# ワクチン産業ビジョン作成から現在までの主な活動

平成19年3月:ワクチン産業ビジョン策定

平成19年3月:ワクチン産業ビジョン推進 委員会の立ち上げ

〇 個別ワクチンの開発にかかる現状及び諸課題の網羅的な検討を開始



平成20年3月:ワクチン産業ビジョン推進委員会ワーキンググループ検討とりまとめ

○ 個別ワクチンの開発にかかる諸課題を 整理するとともに、一部のワクチンについて さらに詳細を検討する必要性等を指摘



平成20年12月:ワクチン産業ビジョン推進 委員会混合ワクチン検討ワーキングループ 設置(本日の検討課題)

# 〇ワクチン産業関連の最近の動き

- ▶ワクチンにかかる非臨床試験及び 臨床試験ガイドラインの作成を開始 (医薬食品局審査管理課)
- ▶ワクチン開発研究協議会[事務局:医薬基盤研]の設立、それを基礎とした次世代・感染症ワクチン・イノベーション特区推進協議会の設立
- ▶予防接種検討会等における種々の検討(健康局結核感染症課)
- ▶産業界においてはH5N1インフル エンザワクチンの研究開発など
- ▶その他(ワクチン学会での検討等)

### 図1 ワクチン導入時期の国際比較(混合ワクチンを中心に)

|      | 日本 | <br>本               | 米国 | <u> </u>              |
|------|----|---------------------|----|-----------------------|
| 1985 | 4  | B 型肝炎ワクチン(米国は 1982) |    |                       |
| 1987 | 4  | 水痘生ワクチン             | 4  | Hib ワクチン              |
|      |    |                     | 4  | 不活化ポリオワクチン(IPV)       |
| 1988 | 4  | 肺炎球菌ワクチン(米国は 1977)  |    |                       |
|      | 4  | 遺伝子組換えB型肝炎ワクチン      |    |                       |
|      | #  | MMRワクチン(米国は 1971)   |    |                       |
| 1991 |    |                     | 4  | aP(無細胞百日咳)ワクチン(日本から   |
|      |    |                     |    | 導入 日本は 1981)          |
| 1992 |    |                     | 4  | <u>DTaP ワクチン</u>      |
|      |    |                     | 4  | 日本脳炎ワクチン(日本から導入 日本は   |
|      |    |                     |    | 1976)                 |
| 1993 |    |                     | +  | <u>DTaP-Hib</u>       |
| 1994 |    |                     | #  | ペストワクチン               |
| 1995 | #  | 不活化A型肝炎ワクチン         | 4  | 水痘生ワクチン(日本から技術導入)     |
| 1996 |    |                     | 4  | <u>Hib−B 型肝炎ワクチン</u>  |
|      |    |                     | 4  | 不活化A型肝炎ワクチン           |
| 2000 |    |                     | 4  | 7 価(コンジュゲート)肺炎球菌ワクチ   |
|      |    |                     |    | ン(小児用)                |
| 2001 |    |                     | 4  | <u>A 型−B 型肝炎ワクチ</u> ン |
| 2002 |    |                     | 4  | DTP-IPV- B 型肝炎ワクチン    |
| 2003 |    |                     | 4  | 経鼻インフルエンザ生ワクチン        |
|      |    |                     | 4  | <u>DPT ワクチン(成人用)</u>  |
| 2005 | #  | <u>MRワクチン</u>       | 4  | MMR-水痘ワクチン            |
|      |    |                     | 4  | 髄膜炎菌ワクチン(結合ワクチン)      |
| 2006 |    | •                   | 4  | ロタウイルスワクチン            |
|      |    |                     | 4  | HPV ワクチン              |
|      |    |                     | 4  | 帯状疱疹生ワクチン             |
| 2007 | 4  | Hib ワクチン            | 4  | プレパンデミックインフルエンザ       |
|      | #  | 沈降新型インフルエンザワクチン     |    | ワクチン(H5N1 株)          |
|      |    | (H5N1 株)            |    |                       |
| 2008 |    |                     | 4  | DTaP-IPV-Hib ワクチン     |
|      |    |                     | #  | DTaP-IPV ワクチン         |

太字は日本未導入品、<u>下線</u>は混合ワクチンを示す。

<sup>・</sup>本表は、「ワクチン産業ビジョン [平成 19 年 3 月] 表 5 最近 20 年間の開発品目の導入時期 国際比較」を、 2006 年以降について(社)細菌製剤協会の協力によりリバイズしたものである。

### 混合ワクチンにかかる現在の検討状況等(日本)

〇ワクチン産業ビジョン推進委員会中間とりまとめ [平成20年3月](関連部分抜粋)

- DPT-IPV4種混合ワクチン
   DPT-IPV4種混合ワクチン開発
- DPT-IPV4種混合ワクチンの開発については、国内のDPTにIPVを組み合わせたワクチンとして国内DPTワクチンメーカー4社4製剤を開発中。開発ステージは、IPVとの四種混合で一部早いところでフェーズⅡ、Ⅲを準備中。2011年ごろから順次申請が予定されている。

- 2. DT(2期)ワクチンについて(百日せき追加接種の必要性について)
- (2)わが国における成人用百日せきワクチン開発について 諸外国の百日せき流行状況と予防接種施策を見る限り、わが 国もいずれ成人百日せき対策は必要で、ワクチン開発期間も考慮 して具体的検討を開始すべきである。TDにかわってTdap、DTaP の必要性や、日本で開発したDTaPを0.5mLで思春期・成人用に接 種するのか、あるいは0.1mLに減量するのか、あるいは抗原量を 調整して0.5mLで統一するのか、海外で使われているTdapを導入 するのか、今後開発されるDPT-IPVを利用するかなどが検討課 題。

必要なワクチン開発には一定の時間を要することから、成人百日せきに対して、感染症対策として基本的な戦略・対策を確立し、それに必要などのようなワクチンを開発していくべきか、製造販売業者や医薬品医療機器総合機構や感染研や学会などで、基本的な戦略をさらに具体的に発展させていける体制が必要。

## 混合ワクチンにかかる現在の検討状況等(米国)

### O ACIP

1. MMRV Vaccine Safety Working Group MMRV\*ワクチン投与後の副作用が2008年3月のMMWR\*\*に掲載される。その後、MMRVに関するリスク評価とそれを踏まえたリスクマネジメントや接種政策を検討するためのワーキンググループ。

\* MMRV: measles, mumps, rubella and varicella

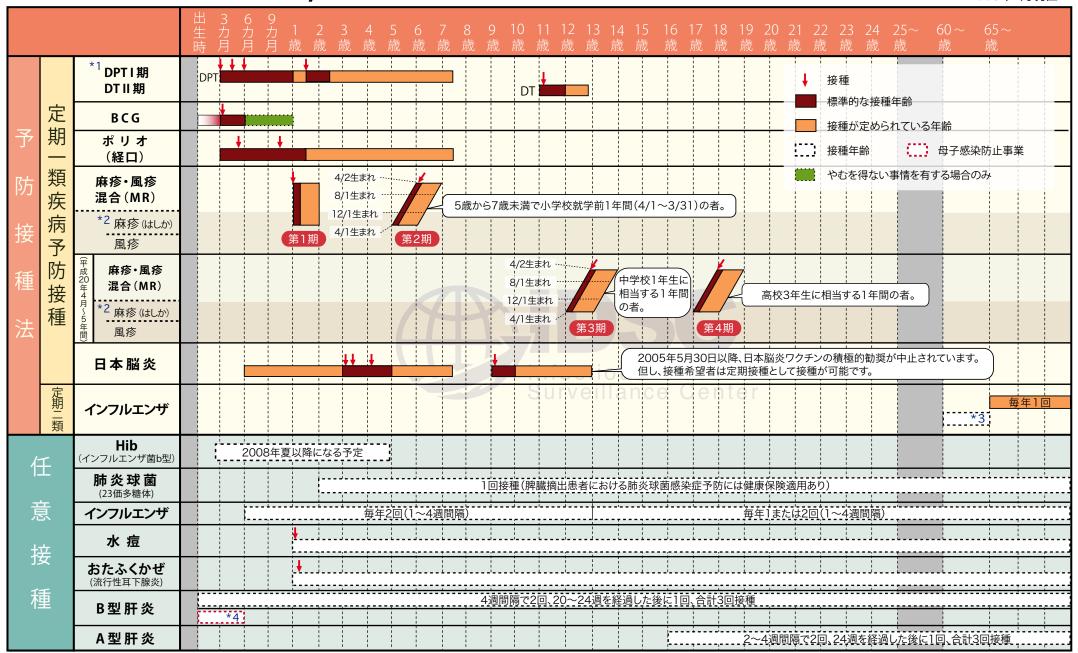
\*\*MMWR: CDC's Morbidity and Mortality Weekly Report

2. Combination Vaccines Working Group 米国で新たに市販された混合ワクチンについて、その有用性や使用方法等について評価するためのワーキンググループ。現在の検討対象は、DTaP-IPVとDTaP-IPV-Hib。



# 日本の定期/任意予防接種スケジュール(2008年4月1日施行)

2008年4月現在



<sup>\*1</sup> D:ジフテリア、P:百日咳、T:破傷風 を表す。

<sup>\*2</sup> 原則としてMRワクチンを接種。なお、同じ**期**内で麻疹ワクチンまたは風疹ワクチンのいずれか一方を受けた者、あるいは特に単抗原ワクチンの接種を希望する者は単抗原ワクチンを接種。

<sup>\*3 60</sup>歳以上65歳未満の者であって一定の心臓、腎臓若しくは呼吸器の機能叉はヒト免疫不全ウイルスによる免疫の機能の障害を有する者。

<sup>\*4</sup> 妊娠中に検査を行い、HBs抗原陽性 (HBe抗原陽性、陰性の両方とも)の母親からの出生児は、出生後できるだけ早期及び、生後2ヶ月にHB免疫グロブリン(HBIG)を接種、ただし、HBe抗原陰性の母親から生まれた児の場合は2回目のHBIGを省略しても良い。 更に生後2,3,5カ月にHBワクチンを接種する。生後6ヶ月後にHBs抗原及び抗体検査を行い必要に応じて任意の追加接種を行う(健康保険適用)。 ② Copyright 2004 IDSC All Rights Reserved. 無断転載・改編を禁ずる。

# Recommended Immunization Schedule for Persons Aged 0-6 Years—UNITED STATES • 2008

For those who fall behind or start late, see the catch-up schedule

| Vaccine <b>▼</b> Age <b>►</b>               | Birth                                   | 1<br>month                             | 2<br>months | 4<br>months                           | 6<br>months                            | 12<br>months                            | 15<br>months                            | 18<br>months                            | 19–23<br>months                        | 2–3<br>years | 4–6<br>years     |
|---|---|--|-------------|---------------------------------------|--|---|---|---|--|--------------|------------------|
| Hepatitis B <sup>1</sup>                    | НерВ                                    | He                                     | рВ          | see<br>footnote1                      |  | He                                      | рВ                                      |   | •<br>•<br>•<br>•                       |              |                  |
| Rotavirus <sup>2</sup>                      | 9                                       | 0                                      | Rota        | Rota                                  | Rota                                   | 9 · · · · · · · · · · · · · · · · · · · | 0 · · · · · · · · · · · · · · · · · · · | 9 · · · · · · · · · · · · · · · · · · · |  |              |                  |
| Diphtheria, Tetanus, Pertussis <sup>3</sup> | **************************************  | ************************************** | DTaP        | DTaP                                  | DTaP                                   | see<br>footnote3                        | DT                                      | аР                                      | 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0  |              | DTaP             |
| Haemophilus influenzae type b⁴              | ## * * * * * * * * * * * * * * * * * *  | ************************************** | Hib         | Hib                                   | Hib⁴                                   | Н                                       | ib                                      | **************************************  |  |              |                  |
| Pneumococcal⁵                               | # * * * * * * * * * * * * * * * * * * * | ************************************** | PCV         | PCV                                   | PCV                                    | P                                       | CV                                      | **************************************  | ************************************** | P            | PV               |
| Inactivated Poliovirus                      | **************************************  | ************************************** | IPV         | IPV                                   |  | IF                                      | V                                       |   |  |              | IPV              |
| Influenza <sup>6</sup>                      | **************************************  | ************************************** |             |                                       | Influenza (Yea                         |   | rly)                                    |   |  |              |                  |
| Measles, Mumps, Rubella <sup>7</sup>        | **************************************  | ************************************** |             | • • • • • • • • • • • • • • • • • • • | ************************************** | MI                                      | MR                                      | **************************************  |  |              | MMR              |
| Varicella <sup>®</sup>                      |   |  |             | • • • • • • • • • • • • • • • • • • • | ************************************** | Vari                                    | cella                                   | 9 · · · · · · · · · · · · · · · · · · · |  |              | <b>Varicella</b> |
| Hepatitis A <sup>9</sup>                    | g                                       | P                                      |             |                                       |  |   | НерА (                                  | 2 doses                                 | )                                      | НерА         | Series           |
| Meningococcal <sup>10</sup>                 |   |  |             |                                       |  |   |   |   |  | MC           | V4               |

Range of recommended ages

Certain high-risk groups

This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2007, for children aged 0 through 6 years. Additional information is available at <a href="https://www.cdc.gov/vaccines/recs/schedules">www.cdc.gov/vaccines/recs/schedules</a>. Any dose not administered at the recommended age should be administered at any subsequent visit, when indicated and feasible. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components of the vaccine are not

contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective Advisory Committee on Immunization Practices statement for detailed recommendations, including for high-risk conditions: http://www.cdc.gov/vaccines/pubs/ACIP-list.htm. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at www.vaers.hhs.gov or by telephone, 800-822-7967.

# 1. Hepatitis B vaccine (HepB). (Minimum age: birth) At birth:

- Administer monovalent HepB to all newborns prior to hospital discharge.
- If mother is hepatitis B surface antigen (HBsAg) positive, administer HepB and 0.5 mL of hepatitis B immune globulin (HBIG) within 12 hours of birth.
- If mother's HBsAg status is unknown, administer HepB within 12 hours of birth. Determine the HBsAg status as soon as possible and if HBsAg positive, administer HBIG (no later than age 1 week).
- If mother is HBsAg negative, the birth dose can be delayed, in rare cases, with a provider's order and a copy of the mother's negative HBsAg laboratory report in the infant's medical record.

### After the birth dose:

The HepB series should be completed with either monovalent HepB or a
combination vaccine containing HepB. The second dose should be administered
at age 1–2 months. The final dose should be administered no earlier than age
24 weeks. Infants born to HBsAg-positive mothers should be tested for HBsAg
and antibody to HBsAg after completion of at least 3 doses of a licensed HepB
series, at age 9–18 months (generally at the next well-child visit).

#### 4-month dose:

- It is permissible to administer 4 doses of HepB when combination vaccines are administered after the birth dose. If monovalent HepB is used for doses after the birth dose, a dose at age 4 months is not needed.
- 2. Rotavirus vaccine (Rota). (Minimum age: 6 weeks)
  - Administer the first dose at age 6-12 weeks.
  - Do not start the series later than age 12 weeks.
  - Administer the final dose in the series by age 32 weeks. Do not administer any dose later than age 32 weeks.
  - Data on safety and efficacy outside of these age ranges are insufficient.
- 3. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). (Minimum age: 6 weeks)
  - The fourth dose of DTaP may be administered as early as age 12 months, provided 6 months have elapsed since the third dose.
  - Administer the final dose in the series at age 4–6 years.
- Haemophilus influenzae type b conjugate vaccine (Hib). (Minimum age: 6 weeks)
  - If PRP-OMP (PedvaxHIB® or ComVax® [Merck]) is administered at ages 2 and 4 months, a dose at age 6 months is not required.
  - TriHIBit® (DTaP/Hib) combination products should not be used for primary immunization but can be used as boosters following any Hib vaccine in children age 12 months or older.

- 5. Pneumococcal vaccine. (Minimum age: 6 weeks for pneumococcal conjugate vaccine [PCV]; 2 years for pneumococcal polysaccharide vaccine [PPV])
  - Administer one dose of PCV to all healthy children aged 24–59 months having any incomplete schedule.
  - Administer PPV to children aged 2 years and older with underlying medical conditions.
- **6. Influenza vaccine.** (Minimum age: 6 months for trivalent inactivated influenza vaccine [TIV]; 2 years for live, attenuated influenza vaccine [LAIV])
  - Administer annually to children aged 6–59 months and to all eligible close contacts of children aged 0–59 months.
  - Administer annually to children 5 years of age and older with certain risk factors, to other persons (including household members) in close contact with persons in groups at higher risk, and to any child whose parents request vaccination.
  - For healthy persons (those who do not have underlying medical conditions that predispose them to influenza complications) ages 2–49 years, either LAIV or TIV may be used.
  - Children receiving TIV should receive 0.25 mL if age 6–35 months or 0.5 mL if age 3 years or older.
  - Administer 2 doses (separated by 4 weeks or longer) to children younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time last season but only received one dose.
- 7. Measles, mumps, and rubella vaccine (MMR). (Minimum age: 12 months)
  - Administer the second dose of MMR at age 4–6 years. MMR may be administered before age 4–6 years, provided 4 weeks or more have elapsed since the first dose.
- 8. Varicella vaccine. (Minimum age: 12 months)
- Administer second dose at age 4–6 years; may be administered 3 months or more after first dose.
- Do not repeat second dose if administered 28 days or more after first dose.
- 9. Hepatitis A vaccine (HepA). (Minimum age: 12 months)
  - Administer to all children aged 1 year (i.e., aged 12–23 months). Administer the 2 doses in the series at least 6 months apart.
  - Children not fully vaccinated by age 2 years can be vaccinated at subsequent visits.
  - HepA is recommended for certain other groups of children, including in areas where vaccination programs target older children.
- 10. Meningococcal vaccine. (Minimum age: 2 years for meningococcal conjugate vaccine (MCV4) and for meningococcal polysaccharide vaccine (MPSV4))
  - Administer MCV4 to children aged 2–10 years with terminal complement deficiencies or anatomic or functional asplenia and certain other high-risk groups. MPSV4 is also acceptable.
  - Administer MCV4 to persons who received MPSV4 3 or more years previously and remain at increased risk for meningococcal disease.

### Recommended Immunization Schedule for Persons Aged 7–18 Years—UNITED STATES • 2008

For those who fall behind or start late, see the green bars and the catch-up schedule

| Vaccine <b>▼</b> Age <b>►</b>               | 7–10 years         | 11–12 years      | 13–18 years |                      |  |  |  |
|---|--------------------|------------------|-------------|----------------------|--|--|--|
| Diphtheria, Tetanus, Pertussis <sup>1</sup> | see footnote 1     | Tdap             | Tdap        |                      |  |  |  |
| Human Papillomavirus²                       | see footnote 2     | HPV (3 doses)    | HPV Series  | Range of recomme     |  |  |  |
| Meningococcal <sup>3</sup>                  | MCV4               | MCV4             | MCV4        | ages                 |  |  |  |
| Pneumococcal <sup>4</sup>                   |                    | PPV              |             | Catch-up             |  |  |  |
| Influenza <sup>5</sup>                      | Influenza (Yearly) |                  |             |                      |  |  |  |
| Hepatitis A <sup>6</sup>                    |                    | HepA Series      |             |                      |  |  |  |
| Hepatitis B <sup>7</sup>                    |                    | HepB Series      | :           | Certain<br>high-risk |  |  |  |
| Inactivated Poliovirus <sup>8</sup>         | IPV Series         |                  |             |                      |  |  |  |
| Measles, Mumps, Rubella <sup>9</sup>        |                    | MMR Series       | :           |                      |  |  |  |
| Varicella <sup>10</sup>                     |                    | Varicella Series |             |                      |  |  |  |

This schedule indicates the recommended ages for routine administration of currently licensed childhood vaccines, as of December 1, 2007, for children aged 7–18 years. Additional information is available at <a href="https://www.cdc.gov/vaccines/recs/schedules">www.cdc.gov/vaccines/recs/schedules</a>. Any dose not administered at the recommended age should be administered at any subsequent visit, when indicated and feasible. Additional vaccines may be licensed and recommended during the year. Licensed combination vaccines may be used whenever any components of the combination are indicated and other components of the vaccine are not

contraindicated and if approved by the Food and Drug Administration for that dose of the series. Providers should consult the respective Advisory Committee on Immunization Practices statement for detailed recommendations, including for high risk conditions: http://www.cdc.gov/vaccines/pubs/ACIP-list.htm. Clinically significant adverse events that follow immunization should be reported to the Vaccine Adverse Event Reporting System (VAERS). Guidance about how to obtain and complete a VAERS form is available at www.vaers.hhs.gov or by telephone, 800-822-7967.

- 1. Tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap). (Minimum age: 10 years for BOOSTRIX® and 11 years for ADACEL™)
  - Administer at age 11–12 years for those who have completed the recommended childhood DTP/DTaP vaccination series and have not received a tetanus and diphtheria toxoids (Td) booster dose.
  - 13–18-year-olds who missed the 11–12 year Tdap or received Td only are encouraged to receive one dose of Tdap 5 years after the last Td/DTaP dose.
- 2. Human papillomavirus vaccine (HPV). (Minimum age: 9 years)
  - Administer the first dose of the HPV vaccine series to females at age 11–12 years.
  - Administer the second dose 2 months after the first dose and the third dose 6 months after the first dose.
  - Administer the HPV vaccine series to females at age 13–18 years if not previously vaccinated.

#### 3. Meningococcal vaccine.

- Administer MCV4 at age 11–12 years and at age 13–18 years if not previously vaccinated. MPSV4 is an acceptable alternative.
- Administer MCV4 to previously unvaccinated college freshmen living in dormitories.
- MCV4 is recommended for children aged 2–10 years with terminal complement deficiencies or anatomic or functional asplenia and certain other high-risk groups.
- Persons who received MPSV4 3 or more years previously and remain at increased risk for meningococcal disease should be vaccinated with MCV4.

### 4. Pneumococcal polysaccharide vaccine (PPV).

• Administer PPV to certain high-risk groups.

### 5. Influenza vaccine.

- Administer annually to all close contacts of children aged 0-59 months.
- Administer annually to persons with certain risk factors, health-care workers, and other persons (including household members) in close contact with persons in groups at higher risk.

- Administer 2 doses (separated by 4 weeks or longer) to children younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time last season but only received one dose.
- For healthy nonpregnant persons (those who do not have underlying medical conditions that predispose them to influenza complications) ages 2–49 years, either LAIV or TIV may be used.

### 6. Hepatitis A vaccine (HepA).

- Administer the 2 doses in the series at least 6 months apart.
- HepA is recommended for certain other groups of children, including in areas where vaccination programs target older children.

### 7. Hepatitis B vaccine (HepB).

- Administer the 3-dose series to those who were not previously vaccinated.
- A 2-dose series of Recombivax HB® is licensed for children aged 11–15 years.

### 8. Inactivated poliovirus vaccine (IPV).

- For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if the third dose was administered at age 4 years or older.
- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.

### 9. Measles, mumps, and rubella vaccine (MMR).

 If not previously vaccinated, administer 2 doses of MMR during any visit, with 4 or more weeks between the doses.

### 10. Varicella vaccine.

- Administer 2 doses of varicella vaccine to persons younger than 13 years of age at least 3 months apart. Do not repeat the second dose if administered 28 or more days following the first dose.
- Administer 2 doses of varicella vaccine to persons aged 13 years or older at least 4 weeks apart.

# **Catch-up Immunization Schedule**

## for Persons Aged 4 Months-18 Years Who Start Late or Who Are More Than 1 Month Behind

The table below provides catch-up schedules and minimum intervals between doses for children whose vaccinations have been delayed. A vaccine series does not need to be restarted, regardless of the time that has elapsed between doses. Use the section appropriate for the child's age.

|   |                     | CATCH-UP SCHEDULE FOR PER  | SONS AGED 4 MONTHS-6 YEARS  |  |                       |  |  |  |  |
|---|---------------------|--|---|--|-----------------------|--|--|--|--|
| Vaccine   | Minimum Age         | Minimum Interval Between Doses   |   |  |                       |  |  |  |  |
| vaccine   | for Dose 1          | Dose 1 to Dose 2   | Dose 2 to Dose 3  | Dose 3 to Dose 4   | Dose 4 to Dose 5      |  |  |  |  |
| Hepatitis B <sup>1</sup>  | Birth               | 4 weeks  | <b>8 weeks</b><br>(and 16 weeks after first dose)   |  | ,                     |  |  |  |  |
| Rotavirus <sup>2</sup>  | 6 wks               | 4 weeks  | 4 weeks   |  | ]                     |  |  |  |  |
| Diphtheria, Tetanus, Pertussis <sup>3</sup>                             | 6 wks               | 4 weeks  | 4 weeks   | 6 months   | 6 months <sup>3</sup> |  |  |  |  |
| Haemophilus<br>influenzae type b <sup>4</sup>                           | 6 wks               | 4 weeks if first dose administered at younger than 12 months of age 8 weeks (as final dose) if first dose administered at age 12-14 months No further doses needed if first dose administered at 15 months of age or older   | 4 weeks <sup>4</sup> if current age is younger than 12 months  8 weeks (as final dose) <sup>4</sup> if current age is 12 months or older and second dose administered at younger than 15 months of age  No further doses needed if previous dose administered at age 15 months or older | 8 weeks (as final dose) This dose only necessary for children aged 12 months-5 years who received 3 doses before age 12 months |                       |  |  |  |  |
| Pneumococcal <sup>5</sup> 6 wk  |                     | 4 weeks if first dose administered at younger than 12 months of age  8 weeks (as final dose) if first dose administered at age 12 months or older or current age 24–59 months  No further doses needed for healthy children if first dose administered at age 24 months or older | 4 weeks if current age is younger than 12 months 8 weeks (as final dose) if current age is 12 months or older No further doses needed for healthy children if previous dose administered at age 24 months or older  | 8 weeks (as final dose) This dose only necessary for children aged 12 months-5 years who received 3 doses before age 12 months |                       |  |  |  |  |
| Inactivated Poliovirus <sup>6</sup>                                     | 6 wks               | 4 weeks  | 4 weeks   | 4 weeks <sup>6</sup>   | Ì                     |  |  |  |  |
| Measles, Mumps, Rubella <sup>7</sup>                                    | 12 mos              | 4 weeks  |   |  |                       |  |  |  |  |
| Varicella <sup>8</sup>  | 12 mos              | 3 months   |   |  |                       |  |  |  |  |
| Hepatitis A <sup>9</sup>  | 12 mos              | 6 months   |   |  |                       |  |  |  |  |
|   |                     | CATCH-UP SCHEDULE FOR  | PERSONS AGED 7–18 YEARS   |  |                       |  |  |  |  |
| Tetanus, Diphtheria/<br>Tetanus, Diphtheria,<br>Pertussis <sup>10</sup> | 7 yrs <sup>10</sup> | 4 weeks  | 4 weeks if first dose administered at younger than 12 months of age 6 months if first dose administered at age 12 months or older   | 6 months<br>if first dose administered at<br>younger than 12 months of age   |                       |  |  |  |  |
| Human Papillomavirus <sup>11</sup>                                      | 9 yrs               | 4 weeks  | <b>12 weeks</b> (and 24 weeks after the first dose)   |  |                       |  |  |  |  |
| Hepatitis A <sup>9</sup>  | 12 mos              | 6 months   |   |  | ]                     |  |  |  |  |
| Hepatitis B <sup>1</sup>  | Birth               | 4 weeks  | <b>8 weeks</b> (and 16 weeks after first dose)  |  | ,                     |  |  |  |  |
| Inactivated Poliovirus <sup>6</sup>                                     | 6 wks               | 4 weeks  | 4 weeks   | 4 weeks <sup>6</sup>   |                       |  |  |  |  |
| Measles, Mumps, Rubella <sup>7</sup>                                    | 12 mos              | 4 weeks  |   |  | [                     |  |  |  |  |
| Varicella <sup>8</sup>  | 12 mos              | 4 weeks if first dose administered at age 13 years or older 3 months if first dose administered at younger than 13 years of age  |   |  |                       |  |  |  |  |

#### 1. Hepatitis B vaccine (HepB).

- Administer the 3-dose series to those who were not previously vaccinated.
- A 2-dose series of Recombivax HB® is licensed for children aged 11-15 years.

### 2. Rotavirus vaccine (Rota).

- Do not start the series later than age 12 weeks.
- · Administer the final dose in the series by age 32 weeks.
- Do not administer a dose later than age 32 weeks.
- · Data on safety and efficacy outside of these age ranges are insufficient.

#### 3. Diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP).

- The fifth dose is not necessary if the fourth dose was administered at age 4 years or older.
- DTaP is not indicated for persons aged 7 years or older.

#### 4. Haemophilus influenzae type b conjugate vaccine (Hib).

- Vaccine is not generally recommended for children aged 5 years or older.
- If current age is younger than 12 months and the first 2 doses were PRP-OMP (PedvaxHIB® or ComVax® [Merck]), the third (and final) dose should be administered at age 12–15 months and at least 8 weeks after the second dose.
- If first dose was administered at age 7–11 months, administer 2 doses separated by 4 weeks plus a booster at age 12–15 months.

### 5. Pneumococcal conjugate vaccine (PCV).

- Administer one dose of PCV to all healthy children aged 24–59 months having any incomplete schedule.
- For children with underlying medical conditions, administer 2 doses of PCV at least 8 weeks apart if previously received less than 3 doses, or 1 dose of PCV if previously received 3 doses.

### 6. Inactivated poliovirus vaccine (IPV).

 For children who received an all-IPV or all-oral poliovirus (OPV) series, a fourth dose is not necessary if third dose was administered at age 4 years or older.

- If both OPV and IPV were administered as part of a series, a total of 4 doses should be administered, regardless of the child's current age.
- IPV is not routinely recommended for persons aged 18 years and older.

### 7. Measles, mumps, and rubella vaccine (MMR).

- The second dose of MMR is recommended routinely at age 4–6 years but may be administered earlier if desired.
- If not previously vaccinated, administer 2 doses of MMR during any visit with 4 or more weeks between the doses.

#### 8. Varicella vaccine.

- The second dose of varicella vaccine is recommended routinely at age 4–6 years but may be administered earlier if desired.
- Do not repeat the second dose in persons younger than 13 years of age if administered 28 or more days after the first dose.

### 9. Hepatitis A vaccine (HepA).

 HepA is recommended for certain groups of children, including in areas where vaccination programs target older children. See MMWR 2006;55(No. RR-7):1–23.

#### Tetanus and diphtheria toxoids vaccine (Td) and tetanus and diphtheria toxoids and acellular pertussis vaccine (Tdap).

- Tdap should be substituted for a single dose of Td in the primary catch-up series or as a booster
  if age appropriate; use Td for other doses.
- A 5-year interval from the last Td dose is encouraged when Tdap is used as a booster dose. A
  booster (fourth) dose is needed if any of the previous doses were administered at younger than
  12 months of age. Refer to ACIP recommendations for further information.
   See MMWR 2006;55(No. RR-3).

### 11. Human papillomavirus vaccine (HPV).

Administer the HPV vaccine series to females at age 13–18 years if not previously vaccinated.



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### **Childhood Vaccination Schedule**



Austria Belgium Bulgaria Croatia Cyprus Czech Republic Denmark Estonia Finland France Germany Greece Hungary Iceland Ireland Italy Latvia Lithuania Luxembourg Malta The Netherlands Norway Poland Portugal Romania Slovakia Slovenia Spain Sweden Switzerland Turkey United Kingdom

### Summary chart

**Abbreviations** 

| The United Kingdom Childhood Vaccination Schedule |                  |                  |                  |                  |      |     |                  |                  |  |
|---|------------------|------------------|------------------|------------------|------|-----|------------------|------------------|--|
|   | DTaP             | IPV              | Hib              | MenC             | PCV7 | MMR | BCG <sup>5</sup> | Td               |  |
| At birth  |                  |                  |                  |                  |      |     | Yes <sup>6</sup> |                  |  |
| 2 months  | Yes <sup>1</sup> | Yes <sup>1</sup> | Yes <sup>1</sup> |                  | Yes  |     |                  |                  |  |
| 3 months  | Yes <sup>1</sup> | Yes <sup>1</sup> | Yes <sup>1</sup> | Yes              |      |     |                  |                  |  |
| 4 months  | Yes <sup>1</sup> | Yes <sup>1</sup> | Yes <sup>1</sup> | Yes              | Yes  |     |                  |                  |  |
| Around 12 months                                  |                  |                  | Yes <sup>2</sup> | Yes <sup>2</sup> |      |     |                  |                  |  |
| Around 13 months                                  |                  |                  |                  |                  | Yes  | Yes |                  |                  |  |
| 3 years 4 months-5 years                          | Yes <sup>3</sup> | Yes <sup>3</sup> |                  |                  |      | Yes |                  |                  |  |
| 13-18 years                                       |                  | Yes <sup>4</sup> |                  |                  |      |     |                  | Yes <sup>4</sup> |  |

The United Kingdom Childhood Vaccination Schedule as on 10 January 2007

- 1 DTaP, IPV and Hib are given as a combined vaccine.
- 2 Hib and MenC are given as a combined vaccine.
- 3 DTaP (or dTaP) and IPV are given as a combined vaccine.
- 4 Td and IPV are given as a combined vaccine.
- 5 In addition to the recommendations for targeted and high risk group infants to receive BCG (see below 6) the BCG vaccination policy extends to:
  - Previously unvaccinated new immigrants from high prevalence countries for TB.
  - Children who after screening for TB risk factors and tested and result negative using the Mantoux test.
- 6 BCG is recommended to all:
  - Infants living in areas where the incidence of TB is 40/100,000 or greater.
  - Infants whose parents or grandparents were born in a country with a TB incidence of 40/100,000 or higher.

### **Additional comments**

Human papillomavirus (HPV) vaccination programme for all 12- to 13-year-old girls is planned to start in 2008, with a catch-up campaign for girls up to 18 years old. [1]

Hepatitis B vaccination is recommended for babies born to mothers who are chronic carriers of hepatitis B virus or to mothers who have had acute hepatitis B during pregnancy plus their close family members. It is also recommended for those likely to be in close contact with carriers.

### Historic changes

1999: Introduction of MenC into childhood vaccination schedule.

2005: BCG vaccination programme - As from July 2005 an improved targeted neonatal and other at risk based programme replaced the current schools' programme for older children.

2006: Pneumococcal vaccine added to the childhood vaccination schedule.

2006: Hib-MenC booster to be given at around 12 months added to the childhood vaccination schedule.

This summary chart is adapted from the national immunisation schedule for the UK based upon advice from the UK Joint Committee for Vaccination and Immunisation (JCVI). The latest information on vaccines and vaccination procedures for all the vaccine preventable infectious diseases that may occur in the UK is available at this website or PDF document.