The Feasibility of Universal Influenza Vaccination for Infants and Toddlers

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Background: Physicians' opinions on the feasibility of routine influenza vaccination of infants and toddlers are unknown.

Objective: To assess the opinions of primary care providers regarding (1) the feasibility of an expanded influenza vaccination recommendation, (2) potential barriers, and (3) current and projected use of immunization reminder systems for influenza vaccination.

Methods: In February 2001, we mailed a 20-item, self-administered survey to a national random sample of pediatricians and family physicians (FPs). The survey primarily focused on a scenario of routine influenza vaccination for children aged 12 through 35 months using either injected or intranasal spray vaccine.

Results: Four hundred fifty-eight eligible physicians completed the survey (eligible response rate: pediatricians, 72%; FPs, 52%). Regarding the scenario mentioned above, most physicians agreed that implementation would be feasible (pediatricians, 80%; FPs, 69%); would significantly decrease illness visits during influenza season (pediatricians, 67%; FPs, 57%); and was justified by influenza's severity and complications (pediatricians, 61%; FPs, 41%). When considering a scenario that extended down to 6 months of age and only allowed use of injectable vaccine for infants, fewer physicians (pediatricians, 50%; FPs, 40%) considered implementation feasible. The issues most frequently cited as important potential barriers for practices were costs (77%), vaccine safety issues (52%), and the inability to identify eligible children (46%).

Conclusion: To make widespread implementation feasible, the following are needed: minimizing costs for families and physician practices, educational campaigns on key issues, and primary care system changes (eg, tracking of eligible children, reminder and/or recall systems, and immunization clinics).

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Because of high rates of influenza-related hospitalizations among healthy infants and young children in October 2003, the Advisory Committee on Immunization Practices published a new recommendation to routinely vaccinate healthy children 6 to 23 months old. This followed an earlier recommendation to vaccinate children in this age group whenever feasible.

Little is known about the feasibility of adding universal influenza vaccination to the already complex pediatric schedule. Unlike other vaccines, influenza vaccine must be given annually. A second dose should be given at least 4 weeks after the first dose for children younger than 9 years who are receiving the influenza vaccine for the first time. The window of opportunity for influenza vaccination is relatively short, with most doses given in autumn and early winter, and the optimal time being October through November. Because a high proportion of age-eligible children would not normally make the requisite 1 or 2 visits to their primary care provider during these months, systems for identifying and notifying eligible families and for vaccinating large numbers of children are needed.

The number of children who become eligible for inactivated influenza vaccination under expanded recommendations is large; in the United States there are approximately 5.5 million children 6 to 23 months old.

The objectives of this study were to assess the opinions of primary care physicians across the United States regarding (1) the feasibility of an expanded influenza vaccination recommendation for young children, (2) the potential barriers to implementation of such a recommendation, and (3) their current and projected use of immunization reminder systems for influenza vaccination.
METHODS

SUBJECTS

The American Medical Association Masterfile14 was used as a source of subjects. This file contains the most extensive listing of US physicians and includes demographic information on both American Medical Association members and nonmember physicians.15 We requested information on 1200 randomly selected primary care physicians (600 pediatricians, 600 family physicians [FPs]) located throughout the United States. Physicians were eligible if they were working in a primary care practice that vaccinated at least 5 patients between the ages of 12 and 35 months in a typical week.

DEMOGRAPHIC AND PRACTICE MEASURES

Demographic and practice measures were obtained from either the American Medical Association Masterfile or the survey questions, and included physician specialty, sex, region, and year of medical school graduation, as well as practice type, major patient insurance type, and the annual number of newborn to 12-month-old patients seen by the physician.

SURVEY TOOL

In February 2001, we mailed subjects (1) a cover letter about the study, (2) a background information sheet, and (3) a 20-item, 4-page, forced-choice questionnaire that had been piloted locally for content validity and readability. Scaled survey items were in the format of a 5-point Likert scale. Up to 4 mailings were sent to nonresponders, and following the third mailing, physician offices were contacted by telephone and encouraged to complete the survey.

Background Information Sheet

This sheet included the answers to 5 common questions about the potential influenza recommendation. Notably, we suggested as a baseline assumption that insurance companies and the Vaccines for Children Program would cover the cost of the influenza vaccination.

Dependent Measure

Given the assumption that they could offer either intranasal spray or injectable vaccine, we asked participants, “Overall, what is your opinion of the potential recommendation to give influenza vaccine to all 12- to 35-month-old children?” The age range and choice of vaccines were posited because these appeared likely scenarios to us at the time the survey was developed. Subsequently, the American Academy of Pediatrics and Advisory Committee on Immunization Practices encouraged vaccination of children 6 through 35 months old at present, the intranasal spray vaccine has not been licensed for children younger than 5 years old.

Other Survey Questions

Additional questions focused on physician attitudes toward influenza vaccination of 6- to 12-month-old children with injectable vaccine and a variety of feasibility issues regarding influenza vaccination of an entire cohort of children, potential practice and family barriers, and use of reminders.

ANALYSIS

We collapsed 5-point Likert scale responses to a 3-point scale for ease of presentation. Bivariate analyses ($\chi^2$ and t tests) compared responses by pediatricians vs FPs, as well as responses by other practice and physician variables. Because some of the physician factors were likely to be associated with each other, multivariate logistic regression was performed for key questions using variables that were significant predictors on bivariate analyses. This analysis identified the variables that independently predicted the dependent measure, overall opinion (described in the “Dependent Measure” subsection of the “Methods” section).

RESPONSE RATES AND DEMOGRAPHIC CHARACTERISTICS

Accurate address, telephone, or fax numbers were available for 972 of the 1200 physicians initially sampled. Of these, 846 responded to our survey—283 (33%) were ineligible, 105 (12%) refused to participate, and 458 (54%) completed the survey (306 pediatricians, 152 FPs). Eliminating ineligibles, we found an overall eligible response rate of 66% (458 of 722 potential respondents of which 283 were ineligible) (72% pediatricians, 52% FPs). Demographic characteristics of the respondents and differences between the specialty groups are listed in Table 1.

ATTITUDES TOWARD AN EXPANDED RECOMMENDATION

The dependent measure, overall opinion of an expanded recommendation for influenza vaccination, was favored by 58% (64% pediatricians, 46% FPs), neither opposed nor favored by 23% (22% pediatricians, 27% FPs), and opposed by 19% (14% pediatricians, 28% FPs). Table 2 gives physician responses to statements about an expanded influenza vaccination recommendation including healthy 12- through 35-month-old children using either intranasal spray or injectable influenza vaccine (the “Toddler Scenario”). While most physicians believed that implementing this influenza recommendation would be feasible, a substantial minority expressed some concerns about parental objections, deterring other vaccinations, and the safety of live vaccines. Concerns were noted more frequently among FPs than pediatricians, although the differences were seldom statistically significant.

Physicians were asked how much more difficult it would be to implement the Toddler Scenario if only injected vaccine were available (ie, no intranasal vaccine). Eight percent responded that this would be “nearly impossible” to implement, 44% indicated “much more difficult,” 37% noted “slightly more difficult,” and 10% indicated “no more difficult.” When asked how much more difficult it would be to implement the Toddler Scenario if intranasal influenza vaccine were not licensed for concurrent administration with other vaccines, 12% indicated nearly impossible, 53% noted much more difficult, 27% indicated slightly more difficult, and 6% chose no more difficult.

Physicians were asked about their perceptions of a scenario like the Toddler Scenario except that it also included influenza vaccination of infants 6- through 12-months-old using the injectable, but not the intranasal spray vaccine (the Infant-Toddler Scenario). More physicians expressed concerns about implementation issues
for the Infant-Toddler Scenario (Table 3) than for the Toddler Scenario and, again, FPs had more concerns than pediatricians.

### Preferred Setting and Time Needed for Influenza Vaccinations

Almost all physicians (97%) indicated their practice was an acceptable place and 77% considered it the optimal place for their patients to receive influenza vaccination. Public health clinics were acceptable to 81%, child care centers to 28%, and pharmacies to 18%.

Physicians were asked to assume that an expanded influenza recommendation was adopted and implemented at their office. Physicians estimated that 49% of the 12- through 35-month-old children would be vaccinated during well-child care visits, 20% during illness or follow-up visits, 25% during influenza vaccine only visits, and 6% during other types of visits.

Physicians were asked to estimate the average number of minutes that a family bringing in children for influenza vaccine-only visits would spend with a physician, nurse practitioner, or physician’s assistant for the purpose of answering questions about influenza vaccine or related concerns. The median response was 5 minutes (range, 0-15 minutes).

### Barriers to Implementing an Expanded Recommendation

The survey contained separate lists of practice issues and family issues relevant to implementation of an expanded influenza vaccination recommendation (Table 4). Physicians were asked to check those items that they considered potential barriers and then pick the single most important barrier from each list. Commonly perceived practice-based barriers included up-front costs for vaccines, the inability to identify eligible patients, the need to discuss vaccine safety concerns with parents, and difficulty handling the extra immunization visits. Commonly perceived family concerns were vaccine costs, safety, and the addition of yet another vaccination.

### Reminder Systems

The inability to identify and notify children to come in for influenza vaccination was considered a barrier by 46% of the physicians. Currently, to identify children with high-risk medical conditions (eg, asthma) who need influenza vaccination, 35% of the respondents stated that they use computer files, 24% use manual medical record review, and 31% rely on handwritten...
lists. The methods for delivering specific reminders included mail (37%), telephone call (35%), or other means (6%). In addition, 45% use group reminders such as newsletters and posters distributed in waiting rooms. While some offices use more than 1 method, 18% reported that they currently use no reminders for children with high-risk conditions. When asked what they would consider using for identifying and notifying families if a recommendation were in place to give annual influenza vaccination to all children 12 through 35 months old, the results were similar except that more physicians (64%) would use group reminders and fewer physicians (18%) would maintain handwritten lists of eligible children.

Table 2. Pediatrician and Family Physician Attitudes Toward an Expanded Influenza Vaccination Recommendation: The Toddler Scenario*

| The Toddler Scenario: 12- to 35-Month-Old Who Could Receive Intranasal or Injectable Influenza Vaccine | No. of Respondents | Agree | Neutral | Disagree | No. of Respondents | Agree | Neutral | Disagree | P Value† |
|---|---|---|---|---|---|---|---|---|---|---|
| Implementing this influenza recommendation would be feasible in my practice | 303 | 79.5 | 12.9 | 7.6 | 152 | 69.1 | 23.0 | 7.9 | .02 |
| >50% of the parents in my practice would be interested in having their 12- to 35-month-old children vaccinated against influenza | 303 | 58.7 | 19.5 | 21.8 | 152 | 34.2 | 29.6 | 36.2 | <.001 |
| >5% of the parents in my practice would strongly oppose having their 12- to 35-month-old children vaccinated against influenza | 306 | 45.1 | 18.6 | 36.3 | 152 | 54.6 | 19.1 | 26.3 | .08 |
| Adding this vaccine would deter or delay administration of other vaccines to 12- to 35-month-old children | 305 | 14.8 | 16.7 | 68.5 | 152 | 15.8 | 25.7 | 58.6 | .06 |
| Influenza vaccine would significantly decrease the number of subsequent illness visits to my practice during the influenza season | 306 | 67.3 | 18.6 | 14.1 | 152 | 56.6 | 23.7 | 19.7 | .08 |
| Influenza and its serious complications justify annual vaccination | 305 | 60.7 | 21.6 | 17.7 | 152 | 40.8 | 26.3 | 39.2 | <.001 |
| I am hesitant to introduce another live virus vaccine in my practice because of safety concerns | 304 | 17.4 | 24.7 | 57.9 | 151 | 15.8 | 25.7 | 58.6 | .10 |

*Data are given as percentages of respondents unless otherwise stated.
†Comparisons of pediatricians with family physicians.

Table 3. Pediatrician and Family Physician Attitudes Toward an Expanded Influenza Vaccination Recommendation: The Infant-Toddler Scenario*

| Infant-Toddler Scenario: Toddler Scenario Plus Infants Aged 6 to 12 Months Who Could Receive Injectable Influenza Vaccine Only | No. of Respondents | Agree | Neutral | Disagree | No. of Respondents | Agree | Neutral | Disagree | P Value† |
|---|---|---|---|---|---|---|---|---|---|---|
| Implementing this influenza recommendation would be feasible in my practice | 300 | 50.3 | 26.0 | 23.7 | 152 | 40.1 | 30.9 | 28.9 | .12 |
| >50% of the parents in my practice would be interested in having their 6- to 12-month-old children vaccinated against influenza | 300 | 31.0 | 26.3 | 42.7 | 151 | 20.5 | 22.5 | 57.0 | .01 |
| >5% of the parents in my practice would strongly oppose having their 6- to 12-month-old children vaccinated against influenza | 300 | 67.0 | 12.0 | 21.0 | 152 | 72.4 | 13.2 | 14.5 | .25 |
| Adding this vaccine would deter or delay administration of other vaccines to 6- to 12-month-old children | 300 | 43.7 | 18.7 | 37.7 | 151 | 46.4 | 27.8 | 25.8 | .02 |

*Data are given as percentages of respondents unless otherwise stated.
†Comparison of pediatricians with family physicians.
Table 4. Potential Barriers to Implementation of an Expanded Influenza Vaccination Recommendation*

<table>
<thead>
<tr>
<th>Practice Issues Related to the Toddler Scenario†</th>
<th>Pediatricians (n = 257)</th>
<th>Family Physicians (n = 127)</th>
<th>P Value</th>
<th>Pediatricians (n = 306)</th>
<th>Family Physicians (n = 152)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Upfront costs for influenza vaccine purchase or vaccination of children without insurance coverage</td>
<td>77.1</td>
<td>76.3</td>
<td>.88</td>
<td>52.5</td>
<td>40.9</td>
<td>.03</td>
</tr>
<tr>
<td>Need to discuss vaccine safety concerns with parents</td>
<td>45.1</td>
<td>64.5</td>
<td>&lt;.001</td>
<td>9.7</td>
<td>16.5</td>
<td>.05</td>
</tr>
<tr>
<td>Inability to identify and notify these children to come in</td>
<td>41.2</td>
<td>56.6</td>
<td>.002</td>
<td>12.8</td>
<td>18.9</td>
<td>.12</td>
</tr>
<tr>
<td>Cost of additional personnel time</td>
<td>45.8</td>
<td>44.1</td>
<td>.74</td>
<td>5.1</td>
<td>6.3</td>
<td>.62</td>
</tr>
</tbody>
</table>

*Bivariate and Multivariate Analyses

Bivariate Analysis

Physicians were grouped as “favorable” (favorable or strongly favorable) or “not favorable” (neutral, unfavor- able, or strongly unfavorable) based on their overall opinion of the Toddler Scenario. We compared favorable and not favorable groups for demographic characteristics (specialty and those seen in Table 1), attitudinal characteristics (Table 2), and perceived barriers (Table 4). Those significantly associated with favoring the expanded recommendation included all the attitudinal questions and many perceived barriers, but only 2 demographic characteristics: pediatricians were more likely than FPs to favor the Toddler Scenario (63% vs 46%, P<.001) and physicians who had more than 100 infants younger than 1 year in their patient panel were more likely to favor the scenario than were physicians who had fewer infants (68% vs 50%, P = .004).

Multivariate Analysis

We performed multivariate logistic regression using variables that were significant predictors on bivariate analyses. Neither specialty nor any of the other demographic characteristics and only a few attitudinal variables remained significantly associated with physician agreement with an expanded influenza recommendation. The perception that parental refusals because of vaccine safety concerns would impede implementation was negatively associated with favoring the expanded recommendation (odds ratio [OR], 0.3; 95% confidence interval [CI], 0.1-0.9; P<.02). Variables that remained significantly positively associated with favoring the expanded recommendation included:

- Implementing the expanded recommendation would be feasible in their practice (OR, 2.8; 95% CI, 1.1-7.0; P = .03).
- Many parents of children in the physician’s practice would be interested in having their child vaccinated against influenza (OR, 2.7; 95% CI, 1.3-5.6; P = .007).

In this study, most primary care physicians favored an expansion of the influenza vaccination recommendation for children 12 through 35 months old that involved administration of either injectable or intranasal vaccine. Physicians were less favorable toward a scenario that included 6- through 12-month-old infants; one in which only injectable vaccine could be used; or one in which intranasal influenza vaccine could not be given simultaneously with other vaccines. Most physicians believed that influenza vaccination should occur in the medical home (ie, a primary care office with which a family has an established bond). The major perceived barriers were costs, parental concerns about vaccine safety, and the need for additional vaccinations or visits. A small percentage of physicians reported using reminder systems to identify and notify families of children who were eligible for influenza vaccination and few planned to add such systems for an expanded recommendation, choosing instead to expand their use of group reminders such as newsletters and waiting room posters. Neither specialty nor any of the other demographic characteristics and only a few attitudinal variables were significantly associated with physician agreement with an expanded influenza recommendation.

In its statement on the reduction of the influenza burden in children, the American Academy of Pediatrics Committee on Infectious Diseases summarized the logistic constraints to influenza immunization of healthy children. These included limited vaccine quantity, seasonal vaccine availability, and liability issues, as well as multiple injections, complicated schedule, recall systems, personnel demands, and reimbursement. In this sur-
vey, we assumed sufficient vaccine for pediatric use and that a full recommendation would be in place, shifting liability concerns to the National Vaccine Injury Compensation Program of the Department of Health and Human Services.37 Our findings shed light on practice-based barriers and possible solutions.

MULTIPLE INJECTIONS, COMPLICATED SCHEDULES, AND ADDITIONAL VISITS

Almost all survey respondents indicated their practice was an acceptable place for their patients to receive influenza vaccination and 77% considered it the optimal place. Within the medical home, 2 methods for influenza vaccination delivery are used commonly: incorporating this vaccine into the routine well-child care visits or setting up influenza immunization clinics—times set aside for part or all of the office and staff to be dedicated to rapid, focused, systematic influenza vaccination.

The American Academy of Pediatrics Committee on Infectious Diseases’ technical report18 notes that it is generally assumed that the newly recommended influenza vaccination could be administered at the same visit as other childhood immunizations. Physicians in our survey believed that about half of these vaccinations would be given during well-child care visits. Nevertheless, incorporating this vaccine into the routine well-child care visits necessitates an additional vaccination within an already crowded schedule21 and—because the safety of live intranasal influenza virus vaccine (FluMist; MedImmune Vaccines Inc, Mountain View, Calif) has not been established for children younger than 60 months29—an additional injection. Notably, while most physicians in our study believed that influenza vaccination would not deter other vaccinations, more than half indicated that it would be more difficult to implement an expanded recommendation if only injected vaccine were available.

About 75% of physicians believed “parental concern that this would be one more vaccine in a crowded vaccine schedule” was a potential barrier. Previous research has shown parents were more likely than office nurses to find it acceptable to administer 3 or 4 vaccines at a single visit23 and that parents asked about the switch from oral polio vaccine to inactivated polio vaccine were willing to have their child receive more injections to avoid a small risk of severe disease.22 Education for primary care providers and office staff about multiple injections will be critical to overcome reluctance to add more injections.

Immunization clinics may be important adjuncts to vaccination at well-child care visits. This relatively new concept is supported by the finding that 38% of physicians believed the extra immunization visits during existing office hours would be a barrier in their practice. A recent study found that—assuming a 3-month influenza vaccination window and assuming that no opportunities were missed—if only well-child care visits were used for influenza vaccination, then 74% of 6- to 23-month-olds would require at least 1 additional visit for vaccination.9 Further, a time and motion study noted that even though vaccination-only visits tend to be short, if an entire age cohort were vaccinated during these visits, substantial clogging of practices and patient rooms would occur.21 Thus, immunization clinics during the weekday, evening, or weekends may be a potential solution.

Recent widespread publicity on influenza-related childhood deaths24 caused a sudden frantic demand for the vaccine in many communities and was partially responsible for subsequent shortages.2526 Similar experiences in the future will further tax practices, making it even more important to implement (1) tracking, reminder, and recall systems to vaccinate children before influenza illness season, and (2) efficient practice-based means to vaccinate large numbers of children using immunization clinics or other strategies.

RECALL SYSTEMS

Our data corroborated the American Academy of Pediatrics Committee on Infectious Diseases statement14 and other studies27,28 showing that many offices do not use computerized tracking and recall systems to identify eligible patients for vaccination. In this study, only 33% of the respondents reported using computer files to identify children with high-risk medical conditions who need influenza vaccination. The inability to identify and to notify children to come in for influenza vaccination was considered a barrier by many pediatricians (41%) and FPs (57%). Efforts to promote the use of recall systems should be undertaken.

PERSONNEL

For both pediatricians and FPs, about 45% of the respondents indicated that the cost of additional office personnel time would make implementation of the expanded influenza recommendation difficult. About 11% and 23% reported that they foresaw difficulties with physician and non-physician staff, respectively, having to work more hours. More than half of pediatricians (67%) and FPs (57%) felt influenza vaccination would significantly decrease the number of subsequent illness visits to their practice during influenza season, but published estimates19 show it is unlikely this would offset the additional visits for vaccination.

REIMBURSEMENT

The office costs for influenza vaccination include the vaccine, needles, and refrigeration as well as personnel time for vaccine ordering, storage, and handling, administration, risk-and-benefit communication, and medical record documentation.29 Patient reminders create additional expenses. Most respondents to our survey (77%) believed implementation would be made difficult by upfront costs for vaccine purchase or vaccination of children without insurance. This was the most frequently cited “most important” practice barrier by pediatricians (53%) and FPs (41%). Many studies have noted that improved reimbursement to primary care providers (often within the Vaccine for Children Program) seems to improve vaccination coverage.30-38 An expanded recommendation would need to be complemented by appropriate reimbursement by Vaccines for Children Program and private insurers.
VACCINE SAFETY

Pediatricians (68%) and FPs (70%) cited “parental refusals because of vaccine safety concerns” as a potential barrier to influenza immunization. While this confirms other studies regarding parental concerns about vaccine safety, more study is needed to assess precisely what concerns parents have about influenza vaccination to be helpful in providing accurate information within primary care practices. In this study, physicians affirmed that the number of vaccines in the schedule was of concern to parents.

PHYSICIAN CHARACTERISTICS AND ATTITUDES

On bivariate analyses, FPs were less likely than pediatricians to favor universal influenza vaccination, but on multivariate analyses these differences disappeared, suggesting that factors other than specialty played a key role. The factors that remained significant on multivariate analyses all involved physician beliefs about disease burden, vaccine effectiveness, feasibility, or perceived parental interest in the vaccine. Effective education39 on these topics would be helpful to primary care physicians.

LIMITATIONS

This study has several limitations. We used the American Medical Association Masterfile14 as a source of physician addresses and we obtained a response rate comparable to other studies.42,43 but there may have been a nonresponse bias in either direction. Since this study was a physician self-reported survey we could not measure the actual ability of physicians to realize an expanded influenza vaccination recommendation.

The main assumptions (age group 12-35 months; a choice of intranasal or injectable influenza vaccine) were made because they appeared likely to us at the time the survey was developed. Subsequently, the focus of the American Academy of Pediatrics and Advisory Committee on Immunization Practices influenza vaccination encouragement and recommendations has been children 6 to 23 months of age and the Food and Drug Administration licensure of live intranasal influenza virus vaccine (included only healthy people 5 to 49 years of age). Results of this survey also may have been different after the 2003-2004 influenza season during which there were several highly publicized pediatric deaths from influenza,24 presumably making parental demand greater and physician attitudes more positive. There was also an influenza vaccine shortage25,26 and a possible mismatch with the prevailing strain27 presumably increasing skepticism.

CONCLUSIONS AND IMPLICATIONS

Primary care physicians who vaccinate young children tend to have favorable opinions toward an expanded influenza vaccination recommendation that would include healthy children aged 12 to 35 months. Including infants 6 to 11 months of age and the fact that intranasal spray vaccine is not licensed for young children will make implementation more challenging. Physicians considered the major barriers to implementation of universal influenza vaccination to be costs to practices and parents, parental concerns about vaccine safety, and the need for additional vaccinations or visits without the practices having reminder-recall capabilities, or efficient methods to handle the large volume of visits. Physicians believe in vaccine effectiveness, feasibility, and perceived parental interest in influenza vaccine all made it more likely that they would implement this recommendation.

To make widespread implementation feasible, the following are needed:

- Minimizing family out-of-pocket costs and providing appropriate reimbursement for practices.
- Educational campaigns focusing on evidence of disease burden as well as vaccine effectiveness and safety.
- Systems changes within primary care offices including tracking of eligible children, reminder-recall systems, and immunization clinics or other methods to handle the large volume of visits during the vaccination season.

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REFERENCES