Burden Memo for the Generic Clearance of Emergency Epidemic Investigation Data Collections (0920-1011)

GenIC No.:	2014006-057
EPI AID No. (if applicable):	2014-057
Requesting entity (e.g., jurisdiction):	Federated States of Micronesia (FSM) Department of Health and Social Affairs
Title of Investigation:	Undetermined risk factors and agent in a suspected measles outbreak among a highly vaccinated population—Federated States of Micronesia, 2014
Purpose of Investigation: (Use as much space as necessary)	FSM experienced an outbreak of measles which involved three states consecutively, Kosrae, Pohnpei and Chuuk. The date of rash onset for the first case was 3/17/14, the last rash onset in a confirmed case was 8/3/14 though lab results are pending from 2 suspected cases with rash onset 8/26. Initially there was a concern that other etiologies than measles might be causes of some of the cases, as dengue, zika and chikungunya viruses may be found in this region. There was one measles death in a 10 month old infant in Pohnpei. Vaccination efforts were completed in Kosrae, but are ongoing in Pohnpei, Chuuk and the fourth state, Yap, which has not had a confirmed case of measles. The age distribution in Kosrae and Pohnpei was focused among adults, which is unusual for measles. Many of the cases had received two doses of vaccine, which raised the concern of vaccine failure. There were several importations of measles into to the US from FSM. CDC on site assistance to the outbreak response was completed on 9/11/14. Several rotations of CDC staff assisted FSM national and State health department staff in Kosrae, Pohnpei and Chuuk. Technical assistance included 1) Establish specimen collection algorithms and shipping procedure to identify the pathologic agents involved in this outbreak 2) Establish health care facility infection control procedures 3) Provide training and oversight in case investigation, contact tracing and vaccination and epidemiologic analysis 4) Evaluate the vaccine cold chain 5) Assist with planning and executing immunization campaigns and 6) Perform a household secondary attack rate epidemiologic study to estimate vaccine effectiveness and determine if vaccine failure is an major factor in this outbreak and determine other risk factors for measles transmission in this highly immunized population. The epidemiologic study originally planned was a case control study in Kosrae. However, this study was not feasible because 1) CDC team arrived in Kosrae late in the course of the outbreak and it was not possible to get accurate histories on prior clinical history or vaccination status and 2) Many of the reported cases were not laboratory confirmed, reducing the confidence that they were true measles cases and 3) Very few of the reported cases were unvaccinated, making it difficult to calculate vaccine efficacy. When the outbreak spread to Pohnpei, the CDC team was on the ground and the situation was appropriate to conduct a vaccine effectiveness study. Because much of the transmission was focused in households and case investigation and contact tracing were ongoing as part of the outbreak response, a household study of secondary attack rate cohort was selected as the best method to estimated vaccine effectiveness. To assemble the cohort, the household of suspected or confirmed measles cases was visited and all household contacts enumerated. Vaccine was provided as indicated for any of the exposed contacts as part of the outbreak response and not as a component of the study. The clinical history of each household contact was taken using a standardized form (attached). We collected the following types of information: Patient age, gender, vaccination status including dates of vaccination, history of any measles symptoms and onset dates of symptoms. Immunization cards and centralized immunization records of all cases and their household contacts were examined to confirm their vaccination status. To confirm measles cases serum (acute and/or convalescent) and nasopharyngeal or throat swabs were collected, as indicated for outbreak response, if the case was seen within the prescribed period for testing. Biospecimen samples were collected by FSM personnel and tested at CDC. Specimens were collected from the household contacts in the cohort study only if they met the definition of suspected measles case, as indicated for outbreak response purposes.

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Duration of Data Collection:	
Date Began:	6/26/2014
Date Ended:	Household surveys ended 7/17/2014. The Pohnpei Health Department is doing a final check on the immunization status of the contacts in the cohort reviewing centralized records. A few dozen contact immunization records still need to be verified.
Lead Investigator	
Name:	Craig Hales, M.D.
CIO/Division/Branch:	NCIRD/DVD/EB

Complete the following for <u>each</u> instrument used during the investigation.

Data Collection Instrument 1

Name of Data Collection Instrument: Measles_Household Line Listing

Type of Respondent

☐ General public ☐ Healthcare staff ☐ Laboratory staff ☐ Patients ☐ Restaurant staff

☒ Other (describe): "Heads of Households"- Defined as a responsible adult available in the household of a reported measles case at the time of the visit by study investigators

Data Collection Methods (check all that apply)

☒ Epidemiologic Study (indicate which type(s) below)

☐ Descriptive Study (describe):	
☐ Cross-sectional Study (describe):	
☒ Cohort Study (describe):	Cohort study of exposed household contacts of measles cases was conducted to identify risk factors for measles transmission and estimate vaccine effectiveness and factors which may have affected effectiveness such as demographics and vaccination history including number and timing of measles vaccine doses. Households were selected for study enrollment by convenience sampling of measles cases reported in Pohnpei, focusing on investigation of households of confirmed cases. The study compared rates of measles in vaccinated and unvaccinated household members of the first measles case in each household.
☐ Case-Control Study (describe):	
☐ Other (describe):	

☐ Environmental Assessment (describe):	
☒ Laboratory Testing (describe):	Laboratory testing for all suspect measles cases was attempted as indicated in outbreak response guidelines and not as a component of the study. Serum (acute and/or convalescent) and nasopharyngeal or throat swabs were collected from cases by FSM staff and tested at CDC for measles and arbovirus. The results from these tests will be incorporated in the analysis of the cohort study data, although the tests were performed according to outbreak response guidelines
☐ Other (describe):	

Data Collection Mode (check all that apply)

☒ Survey Mode (indicate which mode(s) below):

☒ Face-to-face Interview (describe):	Heads of households with reported measles cases were interviewed to determine whether or not household members developed fever and rash 7-21 days after the initial case in the household. 58 of the 93 households were interviewed a second time after the 21 day period had passed to determine if any additional cases of fever and rash had occurred. Data was collected on Household Line Listing Form

☒ Telephone Interview (describe):	(Attached) Some follow up interviews described above were conducted by phone if a phone number was available.
☐ Self-administered Paper-and-Pencil Questionnaire (describe):	
☐ Self-administered Internet Questionnaire (describe):	
☐ Other (describe):	
☒ Medical Record Abstraction (describe):	As part of the cohort study of household contacts of measles cases, immunization records, either cards or centralized immunization records (paper logs and electronic database) of all cases and their household contacts were reviewed to confirm their vaccination status; results were recorded in the Household Line Listing Form.
☐ Biological Specimen Sample	
☐ Environmental Sample	
☐ Other (describe):	

Response Rate (if applicable)

Total No. Responded (A):	93
Total No. Sampled/Eligible to Respond (B):	95
Response Rate (A/B):	98%

Complete the following burden table. Each data collection instrument should be included as a separate row.

Burden Table (insert rows for additional respondent types if needed)

Data Collection Instrument Name	Type of Respondent	No. Respondents (A)	No. Responses per Respondent (B)	Burden per Response in Minutes (C)	Total Burden in Hours (A x B x C)/60*
Measles_Household Line Listing	Heads of Households with measles cases	58	2	55	107
Measles_Household Line Listing	Heads of Households with measles cases	35	1	55	33

Return completed form and a blank copy of each final data collection instrument within 5 business days of data collection completion to the EEI Information Collection Request Liaison, Danice Eaton (dhe0@cdc.gov).

EEI Information Collection Request Liaison:
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