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A WORD FROM THE MEMBERSHIP COMMITTEE

Dear Members,

Thank you so much for your membership; MPhA would not exist without you! As you know, membership enables you to stay up-to-date on pharmacy matters, connect with colleagues and old friends, as well as meet new practitioners who are full of enthusiasm and excitement. MPhA helps us every day by acting as a united voice at the MS Capitol and agencies and on the federal level. This representation is not free; it requires pharmacists' participation through membership. A few members cannot do it alone.

As the co-chairs of the MPhA Membership Committee, we are writing to let you know it is time to renew your membership. Last year, MPhA worked hard to get all members on a calendar renewal cycle, this means all memberships are now due to be renewed for 2020. To be a better steward of your dollars, we will not be mailing out renewal forms but you will receive an email with renewal instructions. You can also go online to renew at www.mspharm.org or call the office at 601.981.0416-we'd would love to hear from you!

A membership with MPhA includes:

- Email and Facebook updates regarding upcoming events and breaking news- these often include FREE CEs.
- Our quarterly journal, *Mississippi Pharmacist,* which includes up to eight free CE hours per year, association updates, event coverage, and academic articles.
- Discounts on MPhA meetings such as Mid-Winter Meeting, Consultants Seminar, Immunization Certification, and the Annual Convention (next year in New Orleans June 6-9).
- Government affairs representation at the Capitol and with agencies, yes, you read that right. We have a lobbyist working on behalf of YOU!
- New committees including a New Practitioner, Pharmacy Technician, and Pharmacy Business for independents and decision makers.
- New for 2020: District Meetings with free live CEs!

Pharmacy is a profession where "you can do well by doing good." Isn't that the truth? As pharmacists, we have rich and rewarding careers and want to ensure new generations of pharmacists do, too. The Membership Committee is working hard to retain your membership, to recruit new members AND to bring your concerns to the Executive Committee. Please contact us at membership@mspharm.org if we can help you or if you have comments or concerns.

We know everyone is busy this time of year, but renewing now has perks. Renew before January 1, and you will be entered into a drawing for some great prizes.

We have big goals for 2020. Come join us, we are going to have a lot of fun!

Best,

Judy Polk Clark

Emily Melton Bond

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IMMUNIZATION SEMINAR

The 2019 Immunization Seminar was held at MPhA headquarters on August 29, 2019. Thirteen attendees from across Mississippi were updated on national educational standards for immunization procedures. This training offered pharmacists comprehensive knowledge, skills, and resources necessary to provide immunization services to patients across the life span.

CONSULTANT SEMINAR

In September, the Mississippi Pharmacists Association hosted the 2019 Consultant Seminar. The seminar, which took place at the Powerhouse in Oxford and the Ag and Forestry Museum in Jackson, hosted 130 pharmacists who learned about subjects ranging from blood thinners to cannabinoids. We are already looking forward to the 2020 Consultant Seminar!

LAST CALL
for 2020
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VAXELIS®: A Vaccination for Protection against Six Different Preventable Diseases

By: Tucker Vanderburg, PharmD Candidate of 2020, and Sarah Medeiros, PharmD Candidate of 2020
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BACKGROUND

The current Advisory Committee on Immunization Practices (ACIP) vaccination schedule includes 32 doses of different vaccinations before the age of 7.[1] The hepatitis B, DTaP (diphtheria, tetanus and pertussis), Hib (*Haemophilus influenzae* Type B), pneumococcal vaccinations are all four shot series across the first fifteen months of an infant's life. In addition to those vaccinations, infants are also receiving three dose series of the rotavirus and poliovirus immunizations.[1] There are currently four combination vaccines on the market. Pediarix™, which combines DTaP, Hep B, and IPV (inactivated poliovirus), is a three-dose series for patients aged 6 weeks to 6 years old. ProQuad®, which combines measles, mumps, and rubella (MMR) and varicella, is a two-dose series that is given between 15 months and 6 years of age.[2] Pentacel®, which combines DTaP, IPV, and Hib, is a four-dose series administered at 2, 4, 6 and 15-18 months of age. Kinrix®, which combines DTaP and IPV, is a single-dose used for the fifth dose of DTaP and the 4th dose of IPV.[2] These vaccine combinations have the potential to reduce the number of needle sticks required. However, a new vaccination coming to the market in early 2020 can drastically impact the number of infant needle sticks. Vaxelis® is the new "six-in-one" vaccination that has the ability to reduce the number of childhood immunization doses from 32 to 22.[2,3] Table 1 shows a potential adjustment to the current CDC Birth-18 Years Immunization Schedule.

Vaxelis® is a new FDA approved vaccination against six different preventable diseases. It provides protection against diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type B, in a three dose series.[3,4] Table 2 shows current vaccines against these illnesses, and how Vaxelis® compares to those vaccinations in terms of dose, route, type, and schedule. Vaxelis® may be administered as early as 6 weeks of age through 4 years of age.[3,4] Vaxelis® three dose series will begin at 2 months of age and be given every 2 months thereafter for 2 additional doses. The vaccination will still require additional doses of DTaP and Hepatitis B to complete those series for full immunity. Vaxelis® has been shown to be safe and efficacious throughout its trial data, and is set to have a clinically significant impact on the U.S. market.

Vaxelis® offers protection against multiple diseases in just one vaccination. Before modern medicine and vaccinations, these diseases were extremely common and sometimes fatal. Table 3 provides a general overview of each disease state and how it can present in patients.[5-10] These disease states can still pose a threat to the public today with patients' fear of needles, lack of education, and limited access to care. However, the ability to save a few trips to the pediatrician's office, reduce the number of needle sticks, and still provide the same protection from these diseases that has been in place for years now, could help to overcome some of these barriers. Vaxelis® will provide this answer within the coming years, as it will eliminate the individual vaccination for each disease state, and provide a protection against diphtheria, tetanus, pertussis, polio, hepatitis B and haemophilus influenzae type B.

Indications and Recommendations

Vaxelis® is indicated for the prevention of diphtheria, tetanus, pertussis, poliomyelitis, hepatitis B and Haemophilus influenzae type b. It is approved for usage in pediatric patients from 6 weeks through 4 years of age.[3,4] Since Vaxelis® is a 3 dose series, it does not fulfill the required dosing series for immunity against pertussis or hepatitis B. The CDC recommends children receive at least four doses of hepatitis B vaccinations. However, this vaccine may be used to complete the hepatitis B vaccination series if the infant received the hepatitis B vaccine at birth or prior to one month of age.[3,4]

Dosage, Storage, and Administration

Vaxelis® should be administered intramuscularly as three doses (0.5 mL each) at two, four, and six months of age.[3,4] Regardless if a dose in the series is missed, and is then given outside of the regular dosing schedule, the final immunity achieved by Vaxelis® will not be affected nor will the dose series need to be restarted. Vaxelis® does not contain any components that require reconstitution.[3,4] Vaxelis® is available as a

Table 1: Preview of a proposed vaccination schedule for Vaxelis®.

Vaccines	Birth	2 months	4 months	6 months	15 months	4 – 6 years
HepB Hepatitis B	1st dose					
Vaxelis® Hepatitis B, Diptheria, tetanus, acellular pertussis, Hib, & Poliomyelitis		1st dose	2nd dose	3rd dose		
DTaP Diptheria, tetanus, & acellular pertussis					4th dose	5th dose
IPV Poliomyelitis						Booster Dose

*Vaxelis® is available as a booster dose for those aged 12-23 to complete CDC recommended series that have already been administered to the patient.
*HepB will still be administered at birth. Administration of 4 doses is permitted when a combination vaccine containing HepB is used after the patient has received one dose of HepB vaccine at < 1 month old.

TABLE 2: COMPARISON CHART OF VAXELIS® AND ITS COMPONENTS CURRENT VACCINATIONS.

	Vaxelis®	DTaP	ActHIB/PedavaxHIB	HepB	OPV/IPV
Vaccine Content	Diphtheria, tetanus, acellular pertussis, haemophilus influenzae type B, hepatitis B, and poliovirus	Diphtheria, tetanus, & acellular pertussis	Haemophilus influenzae type B	Hepatitis B	Poliovirus
Vaccine Type	Inactivated	Inactivated	Inactivated	Killed, Recombinant	Live (OPV) / killed (IPV)
Dose & Route of administration	0.5 mL IM	0.5 mL IM	0.5 mL IM	0.5 mL IM	0.5 mL IM or SubQ
Schedule	3-dose series at 2, 4, and 6 months of age	5-dose series at 2, 4, 6, 15–18 months, 4–6 years	4-dose series at 2, 4, 6, 12–15 months (ActHIB) / 3-dose series at 2, 4, 12–15 months	3-dose series at 0, 1–2, 6–18 months	4-dose series at ages 2, 4, 6–18 months, 4–6 years

Abbreviations: IM-intramuscular, SQ-subcutaneous

single-dose vial or pre-filled syringe and should be stored at the recommended temperature of 2°C to 8°C (36°F to 46°F).

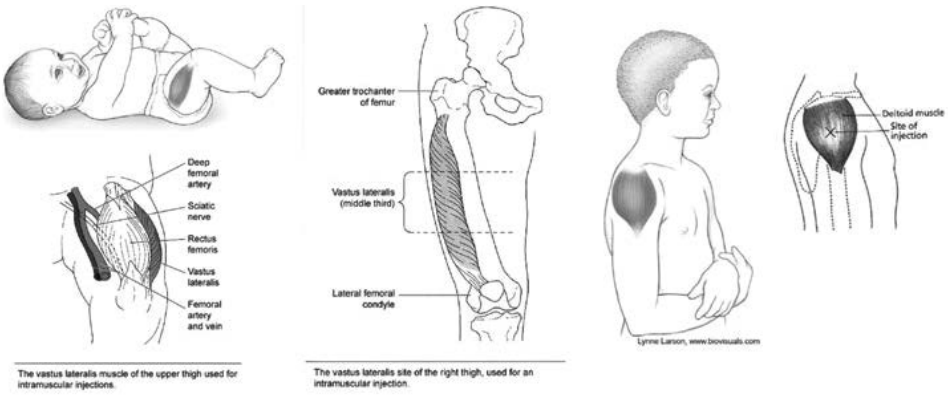
Procedures for Vaxelis® Administration:

1. Inspect the product to confirm the contents are not expired or frozen. In the event that the vaccine is frozen, it should not be used and should be disposed.
2. If using a vial:
   a. Shake the vial until the liquid is homogenous, white, and opaque.
   b. Using aseptic technique, draw up the entire contents of the vial (0.5 mL).
3. If using a pre-filled syringe:
   a. Shake the syringe gently to ensure the liquid is homogenous, white, and opaque.
4. Using a 25 gauge 1 inch sized needle, inject the vaccine in the anterolateral aspect of the thigh, the preferred intramuscular injection site in infants < 12 months of age.
   a. If this is not possible, the deltoid muscle of the arm is also appropriate for administration.
   b. Gluteal injection should be avoided, as administration at this site has shown to decrease efficacy of H influenzae B.
   c. Figure 1 shows ideal administration targets on an infant.[5]
5. In the instance that Vaxelis® is given with other inactivated or live vaccines, the administration sites should not be the same. It is important to use a separate injection site, at least 1 inch away, if the vaccination is given in the same area.
6. Vaxelis® should never be reconstituted with other vaccinations for administration in the same syringe.[3,4]

Contraindications and Precautions

Vaxelis® is contraindicated in patients who have had an anaphylactic reaction to any component of the vaccine, this includes hypersensitivity to previous vaccinations containing diphtheria toxoid, tetanus toxoid, pertussis-containing vaccine, inactivated poliovirus vaccine, hepatitis B vaccine, or Haemophilus influenzae type b vaccine.[3,4] Vaxelis® is contraindicated in patients who have a progressive neurological disorder not stabilized with treatment. Patients who developed encephalopathy within 7 days of receiving previous pertussis-containing vaccine should not receive Vaxelis®. Caution should be used when administering this vaccine to patients who have a past medical history of seizures that occurred within 3 days of receiving a pertussis containing vaccine. Additionally, patients who had a fever ≥ 105 °F or crying lasting ≥ 3 hours within 48 hours of receiving a pertussis-containing vaccine.[3,4]

Figure 1: The anterolateral aspect of the thigh or the deltoid muscle are the proper administration sites for infants and children.[5]



Efficacy

The efficacy of Vaxelis® is based on two studies investigating its immunogenicity of individual antigens compared to available US vaccines.[12,13] In the first study, participants were randomized into two cohorts. The first group was randomized to receive 3 doses of Vaxelis® at 2, 4 and 6 months of age and Daptacel® and PedvaxHIB® at 15 months of age to complete the vaccine schedule. Daptacel® provided coverage for diphtheria, pertussis, and tetanus at the age of 15 months as the fourth and final dose of the series. The additional dose of Daptacel® will be common practice with Vaxelis® in order to give patients full immunity to diptheria, pertussis, and tetanus. PedvaxHIB® provided coverage for ***H. influenzae*** as an additional dose to finish the 4 dose series after Vaxelis® administration. The study concluded that the additional dose of PedvaxHIB® will not be needed to provide complete immunity to H. ***influenzae*** Type B, and it will not be a part of common practice with Vaxelis® administration. The second randomization group was the control group who received 3 doses of Pentacel® at 2, 4 and 6 months of age, Recombivax HB® at 2 and 6 months of age, and ActHIB® at 15 months of age.

At baseline, all infants in the study received one dose of hepatitis B vaccine prior to one month of age. The patients' sera antibody and antigen levels for diphtheria, tetanus, pertussis, poliovirus (types 1, 2, and 3), hepatitis B, and H. influenzae type B, were tested one month following the 3rd dose of Vaxelis® or Pentacel® + Recombivax HB® vaccines. Serologies were tested again after all patients in the trial received their 4 dose primary vaccination series for pertussis (after all patients

TABLE 3: OVERVIEW OF DISEASE STATES [6-11]

Disease	Cause	Major Symptoms	Prognosis	Incidence
Hepatitis B (HBV)	Virus	Usually asymptomatic Anorexia, nausea, vomiting, fever, myalgia/arthralgia, and headache	Fulminant hepatitis, hepatocellular carcinoma, and death	~800,000 to 1.4 million people are infected chronically in the United States ~5,000 people newly infected each year
Diphtheria	Bacterial	Malaise, sore throat, anorexia, and low-grade fever (<101°F)	Myocarditis and neuritis Death occurs in 5 to 10% of patients, increasing up to 20% in patients < 5 years old.	5 cases have been reported to the CDC since 2000
Tetanus	Bacterial	Muscle stiffness, muscle rigidity, lock jaw, convulsive back spasms, fever, diaphoresis, hypertension, and episodic tachycardia	Spasms may continue for 3-4 weeks while complete recovery can take months	~50-100 cases per year
Pertussis	Bacterial	"Whooping" cough, vomiting, fever, nasal congestion and "coughing attacks"	Resolution of illness may take weeks to months. Secondary bacterial pneumonia is common. Neurologic complications are common in neonates (seizures, encephalopathy)	~13,000 cases in 2018
Haemophilus influenzae type B (Hib)	Bacterial	Bacterial infections secondary to influenza: meningitis, epiglottitis, pneumonia, arthritis and cellulitis	~3-6% of all cases in children are fatal 20% of patients who survive Hib meningitis have permanent neurologic damage	~2,562 cases were reported per year between the years 2003-2010
Polio	Viral	Neck, back or leg stiffness Muscle weakness, loss of superficial reflexes, muscle spasms/myalgias.	Permanent weakness and paralysis Death is most common in spinal-bulbar polio	The last case of poliovirus contracted in the US was in 1979.

received Daptacel®). The study found Vaxelis® to be non-inferior to the Pentacel® + Recombivax HB® at the end of the 3 dose series as well as after the primary 4 dose pertussis vaccination schedule. This means one dose of Recombivax HB® should be given at birth before the start of the 3 dose series of Vaxelis® and an additional dose of Pentacel© should be given after the 3 doses series of Vaxelis®. Table 4 indicates the results of the patient serologies of the trial.[3,12]

The second trial investigating Vaxelis's® efficacy had a similar methodology to the first trial except it was investigating vaccine lot consistency. Similarly, to the previous trial, participants were randomized to receive either 3 doses of Vaxelis® (2, 4 and 6 months of age) with Pentacel© (at 15 months) or the control group.[13] The control vaccine series composed of the same vaccines as investigated in the first trial. Like the previous trial serologies were obtained to test immunogenicity for diphtheria, tetanus, pertussis, poliovirus (types 1, 2, and 3), hepatitis B, and H. influenzae B, following the 3rd dose of Vaxelis® or control vaccines. The study found that the non-inferiority criteria for antibody vaccine response rates and geometric mean antibody concentration for all pertussis antigens were not met following the 3rd dose, but were met after the patients received the 4th dose of Vaxelis®. Patients in this study were given an additional dose of Vaxelis® to provide full immunity to pertussis instead of receiving the DTaP booster alone. However, in practice patients will receive DTaP booster instead. All other serologies met non-inferiority criteria following the 3rd dose of Vaxelis®.[3,13]

Safety

Incidence of adverse reactions varied depending on the number of doses of Vaxelis® the patient received.[14] Vaxelis® had a similar side effect profile compared to the traditional series of immunizations that are used in today's CDC immunization schedule. The most common adverse reactions occurring within the first 5 days of receiving the vaccine were irritability (55%), crying (45%), injection site pain (44%), somnolence (40%), erythema around the injection site (25%), decreased appetite (23%), fever ≥ 38 °C or 100.4 °F (19%), injection site swelling (18%) and vomiting (9%). The safety profile of Vaxelis® was evaluated in six studies. Fever was at an increased incidence at each of the three doses during the series when compared to the immunizations that are used in the current CDC vaccination schedule. The two previous studies mentioned in the efficacy section, also monitored safety outcomes. Parents or guardians of the patients receiving Vaxelis® were advised to record adverse events on daily vaccination report cards. Death was reported in 1 (0.1%) of control group participant and 6 (0.2%) Vaxelis® participants. However, these deaths were assessed to be unrelated to the vaccine.[3,14]

Conclusions

All of the components of Vaxelis® are available as components in other immunizations that provide immunity and decrease the incidence of these diseases over time.[6-11] However, Vaxelis® is a new combination vaccine that allows pediatric patients to receive fewer injections while at the same time ensuring they still receive protective immunity from dangerous childhood illnesses. Vaxelis® is a three-dose series to be completed at the age of 2, 4, and 6 months, but will require additional doses of the hepatitis B and DTaP vaccinations to complete those series.[3,4] Vaxelis® has shown in multiple clinical trials to be noninferior to the dosing of each individual vaccination. Furthermore, in clinical studies Vaxelis® has proven to be safe in use of pediatrics, showing a similar adverse event profile

TABLE 4: SEROLOGY RESULTS [3,12]

	VAXELIS® + Prevnar 13® + RotaTeq® (N=688 - 810)	Pentacel® + RECOMBIVAX HB® + Prevnar 13® + RotaTeq® (N=353 - 400)
Anti-Diphtheria Toxoid % [3] 0.1 IU/mL	82.4*	86.3
Anti-Diphtheria Toxoid % [3] 0.1 IU/mL	99.9†	99.5
Anti-PT % vaccine response‡ GMC	 98.1* 109.6§	 98.5 85.4
Anti-FHA % vaccine response‡ GMC	 87.3* 46.6¶	 92.0 72.3
Anti-PRN % vaccine response‡ GMC	 79.3* 55.8§	 82.0 66.8
Anti-FIM % vaccine response‡ GMC	 90.2* 235.9§	 86.2 184.4
Anti-Poliovirus Type 1 % ≥1:8 dilution	100†	98.2
Anti-Poliovirus Type 2 % ≥1:8 dilution	100†	99.7
Anti-Poliovirus Type 3 % ≥1:8 dilution	100†	99.8
Anti-PRP % ≥0.15 µg/mL % ≥1.0 µg/mL	 97.3† 85.0*	 92.4 75.3
Anti-HBsAg % [3]10 mIU/mL	99.4*	98.6

N= The number of participants with available data.
* Non-inferiority criterion met (lower bound of 2-sided 95% CI for the difference [VAXELIS® group minus Control vaccines group] was >-10%).
† Non-inferiority criterion met (lower bound of 2-sided 95% CI for the difference [VAXELIS® group minus Control vaccines group] was >-5%).
‡ Vaccine response = if pre-vaccination antibody concentration was <4x lower limit of quantitation [LLOQ], then the post-vaccination antibody concentration was ≥4 x LLOQ; if pre-vaccination antibody concentration was ≥4 x LLOQ, then the post-vaccination antibody concentration was ≥pre-vaccination levels (pre-Dose 1).
§ Non-inferiority criterion met (lower bound of 2-sided 95% CI for the GMC ratio [VAXELIS® group/Control vaccines group] was >0.67).
¶ Non-inferiority criterion not met for anti-FHA GMC (lower bound of 2-sided 95% CI for the GMC ratio [VAXELIS® group/Control vaccines group was 0.59 which is below the non-inferiority criterion >0.67).

as seen with other vaccinations on the market.[12-15]

Pharmacists can impact the use of the Vaxelis® vaccination through education on the importance of immunity against these common childhood diseases. While promotion of the vaccine is helpful, patients will also need access to the vaccination. This is another important role that pharmacists can play by increasing access to the vaccination and being more involved in pediatric vaccination administration.[16] Pharmacists are already a vital part of the healthcare team by being a resource of drug information for both patients and providers. Pharmacists can further supplement this resource by collecting and documenting vaccination histories to ensure patients are up to date on their recommended vaccinations. Pharmacy technicians can also help with increasing immunization rates by familiarizing themselves with the vaccinations indications, dosing schedule, and age requirement. This will allow them to target specific patients who may be good candidates for Vaxelis®.[16]

Vaxelis® is currently in use in European countries for the recommended pediatric indications.[15] However, Vaxelis® is FDA-approved for use in the United States and is set to come to the U.S. market in 2020. Vaxelis's® place in therapy is aimed at reducing the number of needlesticks and thus increase the pediatric vaccination rate.

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VAXELIS®: A VACCINATION FOR PROTECTION AGAINST SIX DIFFERENT PREVENTABLE DISEASES

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1. Which of the following is a component of Vaxelis®?
   a. Pneumococcal
   b. Varicella
   c. Polio
   d. Rotavirus
2. What is the most common adverse effect of Vaxelis®?
   a. Irritability
   b. Fever
   c. Injection site pain
   d. Rash
3. Which of the following vaccines should be given before starting the Vaxelis® immunization series?
   a. Hepatitis B
   b. Polio
   c. Diphtheria
   d. Tetanus
4. Which of the following vaccines requires one booster dose after completing the Vaxelis® immunization series?
   a. Hepatitis B
   b. Polio
   c. Haemophilus influenzae type B
   d. None of the above
5. What is the preferred site of injection for Vaxelis®?
   a. Deltoid
   b. Gluteal
   c. Anterolateral thigh
   d. A and C
6. When is the first dose of Vaxelis® ideally given?
   a. At birth
   b. 1 month
   c. 2 months
   d. 4 months
7. Which of the following are combination vaccines currently available in the US market?
   a. Kinrix
   b. Pediarix
   c. Pentacel
   d. All the above
8. How many doses are required in the Vaxelis® vaccine series?
   a. 1
   b. 2
   c. 3
   d. 4
9. If a patient receives their first dose of Vaxelis® in September, what is the recommended month they should return for their second dose?
   a. October
   b. November
   c. December
   d. None of the above
10. Which of the following patients has a contraindication to Vaxelis®?
    a. A 6-month-old infant who had a fever ≥ 105 °F after receiving a pertussis containing vaccine.
    b. A 6-month-old infant who had a fever ≥ 102.1°F after receiving a pertussis containing vaccine.
    c. An 8-month-old infant who cried > 1 hour after receiving a pertussis containing vaccine.
    d. An 8-month-old infant with epilepsy currently controlled with antiepileptic medications.
11. Which of the following patient populations is indicated to receive Vaxelis®?
    a. Children and infants aged 6 weeks to 7 years of age.
    b. Children and infants aged 8 weeks to 4 years of age.
    c. Children and infants aged 6 weeks to 4 years of age.
    d. Children and infants aged 8 weeks to 7 years of age.
12. What is an alternative injection site for Vaxelis® in children >12 months of age?
    a. Gluteal
    b. Abdomen
    c. Deltoid IM
    d. Deltoid SC
13. In clinical trials, Vaxelis® was found to be non-inferior to which current combination vaccine?
    a. Pentacel
    b. Kinrix
    c. Pediarix
    d. All the above
14. Where is Vaxelis® currently available on the market?
    a. United States
    b. Australia
    c. European Union
    d. Japan
15. In what instance may Vaxelis® be reconstituted with other vaccines?
    a. It may be reconstituted with any vaccine at any time.
    b. It may be reconstituted with live vaccines only.
    c. It may be reconstituted with inactivated vaccines only.
    d. It should never be reconstituted with other vaccines.
16. An 8 month old patient, JM, presents to clinic and has only received one dose of Vaxelis® at 2 months of age. What is the vaccine "catch-up" schedule for Vaxelis® for JM?
    a. JM should restart the dosing series.
    b. JM will be given both doses of Vaxelis® he should have received at his 4 month and 6 month appointments.
    c. JM will get one dose of Vaxelis® today and return to clinic in 2 months to complete the vaccination series. No "catch-up" dosing is necessary.
    d. JM should receive the components of Vaxelis® separately either in a different combination vaccine or separately. Vaxelis® may not be restarted.

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