Impact of Postpartum Influenza Vaccination of Mothers and Household Contacts in Preventing Febrile Episodes, Influenza-like Illness, Healthcare Seeking, and Administration of Antibiotics in Young Infants During the 2012–2013 Influenza Season

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Background. Influenza is associated with an increased risk for serious illness, hospitalization, and mortality in infants aged <6 months. However, influenza vaccines are not licensed for administration in this age group. The study evaluated the effectiveness of postpartum influenza vaccination of mothers and household members in infants.

Methods. The influenza vaccine was offered to mothers and household members of neonates born or hospitalized in 3 hospitals prior to the 2012–2013 season. Mothers were contacted every 2 weeks during the influenza season, and data regarding the onset of fever and/or respiratory symptoms in infants, healthcare seeking, hospitalization, and administration of antibiotics were collected.

Results. The study group consisted of 553 mothers who delivered 573 neonates. The influenza vaccine was administered to 841 of 1844 (45.6%) household contacts. Vaccination coverage rates ranged between 41.9% for neonates siblings and 49% for mothers. Five hundred thirty infants were analyzed for vaccine effectiveness. For outcomes in the infant, postpartum maternal vaccination had 37.7% effectiveness against acute respiratory illness (ARI), 50.3% against a febrile episode, 53.5% against influenza-like illness (ILI), 41.8% against related healthcare seeking, and 45.4% against administration of antibiotics. Multiple logistic regression analyses showed that maternal influenza vaccination was significantly associated with a decreased probability for febrile episodes, ARIs, and/or ILIs in infants, related healthcare seeking, and/or administration of antibiotics during the influenza season. Vaccination of other household contacts had no impact.

Conclusions. Maternal postpartum vaccination against influenza was associated with a significant reduction of influenza-related morbidity, healthcare seeking, and antibiotic prescription in infants during the influenza season.

Keywords. influenza vaccination; cocooning; infants; postpartum; mothers.
Seasonal influenza has been established as a leading cause of morbidity, mortality, and utilization of healthcare services globally, and the disease burden in young infants has been acknowledged during recent years [1–3]. Seasonal influenza is associated with an increased risk of serious illness, complications, outpatient visits, and hospitalizations among young infants. Studies have indicated elevated attributable hospitalization rates in infants <6 months of age that are similar to those documented in high-risk populations >65 years of age [1–4]. In addition, influenza-associated deaths during childhood most frequently involve infants <6 months of age [3]. The prevention and management of influenza remains a primary concern of healthcare professionals attending to young infants, given that influenza vaccines are not licensed for infants <6 months of age and that oseltamivir treatment was only recently approved for this age group [4–6]. Antepartum maternal vaccination has been associated with a significant reduction of laboratory-confirmed influenza and associated hospitalizations in infants [7, 8]. However, to date the vaccination coverage rate among pregnant women remains suboptimal [9, 10].

Vaccination of close contacts in an attempt to protect infants <6 months of age, sometimes referred to as the “cocooning” strategy, is recommended by the US Centers for Disease Control and Prevention Advisory Committee on Immunization Practices and other public health bodies worldwide [4]. The rationale for the cocooning strategy is based on the fact that young infants contract influenza almost exclusively from their household members. Hence, vaccination of household contacts provides protection to them, and, albeit indirectly, to infants [11]. In Greece, the cocooning strategy against influenza was first implemented during the 2009–2010 influenza A(H1N1) pandemic. Vaccination against influenza of mothers and household contacts of neonates has been recommended thereafter annually.

During the 2011–2012 influenza season, we assessed the feasibility and acceptance of the cocooning strategy in a maternity hospital and a neonatal unit [12]. The study aim was to evaluate the effectiveness of the cocooning strategy for young infants whose mothers and other household members were offered influenza vaccination during the early postpartum period.

**METHODS**

**Setting**

The study was prospectively conducted during the 2012–2013 influenza season at the Aghia Sophia Children’s Hospital, the Alexandra General Hospital, and the Elena Venizelou Maternity Hospital, all located in Athens, Greece.

**Enrollment of Participants**

Women who delivered a neonate at either the Alexandra General Hospital or the Elena Venizelou Hospital, as well as mothers whose neonates were admitted to the level II Neonatal Unit of the Aghia Sophia Children’s Hospital from 1 October 2012 through 5 January 2013, were eligible for study participation. Only mothers whose neonates were expected to be discharged from the hospital prior to the onset of the influenza season were asked to participate. Mothers who had been already vaccinated against influenza that season and mothers who were unable to communicate in either Greek or English were excluded. The study protocol was approved by the ethics committees of the participating hospitals. Oral consent was requested in 2 hospitals and written consent in the third.

**Data Collection and Influenza Vaccination**

Data were collected prospectively from mothers by 3 trained healthcare professionals (1 per hospital) using standardized questionnaires. Data were collected by personal interviews and by medical record reviews. Mothers were informed of the recommendations for influenza vaccination in household contacts of infants <6 months of age, as well as the efficacy and safety of the influenza vaccine for themselves and the expected effectiveness for their offspring. After inquiring for any contraindication for influenza vaccination (history of allergic reaction after previous influenza immunization, history of Guillain-Barré syndrome, and/or febrile illness during the interview), mothers were offered the option of being immunized against influenza. Mothers who either refused influenza vaccination and/or reported any of the aforementioned contraindications were requested to participate in the unvaccinated (control) group. Given the fact that the cocooning strategy is recommended by the Ministry of Health, randomization was not feasible as a result of ethical considerations. Fathers and all household members of the neonates (siblings, grandparents, and other caregivers) were informed of the vaccine’s safety, efficacy, and expected effectiveness for neonates, and following consent they were offered immunization. The 2012–2013 northern hemisphere trivalent seasonal influenza vaccine, containing A/California/7/2009(H1N1)pdm09-like virus, A/Victoria/361/2011 (H3N2)-like virus, and B/Wisconsin/1/2010-like virus, was administered (Influvac by Abbott or Vaxigrip by Sanofi-Aventis). Vaccinations were given free of charge and before hospital discharge.

**Follow-up of Infants**

Mothers were contacted by telephone by 6 trained healthcare professionals every 2 weeks during the 2012–2013 influenza season, for a total of 6 calls each. The investigators were blinded to the influenza vaccination status of participants. Information regarding onset of fever and/or respiratory symptoms in infants (eg, cough, runny nose, difficulty in breathing) was collected using standardized questionnaires, including the date of symptom onset, any related healthcare seeking, hospital admission and/or...
antibiotic administration, and disease diagnosed by the attending pediatrician (if any). New-onset fever and/or respiratory symptoms were recorded after the complete resolution of a prior episode of fever and/or respiratory symptom and an asymptomatic duration ≥3 days. Non-influenza-related illnesses (eg, urinary tract infection, gastroenteritis) diagnosed by a pediatrician were not recorded. Data regarding breast-feeding, passive smoking, and pneumococcal immunization (including number and dates of doses) were also collected.

Definitions
Fever was defined as a temperature of ≥38.0°C in at least 2 measurements within 24 hours. Febrile episode was defined as the onset of fever in the absence of any other sign and/or symptom of infection. Acute respiratory infection (ARI) was defined as the acute onset of ≥1 respiratory symptom. Influenza-like illness (ILI) was defined as acute onset of fever and cough or other respiratory symptom. Utilization of healthcare services was defined as any healthcare seeking (primary healthcare or hospital-based, public or private sector visit) or hospitalization related to the onset of fever and/or respiratory symptoms. The diagnoses of bronchiolitis, pneumonia, and acute otitis media were documented if they were made by a pediatrician. Urban residence was defined as residing in a town of ≥2000 residents [13]. Household contacts were defined as persons either living in the same residence or having close contact with participating infants for ≥4 hours daily. Timely pneumococcal vaccination (10- or 13-valent conjugate vaccines) was defined as administration of the first, second, and third doses by the age of 75, 135, and 195 days, respectively.

Statistical Analysis
Categorical and continuous variables were studied using the χ² test and t test, respectively. Confidence intervals were calculated. Stepwise multiple logistic regression was applied in order to investigate the association between maternal demographic, pregnancy, neonatal, and household characteristics and maternal vaccination against influenza. Multiple logistic regression analysis was subsequently applied to investigate the association between maternal demographic, pregnancy, neonatal, and household vaccination against influenza; pneumococcal vaccination of infant; passive smoking; and breast-feeding with the onset of a febrile episode, ARI, or ILI in the infant, and related healthcare seeking, hospitalization, and/or administration of antibiotics. P values of ≤.05 were considered statistically significant. The effectiveness of influenza vaccine was estimated as [1 – (incidence rate in infants with vaccinated mothers/incidence rate in infants with unvaccinated mothers) × 100] [14]. Statistical analysis was conducted using Stata software, version 8.0 logistic.

RESULTS
During the study period, 622 mothers were asked to participate in the study; 14 refused to participate and 55 who could not communicate in Greek or English were excluded. None of the mothers had been vaccinated antepartum. Thus, the study group consisted of 553 mothers. The 553 mothers gave birth to 573 neonates (range, 1–3 neonates each) with a mean birth weight of 3000 g (range, 600–4910 g) at a mean gestational age of 37.4 weeks (range, 23–43 weeks). In 537 households (97.1%) an additional household member existed, and at least 1 sibling was present in 260 (47%) households. Overall, there were 1844 members in the 553 studied households, including 553 mothers, 525 fathers, 358 siblings, 323 grandparents, 73 other relatives, and 12 caregivers.

Influenza vaccine was delivered to 841 of 1844 (45.6%) household contacts. Vaccination rates were 49% (271/553) among mothers, 43.6% (229/525) among fathers, 41.9% (150/358) among siblings, and 46.8% (191/408) among other household contacts. Table 1 shows the characteristics of mothers, infants, and residencies according to maternal influenza immunization status. The 2 groups differed in terms of gestational age (P = .008), neonatal birth weight (P = .014), infant age at the onset of the influenza season (2.9 months in unvaccinated mothers vs 2 months in vaccinated mothers; P < .001), and number of household contacts other than the mother (P = .043). Multiple logistic regression analysis showed that infants with mothers belonging to larger households, infants with lower gestational age, and younger infants at the onset of the influenza season had an increased likelihood for influenza immunization uptake (P = .049, P = .008, and P < .001, respectively).

Fathers of neonates with vaccinated mothers more frequently received the vaccine compared to fathers of neonates with unvaccinated mothers (79.5% vs 6.2% vaccine uptake; P < .001). Likewise, more household members were vaccinated in

The 2012–2013 Influenza Season in Greece
In Greece the 2012–2013 influenza activity started on 20 January 2013 and ended on 15 April 2013. In accordance with the virological surveillance data, 95.7% of isolates were of type A (57.1% subtype A[H3N2] and 42.9% subtype A[H1N1] pdm09) and 4.3% were of type B [15].
No serious adverse event associated with in-fluenza vaccination was reported. Of the 573 infants, 43 were excluded from the analysis because of loss to follow-up due to an incorrect telephone number (30 infants), declination to follow-up (6 infants), relocation to another country (3 infants), readmission and hospitalization throughout the influenza season (3 infants), or death before the onset of the influenza season (1 infant). Thus, 530 infants were included in the analysis. During the 12-week follow-up, a total of 227 episodes of ARI, 91 febrile episodes, and 81 episodes of ILI were reported. Healthcare services were sought in 201 of these episodes, of which 59 resulted in admission to the hospital (18, 10, and 31 because of ARI, febrile episode, and ILI, respectively), whereas in 74 episodes an antibiotic was administered. No deaths occurred.

Table 2 shows the number of infants who had at least 1 episode of illness (febrile episode, ARI, and/or ILI) by maternal influenza vaccination status. Infants of unvaccinated mothers more frequently developed episodes of ARI compared to infants of vaccinated mothers (mean number of episodes of ARI per infant, 0.5 vs 0.3; \( P < .001 \)), febrile episodes (mean number of febrile episodes per infant, 0.3 vs 0.1; \( P < .001 \)), and episodes of ILI (mean number of episodes of ILI per infant, 0.2 vs 0.1; \( P < .001 \)). Healthcare was sought and antibiotics were prescribed more frequently among infants of unvaccinated mothers compared to infants of vaccinated mothers (mean number of healthcare-seeking episodes per infant, 0.5 vs 0.3, respectively, and mean number of courses of antibiotics per infant, 0.2 vs 0.1, respectively; \( P < .001 \) for both comparisons). Postpartum maternal vaccination had 37.7% effectiveness against ARI, 50.3% against a febrile episode, 53.5% against ILI, 41.8% against related healthcare seeking, and 45.4% against antibiotic administration.

Breast-feeding was sustained for shorter periods in infants of unvaccinated mothers (5.1 vs 6.2 weeks; \( P = .016 \)). Infants of unvaccinated mothers were more likely to have received complete and timely pneumococcal immunization (5.1% vs 0.4%; \( P = .002 \)). The groups did not differ with respect to proportion of breast-fed infants and the timely uptake of 1 or 2 doses of pneumococcal vaccine.

Table 3 shows the results of the multiple logistic regression analyses. Maternal postpartum influenza vaccination was significantly associated with a decreased probability for the onset of a febrile episode, ARI, and/or ILI in infants, and related healthcare seeking and/or administration of antibiotics during the influenza season. Infants residing in large households were more likely to develop a febrile episode and/or ILI, and to be hospitalized during the influenza season. Paternal vaccination and percentage of vaccinated household contacts had no impact on the onset of a febrile episode, ARI, ILI, healthcare seeking, or administration of antibiotics in infants.

**DISCUSSION**

This is a prospective study that was conducted in 3 large urban hospitals to evaluate the effectiveness of the influenza cocooning strategy in infants. Postpartum maternal influenza vaccination...
emerged as the only factor consistently associated with reduced probability for the onset of a febrile episode, ARI, and/or ILI in young infants during the influenza season. In addition, this intervention significantly reduced healthcare seeking and antibiotic administration, which is important given the high rates of unnecessary prescriptions for young children with viral respiratory infections [16]. These effects were documented despite the large households studied and the suboptimal (45%–68%) influenza vaccine effectiveness reported in 2012–2013 against influenza A virus, which prevailed in Greece [17–20]. Similar hospitalization rates between the 2 groups may be due to postpartum vaccination having protected the infants against mild disease. Vaccination of fathers and other household contacts had no statistically significant impact on influenza-related morbidity of their infants. Our findings strongly support the recommendations to vaccinate mothers during the early postpartum period.

In our study, postpartum maternal vaccination was associated with 53.5% vaccine effectiveness against ILI, which is higher

### Table 2. Incidence of Reported Morbidity in Infants by Maternal Influenza Vaccination Status

<table>
<thead>
<tr>
<th>Type of Illness</th>
<th>Unvaccinated Mothers (n = 264)</th>
<th>Vaccinated Mothers (n = 266)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. (%)</td>
<td>95% CI</td>
<td></td>
</tr>
<tr>
<td>ARI</td>
<td>105 (39.8)</td>
<td>33.8–45.7</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Febrile episode</td>
<td>50 (18.9)</td>
<td>14.2–32.7</td>
<td>.002</td>
</tr>
<tr>
<td>ILI</td>
<td>45 (17.0)</td>
<td>12.5–21.6</td>
<td>.001</td>
</tr>
<tr>
<td>Acute otitis media*</td>
<td>9 (3.4)</td>
<td>1.2–5.6</td>
<td>.156</td>
</tr>
<tr>
<td>Bronchiolitis*</td>
<td>40 (15.2)</td>
<td>10.8–19.5</td>
<td>.061</td>
</tr>
<tr>
<td>Pneumonia*</td>
<td>2 (0.8)</td>
<td>.3–1.8</td>
<td>.994</td>
</tr>
<tr>
<td>Healthcare seeking</td>
<td>99 (37.5)</td>
<td>31.6–43.4</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Admission to hospital</td>
<td>26 (9.8)</td>
<td>6.2–13.5</td>
<td>.633</td>
</tr>
<tr>
<td>Administration of antibiotics</td>
<td>40 (15.2)</td>
<td>10.8–19.5</td>
<td>.014</td>
</tr>
</tbody>
</table>

Abbreviations: ARI, acute respiratory illness; CI, confidence interval; ILI, influenza-like illness.

* Diagnosed by a pediatrician.

### Table 3. Multivariate Analyses for Factors Associated With Reported Morbidity and Utilization of Healthcare Services in Infants During the 2012–2013 Influenza Season

<table>
<thead>
<tr>
<th>Endpoint</th>
<th>Statistically Significantly Associated Factors</th>
<th>OR</th>
<th>95% CI</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Febrile episode</td>
<td>No postpartum maternal vaccination against influenza</td>
<td>2.358</td>
<td>1.324–4.201</td>
<td>.004</td>
</tr>
<tr>
<td></td>
<td>Large number of household contacts</td>
<td>1.301</td>
<td>1.087–1.556</td>
<td>.004</td>
</tr>
<tr>
<td>ARI</td>
<td>Increased number of parities</td>
<td>1.501</td>
<td>1.164–1.936</td>
<td>.002</td>
</tr>
<tr>
<td></td>
<td>No postpartum maternal vaccination against influenza</td>
<td>1.791</td>
<td>1.185–2.708</td>
<td>.006</td>
</tr>
<tr>
<td></td>
<td>No pneumococcal vaccination of infant</td>
<td>1.695</td>
<td>1.042–2.757</td>
<td>.033</td>
</tr>
<tr>
<td>ILI</td>
<td>No postpartum maternal vaccination against influenza</td>
<td>2.718</td>
<td>1.460–5.061</td>
<td>.002</td>
</tr>
<tr>
<td></td>
<td>Large number of household contacts</td>
<td>1.354</td>
<td>1.124–1.630</td>
<td>.003</td>
</tr>
<tr>
<td>Healthcare seeking</td>
<td>Increased number of parities</td>
<td>1.484</td>
<td>1.154–1.909</td>
<td>.002</td>
</tr>
<tr>
<td></td>
<td>No postpartum maternal vaccination against influenza</td>
<td>3.122</td>
<td>1.479–6.590</td>
<td>.003</td>
</tr>
<tr>
<td></td>
<td>No breast-feeding or breast-feeding of short duration</td>
<td>1.103</td>
<td>1.018–1.194</td>
<td>.016</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>Large number of household contacts</td>
<td>1.357</td>
<td>1.107–1.664</td>
<td>.003</td>
</tr>
<tr>
<td></td>
<td>Unvaccinated infants against pneumococcus</td>
<td>3.122</td>
<td>1.479–6.590</td>
<td>.003</td>
</tr>
<tr>
<td></td>
<td>Older infant age at the onset of the influenza season</td>
<td>1.284</td>
<td>1.022–1.614</td>
<td>.032</td>
</tr>
<tr>
<td>Administration of antibiotics</td>
<td>Younger maternal age</td>
<td>1.110</td>
<td>1.053–1.169</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>Increased number of parities</td>
<td>1.997</td>
<td>1.418–2.811</td>
<td>&lt;.001</td>
</tr>
<tr>
<td></td>
<td>No postpartum maternal vaccination against influenza</td>
<td>2.115</td>
<td>1.097–4.079</td>
<td>.025</td>
</tr>
<tr>
<td></td>
<td>Older infant age at the onset of influenza season</td>
<td>1.340</td>
<td>1.073–1.673</td>
<td>.010</td>
</tr>
</tbody>
</table>

Abbreviations: ARI, acute respiratory illness; CI, confidence interval; ILI, influenza-like illness; OR, odds ratio.
than the 28.9% effectiveness against respiratory illness and fever reported by Zaman et al in infants whose mothers received the vaccine during pregnancy [7]. In their study, the clinical effectiveness in infants of mothers vaccinated during pregnancy was 63% against laboratory-confirmed influenza and 42% against a clinic visit [7], which is comparable to the 41.8% vaccine effectiveness against healthcare seeking seen in infants of mothers vaccinated in the early postpartum period in our study. In the Zaman et al study, infants were observed for 24 weeks following birth, which may explain the lower rates of protection against respiratory illness and fever compared to our study. In a case-control study conducted by Benowitz et al, very high (91.5%) vaccine effectiveness against laboratory-confirmed influenza was found among infants aged <6 months whose mothers were vaccinated antepartum [8]. Antepartum vaccination offers the advantage of conferring immunity during pregnancy as well; however, its overall benefits are hampered by the low coverage rates among pregnant women [9]. Despite the fact that annual influenza vaccination has been recommended in Greece for pregnant women since 2009–2010, the vaccine uptake among this group remains negligible, as also documented by the fact that none of the mothers had received the vaccine antepartum. It is of great importance to increase vaccination rates in pregnancy as an alternative to postpartum vaccination.

Reduced transmission conferred through influenza vaccination has also been reported in other settings. Vaccination of healthcare workers in long-term care reduced ILI; ILI-associated consultations, hospitalizations, mortality, and all-cause mortality among elderly patients [21, 22]. Similarly, vaccination of children in day care reduced influenza-related morbidity in their household contacts, with the highest impact among school-aged contacts [23]. Neonatal intensive care units and maternity clinics are ideal settings in which to access household members during the early postpartum period and thus to build immunity around the neonates as early as 2 weeks of age. Offering vaccination at a second visit is another option [24]; however, there is approximately a 2-week window until immunity is achieved, which may be a problem for neonates delivered during the period immediately preceding the influenza season. Furthermore, limited vaccine uptake by parents when their vaccination relies only on their own motivation is of concern. A recent study revealed that only 32.6% of 92 parents who participated in an information program about influenza vaccine were vaccinated, despite their high (92%) intention rates to get vaccinated; the prevailing reason for failure to become vaccinated was inconvenience [25]. Hospital-based cocooning programs vaccinating at no cost appears to overcome many barriers [11].

The organization and implementation of the cocooning strategy required notable human resources and effort. On several occasions the vaccine was offered during evening hours or weekends. Siblings aged <12 years are not allowed to enter obstetric clinics and neonatal units, so their vaccination was scheduled in outpatient pediatric clinics. Legal and financial issues regarding the vaccination of visitors also had to be considered. Nevertheless, we were successful in protecting neonates who otherwise would be unprotected.

The cornerstone for effective public health policies is their acceptance by both healthcare professionals and the general public. Communication to healthcare professionals involved in the cocooning strategy, resolution of any organizational or financial issues by establishing flexible vaccine-delivery systems, and meeting the demands for delivering the vaccine are of outmost importance for early postpartum vaccination to become the standard of care within the following years.

Our study has several limitations. First, we used definitions based on reported symptoms, and therefore recall bias is possible; however, this methodological approach has been used consistently in influenza vaccine effectiveness studies [23, 26]. Second, although the recorded influenza-associated morbidity may underestimate the true burden of this illness, we believe that active surveillance allowed us to estimate accurately the impact of vaccination. Third, although ILI may be attributed to a broad spectrum of winter-circulating respiratory pathogens, we chose not to test symptomatic infants for influenza because of the inconvenience of referring an infant for testing. Fourth, multivariate analysis can address confounding to some degree. The other option would be to conduct a randomized controlled trial; however, this was not feasible for us because of ethical considerations, given the fact that postpartum vaccination is officially recommended in Greece. Last, the influenza-associated burden may vary substantially by region and year; thus, further studies may be needed to confirm our findings in other settings. Nevertheless, our study provides clear evidence of the benefits of the influenza vaccination cocooning strategy for young infants.

In conclusion, our study provides evidence that maternal influenza vaccination during the early postpartum period reduces influenza-associated morbidity, healthcare seeking, and consumption of antibiotics in young infants during the influenza season. Our findings strongly support the recommendations for the cocooning strategy. Overall, our study provides a good insight on influenza in early infancy, which may help in planning vaccination strategies. Until the cost effectiveness of the cocooning study is evaluated in the field, influenza immunization of mothers during the early postpartum period will provide young infants with the necessary protection from influenza infection and its dire effects in this population.

Supplementary Data

Supplementary materials are available at Clinical Infectious Diseases online (http://cid.oxfordjournals.org). Supplementary materials consist of data provided by the author that are published to benefit the reader. The posted
materials are not copyedited. The contents of all supplementary data are the sole responsibility of the authors. Questions or messages regarding errors should be addressed to the author.

Notes

Acknowledgments. We thank the mothers and family members who participated in the study, as well as the healthcare personnel for their assistance in conducting the study. We acknowledge Vianex for funding the purchase of influenza vaccines. We also acknowledge Elena Critselis for editing assistance.

Disclaimer. The opinions in this article are those of the authors and do not necessarily represent those of the Hellenic Center for Disease Control and Prevention.

Potential conflicts of interest. All authors: No reported conflicts.

All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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