Severe 2009 H1N1 Influenza in Pregnant and Postpartum Women in California

Janice K. Louie, M.D., M.P.H., Meileen Acosta, M.P.H., Denise J. Jamieson, M.D., M.P.H., and Margaret A. Honein, Ph.D., M.P.H., for the California Pandemic (H1N1) Working Group*

ABSTRACT

BACKGROUND
As in previous epidemics and pandemics, 2009 pandemic influenza A (H1N1) may pose an increased risk of severe illness in pregnant women.

METHODS
Statewide surveillance for patients who were hospitalized with or died from 2009 H1N1 influenza was initiated by the California Department of Public Health. We reviewed demographic and clinical data reported from April 23 through August 11, 2009, for all H1N1-infected, reproductive-age women who were hospitalized or died — nonpregnant women, pregnant women, and postpartum women (those who had delivered ≤2 weeks previously).

RESULTS
Data were reported for 94 pregnant women, 8 postpartum women, and 137 non-pregnant women of reproductive age who were hospitalized with 2009 H1N1 influenza. Rapid antigen tests were falsely negative in 38% of the patients tested (58 of 153). Most pregnant patients (89 of 94 [95%]) were in the second or third trimester, and approximately one third (32 of 93 [34%]) had established risk factors for complications from influenza other than pregnancy. As compared with early antiviral treatment (administered ≤2 days after symptom onset) in pregnant women, later treatment was associated with admission to an intensive care unit (ICU) or death (relative risk, 4.3). In all, 18 pregnant women and 4 postpartum women (total, 22 of 102 [22%]) required intensive care, and 8 (8%) died. Six deliveries occurred in the ICU, including four emergency cesarean deliveries. The 2009 H1N1 influenza—specific maternal mortality ratio (the number of maternal deaths per 100,000 live births) was 4.3.

CONCLUSIONS
2009 H1N1 influenza can cause severe illness and death in pregnant and postpartum women; regardless of the results of rapid antigen testing, prompt evaluation and antiviral treatment of influenza-like illness should be considered in such women. The high cause-specific maternal mortality rate suggests that 2009 H1N1 influenza may increase the 2009 maternal mortality ratio in the United States.
A

s in previous influenza epidemics and pandemics, pregnant women with 2009 pandemic influenza A (H1N1) appear to have an increased risk of severe disease.\textsuperscript{4,5} From April 23 to August 11, 2009, a total of 10% of the 1088 patients who were hospitalized with or died from 2009 H1N1 influenza, as reported to the California Department of Public Health (CDPH) were pregnant.\textsuperscript{8} A recent report from the first month of the outbreak noted that the rate of hospitalization among pregnant women was approximately four times the rate in the general population.\textsuperscript{5} This report describes the clinical course of the disease and characteristics of hospitalized pregnant, postpartum, and nonpregnant reproductive-age women with 2009 H1N1 influenza for whom data were reported to the CDPH in the first 4 months of the pandemic.

METHODS

From April 23 through August 11, 2009, the CDPH and 61 local health jurisdictions performed enhanced surveillance of cases of 2009 H1N1 influenza that required hospitalization and those that were fatal. A case patient was defined as a person who was hospitalized for 24 hours or more and had influenza-like symptoms with laboratory results indicative of 2009 H1N1 influenza. Specifically, cases of infection were classified as “probable” or “confirmed.” Probable cases were defined as those with a positive result on the real-time reverse-transcriptase–polymerase-chain-reaction (RT-PCR) assay for influenza A that could not be subtyped as H1 or H3. Confirmed cases were defined as those with a positive result on a real-time RT-PCR assay that was specific for 2009 H1N1 influenza. A fatal case was defined as influenza-like symptoms and probable or confirmed 2009 H1N1 influenza in a patient who died and for whom the medical record or death certificate listed 2009 H1N1 influenza as a contributing or underlying cause of death.

Cases were reported by providers and hospitals to local health jurisdictions. The mechanisms used to capture cases differed among the local health jurisdictions and included active surveillance conducted by hospital infection-control practitioners, case identification through laboratory surveillance, and passive reporting by clinicians. For each case, demographic, clinical, laboratory, and radiographic data, as well as information on the hospital course, were reported on a standardized case-history form and submitted to the CDPH; additional medical-chart abstractions were performed by staff at the local health jurisdiction or the CDPH.

A review of all pregnant, postpartum, and nonpregnant case patients of reproductive age (15 to 44 years of age) was performed. Pregnant patients were those who were pregnant at the time of onset of influenza symptoms. Postpartum patients were those with an onset of influenza symptoms during the first 2 weeks after delivery. For pregnant and postpartum patients who were admitted to an intensive care unit (ICU) while ill, an obstetrician–gynecologist from the research team contacted health care providers when possible to obtain additional detailed information about complications during delivery and the course of the maternal illness.

We estimated the maternal mortality ratio (the number of deaths from 2009 H1N1 influenza in pregnant and postpartum women per 100,000 live births) for California for the period defined by the dates of symptom onset in all patients included in this analysis: April 3 through August 5, 2009. The number of live births in this population in 2009 was estimated on the basis of the number of live births in this population during the same period in 2008 (obtained from the CDPH Center for Health Statistics, Office of Health Information and Research).

This investigation was reviewed by the California Committee for the Protection of Human Subjects. The investigation was determined to be part of the public health response to the 2009 H1N1 influenza pandemic and therefore did not require approval by an institutional review board or informed consent of participant.

RESULTS

From April 23 through August 11, 2009, data were reported for 94 pregnant women, 8 postpartum women, and 137 nonpregnant women of reproductive age who were hospitalized with or died from 2009 H1N1 influenza, for a total of 239 women in this age group. Dates of symptom onset ranged from April 3 to August 5, 2009 (Fig. 1). In all, 41 local health jurisdictions accounting for 96% of the population of California reported cases to the CDPH: 19 jurisdictions accounting for 78% of the population reported pregnant and postpartum cases, and 27 jurisdictions accounting for 86% of the population reported nonpregnant cases.
Of the 94 pregnant patients, 5 (5%) were in the first trimester, 35 (37%) were in the second trimester, and 54 (57%) were in the third trimester. There have been two spontaneous abortions and 35 deliveries: 3 in the second trimester (range, 25 to 28 weeks' gestation) and 32 in the third trimester. Two women delivered twins.

Pregnant and postpartum patients were, on average, younger than the nonpregnant women of reproductive age (Table 1). Of the 78 pregnant women whose race or ethnic group was known, 15 (19%) were non-Hispanic whites and 43 (55%) were Hispanic. An increased number of Hispanics might have been tested early in the surveillance period because of initial CDPH guidance recommending testing of persons traveling from Mexico. The overall distribution of races and ethnic groups did not differ significantly between pregnant and nonpregnant patients. In 79% of pregnant patients and 77% of nonpregnant patients, the onset of symptoms occurred between June 10 and July 25, 2009 (Fig. 1). Statewide laboratory surveillance during the same period showed persistently high levels of circulation of 2009 H1N1 influenza; from June 14 through July 31, 2009, the virus accounted for approximately 50% of cases of influenza-like illness tested and 92 to 100% of influenza viruses identified.

A total of 32 of the 93 pregnant women (34%), 2 of the 8 postpartum women (25%), and 82 of the 137 nonpregnant women (60%) had underlying conditions besides pregnancy that placed them at increased risk for complications from influenza; the most common condition was asthma, affecting 16% of pregnant women and 28% of nonpregnant women (Table 1). The most commonly reported symptoms among pregnant patients were cough (93%), fever (91%), sore throat (41%), shortness of breath (41%), muscle aches (41%), and nausea or vomiting (33%) (Table 2). Shortness of breath, muscle aches, and diarrhea were significantly more common among nonpregnant patients than among pregnant patients.

Of the 61 pregnant women who underwent chest radiography or chest computed tomography, 36 (59%) had abnormalities suggestive of pneumonia or the acute respiratory distress syndrome (ARDS), a proportion that was similar to that in the nonpregnant group (78 of 125 patients [62%]). Nineteen percent of pregnant patients (18 of 94) were admitted to an ICU, as were 50% of postpartum patients (4 of 8) and 30% of nonpregnant patients (41 of 137). Rapid influenza tests were falsely negative in 58 of the 153 patients who were tested (38%). Of these 58 patients, 28 were pregnant; only 7 of the 25 pregnant women with false negative results for whom information was available received early antiviral treatment (within 48 hours after symptom onset).

Among the patients for whom data were available, 81% of both pregnant women (71 of 88) and nonpregnant women (97 of 120) received antiviral treatment; however only 50% of pregnant women (30 of 60) and 34% of nonpregnant women...
(28 of 82) received early antiviral treatment. The percentage of pregnant patients who received early antiviral treatment remained relatively constant throughout the surveillance period. Six pregnant patients and one postpartum patient received oseltamivir for more than 5 days at a dose (150 mg every 12 hours) that was twice the current recommended dose. Forty-five percent of pregnant women (42 of 94) and 58% of nonpregnant women (80 of 137) were treated with antibiotics.

Of the 22 patients (18 who were pregnant and 4 who were postpartum) requiring intensive care, 8 (36%) were otherwise healthy and had had uneventful pregnancies. The time from symptom onset until initial presentation for health care was 5 days or more for 6 of the 22 patients (27%). The time from initial presentation until initiation of antiviral agents was 4 days or more in seven patients (32%). Sixteen patients (73%) required mechanical ventilation, including two who were intubated within 1 hour after assessment in the emergency room and two additional patients who were intubated on the day of hospital admission. One pregnant patient and one postpartum patient had microbiologic evidence of a coinfection with methicillin-resistant *Staphylococcus aureus*, identified by means of culture of a bronchoalveolar-lavage specimen and a lung-tissue autopsy specimen, respectively. Thirteen patients also received a diagnosis of ARDS and required prolonged mechanical ventilation (9 days to 6 weeks, or until death). Twenty-one of the 22 patients requiring intensive care were treated with oseltamivir, including 4 in whom oseltamivir therapy was initiated within 48 hours after symptom onset.

Six of the 18 pregnant patients requiring intensive care were discharged from the hospital while they were still pregnant; the remaining 12

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**Table 1.** Characteristics of Women Who Were Hospitalized with or Died from 2009 H1N1 Influenza, as Reported to the California Department of Public Health during the Period from April 23 to August 11, 2009, According to Pregnancy Status.*

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Pregnant (N = 94)</th>
<th>Postpartum (N = 8)</th>
<th>Nonpregnant (N = 137)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age — no. (%)</td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.001†</td>
</tr>
<tr>
<td>15–19 yr</td>
<td>14 (15)</td>
<td>0</td>
<td>24 (18)</td>
<td></td>
</tr>
<tr>
<td>20–24 yr</td>
<td>29 (31)</td>
<td>1 (12)</td>
<td>24 (18)</td>
<td></td>
</tr>
<tr>
<td>25–29 yr</td>
<td>29 (31)</td>
<td>5 (62)</td>
<td>26 (19)</td>
<td></td>
</tr>
<tr>
<td>30–34 yr</td>
<td>16 (17)</td>
<td>2 (25)</td>
<td>22 (16)</td>
<td></td>
</tr>
<tr>
<td>35–39 yr</td>
<td>4 (4)</td>
<td>0</td>
<td>26 (19)</td>
<td></td>
</tr>
<tr>
<td>40–44 yr</td>
<td>2 (2)</td>
<td>0</td>
<td>15 (11)</td>
<td></td>
</tr>
<tr>
<td>Median age (range) — yr</td>
<td>26 (16–42)</td>
<td>28 (22–33)</td>
<td>28 (15–44)</td>
<td>0.02‡</td>
</tr>
<tr>
<td>Race or ethnic group — no./total no. (%)§</td>
<td></td>
<td></td>
<td></td>
<td>0.24†</td>
</tr>
<tr>
<td>Hispanic</td>
<td>43/78 (55)</td>
<td>3/8 (38)</td>
<td>47/116 (41)</td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic white</td>
<td>15/78 (19)</td>
<td>2/8 (25)</td>
<td>32/116 (28)</td>
<td></td>
</tr>
<tr>
<td>Asian or Pacific Islander</td>
<td>9/78 (12)</td>
<td>2/8 (25)</td>
<td>15/116 (13)</td>
<td></td>
</tr>
<tr>
<td>Non-Hispanic black</td>
<td>6/78 (8)</td>
<td>1/8 (12)</td>
<td>18/116 (16)</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>5/78 (6)</td>
<td>0</td>
<td>4/116 (3)</td>
<td></td>
</tr>
<tr>
<td>Chronic coexisting illness — no./total no. (%)¶</td>
<td></td>
<td></td>
<td></td>
<td>&lt;0.001†</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>16/93 (17)</td>
<td>0</td>
<td>45/135 (33)</td>
<td>0.007†</td>
</tr>
<tr>
<td>Asthma</td>
<td>15/93 (16)</td>
<td>0</td>
<td>38/28 (28)</td>
<td>0.04†</td>
</tr>
<tr>
<td>Other**</td>
<td>2/93 (2)</td>
<td>0</td>
<td>14/10 (10)</td>
<td>0.02</td>
</tr>
<tr>
<td>Metabolic disease</td>
<td>14/90 (16)</td>
<td>1/8 (12)</td>
<td>29/130 (22)</td>
<td>0.21†</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>2/90 (2)</td>
<td>0</td>
<td>19/130 (15)</td>
<td>0.002</td>
</tr>
<tr>
<td>Gestational diabetes</td>
<td>8/90 (9)</td>
<td>1/8 (12)</td>
<td>NA</td>
<td></td>
</tr>
<tr>
<td>Renal disease</td>
<td>3/90 (3)</td>
<td>0</td>
<td>8/130 (6)</td>
<td>0.53</td>
</tr>
<tr>
<td>Other††</td>
<td>1/90 (1)</td>
<td>0</td>
<td>2/130 (2)</td>
<td>1.00</td>
</tr>
</tbody>
</table>
delivered 13 infants (including one pair of twins). One normal, spontaneous vaginal delivery occurred in the labor and delivery unit, and five cesarean deliveries were performed in an operating room. In the ICU, there was one vaginal delivery of twins, one planned cesarean delivery, and four emergency cesarean deliveries. Two of the emergency cesarean deliveries were performed because of fetal bradycardia; in the other two cases, the aim was to improve maternal oxygenation. Eleven of the 13 infants were delivered prematurely (at 26 to 36 weeks’ gestation), including the twins, who were delivered at 30 weeks’ gestation. All 11 premature infants for whom data were available were admitted to the neonatal ICU, primarily for management of complications of prematurity (e.g., respiratory distress or difficulty with feeding) and observation. Neither of the term infants required neonatal intensive care. All 13 infants survived, and none had evidence of influenza.

Eight patients in this series died; symptoms developed in six of the eight patients during pregnancy and in two after delivery (on day 1 and on day 8). Six of the patients who died had underlying medical conditions in addition to pregnancy, including hypothyroidism (in two patients), asthma (in two), gestational diabetes (in one), and a history of Hodgkin’s lymphoma (in one). All eight patients required intensive care. None of the eight received antiviral agents within 48 hours after...
symptom onset; the median time from symptom onset to receipt of antiviral agents was 6.5 days (range, 3 to 36). In six cases, rapid influenza testing was negative. Among 60 pregnant women for whom the timing of antiviral treatment was more than 48 hours after symptom onset were more likely to be admitted to the ICU or to die (13 of 30 patients) than were pregnant women who received antiviral agents earlier (3 of 30 patients) (relative risk, 4.3; 95% confidence interval [CI], 1.4 to 13.7).

There were an estimated 188,383 births in the state of California from April 3 through August 5,
2009 (on the basis of actual birth data from the same period in 2008). The eight deaths due to 2009 H1N1 influenza during this time resulted in a cause-specific maternal mortality ratio of 4.3 (95% CI, 1.8 to 8.4), as compared with XXX deaths per 100,000 live births in 2007.

**DISCUSSION**

In this large series of pregnant and postpartum patients who were hospitalized with or died from 2009 H1N1 influenza, 95% of the pregnant patients were infected in the second or third trimester, and almost one fifth required intensive care. One third of the pregnant patients had medical conditions besides pregnancy that are recognized risk factors for complications from influenza. Eight patients who were hospitalized had an onset of symptoms within 2 weeks post partum; half required intensive care and two died, highlighting the continued high risk immediately after pregnancy. The pregnant women were less likely to have underlying medical conditions than the nonpregnant women hospitalized with 2009 H1N1 influenza. Although pregnant women frequently presented with mild or moderate symptoms, many had a rapid clinical progression and deterioration.

Over the 4-month study period, the cause-specific maternal mortality ratio for 2009 H1N1 influenza was estimated at 4.3 in California. The maternal mortality ratio for death from any cause was 19.3 in California in 20059 and 13.3 in the United States in 2006.10 More than two thirds of maternal deaths in the United States each year are directly related to obstetrical factors, and maternal deaths due to influenza have been rare.11 The high 2009 H1N1 influenza–specific maternal mortality suggests that this pandemic has the potential to notably increase overall maternal mortality in the United States in 2009.

The severity of influenza seen in this case series is consistent with the increased risk of severe disease among pregnant women that has been documented for seasonal influenza and previous pandemics.3,4,6,11,12 Consistent with the excess number of influenza-associated deaths among pregnant women observed during previous pandemics is the disproportionate number of pregnant women, as compared with their prevalence in the overall population, among all patients who have died and all critically ill patients, as was recently reported in the United States5 and other countries13,14 during the current pandemic. Although an association between severe illness and pregnancy is well documented for seasonal influenza, the rapid clinical deterioration observed in some of our patients appears to be qualitatively different from the course of seasonal influenza observed previously.11,12 One quarter of the women requiring mechanical ventilation in our series were severely ill at the time of presentation and required intubation on the day of admission. Six deliveries occurred in an ICU, including four emergency cesarean deliveries, which is a relatively rare obstetrical occurrence and suggests that the condition of the patients was too unstable at the time of delivery for them to be transferred to an appropriate labor and delivery unit.15 Furthermore, although the data are limited, deaths among pregnant women due to seasonal influenza appear to be uncommon. In a study of more than 4000 women enrolled in the Tennessee Medicaid program between 1974 and 1993 who had a cardiopulmonary event during the influenza season,11 none of the 104 maternal deaths that occurred were likely to have been due to influenza.

The Centers for Disease Control and Prevention (CDC) recommends prompt antiviral treatment of pregnant women with suspected or confirmed 2009 H1N1 influenza, ideally within 48 hours after symptom onset.16 In our series, pregnant women who received treatment after 48 hours had a risk of admission to the ICU or death that was about 4 times as high as the risk among those who received earlier treatment. Delay in treatment was often multifactorial in cause; in some cases, pregnant women did not promptly seek medical care after symptom onset, whereas in other cases, there were delays by health care providers in initiating antiviral treatment. The recognition and diagnosis of influenza-like illness may be complicated during pregnancy, when women and their health care providers may attribute certain signs and symptoms (e.g., myalgia or shortness of breath) to pregnancy rather than influenza. Furthermore, pregnant women or their health care providers may want to avoid antiviral treatment during pregnancy because of concerns about the fetus.6 Although rapid influenza tests are widely available and can be completed within 15 minutes, reliance on rapid test results might
have contributed to treatment delays. In this series, 38% of patients who underwent testing had false negative results; less than 30% of the pregnant women with false negative results received antiviral treatment within 48 hours after symptom onset, and five of the patients who died had false negative results. Recently, the CDC issued a health advisory alerting clinicians about the poor sensitivity of rapid test results and stating that clinical decisions about the treatment of influenza should not be guided or delayed by negative results on rapid testing.17-19

The fact that eight of the cases of influenza in our study involved a postpartum onset of symptoms, with severe disease and death in some of these cases, highlights the continued high risk immediately after pregnancy. A variety of cardiac, respiratory, hormonal, and immunologic changes that occur during pregnancy may contribute to the increased risk of influenza-related morbidity and mortality among pregnant women.20 Although it is unknown how long after delivery these changes persist, some of them (i.e., immunologic alterations) might persist longer than others (e.g., decreased lung capacity due to uterine compression). Although some studies of seasonal influenza have not shown an increased period of risk during the postpartum period,11 the immediate postpartum period probably represents a transitional period during which the risk of severe disease is returning to, but has not yet reached, the baseline level. In light of these emerging data, the CDC recently issued revised guidelines, recommending prompt initiation of antiviral treatment in patients with suspected or confirmed influenza up to 2 weeks after delivery.16

The limitations of our study should be noted. Although enhanced surveillance efforts were initiated, case ascertainment relied on passive reporting by clinicians, and underascertainment probably occurred because of both underrecognition of influenza cases and underreporting by clinicians to the CDPH. In addition, recommendations for testing were based on the severity of clinical illness, but despite these guidelines, clinicians may have been more inclined to test pregnant women than nonpregnant women, and pregnant women may have been hospitalized more readily or with less serious coexisting illness. Finally, the medical records of pregnant and postpartum women who required intensive care underwent additional review, with the provision of key missing data by clinicians; the records of nonpregnant women who required intensive care did not undergo the same level of scrutiny in the study, owing to time and resource limitations.

As the current pandemic unfolds, pregnant and postpartum women should be counseled about the importance of vaccination.21-23 Pregnant women are a top-priority group for immunization against 2009 H1N1 influenza. Since the 2009 H1N1 monovalent vaccine is manufactured according to the same processes that are used for the seasonal influenza vaccine, its safety profile among pregnant women is expected to be similar to that of the seasonal influenza vaccine, which has consistently been shown to be safe during pregnancy.24 Preliminary results from a trial of 2009 H1N1 monovalent vaccine have shown a robust immune response in pregnant women, similar to the response in nonpregnant adults, and no safety concerns have been identified.25 Maternal vaccination may also provide a benefit to the newborn infant, with a decreased risk of respiratory infections related to influenza in both the mother and infant during the first 6 months after delivery.23 Regardless of the results of rapid antigen tests, women with suspected or confirmed influenza who are pregnant or who have delivered within the previous 2 weeks should receive aggressive antiviral treatment and undergo close monitoring. Finally, because pregnant women and their fetuses require specialized care and monitoring, early consideration should be given to the transfer of critically ill pregnant and postpartum women hospitalized in non–tertiary care facilities to facilities that provide a higher level of care, including neonatal intensive care for premature infants.

No potential conflict of interest relevant to this article was reported. Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.

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Appendix

Members of the California Pandemic (H1N1) Working Group are as follows: F. Aranki, Fresno County Department of Public Health, Fresno; O. Byron-Cooper, El Dorado County Health Services Department, Placerville; M. Cheung, Orange County Health Care Agency, Santa Ana; S. Cody, County of Santa Clara Public Health Department, San Jose; S. Farley, Contra Costa Health Services, Martinez; M. Ginsberg, San Diego County Health and Human Services, San Diego; L. Hammond, Sonoma County Department of Health Services, Santa Rosa; S. Hathaway, County of Los Angeles Department of Public Health, Los Angeles; L.B. Hernandez, Monterey County Health Department, Salinas; J. Holguin, Long Beach Department of Health and Human Services, Long Beach; J. Kempf, Tulare County Health and Human Services Agency, Visalia; A. Norman, Sacramento County Department of Health and Human Services, Sacramento; M. Ohikhuare, San Bernardino Department of Public Health, San Bernardino; E. Pan, San Francisco Department of Public Health, San Francisco; R. Rylas, Alameda County Public Health Department, Oakland; C.S. Sallenave, San Mateo County Health System, San Mateo; J. Holguin, Long Beach Department of Health and Human Services, Long Beach; J. Kempf, Tulare County Health and Human Services Agency, Visalia; A. Norman, Sacramento County Department of Health and Human Services, Sacramento; M. Ohikhuare, San Bernardino Department of Public Health, San Bernardino; E. Pan, San Francisco Department of Public Health, San Francisco; R. Rylas, Alameda County Public Health Department, Oakland; C.S. Sallenave, San Mateo County Health System, San Mateo; F. Schwartz, County of Marin, Department of Health and Human Services, San Rafael; N. Shah, San Joaquin County Public Health Services, Stockton; J.A. Walker, Stanislaus County Health Services Agency, Modesto.

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