

Protecting and improving the nation's health

Issue 292, March 2019

Vaccine update

Big bang and the Plutopox

Big Bang Fair, Birmingham NEC - 13 to 16 March 2019

Thousands of children from the West Midlands and across the country made their way to the NEC Birmingham to visit the Big Bang fair, one of the many events to celebrate British Science Week 2019 (8-17 March).



Here at the Big Bang Fair our team have been inviting children to dip into a tombola to see if they've been 'infected' with the alien bug 'Pluto Pox'. Infected children were given two cards to pass to random people in the hall, and infected individuals had to visit the stall to notify the PHE epidemiologist team they'd caught the

pox. Their infection status was instantly relayed to a screen on the wall, which kept count of the number of people 'infected' and 'protected' plus the place and time they caught the bug. We've been explaining to the children that in order to investigate the disease and control an outbreak, we need to look at the person, place and time, plus factors like people who are more susceptible to infection. We've collected information from each person on a tablet and extract data hourly to create a real-time epidemiology graph 'epi curve' on a screen, which shows the spread of the disease across each day.

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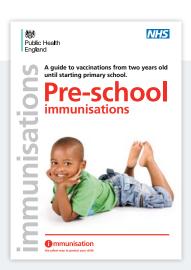
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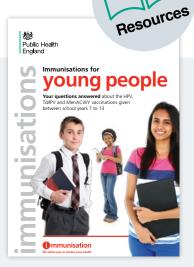
New improved edition of the core leaflets published!



Immunisations up to one year of age weblink 1



Immunisations for pre-school weblink 2



Immunisations for young people weblink 13

New translated What to expect after vaccinations? Leaflet available to download.

Now available to download and print in Kurdish, Lithuanian, Polish, Romanian, Somalian, Urdu, Vietnamese and Chinese.

How we did it?

We will be bringing you articles on immunisation topics sharing examples of new ways of working, collaborating and developing new resources and operational procedures. We want you to get involved and send us your examples of what is working in your area and how you did it!

Production of a GP Receptionist and Admin Staff Training Resource - 2018

During 2018, the South West PHE Screening & Immunisation Team developed and delivered immunisation training for GP receptionists and admin staff. We recognised the important role played by admin staff in GP practices and the significant impact that these staff can make in ensuring people become immunised and wanted to support practices by ensuring their frontline staff had an opportunity to learn more about the routine immunisations offered within their setting.

Receptionists are the front door of the practice, they have a role in contacting patients to book immunisation appointments and interact directly with them, for example, when parents bring their infants in for vaccinations. They are key in creating an environment that promotes immunisation; in ensuring that public health messages around immunisation are positive; and in directing parents to trustworthy and balanced sources of further information.

After an initial pilot of the training in Somerset, we initially offered free, two hour, face-to-face training sessions at multiple locations around the South West. Many practices took up the opportunity to allow their reception and admin staff to attend the training and both Practice Managers and Practice Nurses saw the benefit of increased immunisation knowledge amongst their non-clinical, frontline staff. The sessions were promoted through Local Medical Committees, local Practice Nurse forums and through the NHS England South West GP Bulletin. Whilst the sessions principally covered immunisations, we also gave an overview of the screening programmes. However, it was a challenge for some, particularly in smaller / geographically remote settings, to allow their staff time away from the practice to attend the face-to-face training and so a recorded version of the immunisation training was made available so that those unable to attend in person were able to access a digital version online.

Over 170 GP practice receptionist and admin staff attended the face-to-face training sessions. Each attendee was asked to complete an evaluation form and the feedback was overwhelmingly positive. Many attendees highlighted that they found it useful to understand more about the importance of immunisations, and the role that they can play in supporting parents and families to make positive choices about immunisation.

Attendees were asked about the most important things they learned from the training:

"All very interesting, but especially the MMR as I didn't know how serious measles was"

"The importance of encouraging parents to make an appointment when you speak to them"

"How to educate parents about what they're entitled to and that their immunisations not only benefit themselves but everyone they come into contact with"

"I feel more knowledgeable when dealing with queries regarding imms"

3 modules of the training have now been developed and are now available – Child and Adolescent Immunisations, Adult Immunisations and Cancer Screening.

To look at the online version of the training, please visit weblink 3. If you'd like more information about the training and how it was developed please contact the South West Screening & Immunsiation Team: england.swscreeningandimms@nhs.net.

Annual flu letter published

The Department of Health and Social Care (DHSC), NHS England, and Public Health England (PHE) have published a flu letter providing information about which adults and children are eligible for vaccination in the national flu immunisation programme for 2019/20 at weblink 4.

A second letter will follow with information about frontline healthcare workers.

New translated 'What to expect after vaccinations?

We have translated the leaflet currently available to download and order in hard copy from the orderline.

Now available to download and print in:

Kurdish, Lithuanian, Polish, Romanian, Somalian, Urdu, Vietnamese and Chinese.

The leaflets are available to download now at weblink 5.



Revised rash in pregnancy guidance

Background

PHE has published revised guidance on the investigation and management of viral rash illness or exposure to viral rashes in pregnancy. This revision has been prompted by changes to guidance on the post exposure management of chickenpox and measles and cessation of universal antenatal susceptibility screening for rubella in 2016. The revised guidance has been reviewed and signed off by the PHE Vaccine Science and Surveillance Group.

Exposure to, or illness with, a viral infection during pregnancy can have implications for the pregnant woman and her baby. The guidance primarily focuses on the investigation and diagnosis of women either presenting with or exposed to maculopapular rashes caused by rubella, parvovirus and measles and vesicular rashes caused by chickenpox. Medical intervention in these illnesses can prevent or reduce the potential for adverse outcomes for pregnant women and their babies.

The guidance

- summarises the information that should be collected at ante-natal booking in order to optimise the management of any future exposure or infection
- advises on the investigation and initial management of a woman presenting with a rash
- advises on the risk assessment for a woman reporting contact with a rash illness

Revisions to the guidance

The updated guidance can be found at weblink 6 and includes:

- current recommendations for post-exposure prophylaxis for measles and varicella (chickenpox)
- the interpretation of rubella antibody levels and implications of the cessation of the antenatal rubella screening programme
- a section has also been added on the management of inadvertent shingles immunisation in pregnancy

Questions on the new guidance should be addressed to the Immunisation lead inbox immunisation.lead@phe.gov.uk

Weldome to all of our new readers and thank-you for authoriting to Vaccine Update. Weldome to all of our new readers and thank-you for authoriting to Vaccine Update. We would like to lavidly you so either door immunisations conference in Mile. The conference is the conference of th

NIN conference – places still available!

For full details please see Vaccine Update at weblink 7.

This Public Health England (PHE) two-day meeting will focus on current and emerging scientific issues in immunisation and implementation issues relating to PHE's national immunisation programme.

The theme of the meeting is 'Vaccination: back to the future' celebrating the success of the historic vaccine programmes and looking forward to new and improved vaccines. During this meeting attendees will have the opportunity to hear from experts involved in the work of immunisation across a range of diseases and specialities. As well as presentations from world-class epidemiologists and experts in immunisation from the UK including Professor David Salisbury, we look also forward to welcoming Noel Brewer, Professor of Health Behavior, from the Gillings School of Global Public Health at the University of North Carolina.

By providing you with the science and rationale behind immunisation policy and decision-making, and by sharing your experience and the latest developments, you will feel better equipped in your roles in this important public health work. This is a great opportunity to hear up-to-date information and to network with colleagues from across the immunisation community.

Who should attend:

The first day is open to everyone with an interest in the science behind the immunisation programme. The second day has been designed mainly for colleagues with a local leadership role in the commissioning, delivery and quality assurance of the immunisation programme.

All members of the Screening and Immunisation Teams (SITs) and Health Protection Teams (HPTs) with an interest and/or role in immunisation are encouraged to attend. We hope that at least one member of each SIT and HPT will be able to join us. Fees apply.

The Twitter hashtag for the meeting is: #NIN2019

Vaccine supply (centrally supplied)

Attention to all customers – Easter and May bank holiday deliveries warning notice

Easter Bank Holiday

Due to the Easter Bank Holiday, there will be no deliveries or order processing by Movianto UK on Friday 19th April and Monday 22 April 2019. Please see the table below for revised order and delivery dates.

For customers with standard delivery days of Friday or Monday, please be aware that:

- after Friday 12 April, your next available delivery day will be Friday 26 April
- after Monday 15 April, your next available delivery day will be Monday 29 April

Easter Bank Holidays Friday 19 April – Monday 22 April 2019		
Delivery date	Order cut-off date	Order cut-off time
Monday 15 April 2019	Thursday 11 April 2019	11:55 AM
Tuesday 16 April 2019	Friday 12 April 2019	11:55 AM
Wednesday 17 April 2019	Monday15 April 2019	11:55 AM
Thursday 18 April 2019	Tuesday 16 April 2019	11:55 AM
Friday 19 April 2019	Closed – No deliveries	
Monday 22 April 2019	Closed - No deliveries	
Tuesday 23 April 2019	Thursday 17 April 2019	11:55 AM
Wednesday 24 April 2019	Friday 18 April 2019	11:55 AM
Thursday 25 April 2019	Tuesday 23 April 2019	11:55 AM
Friday 26 April 2019	Wednesday 24 April 2019	11:55 AM

May Bank Holidays

Due to the May Bank Holidays, there will be no deliveries or order processing by Movianto UK on Monday 6 May and Monday 27 May 2019. Please see the table below for revised order and delivery dates.

For customers with standard delivery dates of Monday, please be aware that:

- after the 29 of April, your next available delivery day will be the 13 May 2019
- after the 20 of May, your next available delivery day will be the 3 June 2019

May Bank Holiday orders and deliveries

Early May Bank Holiday Monday 6 May 2019		
Delivery date	Order cut-off date	Order cut-off time
Monday 29 April 2019	Thursday 25 April 2019	11:55 AM
Tuesday 30 April 2019	Friday 26 April 2019	11:55 AM
Wednesday 1 May 2019	Monday 29 April 2019	11:55 AM
Thursday 2 May 2019	Tuesday 30 April 2019	11:55 AM
Friday 3 May 2019	Wednesday 1 May 2019	11:55 AM
Monday 6 May 2019	Closed - No deliveries	
Tuesday 7 May 2019	Thursday 2 May 2019	11:55 AM
Wednesday 8 May 2019	Friday 3 May 2019	11:55 AM
Thursday 9 May 2019	Tuesday 7 May 2019	11:55 AM
Friday 10 May 2019	Wednesday 8 May 2019	11:55 AM

Late May Bank Holiday Monday 27 May 2019		
Delivery date	Order cut-off date	Order cut-off time
Monday 20 May 2019	Thursday 16 May 2019	11:55 AM
Tuesday 21 May 2019	Friday 17 May 2019	11:55 AM
Wednesday 22 May 2019	Monday 20 May 2019	11:55 AM
Thursday 23 May 2019	Tuesday 21 May 2019	11:55 AM
Friday 24 May 2019	Wednesday 22 May 2019	11:55 AM
Monday 27 May 2019	Closed - No deliveries	
Tuesday 28 May 2019	Thursday 23 May 2019	11:55 AM
Wednesday 29 May 2019	Friday 24 May 2019	11:55 AM
Thursday 30 May 2019	Tuesday 28 May 2019	11:55 AM
Friday 31 May 2019	Wednesday 29 May 2019	11:55 AM

You are reminded to be prepared for the breaks in deliveries and to order accordingly. Please make sure you have sufficient room in your fridge for any additional vaccine you wish to stock over these holiday periods, bearing in mind the recommendation that only two to four weeks of vaccine stock be held at any one time.

Please be advised that Emergency or "Out of Schedule" deliveries cannot be arranged for failure to place orders in good time.

The EU Falsified Medicines Directive (FMD) and Delegated Regulation as applicable to centrally supplied vaccines for the National Immunisation Programme

Since the 9 February 2019 there are legal obligations on the UK to prevent the entry of falsified medicinal products into the supply chain. The Delegated Regulation¹ of the Falsified Medicines Directive (FMD)² requires that prescription only medicines (POM) including vaccines entering the supply chain after this date carry safety features including an anti-tampering device (a seal) and a unique identifier (contained in a 2D barcode), and have their product data uploaded onto a central database. In addition, certain parts of the supply chain are required to perform authenticity checks, and at the end of the supply chain 'verify and decommission' products before they are supplied or administered to patients.

These changes affect all ImmForm customers across the UK who access centrally supplied products from PHE, except where the organisation is exempt (see information at the end of this article).

For the majority of PHE customers, in practice this means that at the end of the supply chain before a vaccine is administered to a patient, the integrity of the product seal should be checked and the barcode on the packaging should be scanned to verify authenticity and register the removal of the product from the supply chain on a central database (decommission).

Important points to note on PHE supplied vaccines and FMD

- although the Regulation came into force on 9 February 2019, PHE (via ImmForm) will continue to issue products that are **not** subject to the requirements of FMD for several months. This is due to the large stockpiles of vaccines that are held by PHE, which were manufactured and delivered to PHE prior to the implementation date
- products supplied by PHE that are **not** subject to the requirements of FMD include:
 - products in 'older style' packaging without safety features
 - products carrying safety features that were manufactured and supplied to PHE before the safety features became a legal requirement
 - products **not** licensed in the UK (list available in PHE guidance document available on ImmForm)

¹ https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2016_161/reg_2016_161_en.pdf

² https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

- products carrying safety features that were manufactured and supplied to PHE before the safety features became a legal requirement may or may not be registered on the European Medicines Verification System (EMVS) database. Where such a product IS NOT registered on the EVMS database, it does not need to be verified or decommissioned. Where such a product IS registered on the EVMS database, verification and decommissioning are optional. In either scenario, the product can still be supplied or administered to patients
- PHE will begin distributing fully compliant packs (carrying the safety features and with product data registered to EMVS) at different times throughout 2019, and potentially into 2020 for individual product lines. The first fully compliant packs will be distributed from early summer 2019. This is due to the large volume of non-FMD compliant stock already held by PHE prior to 9 February 2019. A timetable estimating the month that fully-FMD compliant packs for each product line will be distributed will be made available on ImmForm and in Vaccine Update in due course. It is still permissible to supply or administer older packs to patients provided they have not expired

Guidance on FMD and the Delegated Regulation

PHE has produced a guidance document to set out and clarify roles and responsibilities in the application of FMD and the Delegated Regulation to vaccines and other medicines centrally supplied by PHE to the NHS and other customers. This document is currently accessible via the ImmForm news page and in addition will be uploaded to gov.uk.

The UK FMD Working group for Community Pharmacy has produced some guidance to help end users identify the types of packs that will need scanning for verification and authentication, and those that will not. Guidance and examples of "right" and "wrong" packs can be found at weblink 8.

We would encourage all of our customers to visit the gov.uk page on FMD and spend some time becoming familiar with the content and links to various other guidance documents on the implementation of the legislation.

NHS Digital toolkits for various types of healthcare provider to help them in the implementation of FMD can be found at weblink 9. Further information for NHS organisations on FMD can be requested by emailing fmd@nhs.net.

Questions about FMD and the safety features more broadly should be directed to fmd.safetyfeatures@mhra.gov.uk.

Article 23 of the Delegated Regulation

Organisations that are not considered to be healthcare institutions or pharmacies but who still supply medicines to the public are exempt from decommissioning vaccine under Article 23 of the Regulation. Article 23 allows wholesalers (i.e. Movianto, in the case of PHE vaccines) to decommission on behalf of these organisations.

The MHRA has published additional guidance on the use of Article 23 which can be found at weblink 10, along with additional information and guidance on FMD and the safety features.

We would encourage our customers to review this guidance to determine whether the exemption provided by Article 23 applies to your organisation with respect to products ordered from PHE via ImmForm.

If you believe that Article 23 applies to your organisation, you will need to contact helpdesk@immform.org.uk quoting your vaccine ordering account number, so that PHE can agree your assessment and ensure your account is set up correctly.

Organisations classed as Article 23 by ImmForm will receive decommissioned products and will only be required to check the anti-tampering device (seal) before a vaccine is administered to a patient.

BCG vaccine (AJ Vaccines) for the national BCG programme – current stock expires 30 April 2019

The BCG vaccine currently being issued expires 30 April 2019. We will be issuing this stock until the end of March 2019, therefore please do not over order for your requirements. It is advised not to create locally held stockpiles.

The AJ Vaccines BCG vaccine has replaced the InterVax BCG vaccine for the national BCG programme. Please safely dispose of any remaining InterVax BCG product according to local protocols and in line with the guidance specified in **Chapter 32 of the Green Book on Tuberculosis (weblink 11)**.

BCG vaccine supplied by AJ Vaccines is presented as a powder for reconstitution in a glass vial with synthetic stopper. Each pack ordered contains 10 vials, and will be accompanied by a pack of 10 vials of diluent. One vial of reconstituted vaccine contains 1 ml, corresponding to 10 doses (of 0.1 ml) for adults and children aged 12 months or over, or 20 doses (of 0.05 ml) for infants under 12 months of age.

Update on MMR vaccine ordering restriction

There are currently two different vaccines available to order for the MMR programme, M-M-RvaxPro® and Priorix®. Orders for Priorix® are capped at 20 packs per order per week for accounts in England and Wales. Controls are also in place for Scottish customers. This is needed to rebalance central supplies.

The alternative MMR vaccine, M-M-RvaxPro®, remains available to order without restriction. If you specifically require additional Priorix® stock, for example because you serve communities that do not accept vaccines that contain porcine gelatine then please contact the ImmForm Helpdesk for assistance at helpdesk@immform.org.uk or 0844 376 0040.

Flu Vaccine information and availability 2018/19 for the children's national immunisation programme

Ordering for Fluenz Tetra® for the 2018/19 season is now closed. The final batch (KL2241) expires on 1 April 2019. All other batches have already expired. Please ensure that any remaining stock is disposed of in line with local policies and recorded through the ImmForm Stock Incident page. If you are unsure how to record this information you can find help sheets on the ImmForm website or contact the helpdesk@immform.org.uk or 0207 183 8580 for assistance.

Providing a second dose of flu vaccine after all Fluenz Tetra® has expired

If you still need to give a second dose of flu vaccine four weeks after the first dose (for example, for children in clinical risk groups aged two to under nine years who have not received influenza vaccine before), then it is safe and effective to give inactivated vaccine as a second dose.

Vaccine supply (non-centrally supplied)

Vaccine supply for the non routine programme

HEPATITIS A VACCINE

Adult

- GSK: Havrix Adult PFS singles and packs of 10 are available
- Sanofi Pasteur: Avaxim is currently available without order restrictions
- **MSD:** Very limited supplies of VAQTA Adult are available at the wholesaler AAH, but MSD is now out of stock. Replenishment is expected in April 2019

Paediatric

- **GSK:** Havrix Paedatric PFS singles and packs of 10 are currently unavailable Resupply is expected early April 2019
- MSD: VAQTA Paediatric is available

Adult

- GSK: Engerix B PFS singles and packs of 10 are available
- **GSK:** Engerix B vials singles are available
- **GSK:** Engerix B vial packs of 10 are unavailable
- GSK: Fendrix is currently unavailable. Resupply is expected late March 2019
- MSD: HBVAXPRO 10 μg is unavailable until further notice
- MSD: HBVAXPRO 40 μg is unavailable until further notice. Please see MSD statement for further information on supply of HBVAXPRO vaccines at weblink 12

Paediatric

- GSK: Engerix B Paediatric singles are available
- MSD: HBVAXPRO 5µg are available

COMBINED HEPATITIS A & B VACCINE

- **GSK:** Twinrix Adult singles are available
- **GSK:** Twinrix Adult packs of 10 are unavailable. Resupply is expected in April 2019
- GSK: Twinrix Paediatric is available
- GSK: Ambirix is available

COMBINED HEPATITIS A & TYPHOID VACCINE

Sanofi Pasteur: Viatim is available without order restrictions

TYPHOID VACCINE

- Sanofi Pasteur: Typhim is available to order without restrictions
- PaxVax: Vivotif is available

RABIES VACCINE

- **GSK:** Limited supplies of Rabipur are available. GSK is currently experiencing a supply delay due to manufacturing constraints through the first half of 2019
- **Sanofi Pasteur:** Rabies BP is currently out of stock. An alternative vaccine is available, please contact Sanofi Pasteur directly for more information

PPV (Pneumococcal Polysaccharide Vaccine)

- MSD: Limited supplies of Pneumococcal Polysaccharide Vaccine vials are currently available with next replenishment expected late March
- MSD: Limited supplies of PNEUMOVAX 23 PFS are currently available. Please see statement for further information weblink 12

PPV (Pneumococcal Polysaccharide Conjugate Vaccine)

- Pfizer: Prevenar 13 is available
- GSK: Synflorix has now been discontinued from the UK market

VARICELLA ZOSTER VACCINE

- GSK: Varilrix is currently available
- **MSD:** VARIVAX is currently available
- MSD: ZOSTAVAX is currently available

DIPHTHERIA, TETANUS AND POLIOMYELITIS (inactivated) VACCINE

• Sanofi Pasteur: Revaxis is available to order without restrictions

MMR

MSD: Limited supplies of MMRvaxPro are currently available

HUMAN PAPILLOMAVIRUS VACCINE

MSD: GARDASIL is currently available
MSD: Gardasil 9 is currently available

MENINGITIS ACWY VACCINE

GSK: Limited supply of Menveo is available

• **Pfizer:** Nimenrix is currently available

YELLOW FEVER

Sanofi Pasteur: Stamaril is available to order without restrictions

Weblinks	
Weblink 1	https://www.gov.uk/government/publications/a-guide-to-immunisations-forbabies-up-to-13-months-of-age
Weblink 2	https://www.gov.uk/government/publications/pre-school-vaccinations-a-guide-to-vaccinations-from-2-to-5-years
Weblink 3	https://www.england.nhs.uk/south/info-professional/public-health/training/
Weblink 4	www.gov.uk/government/collections/annual-flu-programme
Weblikn 5	https://www.gov.uk/government/publications/what-to-expect-after-vaccinations
Weblink 6	https://www.gov.uk/government/publications/viral-rash-in-pregnancy
Weblink 7	https://www.gov.uk/government/publications/vaccine-update-issue-291-february-2019
Weblink 8	https://fmdsource.co.uk/2018/11/22/right-and-wrong-scanning-guidance-for-fmd-early-adopters
Weblink 9	https://digital.nhs.uk/services/falsified-medicines-directive-fmd#toolkits
Weblink 10	https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/767788/Additional_guidance_on_Article_23_HCI_s_and_Article_26.pdf
Weblink 11	https://www.gov.uk/government/publications/tuberculosis-the-green-book-chapter-32
Weblink 12	https://www.msd-uk.com/products/vaccines.xhtml
Weblink 13	https://www.gov.uk/government/publications/immunisations-for-young-people

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