Očkování nedonošených dětí, doporučení odborných společností

XIV. HRADECKÉ
VAKCINOLOGICKÉ DNY

4.–6. 10. 2018, Kongresové centrum Aldis, Hradec Králové

ČESKÁ VAKCINOLOGICKÁ
SPOLEČNOST ČLS JEP

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MUDR. HANA CABRNOCHOVÁ, MBA

Předčasně narozené děti doporučuje očkovat podle jejich chronologického věku ve stejných termínech jako donošené děti :

- ✓ **American Academy of Peditrics (AAP)**
- ✓ **Advisory committee on Immunization Practices (ACIP)**
- ✓ **Canadian Immunization Guide**
- ✓ **German Standing Committee on Vaccination (STIKO)**
- ✓ **World Health Organization (WHO)**
- ✓ **Public Health England**

- V USA první doporučení na počátku 80. let 20. století a od té doby se nezměnila (1,2). Stejné doporučení platí i v jiných zemích, jako je Velká Británie (3), Německo (4), Rakousko (5), Itálie (6), Francie (7), Kanada (8) nebo Austrálie (9).
- Další dávka se diskutuje v zemích, které používají schéma 2 + 1 (v souladu s údaji SPC) a je zdůrazněna časná posilovací dávka.

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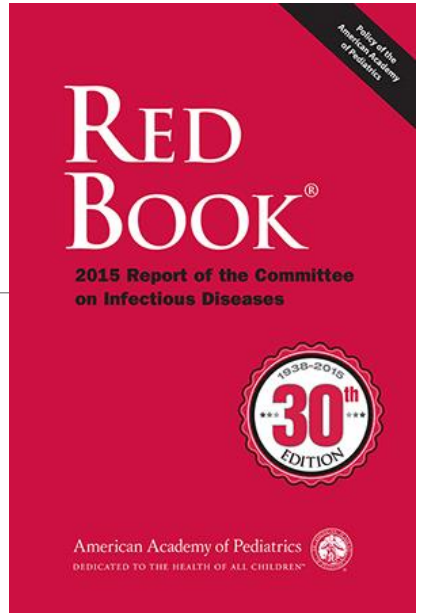
Doporučení pro očkování nedonošených



- Děti narozené předčasně (pod 37. týden) nebo s nízkou porodní hmotností (pod 2500 g) by měly být očkované ve stejném chronologickém věku jako děti donošené a s normální porodní hmotnosti.
- **Gestační věk a porodní hmotnost nejsou omezujícími faktory při rozhodování, zda má být klinicky stabilní nedonošené dítě imunizováno podle plánu.**
- Přestože studie prokázaly sníženou imunitní odpověď na několik vakcín podaných novorozencům s velmi nízkou porodní hmotností (pod 1500 g) a u nedonošených (pod 29. týden), většina předčasně narozených dětí, včetně kojenců, kteří dostávali dexamethason pro chronické onemocnění plic, má po očkování dostatečnou imunitní odpověď, aby se zabránilo onemocnění.
- Dávkování vakcín by nemělo být sníženo nebo rozděleno (nižší kombinace) při podávání předčasně narozeným dětem nebo dětem s nízkou porodní hmotnosti.

Immunisation for the low birth weight and/or preterm infant (updated September 2017)

The Immunisation Advisory Centre

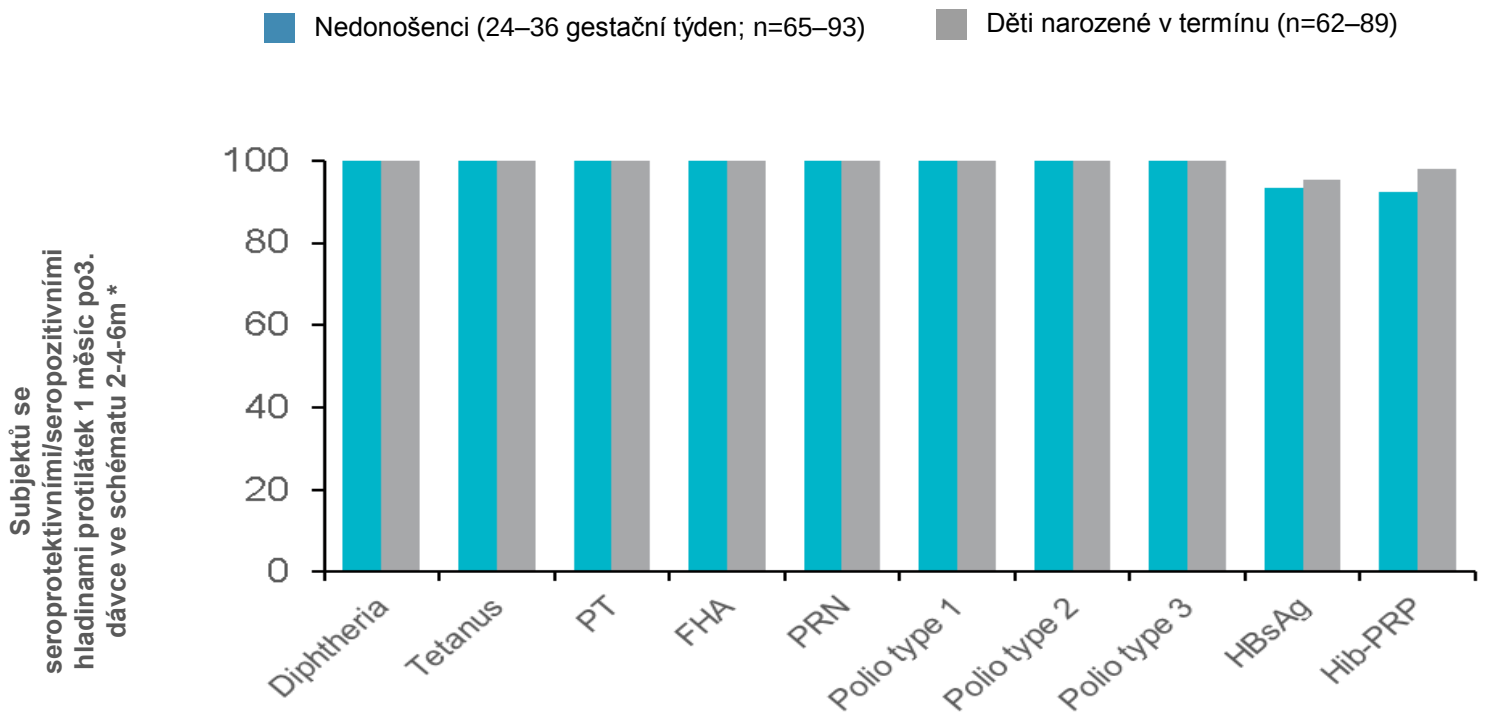
Executive summary

» Premature and low birth weight infants are at greater risk of increased mortality and morbidity from vaccine preventable diseases. » With the exception of BCG, immunisations should be given according to the National Immunisation Schedule at the appropriate chronological age. » Do not adjust age for preterm birth, i.e. National Immunisation Schedule vaccines start at 6 weeks of age from the date of birth. » The usual vaccine dosage should be used.	
Vaccine immunogenicity	» Inferior immune response to some vaccines although evidence suggests the response is still protective.
Vaccine safety	» Immunisation in these infants is safe and effective. However, post-vaccination apnoea with or without associated bradycardia up to 48 hours post-immunisation may be increased in some groups.

- ✓ Očkování proti hepatitidě B podle chronologického stáří od 6-ti týdnů bez ohledu na porodní hmotnost
- ✓ Hexavakcína od 6-ti týdnů
- ✓ BCG vakcína nad 34 týdnů gestačního stáří co nejdříve, pod 34. týden až po jeho dosažení
- ✓ Očkování proti rotavirům u nedonošených (27.-36. týden) v 6-ti týdnech

Infanrix hexa™ má ověřenou imunogenicitu u předčasně narozených dětí

Nedonošení



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Ověřená účinnost pneumokokových vakcín

4510.190

Immunogenicity of the 13-valent Pneumococcal Conjugate Vaccine (PCV13) in Preterm (PT) Infants Compared With Full-Term (FT) Infants

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BACKGROUND

- Streptococcus pneumoniae causes invasive pneumococcal disease (IPD) and noninvasive disease in children throughout the world.
- Preterm (PT) infants (particularly those born at <32 weeks of gestation) have demonstrated a modestly increased risk of IPD compared with their full-term (FT) counterparts.[1]
- In the pivotal efficacy study of the 7-valent pneumococcal conjugate vaccine (PCV7),[1] these risks were estimated to be approximately 2.6 (P=0.02) for infants with birth weight <2,500 g, and approximately 1.6 (P=0.06) among infants with gestational age (GA) <38 weeks
  - increased risk is likely due to:
    - reduced materno-fetal transfer of pneumococcal antibodies
    - immaturity of the immune system
- Previous studies of PCV7 have demonstrated immunogenicity in PT infants:[2-4]
  - immune responses among PT infants may be lower than among FT infants after the infant series
  - posttoddler booster responses were similar to those of FT infants
  - overall responses were likely to be adequate for protection against IPD
- This study will describe the safety and immunogenicity of a 2-, 3-, 4, and 12-month schedule of the 13-valent pneumococcal conjugate vaccine (PCV13) when given to PT infants, compared with FT infants, with routinely recommended concomitant vaccines (diphtheria, tetanus, acellular pertussis-inactivated poliovirus-hepatitis B virus-*Haemophilus influenzae* type b [DTaP-IPV-HB-VHib] and meningococcal serogroup C conjugate vaccine [MnCC]).

OBJECTIVES

- To describe immune response to PCV13 in PT versus FT infants 1 month after the infant series, and before and 1 month after the toddler dose, as measured by:
  - the proportion of subjects achieving a serotype-specific immunoglobulin G (IgG) concentration ≥0.35 µg/mL (World Health Organization [WHO] threshold)[5]
  - serotype-specific antipneumococcal IgG geometric mean concentrations (GMCs)
  - serotype-specific opsonophagocytic activity (OPA) geometric mean titers (GMTs)
- To describe the same responses in subgroups of PT infants stratified by GA.

METHODS

- This was an open-label, phase 4, 2-arm, multicenter, parallel group study.
- All subjects received PCV13 at 2, 3, 4, and 12 months of age, concomitantly with DTaP-IPV-HB-VHib and MnCC vaccines.
- All infants were considered healthy and were aged ≥42 to ≤98 days at the time of enrollment.
- Two groups of 100 subjects each were included:
  - Group 1: PT infants, proportionally enrolled and stratified by gestational age as follows:
    - 1A: 25% of subjects with GA between ≥32 and <37 weeks (32-GA<37 weeks)
    - 1B: 50% of subjects with GA between ≥29 and <32 weeks (29-GA<32 weeks)
    - 1C: 25% of subjects with GA <29 weeks (GA <29 weeks)
  - Group 2: FT infants (≥37 weeks of gestation)

RESULTS

Demographics

- Demographic characteristics of the evaluable infant series population are shown in **Table 1**.

Table 1. Demographic characteristics evaluable infant series population

	Group (as enrolled)		
	Group 1 (PT infants) n=99	Group 2 (FT infants) n=98	Total N=197
Female sex, n (%)	48 (48.5%)	55 (56.1%)	103 (52.3%)
White, n	99	98	197
Gestational age, weeks			
Mean±SD	30.8±2.6	39.5±1.4	35.1±4.8
Range	26.0-36.3	37.0-42.0	26.0-42.0
Weight at birth, kg			
Mean±SD	1.5±0.5	3.3±0.5	2.4±1.0
Range	0.7-3.2	2.0-4.5	0.7-4.5

FT, full-term; PT, preterm; SD, standard deviation.

Immunogenicity

PT (Group 1) versus FT (Group 2) infants

- Antipneumococcal IgG concentrations ≥0.35 µg/mL 1 month after the infant series are shown in **Table 2**.
  - most subjects (>85%) in both groups achieved an IgG antibody concentration ≥0.35 µg/mL 1 month after the infant series
    - a significantly lower response rate at this threshold was observed among Group 1 subjects for serotypes 5, 6A, and 6B
  - 1 month after the toddler dose, the proportion of subjects in both groups achieving a pneumococcal IgG antibody concentration ≥0.35 µg/mL was >97% for all serotypes except serotype 3
  - there were no statistically significant differences between Group1 and Group 2 after the toddler dose

Table 2. Comparison of subjects achieving a pneumococcal IgG antibody concentration ≥0.35 µg/mL 1 month after infant series PT versus FT

	Group (as enrolled)			
	Group 1 (PT infants) (n=98-99)	Group 2 (FT infants) (n=97)		
Serotype	%	%	Difference[a]	(95% CI[a])
PCV7 serotypes				
4	98.97	98.97	−2.00	(−7.65 to 2.88)
6B	72.73	87.63	−14.90	(−26.40 to −3.21)
9V	96.97	96.91	0.06	(−5.84 to 6.05)
14	100.00	97.94	2.06	(−1.71 to 7.23)
18C	96.97	94.85	2.12	(−4.09 to 8.89)
19F	98.99	98.97	0.02	(−4.56 to 4.68)
23F	85.86	92.78	−6.92	(−16.19 to 1.89)
Additional serotypes in PCV13				
1	93.94	93.88	−1.94	(−9.97 to 4.84)
3	85.86	90.72	−4.86	(−14.40 to 4.70)
5	71.72	90.72	−19.00	(−30.10 to −7.16)
6A	82.65	94.85	−12.19	(−21.66 to −3.26)
7F	98.99	98.97	0.02	(−4.56 to 4.68)
19A	98.99	98.97	0.02	(−4.56 to 4.68)

[a]A number of subjects with a determinate IgG antibody concentration to the given serotype.
[b]Difference in proportions: Group 1 minus Group 2, expressed as a percentage.
[c]Exact (Tasked On Based on Clopper and Pearson) for the difference in proportions: Group 1 minus Group 2, expressed as a percentage.
CI, confidence interval; FT, full-term; IgG, immunoglobulin G; PCV7, 7-valent pneumococcal conjugate vaccine; PCV13, 13-valent pneumococcal conjugate vaccine; PT, preterm.

Figure 1. Comparison of antipneumococcal IgG GMCs by time point evaluable immunogenicity population

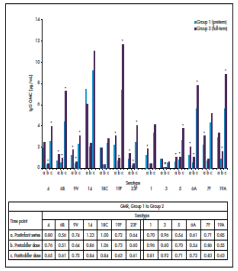
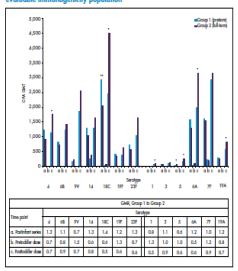


Figure 2. Comparison of antipneumococcal OPA GMTs by time point evaluable immunogenicity population



- Antipneumococcal IgG GMCs are shown in **Figure 1**.
  - Group 1 IgG GMCs were significantly lower (e.g. upper limit of the 95% confidence interval for the geometric mean ratio was <1.0) compared with Group 2
    - for 11 of 13 serotypes for at least one time point
    - for 6 of 13 serotypes for all time points
  - after the toddler dose, a booster response (i.e. postToddler GMC higher than postinfant series GMC) was observed in IgG GMCs in both groups for 12 of the 13 serotypes, and geometric mean fold rises were similar between both groups for all serotypes
  - responses to serotype 3 were low for both groups, and were lower after the toddler dose than after the infant series (**Figure 1**)
- OPA GMTs are shown in **Figure 2**.
  - there were fewer differences in OPA GMTs between the 2 groups after the infant series or before the toddler dose, with Group 1 to Group 2 GMT ratios approximating 1 for most serotypes
  - GMTs increased after the toddler dose in both groups
  - in contrast to the IgG response, the OPA response for serotype 3 was robust in both groups

PT subgroups

- The same analyses were also performed for the subgroups of PT infants, stratified on the basis of GA, with the exception that no comparisons were made between subgroups.
- After the infant series:
  - the proportion of subjects achieving IgG antibody concentrations ≥0.35 µg/mL was >85% in all 3 GA subgroups for 8 of 13 serotypes; for the remaining serotypes, the proportion of responders appeared to decrease with decreasing GA
  - IgG GMCs were higher for subjects in subgroup 1A than in 1B or 1C for all serotypes (**Figure 3**)
- After the toddler dose:
  - the proportion of subjects achieving an antibody response of ≥0.35 µg/mL was >95% for all 3 GA subgroups for all serotypes except for serotype 3
  - the proportion of responders for serotype 3 after the toddler dose ranged from 95.2% for the PT subgroup 1A to 50% for the PT subgroup 1C
  - booster response was observed in all 3 GA subgroups for all serotypes except serotype 3; GMCs were generally higher in the PT subgroup 1A than in the other 2 subgroups (**Figure 3**)
- In general, the pneumococcal IgG results were supported by OPA assay results (**Figure 4**).

Figure 3. Antipneumococcal IgG GMCs by time point for the Group 1 GA subgroups evaluable immunogenicity population

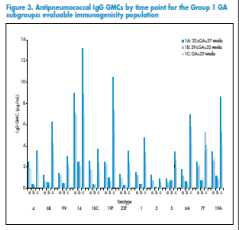
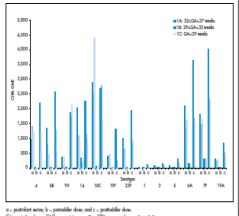


Figure 4. Antipneumococcal OPA GMTs by time point for the Group 1 GA subgroups evaluable immunogenicity population



Safety

- Similar proportions of subjects in Group 1 and Group 2 reported local reactions after each dose of PCV13 during the infant series.
- After the toddler dose, local reactions were reported for 67 subjects (75.3%) in Group 1 and 60 subjects (68.2%) in Group 2; the most commonly reported local reaction was tenderness at the injection site.
- Systemic reactions were reported by similar proportions of subjects in both Groups 1 and 2, with >87% of subjects reporting systemic events after each vaccine dose:
  - irritability or decreased sleep was the most commonly reported systemic event
  - fever was a common systemic event within 7 days after each dose
  - the majority of reports were mild, and only 1 subject had a fever event >40°C

CONCLUSIONS

- When PCV13 is given to PT and FT infants in a series of 4 doses at 2, 3, 4, and 12 months of age, concomitantly with other recommended infant vaccines:
  - the majority of subjects (>85%) in both groups achieve serotype-specific IgG antibody levels after the primary series that exceed the WHO-established threshold of protection, and they achieve functional OPA antibody responses
  - IgG GMCs measured 1 month after the infant series are somewhat lower in PT infants compared with FT infants, and for some serotypes there is evidence of lower response with lower GA
  - although postToddler dose responses vary by serotype and with GA, there is good evidence of adequate priming among PT infants compared with their FT counterparts
  - the response to serotype 3 is similar for both groups, and characterized by generally low IgG GMCs that are lower after the toddler dose; in contrast, OPA GMTs are higher after the toddler dose than after the infant series
    - these findings are consistent with previous studies in European infants, and the results are higher than those reported in studies conducted in North America
- PCV13 is generally well tolerated in both PT and FT infants when administered in this accelerated schedule.
- These results reinforce the importance of timely vaccination for all infants, and especially for those born prematurely.

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Immunization of Preterm Infants With 10-Valent Pneumococcal Conjugate Vaccine

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KEY WORDS
premature infants, pneumococcal conjugate vaccine, *Streptococcus pneumoniae*, safety, immune response

ABBREVIATIONS
7vCRM—7-valent pneumococcal conjugate vaccine
PHiD-CV—pneumococcal nontypeable *Haemophilus influenzae* protein D conjugate vaccine
GSK—GlaxoSmithKline
DTPa-HBV-IPV/Hib—combined diphtheria-tetanus-acellular pertussis-hepatitis B virus inactivated poliovirus, and *H influenzae* type b vaccine
NTHi—nontypeable *H influenza*
AE—adverse event
SAE—serious AE
ELISA—enzyme-linked immunosorbent assay
OPA—opsonophagocytic activity
ELU—ELISA unit
CI—confidence interval
GMC—geometric mean concentration
GMT—geometric mean titer
DTPa-IPV/Hib—combined diphtheria-tetanus-acellular pertussis-inactivated poliovirus, and *H influenzae* type b vaccine

This work was presented in part at the 27th annual meeting of the European Society for Paediatric Infectious Diseases; June 9–13, 2009; Brussels, Belgium; World Society for Pediatric Infectious Diseases 6th World Congress; November 18–22, 2009; Buenos Aires, Argentina; and Excellence in Paediatrics congress, December 3–6, 2009; Florence, Italy.

This trial has been registered at www.clinicaltrials.gov (identifier NCT00390910/NCT00809492).

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WHAT'S KNOWN ON THIS SUBJECT: Preterm infants are at increased risk for pneumococcal infections, and there are few published studies on pneumococcal vaccine. Reports of decreased immunogenicity with some vaccines in this infant group warranted research on use of 10-valent pneumococcal vaccine (PHiD-CV) in preterm infants.

WHAT THIS STUDY ADDS: PHiD-CV was well tolerated and generally as immunogenic in preterm infants as in term infants when given as a 3-dose primary vaccination followed by a booster dose. These results reveal that preterm infants would benefit from PHiD-CV vaccination.

abstract

OBJECTIVE: The safety and immunogenicity of the 10-valent pneumococcal nontypeable *Haemophilus influenzae* protein D conjugate vaccine (PHiD-CV) in preterm infants were assessed in this study.

METHODS: Three parallel groups of infants received 3-dose primary immunization with PHiD-CV at 2, 4, and 6 months of age and a booster dose at 16 to 18 months: preterm I (gestation period ≥ 27 and <31 weeks, $N = 50$); preterm II (≥31 and <37 weeks, $N = 87$); and term (≥37 weeks, $N = 149$). Solicited symptoms and adverse events were recorded. Immune responses to PHiD-CV and coadministered vaccine antigens were measured.

RESULTS: The incidence of solicited general symptoms was similar across groups, and the frequency of grade 3 general symptoms was low. Incidences of redness and swelling were generally lower in preterm infants. PHiD-CV was immunogenic for each of the 10 vaccine pneumococcal serotypes (postprimary, ≥92.7% of infants reached enzyme-linked immunosorbent assay antibody concentrations ≥ 0.2 µg/mL and postbooster, ≥97.6%) and for protein D, with a trend for lower postprimary geometric mean antibody concentrations and opsonophagocytic activity (OPA) titers in preterm infants for some pneumococcal serotypes. Postbooster, ≥91.9% of subjects in each group had an OPA titer ≥ 8 for each of the vaccine serotypes. Pneumococcal antibody concentrations and OPA titers after priming and booster vaccination were comparable between the 2 preterm groups.

CONCLUSIONS: PHiD-CV was well tolerated and immunogenic in preterm infants when given as a 3-dose primary vaccination, with robust enzyme-linked immunosorbent assay antibody and OPA booster responses in the second year of life. *Pediatrics* 2011;128:e000

Očkování nedonošených dětí - stanovisko České společnosti alergologie a klinické imunologie (15.3.2014)

Očkování dětí s nízkou porodní hmotností pod 1500 g:

Postvakcinační imunita u většiny nedonošených je srovnatelná, z důvodů oslabeného imunitního systému se nedonošené dítě řadí mezi imunokompromitované jedince, až dvojnásobné riziko onemocnění pertusí, RVGE, pneumokokem.

Zahájení očkování ve stejném věku jako u donošených, od 9. týdne (rotaviry od 6. týdne). Důvodem odložení pouze progresivní neurologická onemocnění.

Hexavakcína je základním schématem mnoha národních doporučení a to i v případě nedonošených pod 1500 g, použití tetravakcíny postrádá dostatečné EBM zdroje.

Je možná simultánní aplikace (hexavakcíny a pneumokokové vakcíny, případně rotavirové vakcíny) .

Stanovisko ČNeoS a ČSAKI (květen 2015)

Nedonošené děti (pod 37.g.t.): po 32 ukončených týdnech gravidity (nelze-li určit, tak nad 1500 g) stejné schéma jako u donošených dětí

Velmi nedonošené děti (pod 32. g.t.), součástí i extrémně nedonošené děti, tedy novorozenci do 28 týdnů: individuální přístup, pozdější zahájení obvykle 4-6 měsíců chronologického věku, použití Infanrix Hib, bez možnosti přechodu na vyšší kombinaci, hepatitida B od 1 roku, MMR od 2 let (22-24 měsíců).

Stanovisko Česká vakcinologické společnosti (srpen 2016)

Velmi nedonošené děti (pod 32. g.t., pod 1500 g) a extrémně nedonošené děti (pod 28 g.t.):

specifická kategorie dětské populace, která zasluhuje **individuální přístup** k zahajování pravidelného očkování se zohledněním všech skutečností a s ohledem na celkový zdravotní stav v době zahájení vakcinace. Rozhodnutí o zahájení vakcinace náleží **registrujícímu praktickému lékaři pro děti a dorost (PLDD), který tuto otázku případně konzultuje s odborníky, kteří se v některých případech o tuto skupinu dětí také starají.**

Stanovisko České vakcinologické společnosti (srpen 2016)

Očkování zpravidla **nejpozději mezi 4. - 6. měsícem** chronologického věku. V případech, kdy to zdravotní stav umožňuje, **je možné očkovat i dříve**, nejsou-li známé žádné další kontraindikace uvedené v souhrnu údajů o léčivém přípravku (SPC) jednotlivých očkovacích látek.

Pouhá nedonošenost bez dalších komplikací, bez ohledu na hmotnost v den očkování, není důvodem k odložení očkování.

Pro očkování nedonošených i velmi nedonošených dětí se používající dostupné očkovací látky, které mají studiemi ověřené použití pro tuto skupinu dětí.

Očkování nedonošených dětí - stanovisko České vakcinologické společnosti (srpen 2016)

Očkování se může zahájit čtyřsložkovou vakcínou (DTaP-Hib). Z důvodu eliminace opakovaného podávání očkovacích látek **je možný přechod na používanou vyšší kombinaci očkovací látky zahrnující i očkování proti přenosné dětské obrně a virové hepatitidě B.**

V případě přechodu na vyšší kombinaci je nutné doplnit chybějící očkování, za plnohodnotné lze považovat podání **první dávky DTaP-Hib s následných přechodem na schéma 2+1 vakcín s vyšší kombinací (hexa- a pentavalentní).**

V případě nedostupnosti čtyřsložkové vakcíny nebo v situaci, kdy není důvod pro zahájení očkování použitím čtyřsložkové vakcíny, se očkující lékař řídí SPC jednotlivých očkovacích látek, které umožňují podání u nedonošených dětí.

Stanovisko odborných společností ČLS JEP k očkování nedonošených dětí (6/2018)

Stanovisko České neonatologické společnosti, České společnosti alergologie a klinické imunologie, České vakcinologické společnosti a Odborné společnosti praktických dětských lékařů ČLS JEP k pravidelnému očkování nedonošených dětí

Doplnění materiálu:

✓Upřesnění pro přechod na schéma 2+1 ve druhém půlroce života ze zdravotních důvodů:

„děti očkované ze zdravotní indikace až od šestého měsíce korigovaného věku již očkované ve schématu 2+1“

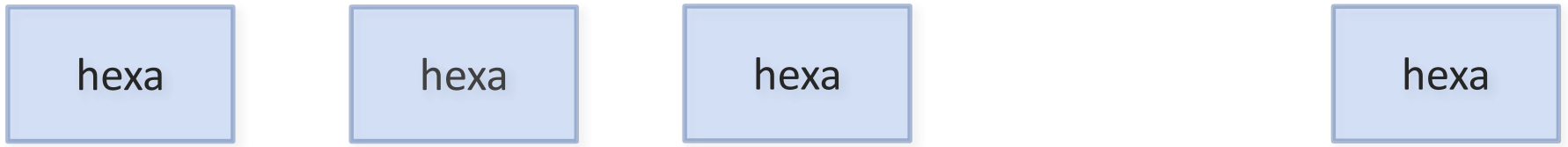
✓ Očkování MMR do souladu s platnou vyhláškou o očkování **13.-18. měsíc**

✓ Individuální postup u nedonošených dětí HBsAg pozitivních matek

✓ Soulad s doporučením ČVS u očkování proti rotavirovým nákazám

Očkování nedonošených dětí

3+1 schéma hexavakcíny



Infanrix Hib (Infanrix + Hib), 2+1 schéma hexavakcíny