Local Health Department Reporting of Zika in Pregnancy and the US Zika Pregnancy and Infant Registry

January 2018

Updated January 2018; updated information in red.

CDC has established a national, voluntary Zika Pregnancy Registry to address the many questions that remain about Zika-associated birth defects and other pregnancy outcomes. The US Zika Pregnancy and Infant Registry is being used for national estimates and to monitor symptomatic and asymptomatic pregnant women with laboratory evidence of possible Zika virus infection and their pregnancy outcomes and their infants.

Starting in late May, 2016, CDC began weekly reporting of the total number of pregnant women who are being actively monitored in the US Zika Pregnancy and Infant Registry as well as the number of liveborn infants and pregnancy losses with birth defects associated with Zika infection.

What does the Registry include?: The US Zika Pregnancy and Infant Registry data collection points include: the time of maternal diagnosis, 2nd trimester, 3rd trimester, delivery, and infant follow-up at 2, 6, 12, 18 and 24 months.

What is CDPH doing?: CDPH is participating in the US Zika Pregnancy and Infant Registry and CDPH is the point of contact for Registry data submission to CDC. CDPH will work with local health departments and health care providers to complete the US Zika Pregnancy and Infant Registry data collection forms and submit data to CDC. The Zika Pregnancy and Infant Registry activities at CDPH are being led by the California Birth Defects Monitoring Program (CBDMP) and conducted in coordination with efforts to achieve enhanced surveillance of Zika-related birth defects in California.

Zika virus infection is a reportable communicable disease in California (Title 17, California Code of Regulations). When CDPH receives a Zika case report for a pregnant woman or infant, the CDPH Zika Pregnancy Registry Coordinators review the report and Maternal Health History and make contact with the Local Health Department (LHD) to provide information and assistance with data collection based on LHD preferences. Following delivery, CBDMP abstractors review hospital medical records in order to collect Neonatal Assessment data and additional maternal health history if available. Efforts are deployed to ensure contact with the family in order to conduct infant follow-up and to provide support and referral to services as needed. CDPH Zika Pregnancy and Infant Registry Coordinators monitor receipt of Infant Follow-up forms and make contact with the LHD or provider to gather outstanding data as needed.

LHD responsibilities:

1) **Test Requests** – When contacted by a health care provider requesting initial Zika testing or confirmatory testing, assess the following and note for your own records:
    - Travel or other exposure history
    - Pregnancy status basics (When is she due? Any concerns for Zika related complications?)
    - Provider's contact information

- Mother's contact information

2) **Case Investigation and Reporting** – For all pregnant women, with or without symptoms, who have any laboratory evidence of possible Zika virus infection. **Timeline:** Within 72 hours.
   - Communicable Disease Reporting - Complete the **CDPH Zika Case Report**. This should be completed within 72 hours via CalREDIE or, if not using CalREDIE, submitted directly to the CDPH Division of Communicable Disease Control (DCDC) via fax to 916-552-9725 or via secure email to charsey.porse@cdph.ca.gov.

     The CDPH Zika Case Report form can be found online: https://www.cdph.ca.gov/CDPH%20Document%20Library/ControlledForms/cdph8680.pdf.

     (Note: Include sexual contact history under "Other Suspected Exposures".)

   - California Zika Pregnancy and Infant Registry – For pregnancies completed on or before March 31st, 2018, complete the CDC **Maternal Health History Form** with as much information as you have gathered. This form should be uploaded to the CalREDIE electronic filing cabinet or submitted directly to CBDMP via fax to 916-620-3152 or submit via secure email to ZikaOutcomes@cdph.ca.gov.

     The CDC Registry Maternal Health History Form can be found online: https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/MaternalHealthHistoryForm.pdf.

3) **Inform your LHD MCAH Director about the pregnant Zika case -** The local MCAH program may be able to assist with provider communication and with resourcing for the family.

4) **Prepare for testing at delivery** – Approximately 1 month in advance of anticipated delivery date, contact the health care provider to ask about the planned delivery hospital and review testing that should be completed at the time of delivery. See "Evaluation and Follow-Up Procedures for Suspected Congenital Zika Virus Infection" on the CDPH Zika webpage for details: https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/GuidanceforCongenitalZikaInfectionEvaluation.pdf.
   - When you become aware of the delivery hospital, please inform the California Zika Pregnancy Registry via email at: ZikaOutcomes@cdph.ca.gov. Also indicate the delivery hospital in the 'notes' section under the 'Case Investigation' tab in CalREDIE.

5) **Prepare for Follow-Up Data Collection** – Identify who within your LHD will be the Zika Pregnancy contact to the CDPH. Determine your preference for data collection, beyond the initial diagnosis and investigation and neonatal testing:
   - ☐ The LHD will contact health care providers to complete data collection.
   - ☐ CDPH to contact health care providers to complete data collection.

   Send your LHD Zika Pregnancy contact's information and your data collection preference (LHD or CDPH) to ZikaOutcomes@cdph.ca.gov.

6) Complete and Submit Data Forms

The US Zika Pregnancy and Infant Registry data collection points include: the time of maternal diagnosis (# 2 above), 2nd trimester, 3rd trimester, delivery, and infant follow-up at 2, 6, and 12, 18 and 24 months.

CDC forms include:

- Maternal Health History Form
  https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/MaternalHealthHistoryForm.pdf

- Infant Follow Up Form
  https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/InfantFollowUpForm.pdf

- Supplemental Imaging Form
  https://www.cdph.ca.gov/Programs/CID/DCDC/CDPH%20Document%20Library/SupplementalMaternalPrenatalImagingDiagnosticsForm.pdf
  (To be used when extra space is needed to record diagnostics, etc.)

- The Neonate Assessment Form will be completed by the CBDMP abstractors.
- Uploading forms to CalREDIE is the preferred method for submission to CDPH.
- If you are a CalREDIE non-participating jurisdiction, you may send the forms via SECURE email (call for instructions before sending: 510-620-3151) to the following address: ZikaOutcomes@cdph.ca.gov.

If faxing or emailing, **please remember to call or email for instructions before faxing or submitting any forms to CDPH,** so that we can ensure the privacy and security of all documents. Send additional inquiries to ZikaOutcomes@cdph.ca.gov.

Frequently Asked Questions

Is this case management? No.

Are we contacting providers to request they do additional testing in order to complete the forms? No, data collection for the US Zika Pregnancy and Infant Registry is intended to capture information already existing in the medical record.

What authority do we have to do this data collection?

- HIPAA Privacy Rule permits providers to disclose PHI without authorization to public health authorities for the purposes of preventing or controlling disease.
- CDC has received authorization for 308(d) Assurance of Confidentiality Protection for "surveillance of pregnancy and infant outcomes following Zika virus infections in Zika surveillance-related data" from the CDC Office of the Associate Director for Science.
- CDC has received a non-research determination from the National Center for Emerging and Zoonotic Infectious Diseases IRB.
- General powers of the Department to investigate causes of morbidity and mortality (H&S section 100325)
- The US Zika Pregnancy and Infant Registry is consistent with the purpose of the California Birth Defects Monitoring Program (CBDMP) to conduct studies to investigate the causes of birth defects, stillbirths, and miscarriages and to determine and evaluate measures designed to prevent their occurrence (H&S section 103840).

Appendix A: Linking Maternal and Infant Incident Reports in CalREDIE

Congenital Zika Virus Infection:
Linking Maternal and Neonatal Investigations in CalREDIE

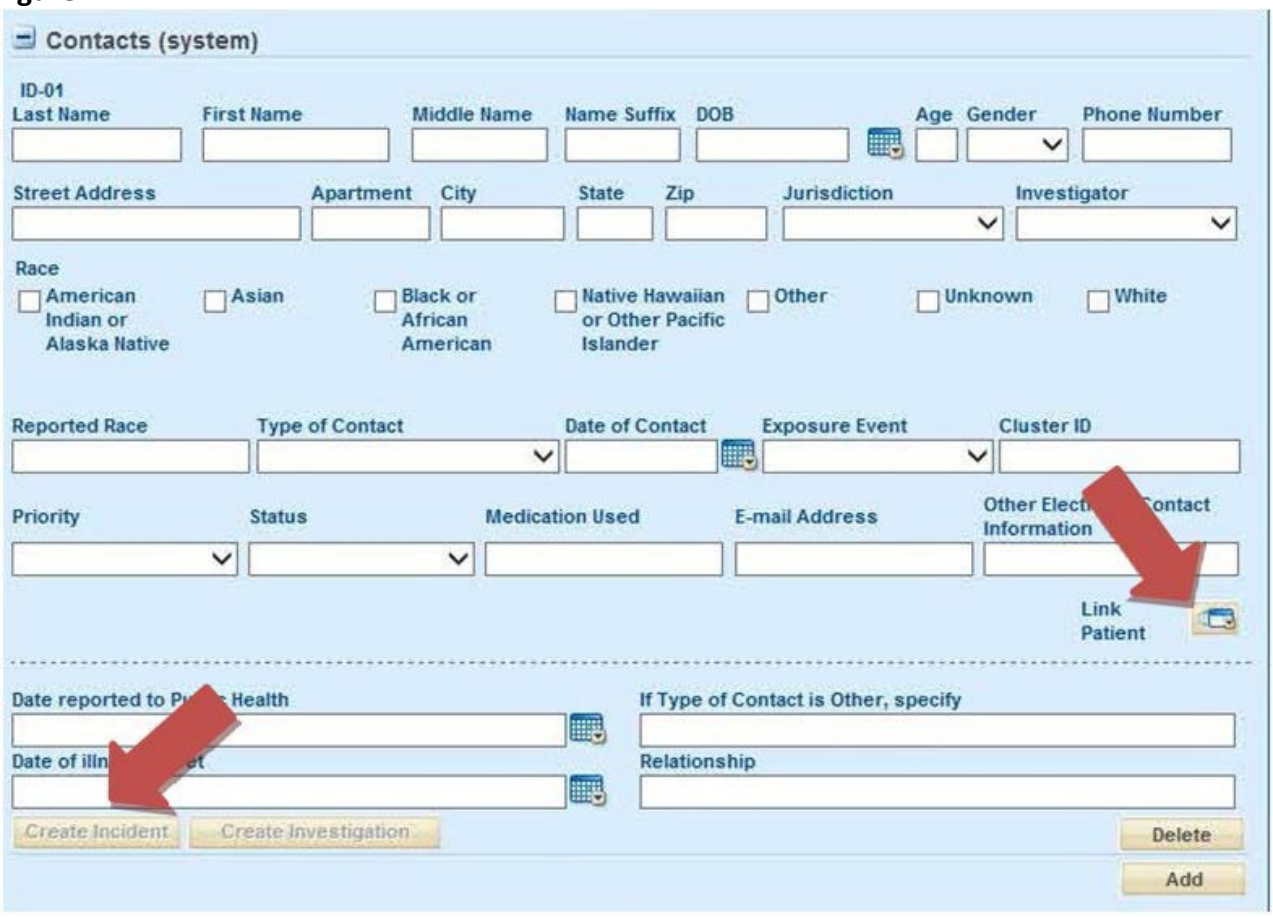
To initiate a neonate investigation:

1. Enter the mother's case information into her own Disease Incident, per standard procedure.

2. With the mother's case open, on the "Epidemiologic Info" tab, scroll down to "Contacts (system)" click '**Link Patient**' to see if the infant already exists in CalREDIE (Figure 1).
    a. Search on any combination of Name, DOB, Address, and/or Phone. If a match is found, click (highlight) your match then click OK.
    b. If not found, click Cancel and enter First and Last Name of the infant as well as any available demographics. ***Minimum fields required: Last Name, First Name.***

Note: If the infant's last name is not yet known, enter the mother's last name for the infant. If the infant's first name is not yet known, enter Baby, Baby Girl, or Baby Boy, as gender-appropriate for the infant.

Figure 1:

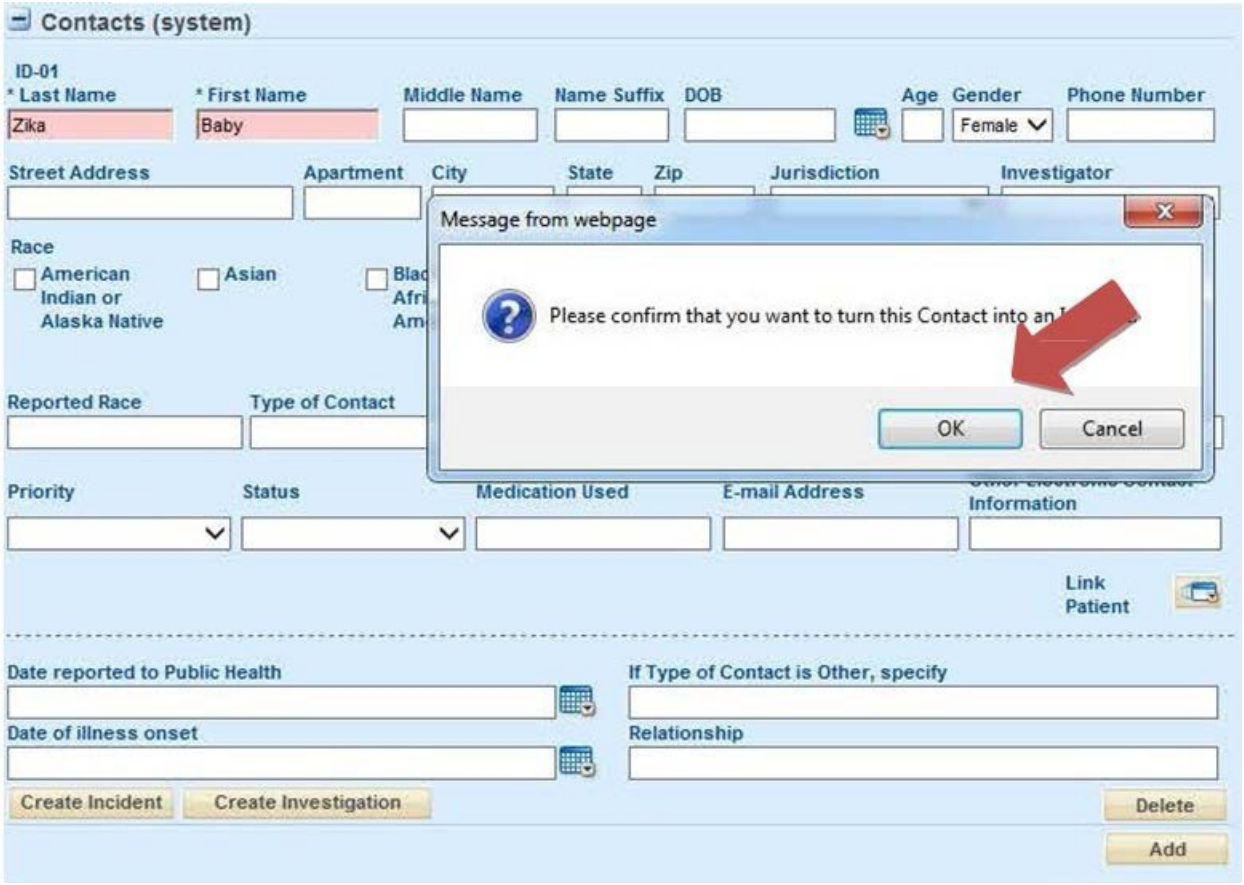


3. Click **Save** to save changes on the Epidemiologic Info tab.

4. Click **"Create Incident"** to turn infant into a new Disease Incident. ***You must Save (step #3) to enable the "Create Incident" button.*** Do not use the Create Investigation button.

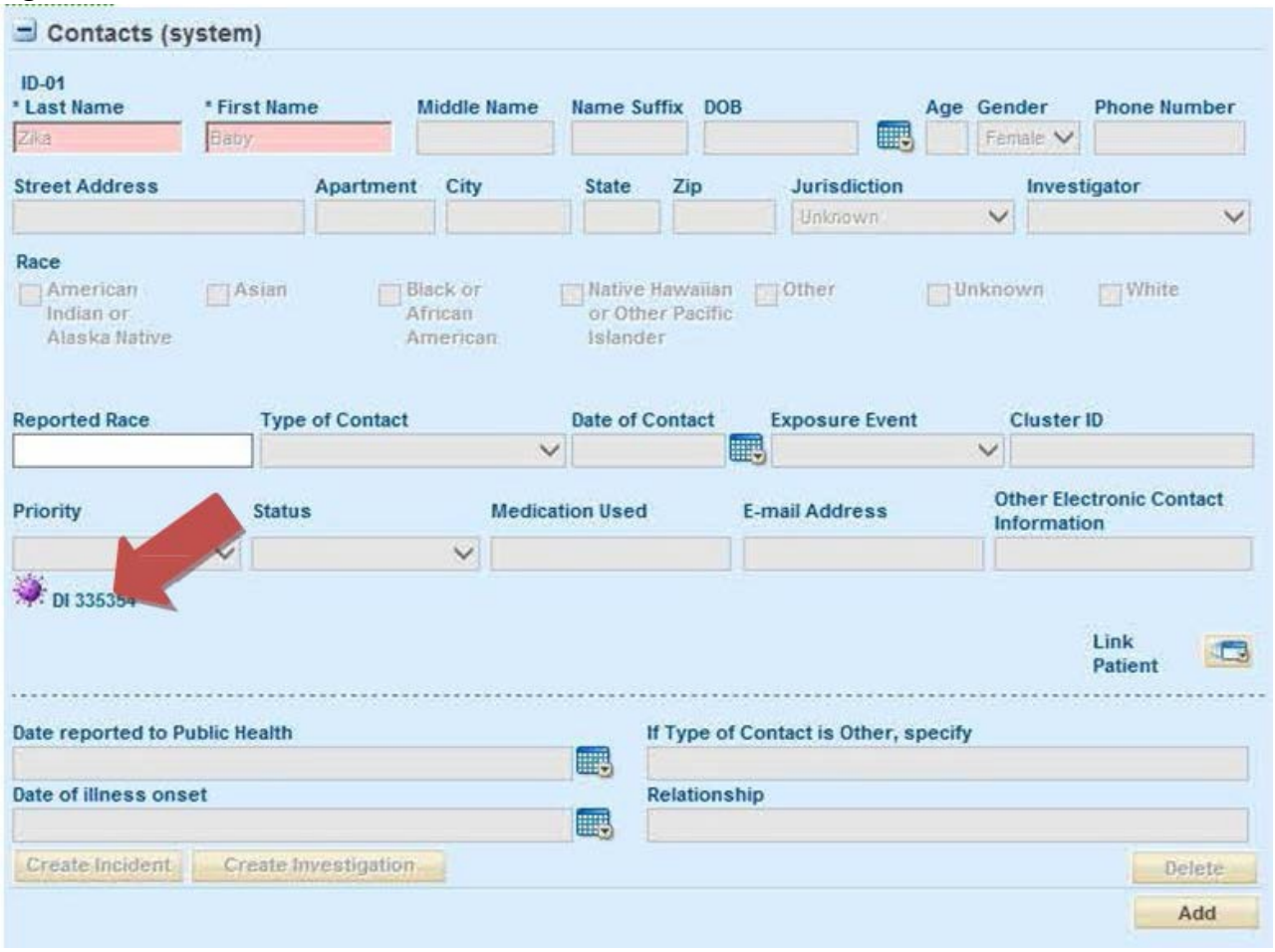
5. Click **"OK"** in pop-up box to confirm that you want to turn the infant into a new Incident. A pop-up box will subsequently notify you that "The contact has been successfully turned to a new incident." (Figure 2)

Figure 2.



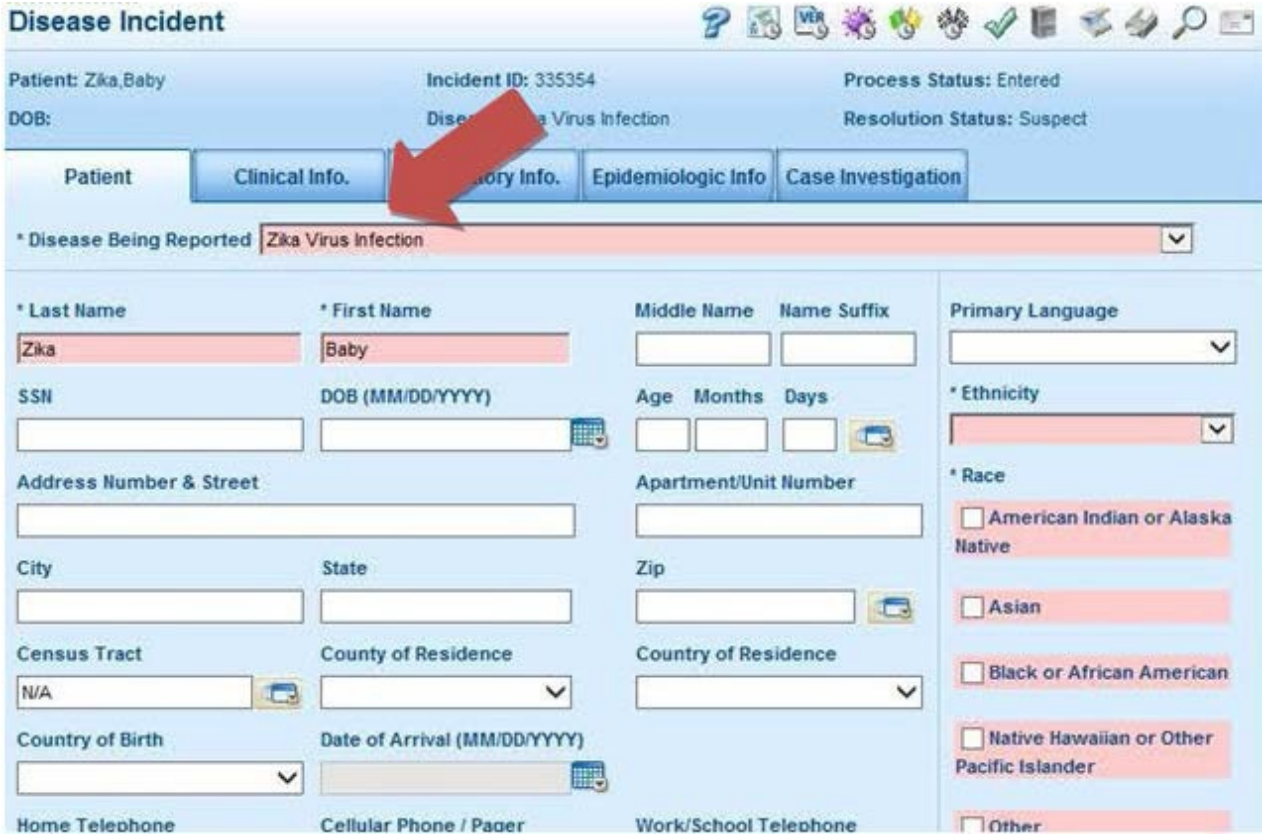
6. Click on new DI Incident link to go to the infant's new Incident (Figure 3).

Figure 3.



7. On the infant's Patient tab, the Disease Condition will default to "Zika Virus Infection". Name, address, race, and gender will carry over from the Contacts (systems) entry in the mother's incident (Figure 4).

Figure 4.



8. Enter required information on the infant's Patient, Clinical, Laboratory, Epidemiology, and Case Investigation Tabs.

9. Click "Submit" to save Incident in CalREDIE.

You have now successfully accomplished:
Creating a new Incident for a Congenital Zika investigation, and generating a link between the infant and mother in CalREDIE! The same steps can be used to link sexually transmitted cases in CalREDIE.