Experience of an Infectious Diseases (ID) Travel Medicine Clinic During a National Shortage of Yellow Fever Vaccine (YFV)

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BACKGROUND

In April 2017, Sanofi Pasteur (SP), the sole supplier of Yellow Fever Vaccine (YFV) in the US, announced that supplies of YFV would be temporarily unavailable in the US. In conjunction with the FDA, SP launched an Expanded Access ID Program (EAP), to allow importation of YFV produced in France (Stamaril) by Sanofi Pasteur. Approximately 250 sites in the US were chosen based on geography, volume, and other factors. Our clinic, located in Eastern PA, was selected as one of those sites.

OBJECTIVE

To describe our clinic's experience with the Stamaril EAP and to evaluate tolerance/adverse effects in our population.

METHODS

Our travel clinic is a medium-sized clinic that is embedded within a 14-Physician ID practice. We performed a 17-month review of Stamaril usage at our clinic.

RESULTS

Our physicians had to complete SP training, CITI (research ethics and compliance) training, and our own internal training before being able to prescribe Stamaril. Through 4/30/18, we have clinic administered 1,255 Stamaril doses, of which 844 were administered in 2018. Clinic visit volumes increased from 716 unique visits in 2017 to 1,402 in 2018 (95%). "Stamaril only" visits were 333 (24%) of total travel visits for 2018. Travelers' came from multiple states outside our catchment area. We documented 3 serious adverse events (SAE) whether or not considered related to the vaccine. One was a CDC confirmed case of Yellow Fever virus associated neurotropic disease (YFV-AND) in a 70-year-old male (fully recovered), another was a new onset generalized seizure (not confirmed YEL-AND), fully recovered in a 55-year-old male. The third was a Brighton Level 1 for diagnostic criteria and probable case for vaccine causality of Viscerotrophic disease (VTD) in a 65 year-old male (recovery). To accommodate increased volumes, we added 1 physician, and 1 Physician Assistant-Extended (PA-C) to our travel rotations – 2 more providers in training. We held 8 evening sessions to accommodate large volumes in need of YFV.

CONCLUSION

The EAP program greatly increased our clinic travel rotations – nearly doubling over one year. This has greatly changed the dynamics of our practice. Volumes continue to rise relative to general ID visits.

SUMMARY

A nationwide shortage of US produced yellow fever vaccine started in early 2017 and has greatly changed our travel practice-patient volumes – nearly doubling over one year. This has greatly changed the dynamics of our practice. Volumes continue to rise relative to general ID visits.

Staging and ultimately our business plan for the future will continue to evolve as the EAP continues to ramp up. Based on our experience, travel clinics will need to find ways to plan and implement rapid changes in staging plans for future vaccine shortages.

SAE's tend to occur in older travelers (median age 64) and were seen only in males. Our numbers of SAE (3 = 0.26%) were numerically higher than previously published rates. The reasons for this are not known but might be in part due to chance with relatively low visit volumes of a single travel clinic.

Enhanced safety surveillance may also have played a role in higher SAE rates, owing to the increased vigilance required of an IRB-approved EAP. Our observations agree with SP and FDA's ongoing assessment of all adverse events, including SAEs for this EAP continued SP and FDA review is appropriate. All clinics involved in future EAP will need to carefully monitor patient adverse events and report any significant events in accordance with the EAP guidelines and IRB requirements.

REFERENCES


DEFINITIONS

1. Yellow Fever Vaccine Associated Neurotropic Disease
2. Yellow Fever Vaccine Associated Viscerotrophic Disease
3. Yellow Fever Neurotrophi-Virologic Disease
4. Yellow Fever Virologic Disease
5. Yellow Fever Virologic Disease
6. YFV-AND

TABLE 1: TRAVEL CLINIC VOLUME IMPACT

<table>
<thead>
<tr>
<th>Year</th>
<th>Travel Visits</th>
<th>Total Visits</th>
<th>Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TABLE 2: STAFFING CHANGES

<table>
<thead>
<tr>
<th>Year</th>
<th>Staffing</th>
<th>Increase</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

TABLE 3: ADVERSE EVENTS

<table>
<thead>
<tr>
<th>Event</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAE</td>
<td>3 = 0.26%</td>
</tr>
</tbody>
</table>

TABLE 4: SAE CASE REPORTS

<table>
<thead>
<tr>
<th>Case</th>
<th>Age/Sex</th>
<th>Date Admitted</th>
<th>Hospitalization</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>66 Male</td>
<td>1/2/18</td>
<td>30 days</td>
</tr>
<tr>
<td>2</td>
<td>65 Male</td>
<td>2/2/18</td>
<td>7 days</td>
</tr>
</tbody>
</table>

TABLE 5: THE EXPERIENCE OF AN INFECTIOUS DISEASE (ID) TRAVEL MEDICINE CLINIC DURING A NATIONAL SHORTAGE OF YELLOW FEVER VACCINE (YFV)

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REFERENCES


ACKNOWLEDGEMENTS

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