroup coordinators are denoted by "*" and project editors are indicated by "**".

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Sources/reference types

The process of forming the recommendations within this document included interviews with various stakeholders from STLT agency staff to large commercial laboratories. Interviews used to inform the content in this document are cited and included as references. Research papers, presentations, previous recommendations, websites, and other sources are used throughout and referenced. A significant assessment effort was completed with four target groups – STLT agencies, federal health agencies, laboratories, and clinicians (i.e., OB/GYN), with over 100 responses and 44 STLT represented. The data from these assessments are used throughout the document to structure and inform content including recommendations. An abridged, de-identified summary is available in Appendix B.

List of Terms

Term/Acronym	Definition/Full Term
AOE	Ask at order entry; a type of field used when clinicians enter order information for a laboratory test
API	Application Programming Interface
CDA	Clinical Document Architecture
CDC	Centers for Disease Control and Prevention
CSTE	Council of State and Territorial Epidemiologists
CMS	Centers for Medicare and Medicaid Services
eCR	Electronic Case Reporting (the process of electronic case reporting between providers and public health)
eICR	Electronic Initial Case Report (the initial case report document)
ELR	Electronic Laboratory Reporting
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Reporting
HL7	Health Level 7
HITEC	Health Information Technology Advisory Committee
HIPAA	Health Insurance Portability and Accountability Act; established protections for health data and information
ICD-10-CM	International Classification of Diseases, Tenth Revision, Clinical Modification codes used to document patient diagnoses
LOINC	Logical Observation Identifiers Names and Codes used in electronic laboratory reporting
OBR	Observation request
OBX	Observation result segment in an HL7 message
ONC	Office of the National Coordinator
ORC	Common Order Segment
PSRW	Pregnancy Status Reporting Workgroup
RCKMS	Reportable Conditions Knowledge Management System; the decision support service within eCR that evaluates eICR documents to determine reportability
SNOMED	Systemized Nomenclature of Medicine
SOGI	Sexual Orientation and Gender Identity
STLT	State, Territorial, Local, and Tribal
USCDI	The United States Core Data for Interoperability

Issue Background

The importance of pregnancy status reporting

Public health uses

STLT prioritizes the determination of pregnancy status primarily in two scenarios:

1) Identification of a reportable condition (infectious or non-infectious) where there is known impact on the pregnant person, fetus, or infant and/or a public health intervention may prevent or mitigate harm to the pregnant person, fetus, or infant; or,
2) Reporting of an emerging or reemerging disease where the potential health impact on a pregnant person, fetus, or infant is unknown.

The first scenario, where a reportable condition is known to impact the health of a pregnant person or their fetus, may require timely identification of pregnancy status to provide clinical or public health interventions. Interventions may include treatment of the pregnant person, deploying measures to prevent the spread of disease to the fetus or provision of prophylactic treatment to an infant following birth.[12,27] Multiple public health interventions may be used to reduce or prevent the impact of the disease or condition. Examples of these conditions include but are not limited to SARS-CoV 2 infection, hepatitis B and C, group B streptococcal infection, Zika virus, listeriosis, HIV, syphilis, rubella, or influenza.[5,9,12,27-35] For diseases where intervention to treat or prevent transmission may not be available, it is still important to facilitate linkage of the newborn and family with early intervention or other social services support.[5,31,36] In all circumstances, tracking the incidence of congenital infection or other impacts to the pregnant person, fetus, or infant is epidemiologically valuable.

In the second scenario, where an emerging or reemerging disease presents an unknown risk to pregnant people, reporting pregnancy status is critical. Public health investigations provide essential epidemiologic and clinical information necessary for forming prevention recommendations and clinical practice guidelines.[6,37] The development of clinical practice guidelines requires structured evaluation and public health data can play a key role in supporting and performing those evaluations. Enhancing large-scale data collection within public health will only increase the ability of these data to contribute to clinical guidelines for the prevention and treatment of an emerging or reemerging disease, or point toward needed research.[38-41]

Even in situations where treatment is not yet available, the use of preventive measures specific to a disease can help mitigate the risk of infection for a pregnant person. These measures may include avoiding exposure, vaccination, personal protective measures, travel guidance, transmission education, etc.[16,42] For example, travel advisories during the Zika virus outbreak, primarily in 2015 and 2016, helped inform pregnant people and clinicians of the risk of exposure to Zika virus in certain Central and South American countries.[43,44] This type of advisory likely reduced travel and therefore risk to pregnant people throughout the duration of the Zika virus outbreak.[16,45]

For more information on specific diseases and how they impact the health of a pregnant person, fetus, or infant, see Appendix A.

The status of reportable condition tracking in the U.S.

Case surveillance is a core function of public health at all jurisdictional levels including federal, state, territorial, local, and tribal. Reportable conditions, which include infectious and non-infectious, pose a threat to human health and often require timely action to prevent further spread or reduce the impact of the condition.[46] Case surveillance begins at the STLT level. STLT jurisdictions are responsible for establishing administrative code or law determining which conditions must be reported by healthcare providers and laboratories, how they are to be reported to public health agencies, and in what time frame.[46] Healthcare providers such as clinicians, hospitals, or laboratories are required to report cases, or in some instances suspected cases, of reportable conditions to public health agencies. Data collected as part of a public health investigations are limited to the minimum necessary elements to investigate a case. It is important to note, public health condition reporting is not subject to the same Health Insurance Portability and Accountability Act (HIPAA) limitations as other protected health data.[47] Covered entities, such as healthcare providers, are required to submit patient information for reportable conditions to protect the health and safety of the public.[46-48]

The types of conditions that are reportable are similar across jurisdictions. The CDC monitors more than 120 notifiable conditions as reported by public health agencies.[46] This overarching reporting process enables local detection of diseases or situations of concern, such as an outbreak of foodborne illness or lead contamination in drinking water, and a national perspective spanning multiple states and other jurisdictions.

CSTE forms recommendations as to which conditions should be nationally notifiable, develops case definitions and provides uniform criteria for the submission of those and other reportable conditions annually. It is important to note, some conditions are reportable in certain jurisdictions but are not nationally notifiable. A comprehensive list of infectious and non-infectious condition case definitions is located here: Surveillance Case Definitions for Current and Historical Conditions (cdc.gov).[49] The CSTE position statements which contain recommendations for surveillance case definitions are located here: Position Statement Archive | Council of State and Territorial Epidemiologists (CSTE).[50]

Case data captured during public health investigations typically includes demographics, symptoms of disease, diagnostic information, treatment, other relevant clinical information, close contacts, and exposure information.[46] The type of case data obtained are different for each reportable condition or category of conditions. For example, the investigation of a case of respiratory illness such as pertussis might involve questions about duration and proximity to others. These same questions might be used for other similar infectious respiratory conditions. Investigation of a case of an enteric pathogen, such as salmonellosis, centers on foods consumed and can be used for other foodborne pathogens.

Case reporting by health care providers and laboratories occurs through a variety of methods, depending on the jurisdiction's reporting code or laws. Reports may be made by phone, fax, mail, ELR, eCR, and occasionally secure email and other methods (e.g., web form).[22] Public health agencies in all 50 states accept ELR to receive reportable laboratory results from laboratories, and more broadly accept syndromic surveillance data, electronic

case report data, and immunization registry data.[51] A more comprehensive method of case reporting from providers and medical facilities is eCR. With support through the CDC's Data Modernization Initiative, eCR has been scaling up rapidly since the early stages of the COVID-19 pandemic. Despite the ability to report to public health in multiple ways, case reporting is not always timely and underreporting is problematic.[52] In addition, many public health jurisdictions struggle with the ability to scale case surveillance efforts in a crisis where the volume of reports is high. Continual challenges with completeness and timeliness of reporting, difficulty obtaining clinical data, lack of automated exchange capabilities, and insufficient staffing, especially in times of public health crisis, inhibit the timely collection and analysis of epidemiologic data and the reporting of cases to STLT. These challenges impede a rapid and efficient public health response.[53] The concerted efforts of CDC's Data Modernization Initiative and federal funding provided in response to COVID-19 are helping public health agencies make progress in resolving some of these challenges.[54-56]

Background on ELR, eCR, and USCDI

Functional process of ELR

For more than a decade, ELR) has been used to provide electronic transmission of lab results of reportable conditions from laboratories to public health. The ELR implementation guide for public health reporting uses HL7 v2 standards.[22,57]

Laboratory test orders are received (electronically) or entered (manually) by a laboratory into their laboratory information management system (LIMS). The information in the LIMS is used to create standardized electronic messages such as HL7 v2 compliant messages. Laboratory test and result information is translated to codes from standard code systems (e.g., LOINC, SNOMED CT) within HL7 message fields. Public health agencies receive HL7 messages either directly from the laboratory, via a Health Information Exchange (HIE) or via the Association of Public Health Laboratories (APHL) APHL Informatics Messaging System (AIMS) and then extract the message contents into a disease surveillance system.[22,58-60]

Functional process of eCR

The electronic Initial Case Report (eICR) and Reportability Response (RR), using CDA or FHIR standards, are the basis of electronic case reporting (eCR). The eICRs are created from clinical encounter data that exist in a patient's record in an EHR.[61] The eICR contains sections of information (e.g., Discharge Summary, Problems List, Medications List), and while there are standard structures in the CDA and FHIR standards, the way each section is populated and whether it is populated is determined by the healthcare provider and EHR vendor.[62-64] The eICRs are transmitted to the AIMS platform as either CDA or FHIR and can contain structured and unstructured data. Structured data might include a medication list, whereas unstructured data might include a clinical image (e.g., x-ray) or free text narrative. The AIMS platform hosts the Reportable Conditions Knowledge Management System (RCKMS), a decision support tool that evaluates eICRs against jurisdictional reporting rules authored by each public health agency.[65] Once a reportability determination is made, AIMS creates a RR that includes information for healthcare providers that identifies if the eICR document met reportability requirements for any condition, what jurisdiction(s) the eICR was reported to (if applicable), and information from the jurisdiction that is relevant to the reportable condition. The RR is returned to the healthcare provider that sent the eICR. For those eICRs determined

reportable, the eICR and the RR are delivered to the appropriate public health agency(ies). (Figure 1).[24,62,65-67]

Once public health agencies receive electronic messages (i.e., CDA or FHIR), each one must be parsed to make it a machine-readable version or they can use the human-readable version. Most public health agencies attach the human-readable version, often a HTML or PDF, to a disease event within the jurisdiction's disease surveillance system.[68-72] The machine-readable data may be moved into a relational database for ingestion into a disease surveillance system, which might require include validation steps such as comparison against ELR data or other version of the reportable disease report.[68,70,72] Some surveillance systems consume the eICR directly.[71] Public health agencies must decide which sections within an eICR to parse and establish a process for extraction. There are similarities for how each EHR vendor generates an eICR, but the contents vary by provider or health system.[69] For example, Health System X may not have opted to use a module within EHR A to capture pregnancy information, whereas Health System Y did. Even though they both have EHR A, pregnancy information is only available to be sent in an eICR from Health System Y.[69,70]

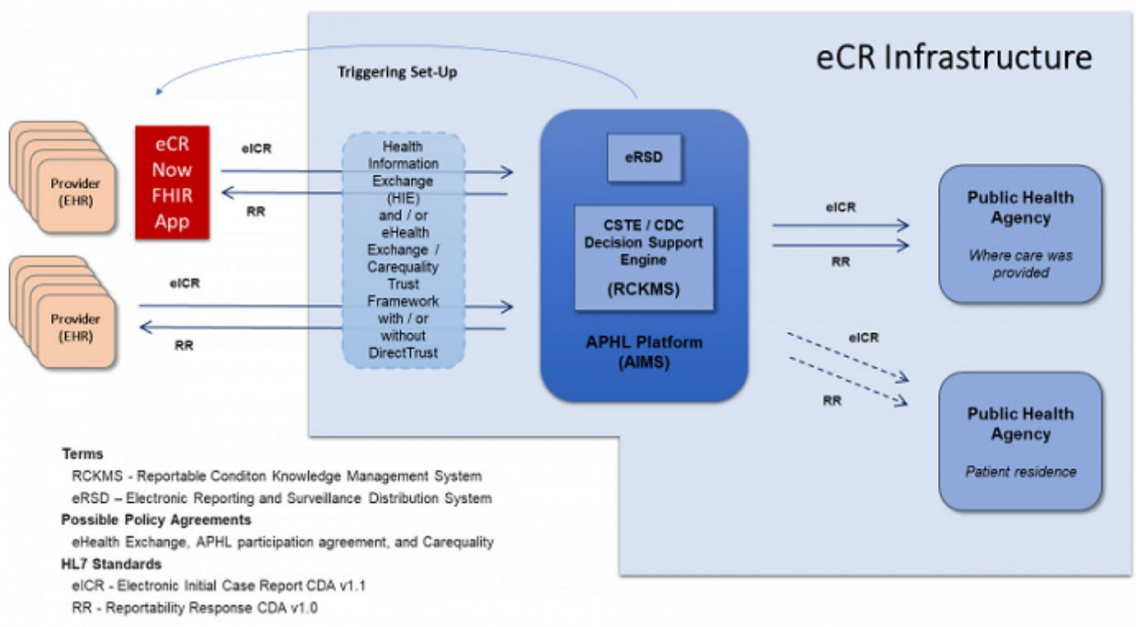

Figure 1. eCR reporting process[57]

As of April 2023, there were more than 25,000 healthcare facilities in all 50 states actively sending eICRs.[73] A total of 208 conditions can be reported through eCR, though reporting at this time is primarily limited to emergent conditions (COVID-19 and mpox).[74] To incentivize healthcare provider reporting, CMS's Promoting Interoperability Program (PIP) required hospitals, critical access hospitals and Merit-based Incentive Payment System (MIPS) providers to develop the capacity to send eICR starting January 1, 2023 in order to meet the public health objective.[75] Despite this requirement, there is still significant work to be done to ensure future usefulness of eCR and expansion to conditions beyond COVID-19.

USCDI

United States Core Data for Interoperability (USCDI) "…is a standardized set of data elements, like patient names and medication lists," that are required to be able to be exchanged electronically from EHRs.[58,76] USCDI serves as a starting point for what data elements EHRs must support. USCDI started with 52 data elements in 16 classes in V1 in 2020. There are now 94 data elements in 19 classes in V3.[77,78]

Data elements are the most granular level of data exchanged. Data elements are grouped into "data classes". New elements and classes are added to future versions of the entire set of standards.[58] USCDI v2 provided new elements and classes to support the sharing of gender identity, sexual orientation, and social determinants of health.[79] USCDI v3 expanded to include 24 new data elements across six data classes focused on laboratory, medications, patient demographics/information, procedures, health status/assessments, and health insurance information.[77] USCDI v3 is the first version of USCDI to contain pregnancy status.[80]

The USCDI version required for EHR certification is determined by an ONC rule-making process. Only USCDI v1 is currently required for EHR certification; a version from 2015.[23,78] A rule proposed in April 2023 would implement the EHR provision of the 21st Century Cures Act. This would set a new baseline version of USCDI to v3 for EHR certification. The rule would include functional requirements for eCR. This change would provide a basis for improved pregnancy data reporting as USCDI v3 includes pregnancy status.[80]

The current state of pregnancy status reporting

Past recommendations

In 2017, the Public Health Task Force of the Health Information Technology Advisory Committee (HITAC) to the Office of the National Coordinator for Health IT (ONC) developed a work product with recommendations for reporting pregnancy status using the case of Zika virus. The group's recommendations included the following[81]:

- Promote reporting of pregnancy status for Zika and other reportable conditions where pregnancy status is relevant
- Prioritization of certain pregnancy-related data elements
- Promote use of "ask at order entry" (AOE) for capturing pregnancy through ELR; also promote use of a specific prenatal Zika test method
- Explore options for patients to self-report
- Encourage STLT to leverage existing public health authority to require reporting of pregnancy status
- Explore the use of clinical decision support to improve access to human readable guidance and identify patients at risk
- Support expanded use of eCR

There is alignment between the Task Force recommendations and the work of the PSRW. Several of the key points of this earlier work were naturally carried forward such as eCR and standard incorporation of pregnancy data elements in eCR; pregnancy status is slated for inclusion in v3 of the USCDI.[78] However, these recommendations were not formalized in a policy or position statement influential to changing reporting requirements.

Similar initiatives

In recent years, efforts to prioritize the capture of health disparities have increased with success. USCDI v2 includes a social determinants of health assessment.[25,26] This addition will provide patient-level information on food, housing, and transportation stability.[76,78]

There is another effort among laboratorians, informaticists, technologists, and public health officials to add sex assigned at birth, sexual orientation and gender identity (SOGI) to laboratory requisitions as separate, codified fields.[26] These demographic factors are clinically relevant to multiple laboratory tests; sex assigned at birth is often needed to determine the appropriate reference range for a lab test. SOGI is included in USCDI v2; however, the details on how laboratories should capture SOGI are still being defined.[76,77]

Syndromic surveillance is a public health data collection initiative that began over two decades ago and focused on quickly receiving de-identified emergency department data to identify unusual clusters of illness or potential bioterrorist events.[82,83] With the evolution of EHR systems and standardized electronic data transfer, it has evolved into a tool for jurisdictions to conduct all hazards health surveillance and monitoring of disease trends with utility across program areas.[84] Pregnancy status has been an optional data element within syndromic surveillance for years, with the most recent HL7 implementation guide moving to change the data element from optional to "RE", required if data are available.[85,86] The method of sending pregnancy status in syndromic surveillance HL7 v2.5.1 messages mirrors the method recommended in Recommendation II within this document, utilizing the OBX-3 and OBX-5 segments.[86] A key difference is the capture within syndromic surveillance is intended to be pregnancy status as reported by the patient, versus in the ELR recommendation the focus is on data entered by a provider. This distinction is captured by the different LOINC values described for use within OBX-3 of each data source.

Context for recommendations in this document

The following recommendations are applicable to COVID-19 and reportable conditions where the health of the pregnant person, fetus, or infant *may* be impacted by infection. This includes infection with pathogens with a *known* impact on a pregnant person, fetus, or infant, such as hepatitis B or COVID-19. These recommendations are also relevant to emerging or reemerging diseases where the impact of infection on a pregnant person, fetus, or infant is unknown. Rapid, early collection of pregnancy status and relevant data for emerging or reemerging cases of disease is essential to evaluating the impact of those diseases.

As previously stated, STLT public health agencies prioritize the determination of pregnancy status primarily in two scenarios:

1) Identification of a reportable condition (infectious or non-infectious) where there is known impact on the pregnant person, fetus, or infant; or,
2) Reporting of an emerging or reemerging disease where the potential health impact on a pregnant person, fetus, or infant is unknown.

At this time, the PSRW is not recommending reporting pregnancy status for all reportable conditions. While pregnancy status is often a data element collected in a public health disease investigation process, it is not presently feasible nor necessary to prioritize reporting

of pregnancy status for every reportable condition. Advances in the standardized pregnancy data capture in EHRs, combined with increased physician awareness and adoption of eCR may lead to widespread reporting of pregnancy status in future years.

Evaluation of practices and beliefs

As part of developing the framework for this recommendations document, the PSRW conducted an assessment in the summer of 2022 targeting STLT, laboratorians, clinicians, and federal agency staff. The assessment evaluated the importance of obtaining pregnancy status for cases of reportable conditions, current practices, and future practice preferences for reporting pregnancy status. The feedback received from those assessments as well as interviews with multiple individuals involved in various aspects of pregnancy status reporting were used to inform recommendations. Full assessment de-identified results are provided in Appendix B.

A total of 44 states and territories were represented in the assessment responses received. Within those states, 67 respondents represented STLT agencies, 15 represented laboratories (two clinical and 13 public health), nine were clinicians, and nine represented federal agencies. Participation of STLT agencies was requested through CSTE listservs routinely used for participation in workgroups, federal agencies included those represented on the PSRW, clinicians were recruited through the American College of Obstetricians and Gynecologists, and laboratorians were solicited through the PSRW and their colleagues. Multiple responses were received for the same agency, clinic, or laboratory.

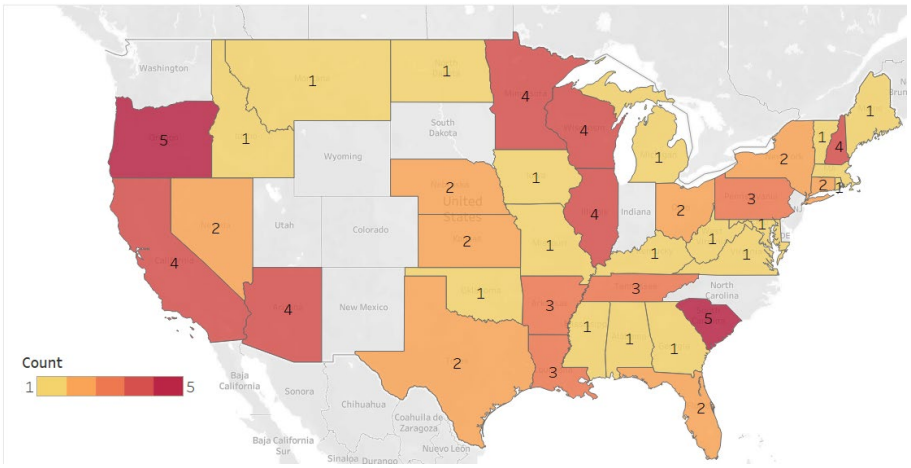

Figure 2. Respondent by employer state/jurisdiction

STLT practices and beliefs

STLT practitioners were asked to rate the importance of collecting pregnancy information across conditions. Respondents indicated pregnancy status was most important (9.79 out of 10) to report for "Notifiable (Reportable) diseases limited to conditions where the health of the mother or infant are impacted" with the next highest response rated 9.28 for "New or emerging diseases where the impact to mothers or infants is unknown" (Table 1).

Table 1. Scoring of the importance of reporting pregnancy status by disease category

For each of the following, indicate the level of importance for collecting...	Avg	Min	Max	Ct
Notifiable diseases limited to conditions where the health of the mother or infant is impacted (e.g., hepatitis B, syphilis)	9.79	7	10	47

New or emerging diseases where the impact on mothers or infants is unknown (e.g., Zika)	9.28	5	10	47
COVID-19	8.22	1	10	46
All notifiable (reportable) diseases/conditions	7.33	2	10	46

STLT agencies are most commonly using patient interviews to obtain pregnancy status, followed by provider outreach or ELR, extraction from electronic files (non-lab), eCR, vital statistics, and hospital discharge data (Table 2).

Table 2. Method for obtaining pregnancy status for COVID-19 and other reportable conditions (multi-select)

Method to obtain pregnancy status	COVID-19 (n)	Other Reportable Conditions (n)
Patient Interview	34	36
ELR (electronic lab reporting)	27	23
Provider reporting or outreach	26	30
Extracted from electronic files (non-lab)	21	19
eCR (electronic case reporting)	20	16
Vital statistics	18	23
Hospital discharge data	17	18

With regard to barriers, STLT agencies report experiencing the following barriers to receiving pregnancy status:

Table 3. Barriers to obtaining pregnancy status for COVID-19 (multi-select)

Q22 - Does your agency experience any barriers to obtaining pregnancy status for COVID-19? (select all that apply) - Selected Choice	Percent
No standard method to receive pregnancy status	64%
Inconsistent provider reporting at lab order entry	62%
Inconsistent receipt through electronic lab reporting	62%
Administrative code/law does not require reporting	52%
Staff time or expertise constraints	46%
Challenges in parsing status out of electronic data (ELR, eCR, or other)	34%
Inability to extract pregnancy status from EMR (electronic medical record)	30%
Other, please describe.	30%
Lack of fields to capture pregnancy in EMR (electronic medical record)	14%
No, we do not encounter barriers to pregnancy reporting or do not solicit pregnancy reporting.	6%

Based on these data, establishing reporting standards is most important followed by a focus on consistency in reporting, the need for administrative code/law, and others (Table 3). Agencies attest they are working on provider education and improving electronic reporting. When considering eCR, all STLT agencies can accept eICR for COVID-19, but only 68% are receiving eICR for non-COVID-19 conditions. More than half of agencies are working to expand the number of diseases accepted through eCR, with 39% indicating expansion of eCR within the next year and another 22% within the next five years. Barriers to expanding eCR include retaining/recruiting in-house expertise, receiving external assistance, insufficient technology infrastructure, and lack of participation from providers.

Reporting of pregnancy status indicated as "yes" or "no" was noted as sufficient for nearly all STLT agencies. Additional data elements preferred include pregnancy outcome, recent delivery, pregnancy outcome date, estimated delivery date, or delivery date.

Laboratory practices and beliefs

Laboratories primarily receive pregnancy status in requisitions for COVID-19 testing in the "ask at order entry" (AOE) field, followed by "relevant clinical information" and "comments". In addition to receiving orders for prenatal panels, the content of those electronic laboratory test order responses are most often pre-configured responses within AOE, then ICD-10-CM code, and free-form text.

Among laboratory respondents, half capture pregnancy status reporting for Zika virus, and 33% for syphilis and HIV from provider orders. Laboratorians agree with STLT that simple "Yes" or "No" responses are adequate. Three-quarters of laboratory respondents believe pregnancy status should not be reported by laboratories, though more than half have the ability. Laboratorians indicate reporting requires 4.2 out of 10 in terms of effort. If reporting is required, laboratorians prefer pregnancy status be codified in AOE.

In additional feedback obtained through 1:1 interviews, Commercial Lab A indicated reporting into the AIMS platform was not arduous but long-term reporting of pregnancy status from laboratories is not appropriate.[25] Commercial Labs A and B agree that laboratories should not be receiving, capturing, or reporting pregnancy information if not clinically relevant to the test being performed. Labs have been asked for decades to capture pregnancy status with no long-term plan for standardization for reporting or specificity by disease whether through agreement between large national labs or laboratory association consensus. COVID-19 was the first-time reporting pregnancy status by laboratories to STLT was required by the Department of Health and Human Services (HHS). Even with a requirement, pregnancy was rarely reported in a patient as clinicians can select or enter "unknown" to meet the data entry reporting requirement.[25,26]

Despite opposition to laboratory responsibility for reporting, Commercial Lab A sees value in reporting laboratory results into a centralized repository such as AIMS.[25] Non-infectious conditions such as lead screening or cancer, in addition to infectious diseases, are already being reported through AIMS. Commercial Lab B is supportive of a centralized reporting repository for public health data exchange but believes incentives, such as financial support to connect to AIMS, should be provided to all participants. Lab B supports national management of a centralized system and believes states would obtain better data if coordinated in this way.[26]

Clinicians' practices and beliefs

Clinicians strongly support reporting pregnancy status for conditions where the pregnant person, fetus, or infant's health may be impacted (9.75 out of 10). Respondents indicated high levels of support for reporting pregnancy status for all reportable conditions. Most indicated pregnancy status is reported to laboratories through dedicated fields or using pregnancy-related diagnostic codes.

When asked about barriers to reporting, clinicians indicated a lack of the ability to program or extract pregnancy status from their EHR to STLT is highest followed by a lack of reporting standards and also lack of provider awareness of the need to report. Clinicians indicate EHR fields are present to capture relevant information. However, it is widely acknowledged there are many different ways pregnancy status is captured in an EHR, which presents added difficulty in uniformly extracting pregnancy status for use in eCR. The fields noted as important to report to STLT include gestational age, estimated delivery date, and evidence-based pregnancy status (e.g., ultrasound).

Federal agencies' practices and beliefs

Federal agency beliefs on the importance of pregnancy status reporting align with those of other respondent groups (9.5 out of 10 for conditions affecting the health of pregnant persons, fetuses, or infants). Federal agency staff express significant effort is required to obtain pregnancy status, which occurs most often through vital records (e.g., birth certificates). This perception does differ from STLT as the mechanism of acquiring pregnancy status through vital records is more labor intensive. Federal agency respondents feel strongly the expansion of eCR is needed to improve pregnancy status reporting. Gestational age and pregnancy outcome were designated as the most important variables to obtain in pregnancy status reporting.

Recommendation I: Inclusion of pregnancy status for reportable conditions in state, territorial, local and tribal administrative code or law

The PSRW recommends jurisdictions draft or modify administrative code or laws to include pregnancy status as a required clinical data element for reportable conditions where the health of a pregnant person, fetus, or infant may be affected. This includes specific language to require a pregnancy indicator for all emerging or reemerging conditions in addition to conditions with known impacts on pregnant people or their fetus/infants.

Jurisdictional reporting requirements should center on the capabilities present and planned within the agency for managing reportable condition investigations. If ELR is the only method available for reporting a condition, a jurisdiction should promote standardization of reporting pregnancy status from laboratories. If both ELR and eCR are available, both should be available for reporting. Jurisdictions should include language to ensure pregnancy status capture in all reporting methodologies. This recommendation aligns with previous recommendations as well as the future of USCDI
EHR configuration requirements.[78,81]

Model state language should include the following elements:

1) A requirement to report pregnancy status for reportable conditions where the health of a pregnant person, fetus, or infant may be affected. This includes:
    a. Reporting requirement specific to certain *conditions* –
        i. Emerging or reemerging diseases (e.g., COVID-19, mpox, Zika virus)
        ii. Any condition with known impacts on a pregnant person, fetus, or infant's health, including but not limited to:
            - COVID-19
            - Hepatitis B
            - Hepatitis C
            - Syphilis
            - HIV
            - Rubella
            - Listeria
            - Zika virus
            - Novel influenza
            - Elevated blood lead
    b. Specificity for reporting *method* using electronic laboratory and electronic case reporting
    c. Reporting of pregnancy status as a *specific data element (and preferably estimated date of delivery)*

It is important to note public health agencies should specify exactly which pregnancy data elements are required when drafting or modifying administrative language. This level of detail may not be appropriate for codification but should be determined before the finalization of administrative language. There may also be a need to ensure pregnancy data

remain protected and are not available for release beyond the purpose of public health investigation.

Administrative code or law language should include a minimum data standard for indicating pregnancy status, such as the recommended ELR guidance in this document or a reference to the version of the current eCR standard utilized for reporting.

Multiple states have comprehensive administrative language for ELR. For example, Florida administrative code contains ELR language including HL7 specificity and pregnancy status reporting (Table 1).[87] Nebraska code outlines a requirement for electronic laboratory reporting and laboratory ordering (Table 1).[88] A listing of some jurisdictions with administrative code or laws addressing pregnancy status reporting is available in Table 1. While not inclusive of all state reporting requirements, the table includes a representation of various approaches to administrative and law verbiage.

Massachusetts administrative code contains a section of language confirming access to medical records including electronic health information.[89] This might be useful to reference when requesting public health data for case investigations regardless of the way health data are provided to the public health agency.

Utah's reportable disease language also requests expected date of delivery (EDD), and specifies the method of data delivery as electronic laboratory reporting and electronic case reporting. Utah is the only state determined to have administrative language for electronic case reporting.[90]

Minnesota administrative code specifies reporting of pregnancy status and expected date of delivery if the infection can be transmitted during pregnancy or delivery. This language is unique in requiring EDD, which is a valuable data element for determining if a pregnancy is current or occurred in the past.[91,92]

Table 4. Pregnancy status reporting language by state

Jurisdiction	Web Citation	Diseases Covered	Reporting Method
Utah[90]	R386-702-Communicable-Disease-Rule.pdf (utah.gov)	Certain perinatally-transmitted diseases include: hepatitis B infection; hepatitis C infection; HIV infection; listeriosis; rubella; syphilis infection; and Zika virus infection	All disease reporting entities
New York City[93,94]	NYC Health Code, TITLE 24. Article 13, §13.03	Hepatitis B; pregnancy status is considered a reporting element	Laboratory/ELR/paper/case investigation
	Article 11 (nyc.gov)	Syphilis specific reporting language for provider testing in pregnancy	

Nebraska[88]	www.nebraska.gov	Pregnancy status should be reported if available and applicable; also specifically for HIV	All disease reporting entities also have ELR requirement
Alaska[95]	7 AAC 27.005 - Reporting by health care providers | State Regulations	All; pregnancy status is considered a reporting element. Also specifically for hepatitis B, HIV, and syphilis.	All disease reporting entities
Kansas[96,97]	Kansas Secretary of State - KAR Regulations (ks.gov) Kansas notifiable disease form	All; pregnancy status is considered a reporting element. Also specifically for hepatitis B and HIV.	All disease reporting entities
Iowa[98]	139A.3.pdf (iowa.gov)	All; pregnancy status is considered a reporting element	All disease reporting entities
Minnesota[91]	4605.7044 - MN Rules Part	All perinatally-transmitted diseases	All disease reporting entities
Rhode Island[99,100]	Section 216-RICR-30-05-1.5 - Timeframe, Methods, and Reportable Conditions, 216-30-05 R.I. Code R. § 1.5	All perinatally-transmitted diseases	All disease reporting entities
	Section 216-RICR-30-05-1.6 - Special Disease Surveillance Projects, 216-30-05 R.I. Code R. § 1.6	Discretionary reporting code	
Philadelphia[101]	Philadelphia Department of Public Health - Report A Disease - PDPH Health Information Portal	Hepatitis B or C, HIV	All disease reporting entities
Arkansas[102]	Rule 007.15.00-003 - Rules and Regulations for Communicable Disease Control - Prenatal testing of pregnant women for sexually transmitted diseases, 007-15-00 Ark. Code R. § 3	HIV, syphilis, hepatitis B	Provider testing, laboratory reporting
Florida[87,103,104]	Disease reporting Notification by laboratories Notification by practitioners	Hepatitis (all types); syphilis, plus special rules for Hepatitis B	Laboratory
Hawaii[105]	Communicable disease reporting	Hepatitis B testing in pregnancy	Laboratory
Mississippi[106]	MDH Rules and Regulations Manual Template (ms.gov)	Hepatitis B and HIV in pregnancy	All disease reporting entities
Missouri[107]	Diseases and Conditions Reportable In Missouri (19 CSR 20-20 (mo.gov)	Hepatitis B and HIV in pregnancy	All disease reporting entities
New Hampshire[108]	Section He-P 301.02 - Reportable Diseases, N.H. Code Admin. R. He-P 301.02	Hepatitis B in pregnancy	All disease reporting entities

Recommendation II: Minimum standards for electronic laboratory reporting

The PSRW recommends minimum standards for capturing and reporting pregnancy status for laboratories. As previously stated, these recommendations are limited to COVID-19 and nationally reportable conditions where the health of the pregnant person, fetus, or infant *may* be impacted by infection. This includes infection with pathogens with a *known* impact on a pregnant person, fetus, or infant, such as hepatitis B or COVID-19. These recommendations are also relevant to new, emerging, or reemerging diseases where the impact of infection on a pregnant person, fetus, or infant is unknown.

Electronic laboratory reporting is not commonly used for capturing and submitting pregnancy status to public health agencies.[59] However, during COVID-19, pregnancy status was a required data element for COVID-19 laboratory reporting which most labs accommodated by using the "ask at order entry" field.[25,26] Outside of COVID-19 case reporting, pregnancy status is not often captured by laboratories as it is not clinically relevant or required for the interpretation of the test results. There is no established field for capturing pregnancy status in a lab order or for reporting it to a public health agency in an ELR data feed. [95,96,59] A few states successfully capture pregnancy status by ELR for explicit conditions such as perinatal hepatitis B, but reporting is not consistently used by all providers ordering labs or laboratories reporting conditions to public health agencies. Jurisdictions receiving pregnancy status through ELR include the City of Philadelphia and New York City (limited to perinatal hepatitis B).[52,109]

Laboratory capture and reporting to STLT

For jurisdictions that want to start capturing pregnancy status via ELR, the best practice is to use the observation (OBX) segment in HL7 v2 messages using the following terminologies for laboratory reporting of pregnancy status[59,110]:

OBX-3 (Observation identifier) using LOINC 82810-3 (Pregnancy status)

AND

OBX-5 (Observation value) using SNOMED CT 77386006 (Patient currently pregnant) or 60001007 (Not pregnant)

Using an OBX to report pregnancy status is the most precise way of exchanging that information to public health regardless of how the knowledge was obtained at the laboratory (either by AOE, diagnosis code (ICD-10-CM code or problem list) or based on the type of test ordered (prenatal panel) or performed (pregnancy test). For more specifications, see Table 2.

Some laboratories use OBR-13 or 31 to indicate pregnancy status using text. This may be manually extracted and analyzed by public health agencies, but extraction requires significant effort and possibly delayed identification of pregnancy. It is recommended to use the OBX reporting approach as previously described.[59]

To reiterate, changes in administrative code or law specific to the condition(s), data elements (i.e., pregnancy status (Y/N/UNK), estimated date of delivery), entities required to report

these data (e.g., providers, laboratories), and reporting method (e.g., ELR, eCR, fax) may be necessary to implement this reporting process. Most laboratory tests for reportable conditions do not require pregnancy status for clinical interpretation of laboratory results; therefore, pregnancy status is not routinely obtained by laboratories.[25,26,59] Pregnancy status can be inferred for lab test panels such as perinatal disease tests.[111]

Table 5. Laboratory guidance for reporting pregnancy status using ELR: Recommended segments and additional options

Field	Value	Source	Notes
Recommended Approach			
OBX-3	82810-3^Pregnancy status^LN	AOE or another source	Observation identifier; not repeatable. Contains the question. OBX-5 contains the response.
OBX-5	77386006^Patient currently pregnant (finding)^SCT 60001007^Not pregnant (finding)^SCT 261665006^Unknown (qualifier value)^SCT OR UNK^Unknown^NULLFL	AOE or another source	Observation value
OBX-29	QST		Added in v2.9, Observation Type distinguishes an observation sent with an order from an observation that is the result of an order. It may not be present in all ELR messages, but adopting its use is recommended.
OBX-30	AOE – at order entry ASC – at specimen collection		Added in v2.9, Observation Sub-Type provides more detail on the Observation Type. In the current example, the proposed values indicate when the pregnancy question was asked. It may not be present in all ELR messages, but adopting its use is recommended.
Alternative Approaches Currently Utilized, though not Recommended			
OBR-13	"Pregnant" "Prenatal" "Probable Pregnant"	Relevant clinical information	This may be abstracted from the DG1 segment included with the related order. Response options depend on lab configuration. This field can contain a simple text string or code. It is often used for tests requiring clinical information and is not the best suited for capturing pregnancy status.
OBR-31	"Pregnant" "Prenatal"	Reason for study	Abstracted from the DG1 segment included with the related order.

	"Probable Pregnant"		Response options depend on lab configuration. While this field is a coded element (may use ICD-10-CM codes and could use SNOMED CT), it is not reserved for pregnancy status. Consequently it is NOT recommended for use as it requires manual or analytic process extraction.
OBR-39	"Pregnant", "Prenatal", "Probable Pregnant"	Collector's Comments	Response options depend on lab configuration. While this field is using a coded element, it is not reserved for pregnancy status and contains only the response. Consequently it is NOT recommended for use as it requires manual or analytic process extraction.
NTE-3	"Pregnant" "Prenatal" "Probable Pregnant"		Follows the OBR. Can contain free-form text. This field is NOT recommended for use as it requires manual or analytic process extraction.

Alternatives to HL7 field-based reporting

Lists of pregnancy-related lab tests (e.g., excel workbook, line list) or patient line list

In several jurisdictions, laboratories provide lists of pregnancy-related lab tests or patient line lists typically associated with pregnancy for when the patient also has a reportable disease. When a pregnancy-related lab test list is provided, a LOINC or local code in the lab order is often used to indicate pregnancy. Laboratories also occasionally supply patient line lists where pregnancy is indicated, whether through the identification of pregnancy or prenatal test type, reporting of an ICD-10-CM code indicating pregnancy, or supplemental data obtained at test order entry. While this approach is not recommended by this group, the PSRW recommends the use of the ICD-10-CM code Z33.1 for denoting pregnancy. [59]

ICD-10-CM reporting within HL7 messages

Several jurisdictions also receive ICD-10-CM confirmation of pregnancy status in various fields of an HL7 ELR message, such as OBR-31, OBR-13, NTE, or PV1. While this approach is not recommended by this group, the PSRW recommends the use of the ICD-10-CM code Z33.1 for denoting pregnancy.

Neither of the aforementioned alternative approaches are recommended by the PSRW as a standardized method of pregnancy status reporting unless already an established process within a jurisdiction.

Recommendation III: Advancement and expansion of electronic case reporting (eCR)

The PSRW recommends all jurisdictions prioritize ingestion, extraction, and use of eCR for pregnancy status reporting. The eCR process requires reporting of a pregnancy status observation, when available.

As previously stated, these recommendations are limited to COVID-19 and reportable conditions where the health of the pregnant person, fetus, or infant *may* be impacted by infection. However, eCR captures pregnancy status when available within an EHR regardless of the condition being reported. Consistent capture of pregnancy status information will improve completeness and quality of data received by PHAs across all reportable conditions available in eCR.

Details on eICR capture

CDA or FHIR HL7 standards are used to instruct the generation of eICRs. For more information on how CDAs are generated, processed by APHL AIMS, and sent to public health agencies, zz. It is important to note, public health agencies cite pregnancy status is not often received through the eCR process.[68-70,72] When pregnancy status is not provided as specified in the eCR implementation guide it is difficult to extract from an eICR document as it may be part of a section of non-coded text or not in a consistent location.[86] The dates needed to determine whether the pregnancy is new or current or in the past are not always present. The structure to report pregnancy status within an eICR via CDA is defined as described below but is not often available or formatted incorrectly.

According to the eICR implementation guide v1.1, pregnancy status is captured as an assertion in a Pregnancy Observation within the Social History section of the CDA document.[69,71,72] According to the eICR implementation guide v3.1, pregnancy status is captured as a Pregnancy Observation within the Social History section, and expands the value set allowed to include options for "Possible pregnancy", "Not pregnant", and "Pregnant". In both v1.1 and v3.1, the Pregnancy Observation is an optional entry in the Social History Section. There is currently no requirement for the inclusion of a Pregnancy Observation within an eICR document.

If pregnancy status is present in the EHR for a provider to indicate, it is expected to be reported as a Pregnancy Observation within the Social History section of the CDA; however, if not present in the EHR, the Pregnancy Observation may be left incomplete. This same decisioning applies to the additional pregnancy-related observations within the Pregnancy Section (i.e., gestational age, pregnancy outcome).[23,64] If an EHR is not configured to report pregnancy status within the Pregnancy Observation of an eICR, pregnancy status may be reported as a Problem Observation. If a patient is currently pregnant, SNOMED or ICD-10-CM codes indicative of pregnancy may incidentally be found as a Problem Observation. The eICR implementation guides do not specify Problem Observation as a standardized method of pregnancy status reporting and this approach is not recommended.

The Pregnancy Section includes an extensible set of observations:

- The pregnancy observation must be present within the Pregnancy Section if the section is present. All other observations within the Pregnancy Section are optional for reporting.
- The following elements are available for capture by eCR:
    - Pregnancy status recorded date
    - Pregnancy status date range
    - Pregnancy status (see Table 6)
    - Pregnancy status determination method
    - Pregnancy intention in the next year
    - Last menstrual period
    - D(Rh) type
    - D(Rh) type sensitized
    - D immune globulin (RhIG) given
    - Estimated gestational age of pregnancy determination date
    - Estimated gestational age of pregnancy method
    - Estimated gestational age (in days)
    - Estimated date of delivery determination date
    - Estimated date of delivery determination method
    - Estimated delivery date
    - Pregnancy outcome (added in V2.1.0)
    - Pregnancy outcome determination date
    - Pregnancy outcome determination method
    - Postpartum status (added in V2.1.0)
    - Postpartum determination date
    - Postpartum determination method

There is currently no requirement for the reporting of pregnancy status as a Pregnancy Observation; in other words, an eICR record will not be rejected if a Pregnancy Observation is not present. As not all EHR systems are able to report pregnancy status within the Pregnancy Observation of an eICR, another data capture method utilized by RCKMS to try and identify pregnancy status is as a Problem Observation. If a patient is currently pregnant, SNOMED or ICD-10-CM codes indicative of pregnancy may incidentally be found as a Problem Observation. The eCR implementation guides do not specify Problem Observation as a standardized method of pregnancy status reporting.

For more information on eCR pregnancy status HL7 FHIR standards[76], use this web link: eCR Pregnancy Status HL7 FHIR standards.

For more information regarding HL7 CDA implementation of eCR[110], see this web link:

https://www.hl7.org/implement/standards/product_brief.cfm?product_id=436

And utilize this version of the HL7 CDA Implementation Guide:

HL7 CDA® R2 Implementation Guide: Public Health Case Report - the Electronic Initial Case Report (eICR) Release 2, STU Release 3.1 - US Realm (see 2.13 pregnancy section)
Please note, current implementation efforts are widely based on v1.1 also located on the site linked above.

The following value set is recommended for use in populating the Pregnancy Observation in the Social History section (Table 6).

Table 6. Pregnancy status value set

102874004	Possible pregnancy (finding)	SNOMED CT
60001007	Not pregnant (finding)	SNOMED CT
77386006	Pregnant (finding)	SNOMED CT
UNK	Unknown	HL7 V3 Nullflavor

Additional eCR recommendations

Evaluation of the frequency and completeness of reporting pregnancy status via eCR is needed. Determining how often pregnancy status is available for reporting from an EHR will help inform whether requiring reporting of the Pregnancy Observation is feasible. Adoption of USCDIv3 into the requirements for certified electronic health record technology (CEHRT) would incentivize EHR vendors to make this data element available for reporting. Efforts should be made during the eCR onboarding process to ensure data within the Pregnancy Observation are correctly formatted when the section is present. Significant work is needed to ensure pregnancy status is consistently included in an eICR with relevant dates and supporting information. Currently, providers/facilities who have implemented eCR have onboarded to send information according to the v1.1 eICR implementation guide, which does not include the supplemental pregnancy information. Readiness to accept data elements contained in the eICR implementation guide v3.1 by the AIMS platform and widespread adoption of the v3.1 standard by senders is essential for capturing additional pregnancy details and should be considered as PHAs set future requirements for active engagement of providers and hospitals desiring to meet the promoting interoperability program requirements. This work will require collaboration from provider groups, EHR vendors, and public health.

Recommendation IV: Essential Supporting Activities

USCDI/Office of the National Coordinator (ONC) and eCR alignment

Promotion of adoption of USCDI v3 and functional standards for eCR

The PSRW recommends adoption of the proposed rule for "Health data, technology, and interoperability: certification program updates, algorithm transparency, and information sharing".[112] This change would establish a new baseline version of the USCDI and would provide enhancements to support information sharing under information-blocking regulations.[112]

With regard to eCR, functional requirements from 2015 are replaced with consensus-based standards according to § 170.315(f)(5) that include:[112,113]

- Standards defining the functional requirements of eCR:
    - Create a case report for electronic transmission;
    - Consume and process a case report response; and
    - Consume and process electronic case reporting trigger codes and parameters.
- Transmit a case report electronically to a system capable of receiving an eICR
    - Agnostic to the recipient of the electronic case report; and
    - Does not prescribe a specific transport standard, reporting mechanism, or platform

The rule also mentions both the current HL7 C-CDA standards and the current HL7 FHIR-based standards as options. Few public health agencies have adopted FHIR-based messaging information systems, but interest may grow with the need to align to other programs using FHIR.[113]

It is important to note, the change from an "edition"-based structure allows more consistent, incremental updates that recognize standards advancement, allow voluntary advancement in between certification standard updates, no longer require the entire certification of the Health IT Module, and provides predictable timelines for standards development cycles.[113]

Lastly, these rule changes are inclusive of a move from USCDI v1 to v3. USCDI v3 includes the Pregnancy Section of a CDA. Adoption of USCDI v3 by ONC into the requirements for EHR certification incentivizes vendors to capture the pregnancy status data elements in EHR systems in a way that is transmittable to public health. While this shift ensures better data capture in the future, the change will take years to implement.[114]

Provider reporting, education, and incentivization

EHR configuration

The PSRW recommends providers and health systems prioritize the inclusion of pregnancy status variables in EHR interfaces for providers to use for reporting. EHR vendors are only required by ONC to provide USCDI v1 elements in EHR technology, which does not include pregnancy status.[115] However, health care providers and health systems have not identified a uniform approach for capturing pregnancy status in an EHR interface. Adoption of USCDI v3 by ONC into the requirements for CEHRT would incentivize vendors to capture the pregnancy status data element in EHR systems in a way that is transmittable to public health.

Education

The PSRW recommends CDC, CSTE, STLT agencies, and the American College of Obstetricians and Gynecologists (ACOG) as well as other obstetrical and gynecological providers work to develop educational materials and approaches to inform providers of the need to report pregnancy status for every biologic female of childbearing age (15-49 years).[116,117]

Opportunities for reporting:

Providers should work with their EHR vendor to understand how to capture and improve reporting of pregnancy status within their EHR so that the elements can be extracted into the eICR for transmission to AIMS or public health via eCR.

AND

If a laboratory requisition has AOE questions or other relevant fields to collect pregnancy status, this information should be completed by the provider for relevant conditions. This utilizes the approach outlined in Recommendation II.

USCDI v3 Adoption & Provider Incentivization

The PSRW recommends the adoption of the proposed rule change to ONC Health IT Certification requiring USCDI v3. This change would establish a new baseline version of the USCDI and would provide enhancements to support information sharing under information-blocking regulations.[112]

With regard to eCR, functional requirements from 2015 are replaced with consensus-based standards according to § 170.315(f)(5):[112,113]

- Standards defining the functional requirements:
    - Create a case report for electronic transmission;
    - Consume and process a case report response; and
    - Consume and process electronic case reporting trigger codes and parameters.
- Transmit a case report electronically to a system capable of receiving an electronic case report
    - Agnostic to the recipient of the electronic case report; and
    - Does not prescribe a specific transport standard, reporting mechanism, or platform

The rule also mentions both the current HL7 C-CDA standards and the current HL7 FHIR-based standards as options. Few public health agencies have adopted FHIR-based messaging information systems, but interest may grow with the need to align to other programs using FHIR.[113]

Lastly, these rule changes are inclusive of a move from USCDI v1 to v3. USCDI v3 includes pregnancy status. Adoption of USCDI v3 by ONC into the requirements for EHR certification incentivizes vendors to capture the pregnancy status data element in EHR systems in a way that is transmittable to public health. While this shift ensures better data capture in the future, the change will take years to implement.[114]

With this rule change, public health agencies could consider including pregnancy status as one of the data elements required to meet promoting interoperability measures.[78,118]

It may also be advantageous to consider financial support to smaller/midsized providers to address the cost of adding pregnancy status reporting to an EHR user interface. Additional incentivization should be considered for electronic ordering for automated capture of pregnancy status to go directly into laboratory orders for relevant conditions.

Use of supplemental methods of reporting

The PSRW recommends the use of peripheral data sources to complement electronic efforts to obtain pregnancy status. Evidence of pregnancy is obtained by a few states and federal agencies through hospital discharge data, prenatal screening, newborn screening, and vital records registries. STLT agencies also use provider outreach, case investigation, including patient interview, and patient self-reporting to supplement current reporting practices. The PSRW believes the use of supplemental reporting methods should be minimized as most are very time-consuming requiring technical or manual intervention. In addition, most supplemental reporting methods are delayed data, which does not provide adequate time for intervention for most reportable conditions.

Policy brief development

The PSRW recommends furthering these recommendations in the form of a CSTE policy statement to place greater emphasis on the importance of STLT and laboratory standardization and progress towards eCR adoption, as well as collaboration with ONC and participation in ONC task forces to ensure robust input into CMS rules.

Sustained funding support for STLT

The PSRW recommends federal and state longitudinal funding for the workforce, technology, and tools required to advance electronic submission of reportable conditions including COVID-19 and other diseases impacting the health of a pregnant person, fetus, or infant. Various COVID-19 emergency and recovery funds are facilitating the rapid advancement of eCR in many states, but the momentum must continue.[52,53] Many states indicate they are decades behind in establishing costly, yet fundamental data infrastructure. Electronic reporting processes require advanced technical skills and abilities, and often complementary statistical knowledge. STLTs need support in setting the right foundation, procuring the right tools, and recruiting, hiring, and retaining a competent workforce. Federal financial support must be reliably sustained to ensure the future sustainability of public health digital activities.

Key components of financial support should be targeted for, though not limited to, the following:

1. STLT infrastructure investments, workforce investments, analytic tools, and other software support and services
2. Electronic reporting advancement efforts
    a. Improvements to ingestion, extraction, and use functions in the electronic data process
    b. Addition of new disease groupings for eICR

    c. Adjustments to current processes to ensure the use of all data elements supplied in electronic transmission processes
3. Technical assistance from CSTE, APHL, and CDC throughout ELR and eCR implementation efforts
4. Training for workforce knowledge advancement
5. Support for provider training to enhance awareness of pregnancy status reporting

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Appendix A

Past and current events of public health significance impacting pregnant people, their fetus or infant

Influenza A(H1N1)pdm09 – a novel pathogen

Influenza disproportionately affects pregnant people and infants, placing them at higher risk for severe illness and death. Pregnant people have been encouraged to be vaccinated against seasonal influenza regardless of trimester since 2004.[1,6] First identified in April 2009, the emergence of a triple reassortant (swine, avian, and human genetic components) presented a unique challenge for public health professionals[119]. There was a need to rapidly assess the impact of this new strain on pregnant people, but seasonal influenza surveillance programs were not equipped to investigate individual cases. Initial cases were manually investigated but reporting and surveillance quickly transitioned to focus on hospitalizations and deaths. To meet the need for surveillance among pregnant people, CDC established a Pregnancy Flu hotline for severely ill pregnant and postpartum case reporting.[37] While this allowed for case tracking of some pregnant people infected with A(H1N1)pdm09, STLT agencies had no reliable way to obtain case reports.[120] It was months into the pandemic before public health officials were able to characterize the heightened risk of severe illness and death among pregnant people.[6,37] Since 2009, enhanced and limited surveillance continues for influenza in pregnant populations, but there is still an absence of standard reporting requirements and mechanisms.[6]

Changes in the immune, respiratory, and cardiovascular systems during pregnancy result in pregnant people being adversely impacted by respiratory diseases, including influenza. Postpartum people are considered at higher risk for serious illness with influenza up to two weeks after delivery.[1] Novel strains of influenza have the potential to affect populations of people differently than seasonal flu viruses. The primary way to evaluate the impact of novel influenza strains is to first identify cases of pregnant or recently pregnant people while infected with influenza to obtain case investigation details to aggregate for population-level interpretation.[6,120]

Second only to vaccination, rapid administration of antiviral medication can significantly improve outcomes of influenza infection in pregnant people.[1,6,37] Public health can assist in the identification of pregnant cases through laboratory, hospitalization, and novel case review. Public health may also educate pregnant people on the need to seek treatment quickly.

When novel strains of influenza emerge in future years, rapid identification of infected pregnant people will be critical for investigation, possible administration of antiviral therapy, tracking differential impacts among pregnant people, and education on the importance of vaccination.

Zika virus – a reemergent pathogen

Zika virus was first discovered in 1947 in the Zika Forest of Brazil followed by a human case in 1952. The virus caused sporadic outbreaks in Micronesia thereafter, an isolated case in Colorado in 2008, then a substantial outbreak in French Polynesia in 2014-2015 which spread

to Brazil. This became the largest outbreak in history concentrated in Brazil and is attributed to interactions between World Cup soccer teams from the French Polynesian region and Brazil.[14,15,31]

Zika virus is spread by mosquitoes, sexual transmission, breastfeeding, and during pregnancy from an infected mother to her fetus.[16] Infection in pregnant people can cause severe brain abnormalities in the infant, with and without microcephaly, eye abnormalities, disabilities, and possible neurodevelopmental abnormalities.[31,43,45,121]

Surveillance for Zika virus infection in the U.S. began shortly after the outbreak began in Brazil. U.S. cases surged in 2016 with more than 5,000 reported, primarily acquired through travel. U.S. territories experienced substantially more cases with over 36,000 cases reported. Cases in the U.S. and its territories remained dramatically higher after 2016. Before 2016, only sporadic, travel-related cases were reported in the U.S.[4,43,44,122] Zika virus case counts could rise again at any time in the future.

Zika virus case investigation forms include the capture of pregnancy status, last menstrual period, pregnancy complications, pregnancy outcomes, and newborn complications.[123]

While there are no vaccines or treatments for Zika virus infection, prevention measures include CDC travel advisories for pregnant people considering or planning travel to countries with active outbreaks, promotion of mosquito repellent, and safe sexual practices.[4,16,43,45] The evidence to support the need for these prevention measures lies with the capture and thorough evaluation of pregnancy case data.

Year	US States Locally acquired**	US States Travel-associated†	US Territories Locally acquired	US Territories Travel-associated
2015	0	62	9	1
2016	224	4,944	36,367	145
2017	7	445	665	1
2018	0	74	147	1
2019	0	28	73	1
2020	0	4	57††	0
2021	0	2	32††	0

*Includes confirmed and probable disease cases
**Locally acquired cases reported from Florida and Texas in 2016 and 2017
†Includes cases acquired through other routes (e.g., sexual and laboratory transmission)
††In 2020 and 2021, all locally acquired cases of Zika in the U.S. territories were diagnosed by antibody testing. Since antibodies against Zika virus can persist for years after infection, serology cannot distinguish between a recent or past infection. Additionally, Zika and dengue virus antibodies cross-react, making it difficult to diagnose which virus is the cause of the current illness. Since 2019, there have been no confirmed Zika virus disease cases reported from U.S. territories.

Figure 3. Zika virus disease cases reported to ArboNET - United States, 2015-2020*[44]

Perinatal hepatitis B, hepatitis C, congenital syphilis, rubella, cytomegalovirus, and
Several other pathogens have known, significant impacts on pregnant people and their infants. For several of these diseases, rapid identification of pregnancy and clinical interventions are crucial to implementing prenatal and perinatal intervention thereby helping to prevent serious impacts on the fetus or infant. Identification of pregnancy must be complete, swift and comprehensive for interventions to be maximally effective.

Perinatal hepatitis B

Hepatitis B (HBV) is a high-risk infection for fetuses and infants born to hepatitis B-infected persons. With no known treatment, early identification of hepatitis B during pregnancy and prophylactic vaccination of exposed newborns along with immune globulin are essential to reduce the risk of transmission to infants during and after birth.[5,12,124,125] Identification of HBV infection in pregnant persons is critical as 40% of infants born to actively infectious mothers will become infected without the recommended post-exposure prophylaxis, with one-quarter of infected persons dying of chronic liver disease.[12]

Universal screening for hepatitis B is recommended during pregnancy and reporting of positivity in pregnant people is required by most state health agencies.[12,13,125] However, capturing and reporting pregnancy status when hepatitis B laboratory results are positive is complex. Most testing for hepatitis B in pregnant people is performed at large commercial laboratories. There is no national standard method for obtaining pregnancy status through hepatitis B laboratory testing requisitions. Laboratories can identify pregnancy status when hepatitis B testing is included as part of a prenatal screening panel.[3,10,13] However, routine clinical tests for hepatitis B infection monitoring (e.g., HBV DNA viral load, HBsAg) may be submitted for testing without pregnancy status indicated.

In an assessment conducted for this recommendations document project (Evaluation of Practices and Beliefs), the majority of state respondents (~72%) indicated the ability to capture pregnancy status for some non-COVID-19 conditions, including perinatal hepatitis B.[126] Electronic case reporting (eCR) standards accommodate the reporting of pregnancy status and supporting elements when present in an EHR. While pregnancy data elements are required to be made available by EHR vendors, health systems and providers must choose to have the elements programmed, and providers must also actively record pregnancy-related information in structured fields that are correctly mapped to the eICR message.[64] Other challenges to the reporting process for hepatitis B include ensuring the delivery hospital received the mother's hepatitis B results before birth. Hospitals might not have access to prenatal lab results which may result in a need to repeat testing at the time of delivery.[26,52]

There are several city public health entities that have demonstrated a degree of long-term success at electronic reporting of pregnancy status for hepatitis B, including New York City (NYC) and the City of Philadelphia. NYC obtains pregnancy status through health code-required reporting and electronically via ELR for 49.5% of cases.[109] When received through electronic laboratory reporting, the sensitivity of accurately identifying pregnancy status is ~93.1% according to the City of Philadelphia[24]. Despite legal, jurisdiction-specific reporting requirements, both cities still struggle to receive pregnancy status for hepatitis B from laboratory reports to preclude the effort of manually extracting text information through chart

reviews, contacting providers, or to a lesser extent, confirming pregnancy with patients.[52,109,127]

CDC has demonstrated success with intensive collaboration with STLT through the Perinatal Hepatitis B Prevention Program. With 64 jurisdictions participating, the program was able to achieve prevention of transmission in >99% of cases, with 97% of infants receiving prophylaxis at birth largely through investigation of individual cases. However, the approach to case management required to conduct this program is intensive and not scalable for diseases with higher incidence as each case must be individually investigated.[127] Electronic reporting of pregnancy status would result in significant efficiencies in case identification for perinatal hepatitis B.

Hepatitis C

Similar to hepatitis B, hepatitis C (HCV) is a high-risk infection transmissible from pregnant person to infant during pregnancy and birth. However, HCV is different from hepatitis B in that treatment is available but not vaccination. Hepatitis C is of growing concern among pregnant persons as rates of new infection among adults 20-39 rose by more than 60% from 2015-2019. HCV is transmitted from pregnant people to their infants in 5.8% of pregnancies with a higher transmission rate if the pregnant person is co-infected with HIV.[10,127,128]

The CDC recommends screening of all pregnant persons for HCV.[128] While treatment is not approved for use during pregnancy, it may be used after birth and the completion of breastfeeding. Treatment is not approved for children under the age of three.[36]

HCV does not cause symptoms in most people, but can lead to cirrhosis and liver cancer if left untreated.[5]

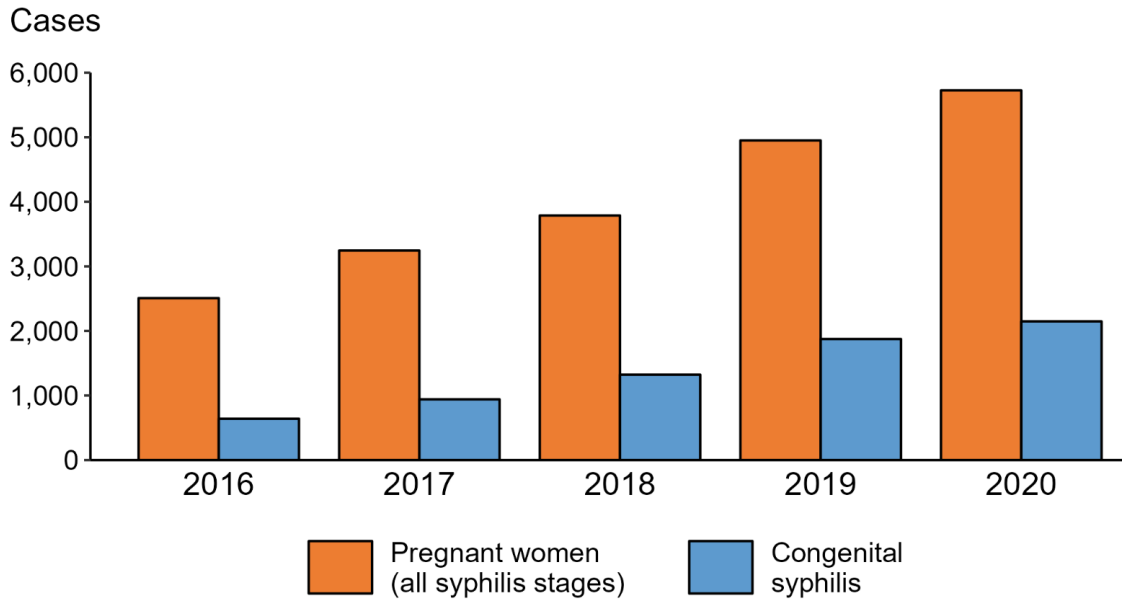
Congenital syphilis

Congenital syphilis incidence was 57.3 per 100,000 live births in 2020, which was a 245% increase from 2016. This increase is directly related to a surge in infections among pregnant people. In 2020, there were over 5,000 cases of syphilis in pregnant people.[7,32]

Syphilis is particularly dangerous for pregnant people and their fetuses or infants as many with people syphilis do not have symptoms that could lead to earlier detection and prevention of further spread. Syphilis during pregnancy can cause miscarriage, stillbirth, prematurity, low birth weight, and even death in pregnant people.[7,32] Of all syphilis cases among pregnant persons, 9% deliver prematurely. Infants born with untreated syphilis can be affected by deformed bones, anemia, hepatic injury, brain and nerve problems, and meningitis.[7,129]

Syphilis must be identified early in pregnancy to prevent fetal infection. Despite increasing transmission nationally, many physicians only test once during pregnancy (Figure 4). The American College of Obstetrics and Gynecology (ACOG) recommends repeating testing at 28 weeks. If detected, early treatment can be started to potentially avert transplacental infection of the fetus.[7] Reporting of pregnancy status along with a syphilis diagnosis is required in many states. However, there is no standardized way to report pregnancy status to STLT. Pregnancy status is reported via ELR, through vital records, hospitalization records, and manually through patient interviews and provider confirmation. Standardized reporting of

pregnancy status would improve time to treatment with public health intervention and provide more accurate epidemiologic insights into a prenatal and congenital infection.



NOTE: The percent of cases missing information on pregnancy status decreased from 20% in 2016 to 11% in 2020.

Figure 4. Syphilis– Reported Cases of Syphilis (All Stages) among Pregnant Women and Reported Cases of Congenital Syphilis By Year of Birth, United States, 2016–2020[74]

Rubella

Congenital rubella syndrome results from vertical transmission of rubella infection from a pregnant person to the fetus. Rubella infection early in pregnancy can have serious outcomes such as severe birth defects, stillbirths, and miscarriages. While eradicated in the U.S. in 2004, the prevalence of rubella in other countries presents a continuous risk for reintroduction. Therefore, vaccination of children, persons of childbearing age, and especially persons born outside of the U.S. is recommended.[33] The American College of Obstetricians and Gynecologists recommend testing for evidence of rubella immunity during pre-partum care.[130]

Cytomegalovirus

Cytomegalovirus (CMV) infects nearly one in three children by age five. By age 40, more than half of adults have been infected, most with no symptoms of illness. CMV can spread from pregnant persons to their fetuses in utero causing low birth weight and prematurity. One out of every 200 infants will be born infected with CMV and of those infected, one in five will have long-term health risks. There are no available treatments for CMV, though antivirals may be used for persons who are immunocompromised.[8]

Detection of these pathogens in pregnant persons does not provide an opportunity for intervention; however, clinical support following identification may improve health outcomes.

Non-infectious conditions

It is important to note that non-infectious conditions, whether surveillance is case-based or aggregate, contribute to the need to better capture pregnancy status. Capturing data on the comorbid conditions of people who are pregnant helps advance research on the possible connections between these conditions and pregnancy outcomes.[131] "[Non-infectious conditions are] important in pregnancy include neoplasms; mental conditions; endocrine or metabolic conditions like diabetes mellitus, hypo and hyperthyroidism; conditions affecting the cardiovascular system, such as hypertension and chronic rheumatic heart disease; and the haematological conditions of anaemia, sickle cell disease or thalassemia. They cover the spectrum of acute, transient, chronic and permanent conditions. Medical and obstetric complications can often be closely interrelated. For example, in diabetes mellitus, immediate medical concerns are focused on glycemic control with related obstetric complications such as macrosomia, obstructed labour and increased risk of infection. Longer term medical complications such as chronic hypertension and obesity are pertinent to obstetric sequelae, which include the future need for Caesarean section with concurrent risks of surgical intervention and requirements for anaesthesia, in line with the individual's overall health. Medical complications can thus affect not only the current pregnancy, but also future pregnancies and long-term health."[132]

Appendix B

CSTE/CDC Pregnancy Status Reporting Assessment Findings

Respondent Profile

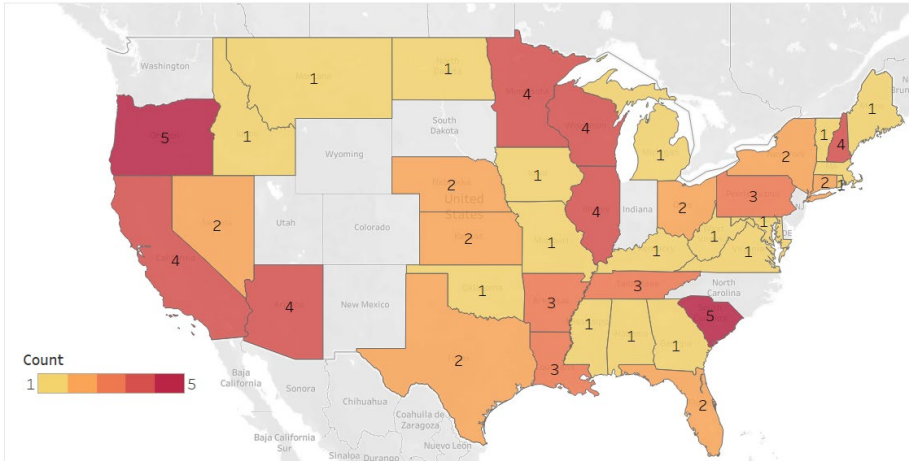
There were 112 responses across four assessments; 24 were anonymous.

Of the four assessment types, the number of respondents for each was the following:

STLT	74
Federal	13
Clinician	15
Lab	14

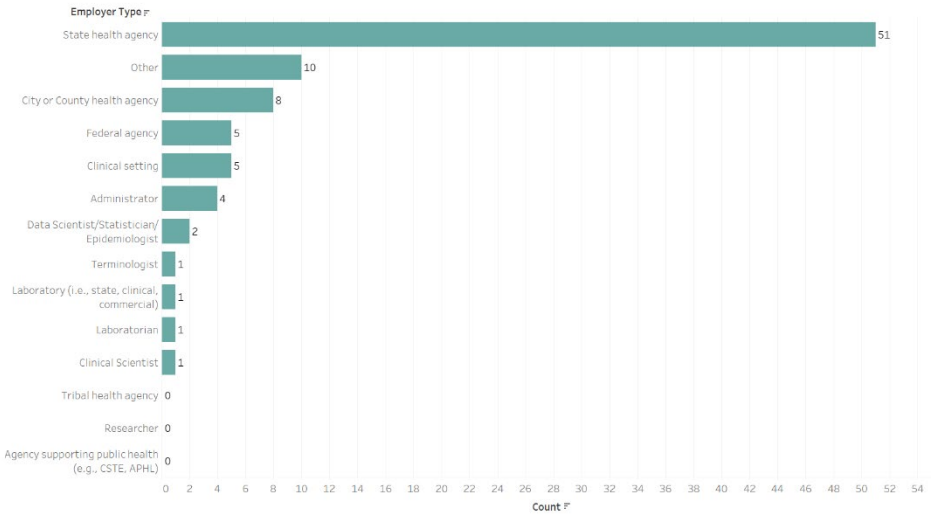
Jurisdictions represented across all assessments included:

- 41 states
- 2 national organizations
- 1 territory

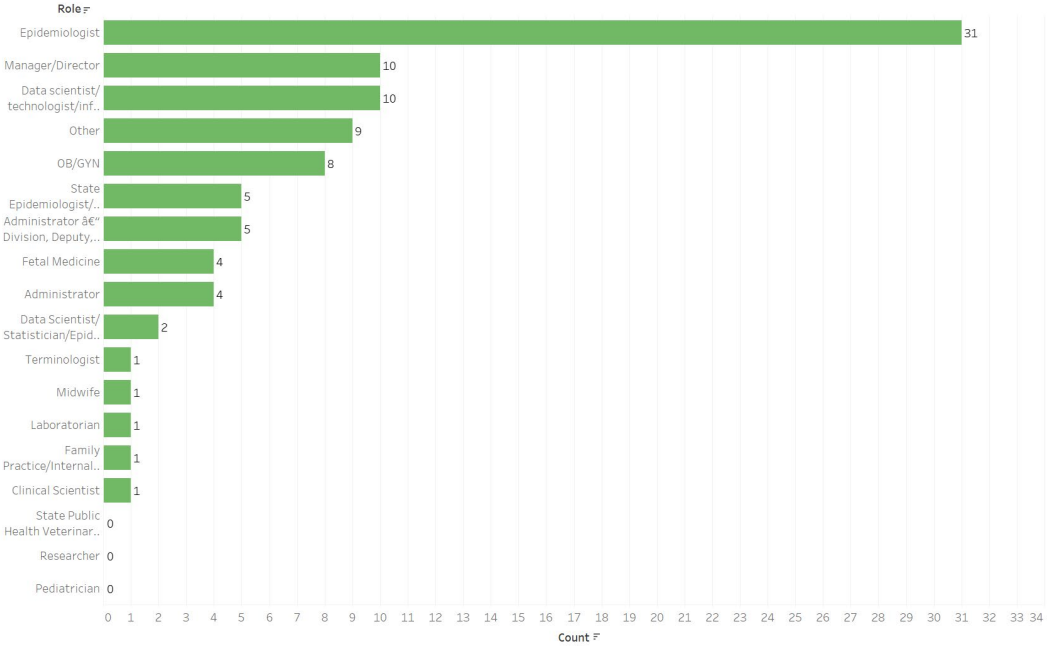


Count of respondents by state and any respondent category

The majority of respondents (n=51) were from state health agencies,10 were from other agency levels, eight from either city/county, five federal, five clinicians, and 10 from other agency types.



Respondent roles extended from epidemiologists (31), those in leadership roles (10), data scientists (10), and others.



Clinician Assessment Summary

Do you submit pregnancy status as part of laboratory test requisitions for patients where reporting to public health might be required (e.g., Perinatal Hepatitis B)?	Count
Yes	8
Not sure	1
No	0
Which field(s) are used to enter pregnancy status within a lab requisition (select all that apply)?	
Pregnancy-related diagnostic codes as billing codes	6
Dedicated pregnancy status fields when available	5
In free text comments	3

Other	0
Which of the following variables are routinely captured in your EMR for each patient (select all that apply)?	
Estimated Delivery Date	8
Evidence-based pregnancy status (i.e., LMP, ultrasound, lab test evidence)	8
Gestational Age	8
Delivery date	7
Last menstrual period	7
Pregnancy status (yes, no, possible, unknown)	7
Recently delivered/postpartum (within the past three months)	7
EDD determination method	6
Number of children born	6
Pregnancy Outcome	6
Date Gestational Age determined	5
Method of Gestational Age determination	5
Pregnancy Outcome date (e.g., date of delivery, miscarriage)	5
Postpartum status	4
Pregnancy status date recorded	3
All of the above	2
Expected delivery facility name	2
What do you perceive are barriers to ensuring public health notification of pregnancy status for COVID-19 and other infectious diseases of concern for pregnant women (select all that apply)?	
Pregnancy related data in EMR is not programmed to be sent electronically directly to public health systems	8
Lack of provider awareness of the need to report pregnancy status to public health	7
Lack of standard and consistent methods to report pregnancy status when ordering laboratory tests	7
Difficult to determine when reporting of pregnancy status is needed by public health	6
Inability of public health to receive electronic case data	4
Lab does not capture and send pregnancy status to public health	4
Staff resources and time are required to review pregnancy related data in medical records and data has to be provided in writing on paper forms or entered into electronic disease reporting systems by staff	4
Complexities of pregnancy status (may not be currently pregnant, do not know they are pregnancy, etc.)	3
Process to report pregnancy status is burdensome for my clinic	3
EMR does not capture pregnancy status data in dedicated fields	0
Other	0
For each of the following, indicate the level of importance for collecting...(1-10 scale)	Average
Notifiable diseases limited to conditions where the health or the mother or infant are impacted (e.g., hepatitis B, syphilis)	9.75
All notifiable diseases/conditions	9.13
New or emerging diseases where the impact to mothers or infants is unknown (e.g., Zika)	9.13
COVID-19	8.75

Laboratory Assessment Summary

Please indicate how your laboratory receives pregnancy status for COVID-19 and other categories of disease/condition.: COVID-19	
Ask at order entry	12
Relevant clinical information	2

Comments	1
Diagnostic codes under billing information	0
Other	0
Part of order name/pregnancy-specific test	0
Reason for study	0
Please indicate how your laboratory receives pregnancy status for COVID-19 and other categories of disease/condition.: Other notifiable diseases (excluding COVID-19)	
Ask at order entry	10
Diagnostic codes under billing information	2
Relevant clinical information	2
Comments	1
Other	0
Part of order name/pregnancy-specific test	0
Reason for study	0
Please indicate how your laboratory receives pregnancy status for COVID-19 and other categories of disease/condition.: Non-notifiable conditions of public health importance (e.g., cancer)	
Ask at order entry	2
Comments	1
Diagnostic codes under billing information	1
Relevant clinical information	1
Other	0
Part of order name/pregnancy-specific test	0
Reason for study	0
In what data format is pregnancy status submitted by providers (select all that apply)?	
Answers to ask at order entry	12
Free text comments	1
ICD-10 code	3
ICD-10 description	0
Other	0
Pregnancy-related test types	0
Which HL7 field(s) does your laboratory routinely use to report pregnancy status to public health agencies (select all that apply)? - Selected Choice	
Comments	2
Other	6
Pregnancy-related test types	1
Reason for study	1
Relevant clinical information	3
Other - Text	3
OBX result field	3
In what data format is pregnancy status submitted to public health agencies?	
A predefined phrase/string indicating pregnancy, e.g., 'pregnant', 'prenatal', 'Pregnant: yes', etc., that is output from a data processing algorithm	3
Answers to ask at order entry	10
Free text comments	2
ICD-10 code	1
ICD-10 description	0
Other	1
Pregnancy-related test types	2
Does your laboratory require reporting of pregnancy status for any tests related to the following conditions? (select all that apply)	
COVID-19	6

Cytomegalovirus (CMV)	1
Hepatitis B	3
Hepatitis C	3
HIV	4
Rubella (diagnostic)	2
Syphilis	4
Zika	6
Other	2
Please indicate which aspects of capturing or reporting pregnancy status to public health agencies require manual effort (select all that apply).	
Data entry (from paper lab requisition forms)	8
Initial system programming, ongoing data management, and quality control activities are required	4
Ongoing data management and quality control	4
Only initial electronic laboratory requisition and data management system programming	7
Other	3
Has your laboratory experienced technical limitations/challenges in capturing and reporting pregnancy status for COVID-19?	
Yes, please describe.	4
No	4
Not sure	4
If Ask at Order Entry is routinely used to capture pregnancy status, which of the following helps guide provider reporting?	
Picklist of Yes, No, Unknown or similar	7
Picklist of specifics about pregnancy status (e.g., Postpartum, currently pregnant)	2
Only a checkbox	3
Other	1
How is reporting of pregnancy within the Ask at Order Entry field configured?	
Provider may leave a response blank	3
Provider may select "unknown" or similar	6
Other	2
What obstacles, if any, might your laboratory have to adding a dedicated field at order entry to capture pregnancy status?	
Laboratories should not be required to report pregnancy status unless clinically relevant to the test being performed	6
Our lab already has a field to capture pregnancy status	5
Technical limitations	3
Other	4
Other limitations	3
If capture of pregnancy status were to become a required data element for reporting to Public Health Agencies, which of the following would be the best approach to obtaining pregnancy information? (select all that apply)	
Codified in Ask at Order Entry	9
Other	2
Other - OBR 31	2
In your opinion, how burdensome is pregnancy status reporting for COVID-19... (1-10 scale)	Average
No or very little burden	4.2

STLT Assessment Summary

How important is obtaining pregnancy status for COVID-19 and other categories of disease/condition for your agency?	Count
Q30_1 - COVID-19	8.12
Q30_2 - Other notifiable diseases excluding COVID-19 (e.g., foodborne, arboviral)	7.29
Q30_3 - Non-notifiable conditions of public health importance (e.g., cancer)	6.49

Indicate how your agency captures pregnancy status for COVID-19 and other categories of disease/condition (select all that apply).: COVID-19	
Patient Interview	32
ELR (electronic lab reporting)	26
Provider reporting or outreach	25
eCR (electronic case reporting)	20
Extracted from electronic files (non-lab)	18
Hospital discharge data	17
Vital statistics	17
Custom data mining	7
I do not know	5
Other	3
Newborn metabolic screening	2
Pregnancy status is NOT captured for this condition	2
Regional health information notifications	2

Indicate how your agency captures pregnancy status for COVID-19 and other categories of disease/condition (select all that apply).: Other notifiable diseases (excluding COVID-19)	
Patient Interview	34
Provider reporting or outreach	29
ELR (electronic lab reporting)	23
Vital statistics	22
Hospital discharge data	18
Extracted from electronic files (non-lab)	17
eCR (electronic case reporting)	16
Custom data mining	10
I do not know	8
Newborn metabolic screening	6
Other	6
Regional health information notifications	5
Pregnancy status is NOT captured for this condition	2

Indicate how your agency captures pregnancy status for COVID-19 and other categories of disease/condition (select all that apply).: Non-notifiable conditions of public health importance (e.g., cancer)	
I do not know	16
Vital statistics	16
Hospital discharge data	12
Newborn metabolic screening	8

Custom data mining	7
Extracted from electronic files (non-lab)	7
Provider reporting or outreach	6
Patient Interview	5
ELR (electronic lab reporting)	4
eCR (electronic case reporting)	3
Other	1
Pregnancy status is NOT captured for this condition	1
Regional health information notifications	1

Does your agency experience any barriers to obtaining pregnancy status for COVID-19?	
Inconsistent provider reporting at lab order entry	31
Inconsistent receipt through electronic lab reporting	31
No standard method to receive pregnancy status	30
Administrative code/law does not require reporting	25
Staff time or expertise constraints	21
Challenges in parsing status out of electronic data (ELR, eCR, or other)	17
Inability to extract pregnancy status from EMR (electronic medical record)	15
Other, please describe.	14
Lack of fields to capture pregnancy in EMR (electronic medical record)	7
Inconsistencies in coding	4
No, we do not encounter barriers to pregnancy reporting or do not solicit pregnancy reporting.	3
I don't know	2

Which of the following approaches has your agency taken to increase reporting of pregnancy status for any disease/condition?	
Education of providers	21
Use of electronic reporting (e.g., ELR fields)	21
Custom data extracts	13
Collaboration/education with laboratories	10
Our agency has not tried to improve pregnancy reporting	10
Other	9
Administrative code/law requirement (please provide the URL to the requirement language if possible)	7

If pregnancy status were to become a required data element for laboratory reporting, which lab order field(s) should be used to capture pregnancy status? In your opinion, how burdensome is pregnancy status reporting for COVID-19 for laboratories?	
No or very little burden	5.67

Would requiring laboratories to report into a central exchange (i.e., AIMS - APHL Informatics Messaging System) improve your ability to capture pregnancy status?	
Maybe	24
Yes	13
No	10

Which categories of diseases/conditions does your agency currently receive through eCR (electronic case reporting)?	
COVID-19 ONLY	24
Our agency is NOT receiving eCR (electronic case reports)	9
Respiratory Conditions (infectious)	9
Sexually Transmitted Diseases	9
Vaccine Preventable Diseases	8
Enteric Diseases	7
Vectorborne Diseases	7
Zoonotic Diseases	7
Bloodborne Diseases	6
Healthcare- Associated Events	6
Waterborne (not enteric)	6
Streptococcal Diseases	5
Cancer	3
Toxic Effect of Non-Medicinal Substances	2
Neurological Diseases	1
Respiratory Conditions (non-infectious)	1
Injuries	0
Systemic Conditions	0

If your agency is working to expand eCR (electronic case reporting), which categories of diseases/conditions is your agency prioritizing?	
Enteric Diseases	23
Respiratory Conditions (infectious)	21
Sexually Transmitted Diseases	21
Vaccine Preventable Diseases	19
Vectorborne Diseases	19
Zoonotic Diseases	19
Streptococcal Diseases	17
Bloodborne Diseases	16
Healthcare- Associated Events	16
Waterborne (not enteric)	15
Systemic Conditions	8
Neurological Diseases	7
Toxic Effect of Non-Medicinal Substances	7
Cancer	6
Respiratory Conditions (non-infectious)	6
Injuries	4

If your agency is planning to expand eCR (electronic case reporting) in the future, what is your agency's timeline?	
Yes, within 1 year	15
Other	12

Yes, within 3-5 years	9
I don't know	7
We are not able to expand eCR (electronic case reporting) receipt, ingestion, or use right now	4
Yes, within 5+ years	0

If your agency experienced difficulty in implementing eCR (electronic case reporting) for any notifiable disease, select all that apply.	
Other	20
In-house staff/specific expertise	18
Retention of in-house staff/specific expertise	18
External technical assistance	14
Insufficient technology infrastructure (e.g., agency ability to receive messages)	13
Lack of provider/health system/laboratory awareness or willingness	12
Lack of EMR vendor willingness	9
Weaknesses in notifiable disease surveillance system	8
Project control is not with business users (i.e., controlled by centralized state IT department)	7
No, the implementation process is easy for our agency	2

In your opinion, what is the most reliable, timely, and complete method to receive pregnancy status for notifiable conditions long-term (drag and drop to rank in order of preference)? Select the most important data elements for capturing pregnancy status for reporting for COVID-19 or	
Pregnancy status (yes, no, possible, unknown)	41
Pregnancy Outcome	30
Pregnancy Outcome date (e.g., date of delivery, miscarriage)	29
Recently delivered/postpartum (within the past three months)	27
Delivery date	26
Estimated Delivery Date	25
Gestational Age	21
Pregnancy status date recorded	18
Evidence-based pregnancy status (i.e., LMP, ultrasound, lab test evidence)	15
Number of children born	11
Postpartum status	10
Last menstrual period	9
Expected delivery facility name	8
All of the above	6
Method of Gestational Age determination	5
EDD determination method	4
Date Gestational Age determined	2

For each of the following, indicate the level of importance for collecting pregnancy status in the future:	
Notifiable diseases limited to conditions where the health or the mother or infant are impacted (e.g., hepatitis B, syphilis)	9.77
New or emerging diseases where the impact to mothers or infants is unknown (e.g., Zika)	9.23

COVID-19	8.19
All notifiable diseases/conditions	7.28

Are you willing to be contacted for a brief follow-up interview?	
Yes	32
No	13

Federal Agency Assessment Summary

Please indicate how your agency receives pregnancy status for COVID-19 and other categories of disease/condition (select all that apply).: COVID-19	Count
Vital statistics	2
eCR	1
Extracted from electronic files (non-lab)	1
Newborn metabolic screening	1
Other	1
Provider reporting or outreach	1
Custom data mining	0
ELR	0
Hospital discharge data	0
Not sure	0
Patient Interview	0
Pregnancy status is NOT captured for this condition	0
Regional health information notifications	0
STLT case report	0

Please indicate how your agency receives pregnancy status for COVID-19 and other categories of disease/condition (select all that apply).: Other notifiable diseases (excluding COVID-19)	
Hospital discharge data	1
Patient Interview	1
Provider reporting or outreach	1
Vital statistics	1
Custom data mining	0
eCR	0
ELR	0
Extracted from electronic files (non-lab)	0
Newborn metabolic screening	0
Not sure	0
Other	0
Pregnancy status is NOT captured for this condition	0
Regional health information notifications	0
STLT case report	0

Please indicate how your agency receives pregnancy status for COVID-19 and other categories of disease/condition (select all that apply).: Non-notifiable conditions of public health importance (e.g., cancer)	
Not sure	1
Custom data mining	0
eCR	0
ELR	0
Extracted from electronic files (non-lab)	0
Hospital discharge data	0
Newborn metabolic screening	0

Other	0
Patient Interview	0
Pregnancy status is NOT captured for this condition	0
Provider reporting or outreach	0
Regional health information notifications	0
STLT case report	0
Vital statistics	0

Does capture of pregnancy status for COVID-19 require manual effort by your program?	
Yes, significant effort	2
Yes, some effort	1
We do not actively solicit pregnancy status information	0
We only capture pregnancy status in a case investigation form	0
Yes, minimal effort	0

Does your program provide technical assistance to states working to improve capture of pregnancy status?	
No	2
Yes, please describe.	1
Not sure	0
Limited. We have not been able to offer additional funding for what is a new item	

Select the most important data elements for capturing pregnancy status for reporting for COVID-19 or	
Delivery date	3
Gestational Age	3
Pregnancy Outcome	3
Pregnancy Outcome date (e.g., date of delivery, miscarriage)	3
Pregnancy status (yes, no, possible, unknown)	3
Estimated Delivery Date	2
Pregnancy status date recorded	2
Recently delivered/postpartum (within the past three months)	2
Expected delivery facility name	1
Last menstrual period	1
Number of children born	1
Postpartum status	1
All of the above	0
Date Gestational Age determined	0
EDD determination method	0
Evidence-based pregnancy status (i.e., LMP, ultrasound, lab test evidence)	0
Method of Gestational Age determination	0

Select the most important data elements for capturing pregnancy status for reporting for COVID-19 or other notifiable diseases/conditions (select all that apply).	
Gestational Age	3
Pregnancy Outcome	3
Estimated Delivery Date	2
Last menstrual period	2
Pregnancy status (yes, no, possible, unknown)	2
Pregnancy status date recorded	2
Expected delivery facility name	1
Method of Gestational Age determination	1
Postpartum status	1
Pregnancy Outcome date (e.g., date of delivery, miscarriage)	1
Certainty status of pregnancy (i.e., LMP, ultrasound, lab test evidence)	0

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Date Gestational Age determined	0
EDD determination method	0
Which initiatives do you believe would be most impactful in improving reporting of pregnancy status (select all that apply)?	
Expanded provider use of eCR	2
Implementation of STLT reporting requirements for pregnancy status	1
Improved receipt, ingestion, and use of eCR by STLT	1
Incentives for providers to report pregnancy status for notifiable diseases/conditions	1
Standardized/codified capture of pregnancy status by laboratories	1
Other	0
USCDI 3 adoption with the inclusion of pregnancy data elements	0
For each of the following, indicate the level of importance for collecting pregnancy status in the future: (1-10 scale)	
Notifiable diseases limited to conditions where the health of the mother or infant are impacted (e.g., hepatitis B, syphilis)	9.5
New or emerging diseases where the impact to mothers or infants is unknown (e.g., Zika)	9
COVID-19	8.33
All notifiable diseases/conditions	8
Are you willing to be contacted for a brief follow-up interview?	
No	2
Yes	1

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