**Title**

Changes to country-specific hepatitis A travel vaccination recommendation for UK travellers in 2017 - Responding to a vaccine shortage in the national context

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**Abstract**

*Objectives* A routine review of hepatitis A (HepA) travel vaccination recommendations was brought forward in June 2017 due to HepA vaccine shortages and a concurrent outbreak in men who have sex with men. There were three objectives; first, to document the review process for changing the recommendations for UK travellers in June 2017. Second, to study the impact of these changes on prescribing in general practice in 2017 compared to the five previous years. Third, to study any changes in HepA notifications in June-October 2017 compared to the five previous years.

*Study design* Observational study.

*Methods* Travelvaccination recommendations for countries with either low (<20%) or high (>90%) risk status according to child HepA seroprevalence were not changed. A total of 67 intermediate risk countries with existing recommendations for most travellers and with new data on rural sanitation levels were shortlisted for analysis. Data on child HepA seroprevalence, country income status, access to sanitation in rural areas, and traveller volumes were obtained. Information about vaccine supply was obtained from Public Health England. Changes to the existing classification were made through expert consensus, based on countries’ HepA seroprevalence, sanitation levels, level of income, volume of travel, and HepA traveller cases. Data on the number of combined and monovalent HepA containing vaccines prescribed in England, 2012-2017, were obtained from the National Health Service Business Service Authorities. The number of monthly prescriptions for January-September 2017, was compared with the mean number of prescriptions for the same month in the previous five years (t-test, α = 5%, *df* = 4). The number of HepA cases notified June-October 2017 not related to the MSM outbreak were compared with the number of notifications in the same months in previous years.

*Results* A totalof 36 countries were downgraded based on good access (80+% of population) to sanitation in rural areas and intermediate risk status in terms of child HepA seroprevalence. For these countries, vaccination would only be recommended to travellers staying long term, visiting friends and relatives, or staying in areas without good sanitation. There was a significant decline in HepA vaccine prescriptions June-September 2017, and no increase in the number of notifications

*Conclusions* HepA vaccination recommendations for travel were revised in 2017 following a systematic approach to maintain continuity of supply following a HepA vaccine shortage and increased HepA vaccine demand related to a large outbreak. Improved access to good sanitation in rural areas and low seroprevalence estimates among children have led to 36 countries to no longer require vaccination for most travellers. These changes do not seem to have impacted on HepA notifications in England, although further research will be needed to quantify the impact more precisely.

**Introduction**

Hepatitis A (HepA) is transmitted faeco-orally via contaminated food and drink, direct contact or sexual activity 1. It typically leads to mild liver disease, but can in rare cases lead to fulminant hepatitis and death. There is no specific treatment for HepA and recovery can take weeks and months 1. Globally, the World Health Organization (WHO) estimates that there are more than 120 million cases per year 2. Most cases in England and Wales are travel-associated and nearly 250 cases in returning travellers were diagnosed in England and Wales in 2014 3.

HepA vaccines are safe and effective. The duration of protection from a completed 2-dose course of vaccine can be expected to be at least 25 years in immunocompetent individuals. Following this primary course, a booster dose is recommended at 25 years for those at ongoing risk 1,4.

An outbreak of HepA among men who have sex with men (MSM) affecting England since July 2016 and also other European countries and parts of the world 5 exacerbated an ongoing global shortage of HepA vaccine. As UK vaccine supply was severely impacted in Spring 2017, Public Health England (PHE) took a multi-pronged approach to mitigate supply constraints and respond to the outbreak in MSM. In June 2017 PHE, with the endorsement of the Joint Committee on Vaccination and Immunisation (JCVI), issued temporary HepA vaccine recommendations on risk-based prioritisation of patients, dose-sparing and alternative vaccine use to preserve stock for those most likely to benefit from the vaccine 6. A planned review of country-specific travel vaccination recommendations was brought forward and implemented alongside PHE’s temporary vaccine recommendations. HepA vaccine was prioritised and offered opportunistically to all MSM attending sexual health services (SHS) 7.

This paper describes the review approach and process for revising the country-specific travel vaccinations and examines evidence of the impact on prescribing in general practice during 2017 versus the previous five years as well as on the number of notified cases of HepA before and during 2017.

**Methods**

The existing country-specific HepA vaccination recommendations for UK travellers before June 2017 were based on WHO data on child HepA virus seroprevalence 8, country income status (high income status versus any lower status) 9, and access to sanitation in rural areas (90+% of population) 10.

Travel vaccination recommendations for countries with either low (<20%) or high (>90%) risk status according to child HepA seroprevalence were not changed. Vaccination continues to be recommended for ‘Most’ travellers to high-risk countries, while vaccination is not recommended for travel to low-risk countries.

As a cautious approach, vaccination was recommended for ‘Most’ travellers to intermediate risk countries in the existing recommendations; except for countries with high income status and where 90+% of the rural population had access to good sanitation. For these countries vaccination would only be recommended for ‘Some’ travellers.

The terminology, ‘Most’ versus ‘Some’ travellers, is routinely used for travel vaccination advice in the UK. For countries with a ‘Most’ recommendation, vaccine is recommended for all travellers unless there is a specific reason not to. Several factors will determine whether travellers visiting countries with a ‘Some’ recommendation should be vaccinated; these include: individual health status, duration and purpose of travel, and planned activities associated with higher risk. In the case of HepA, vaccination is recommended for those planning a long-term stay, visiting friends and relatives (VFR), or visiting areas with poor sanitation.

For the updated classification, the analyses included the most recent WHO and Unicef data on rural sanitation levels 11.

The review of the country-specific recommendation was carried out in two stages. First, a modification of the existing criteria was considered, such as lowering the threshold for access to sanitation in rural areas from 90% to either 80% or 70% and removing the existing high-income country criterion. Second, the results were discussed by an expert panel taking additional factors into account such as available data on foreign travel-associated HepA cases, volumes and purpose of travel.

Data on volume of travel to specific destinations were obtained from the International Passenger Survey on visits abroad undertaken by residents in England, 2013-2016, and averaged over the four years 12.

Information about vaccine supply issues was obtained from PHE’s Vaccine Update newsletters, March-September 2017 13.

Data on the number of HepA containing vaccines (monovalent HepA, combined HepA/hepatitis B (HepB) and HepA/typhoid) prescribed in general practice in England between January 2012 and September 2017 were obtained from the National Health Service (NHS) Business Service Authorities 14. The number of monthly prescriptions between January and September 2017, was compared with the mean number of prescriptions for the same month in the previous five years using t-tests (single versus multiple observation 2-group equivalence of means, α = 5%, *df* = 4) 15.

In order to estimate the combined impact of the revised recommendations and vaccine supply issues on disease incidence, we compared the number of hepatitis A cases (excluding cases associated with the MSM outbreak) notified to PHE between June and October 2017, with the number of notifications in the same time period in previous four years (excluding those associated with the MSM outbreak in 2016), using a test for trends. These cases are not exclusively travel-associated, but as the majority of cases in England are travel related, these numbers can be used as a crude way to evaluate whether the aforementioned factors have had a major impact on disease notifications.

**Results**

*Review of country recommendations review*

A total of 67 intermediate risk countries with existing recommendations for most travellers and with new data on rural sanitation levels were shortlisted for analysis. Jamaica had previously been assigned to the lower risk, ‘Some’ travellers status based on expert consensus, but was included in the analysis for a comparison of the effect of different criteria (Table 1). Removing the high-income criterion, while keeping the 90+% threshold for rural sanitation would ‘release’ 25 lower income countries with good rural sanitation for consideration in a down-grading exercise. Lowering the rural sanitation threshold from 90+% to 80+% would include a further 15 countries. Lowering the threshold further still from 80+% to 70+% would only increase the list of countries with another eight countries. Based on expert consensus taking into account the number of travel-associated cases of HepA against the traveller flows and types of traveller to those countries, and any other factors (such as the rates of other gastro-intestinal illness), Egypt, Syria, and Tunisia were re-assigned to the stricter ‘Most’ travellers category. In some instances, political stability and infrastructure of a country were taken into consideration. Therefore, the total number of countries that were downgraded from ‘Most’ to ‘Some’ as a result of this exercise was 36 (Table 1; as indicated in Column K).

*Hepatitis A vaccine prescribing*

Compared with the mean number of prescriptions of HepA-containing vaccines for the same month in the previous five years, prescription numbers dropped by 23% in June 2017, 33% in July, 47% in August and 56% in September (p<0.05 for all, Figure 1). HepA/HepB vaccine prescriptions were, also significantly lower in February and April of 2017 compared with those months in the previous five years (-24% and -33% respectively).

There were no or only limited supply of most adult vaccines from manufacturers during March to September 2017 (end of study period); although supply constraints for HepA/HepB combination vaccine were only reported from July 2017 onwards (Table 2). The vaccine shortage was less severe for child/adolescent vaccines early in the year, but only limited stock was available from July onwards. There was a limited supply of one of the HepA-typhoid vaccine products in March and April for both adults and adolescents; after which there were no supply of either product for the rest of the study period.

The number of visits abroad to countries where 'Most' travellers would be recommended HepA vaccination (assuming they either had not been vaccinated previously or a booster was due) is estimated, as a result of the revised recommendations, to have fallen from 7.4 million (2013-2016 average) to 2.5 million visits (2017) per year, i.e. a 66% decrease.

*Hepatitis A notifications*

Between June and October 2017, 244 hepatitis cases were notified to PHE, excluding those associated with the MSM outbreak, compared with an average of 230 in 2013-2016 (Table 3). No trend in notification was detected between 2013 and 2017 (p=0.17).

**Discussion**

July is on average the peak month for HepA vaccination in the lead up the main UK holiday period in August. In 2017, however, there was a decrease of 23% in vaccinations between June, the month of the change in recommendations, and of 33%, 47%, and 56% in July, August, and September, respectively. The fact that the total number of HepA and HepA-combination vaccine prescriptions had already begun to decrease in June suggests that the vaccine supply constraints also played a role in the overall decline as ordering restrictions were imposed by manufacturers. The estimated decline in vaccinations required for ‘Most’ travellers was 66% assuming prior unvaccinated status. These data are consistent with the observed decrease in vaccine prescriptions. Limited data on HepA notifications suggest that the changes in recommendations, taken together with the concurrent vaccine supply issues, have not led to a large increase in HepA importation to England. The supply situation is expected to improve in 2018 and only a longer time series will be able to reveal the overall impact on disease incidence, if any, of the changes to the country-specific recommendations.

*Limitations*

Data on HepA vaccinations were only available from general practice (NHS), where the vaccine can be obtained for free both in response to outbreaks and for overseas travel 16. In practice, HepA travel vaccinations are also administered in private travel clinics and private GP practices. There is no centralised database for private travel clinics and private prescriptions 17. Hypothetically, some of the bigger, private chains of travel clinics may be more resilient to shortages compared to the smaller GP practices as stock is likely to be purchased centrally in bulk and distributed within the organisation. So, even though the vaccine is available for free in general practice (NHS), it is possible that some travellers will have been able to obtain vaccination in the private sector during the shortage. The analysis of HepA notifications is limited as it is not possible to differentiate travel-associated cases from others in the current data. While most cases in England are travel-associated and the data provide reassurance that the travel HepA vaccination changes have not led to a large increase in HepA incidence. Restricting the analysis to travel-associated cases, including the country of travel, will enable a more precise estimation of the impact of the changes in recommendations. There is often a lag of several months in these data becoming available.

**Conclusions**

HepA vaccination recommendations for travel were revised in 2017 following a systematic approach to maintain continuity of supply following a HepA vaccine shortage and increased HepA vaccine demand related to a large outbreak. Improved access to good sanitation in rural areas and low seroprevalence estimates among children have led to 36 countries to no longer require vaccination for most travellers. These changes do not seem to have impacted on HepA notifications in England, although further research will be needed to quantify the impact more precisely.

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**Competing interests**

None declared.

**Ethical approval status**

None required. Database study.

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**Figures**



Figure 1 Prescribing of hepatitis A containing vaccines in 2017 versus monthly averages from 2012-2016. Observations significantly different from the 2012-2016 mean at 5% level marked with \* (t-test, df=4). The vertical line indicates the month where changes to country-specific travel vaccination and dose-sparing recommendations were implemented. Abbrev.: HepA = hepatitis A; HepB = hepatitis B.

**Tables**

Table 1 Hepatitis A country classification revisited – With and without high-income status, latest rural sanitation data and variable sanitation threshold. Previous review was based on column D and E resulting in I. The current review on F resulting in K.

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Country** | **Travellers per year 2013-2016** | **VFR%** | **Economic status** | **Sanitation% Rural Previous review** | **Sanitation% Rural NEW** | **2015 Review decision** | **Predicted based on high-income and 90+% rural sanitation (Prev.)** | **Predicted based on 90+% rural sanitation (NEW)** | **Predicted based on 80+% rural sanitation (NEW)** | **Predicted based on 70+% rural sanitation (NEW)** |
| **A** | **B** | **C** | **D** | **E** | **F** | **G** | **I** | **J** | **K** | **L** |
| Albania | 35,423 | 54.2 | Low | 86 | 90 | Most | Most | Some | Some | Some |
| Argentina | 25,607 | 28.9 | Low | 99 | 98 | Most | Most | Some | Some | Some |
| Belarus | 8,563 | 52.4 | Low | 95 | 95 | Most | Most | Some | Some | Some |
| Bosnia & Hz. | 10,624 | 47.3 | Low | 92 | 92 | Most | Most | Some | Some | Some |
| Chile | 12,143 | 22.3 | High | 89 | 91 | Most | Most | Some | Some | Some |
| Egypt\* | 248,480 | 14.9 | Low | 94 | 93 | Most | Most | Some | Some | Some |
| Jordan | 28,327 | 37.8 | Low | 98 | 99 | Most | Most | Some | Some | Some |
| Kazakhstan | 11,284 | 35.9 | Low | 98 | 98 | Most | Most | Some | Some | Some |
| Kyrgyzstan | 2,628 | 40.9 | Low | 92 | 96 | Most | Most | Some | Some | Some |
| Libya | 16,278 | 48.2 | Low | 96 | 96 | Most | Most | Some | Some | Some |
| Malaysia | 102,963 | 39.8 | Low | 95 | 96 | Most | Most | Some | Some | Some |
| Maldives | 48,799 | 1.1 | Low | 100 | 98 | Most | Most | Some | Some | Some |
| Mauritius | 114,408 | 16.5 | Low | 90 | 93 | Most | Most | Some | Some | Some |
| Montenegro | 25,330 | 11.3 | Low | 87 | 92 | Most | Most | Some | Some | Some |
| Palau | - | - | Low | 100 | 100 | Most | Most | Some | Some | Some |
| Samoa | - | - | Low | 91 | 91 | Most | Most | Some | Some | Some |
| Serbia | 47,014 | 61.0 | Low | 96 | 94 | Most | Most | Some | Some | Some |
| Sri Lanka | 112,580 | 41.5 | Low | 94 | 97 | Most | Most | Some | Some | Some |
| Syria\* | 810 | 100 | Low | 95 | 95 | Most | Most | Some | Some | Some |
| Tajikistan | 1,204 | 0 | Low | 95 | 95 | Most | Most | Some | Some | Some |
| Thailand | 372,618 | 18.0 | Low | 96 | 96 | Most | Most | Some | Some | Some |
| Ukraine | 48,176 | 50.3 | Low | 89 | 93 | Most | Most | Some | Some | Some |
| Uzbekistan | 5,154 | 33.1 | Low | 100 | 100 | Most | Most | Some | Some | Some |
| Poland | 1,729,136 | 70.7 | High |  | 97 | Most |  | Some | Some | Some |
| Réunion  | - | - |  |  | 95 | Most |  | Some | Some | Some |
| Algeria | 55,106 | 77.0 | Low | 88 | 82 | Most | Most | Most | Some | Some |
| Azerbaijan | 7,997 | 32.0 | Low | 78 | 87 | Most | Most | Most | Some | Some |
| Belize | 2,044 | 14.5 | Low | 88 | 88 | Most | Most | Most | Some | Some |
| Bulgaria | 289,211 | 33.3 | Low | 100 | 84 | Most | Most | Most | Some | Some |
| Cuba | 134,466 | 3.4 | Low | 88 | 89 | Most | Most | Most | Some | Some |
| Fiji | 2,371 | 40.7 | Low | 82 | 88 | Most | Most | Most | Some | Some |
| Guyana | 2,607 | 0 | Low | 82 | 82 | Most | Most | Most | Some | Some |
| Iran | 48,330 | 80.2 | Low | 82 | 82 | Most | Most | Most | Some | Some |
| Iraq | 41,403 | 63.8 | Low | 82 | 84 | Most | Most | Most | Some | Some |
| Jamaica\*\* | 190,532 | 35.8 | Low | 82 | 84 | Some | Most | Most | Some | Some |
| Lithuania | 238,799 | 77.2 | High | 85 | 83 | Most | Most | Most | Some | Some |
| Tonga | - | - | Low | 89 | 89 | Most | Most | Most | Some | Some |
| Tunisia\*  | 253,878 | 5.9 | Low | 77 | 80 | Most | Most | Most | Some | Some |
| Turkey | 1,172,756 | 6.0 | Low | 75 | 86 | Most | Most | Most | Some | Some |
| Latvia | 152,340 | 68.6 | High |  | 82 | Most |  | Most | Some | Some |
| Armenia | 3,898 | 37.4 | Low | 81 | 78 | Most | Most | Most | Most | Some |
| Myanmar | - | 23.8 | Low | 74 | 77 | Most | Most | Most | Most | Some |
| Georgia | 4,595 | 45.9 | Low | 91 | 76 | Most | Most | Most | Most | Some |
| North Korea | 1,579 | 0 | Low | 73 | 73 | Most | Most | Most | Most | Some |
| Paraguay | 832 | 18.5 | Low | 53 | 78 | Most | Most | Most | Most | Some |
| Philippines | 97,192 | 65.5 | Low | 69 | 71 | Most | Most | Most | Most | Some |
| Vietnam | 79,381 | 23.3 | Low | 67 | 70 | Most | Most | Most | Most | Some |
| Dom. Rep. | 73,176 | 8.2 | Low |  | 76 | Most |  | Most | Most | Some |

\*) Egypt, Syria, and Tunisia retained ‘Most’ traveller status based on return traveller cases and other particular. \*\*) Jamaica had already been re-assigned to the more lenient ‘Some’ traveller status in the previous review, i.e. no change in status as result of the current review.

Table 2 UK Hepatitis A travel vaccine supply constraints information (current situation), March-September 2017.

|  |  |  |  |
| --- | --- | --- | --- |
| Age group | Adult |  | Children/adolescents |
| Product | Havrix Single | Havrixx10 | Avaxim | VAQTA | Twinrix | Hepatyrix | ViATIM |  | HavrixSingle | Havrixx10 | VAQTA | Ambirix | Twinrix Paed | Hepatyrix | ViATIM |
| Hepatitis | A | A | A | A | A/B | A/T | A/T |  | A | A | A | A/B | A/B | A/T | A/T |
| Month |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| Mar | Lim | None | Lim | None |  | None | Lim |  |  |  | None |  |  | None | Lim |
| Apr |  | None | Lim | None |  | None | Lim |  |  |  | None |  |  | None | Lim |
| May |  | None | Lim | None |  | None | None |  |  |  | None |  |  | None | None |
| Jun | None | None | Lim | None |  | None | None |  |  |  | None |  |  | None | None |
| Jul | None | None | Lim | Lim | Lim | None | None |  | None | Lim | None |  | Lim | None | None |
| Aug | None | None | Lim | Lim | Lim | None | None |  | None | Lim | None |  | Lim | None | None |
| Sep | None | None | None | None | Lim | None | Lim |  | None | Lim | Lim | None | Lim | None | Lim |

Market authorisation holder/products: GSK: Ambirix, Havrix, Hepatyrix, Twinrix; MSD: VAQTA; Sanofi Pasteur: Avaxim, ViATIM. T = Typhoid. Lim: limited supply. Source: 13

Table 3 Table 3.Hepatitis A notifications, 2013-2016\*

|  |  |
| --- | --- |
| Time period | Notifications |
| June-October 2013 | 159 |
| June-October 2014 | 232 |
| June-October 2015 | 276 |
| June-October 2016 | 251 |
| June-October 2017 | 244 |

\*Excludes cases associated with the MSM outbreak ongoing since July 2016