



SynflorixTM **Ontario's New Infant Pneumococcal Vaccine**

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Outline

- **Pneumococcal vaccine history**
- **Vaccine profile and formulation**
- **Indication**
- **Synflorix™ dosing**
- **Invasive pneumococcal disease data**
 - **Immunogenicity**
 - **Booster dosing with Synflorix™**
- **Safety**
- **Product image**

Pneumococcal vaccine history

Whole cell vaccine

Capsular Polysaccharide
vaccine

Conjugate vaccine
Conventional Carrier Protein

Conjugate vaccine
Alternative Carrier Protein

Alternative carrier protein (protein D) could potentially minimize risks of carrier mediated immune interference with co-administered vaccines

Synflorix™: vaccine profile

1 4 5 6B 7F 9V 14 18C 19F 23F

Protein D
18C-TT 19F-DT

- Includes 10 pneumococcal serotypes
- *Prevnar*® 7 serotypes plus **1, 5, 7F**

Indication

- **NDS approved December 11, 2008**
- **Synflorix™ is indicated for active immunization of infants and children from 6 weeks up to 2 years of age against *Streptococcus pneumoniae* serotypes 1, 4, 5, 6B, 7F, 9V, 14, 18C, 19F and 23F and invasive disease caused by these serotypes (including sepsis, meningitis, bacteraemic pneumonia, pleural empyema and bacteraemia)¹**
- **Regulatory status**
 - **Approved in over 44 countries including: Canada, Australia, Europe**
 - **Implemented in Ontario, Quebec, Canadian northern territories, NF, PEI, Germany, France, Australia, Brazil.....**



¹ Synflorix™ Product Monograph.

Dosing

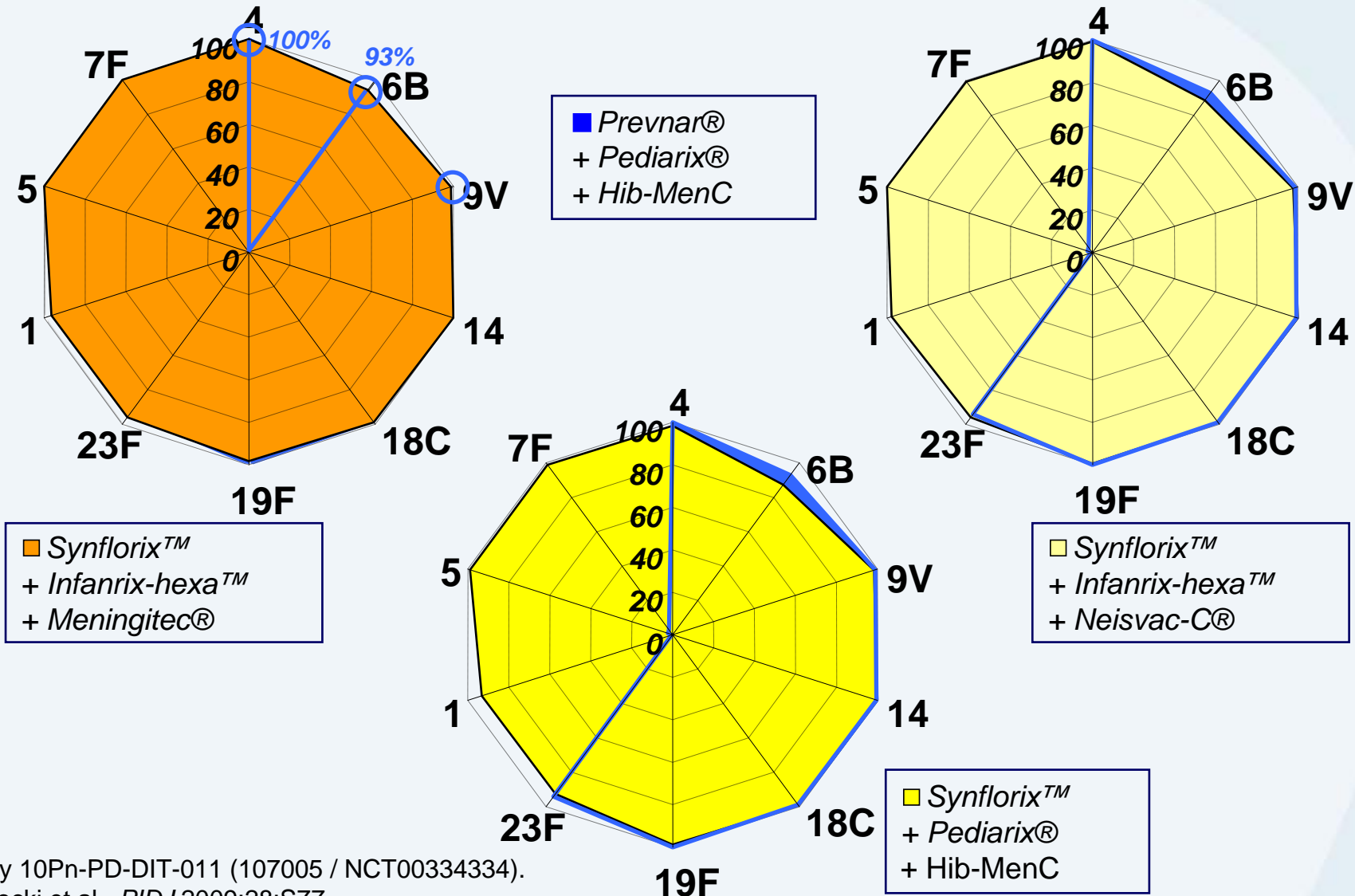
- A number of vaccination schedules for *Synflorix*TM have been studied and are approved for use (see Product Monograph for *Synflorix*TM)
- The primary vaccination schedule for *Synflorix*TM in Ontario is 2, 4, 6 months
- A booster dose of *Synflorix*TM is given at 15 months



Clinical development of *Synflorix*TM

- Immunogenicity compared to Prevnar[®] 1,2,3
- Functional responses (OPA) 1,2,3
- Immunization schedules
 - ❖ 3+1 and 2+1 1,2,3
 - ❖ **Booster** 1,2
 - ❖ Catch-up
- Co-administration with routine vaccines
 - ❖ DTPa-HBV-IPV/Hib, DTPa-HBV-IPV 1,2,4,5
 - ❖ DTPa-IPV/Hib
 - ❖ MenC / HibMenC 2,5
 - ❖ MMRV (with booster dose)⁴
 - ❖ RV ⁶
- Special populations
- **Safety & tolerability** ⁶

Anti-pneumococcal seropositivity rates one month post-dose 3 (% 22F-ELISA ≥ 0.2 $\mu\text{g/ml}$)

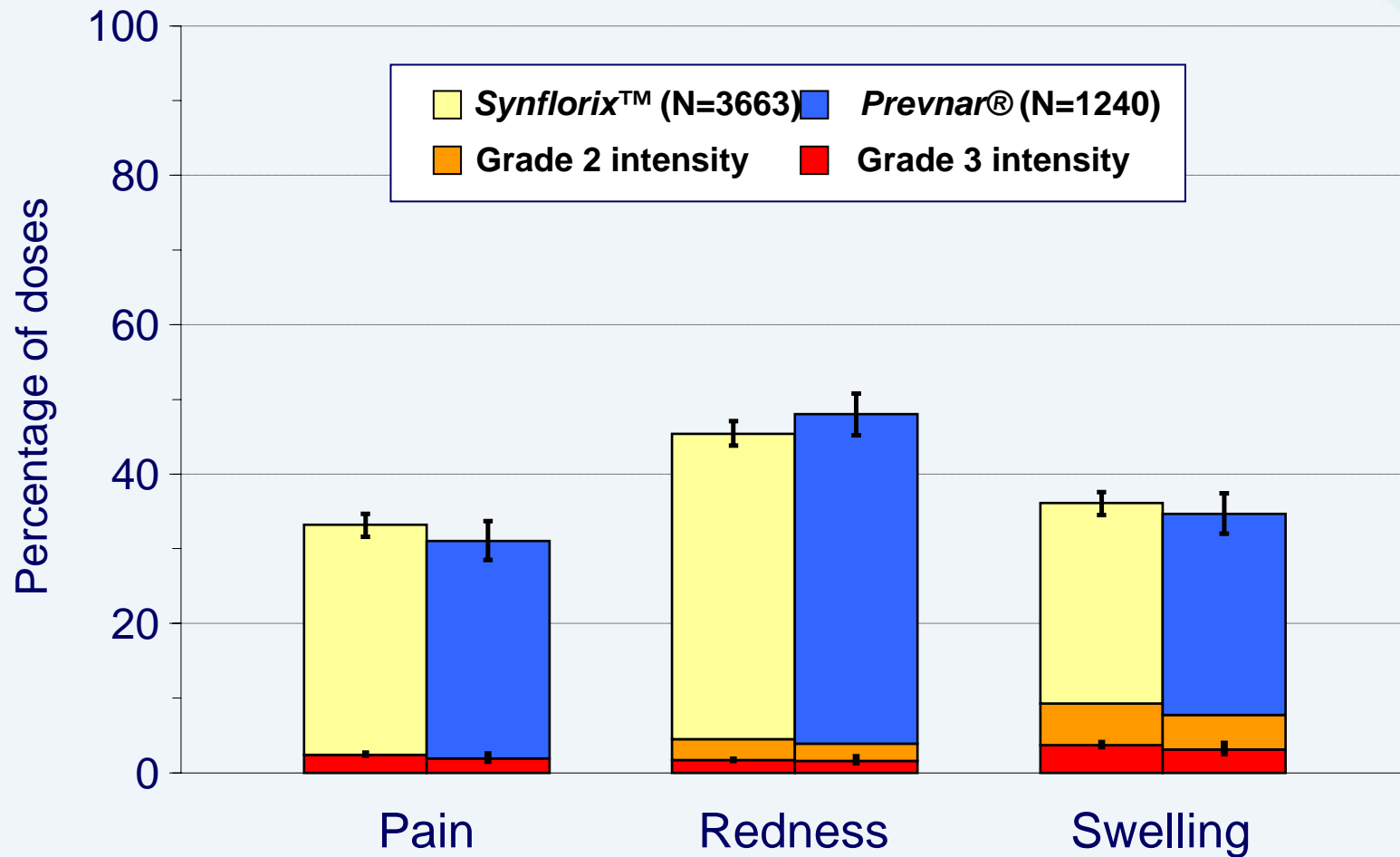


Booster dose of Synflorix™ primed with Pevnar®: ELISA responses

	% subjects ≥ 0.2 $\mu\text{g/mL}$		
	<i>Synflorix™</i>	<i>Pevnar® + Synflorix™</i>	<i>Pevnar®</i>
4	99.7	100	100
6B	96.5	98.5	97.7
9V	100	100	100
14	99.1	100	100
18C	100	99.3	100
19F	99.4	97.8	100
23F	97.4	97.0	98.9
1	99.4	85.0	4.9
5	99.4	85.7	6.1
7F	100	95.5	7.1

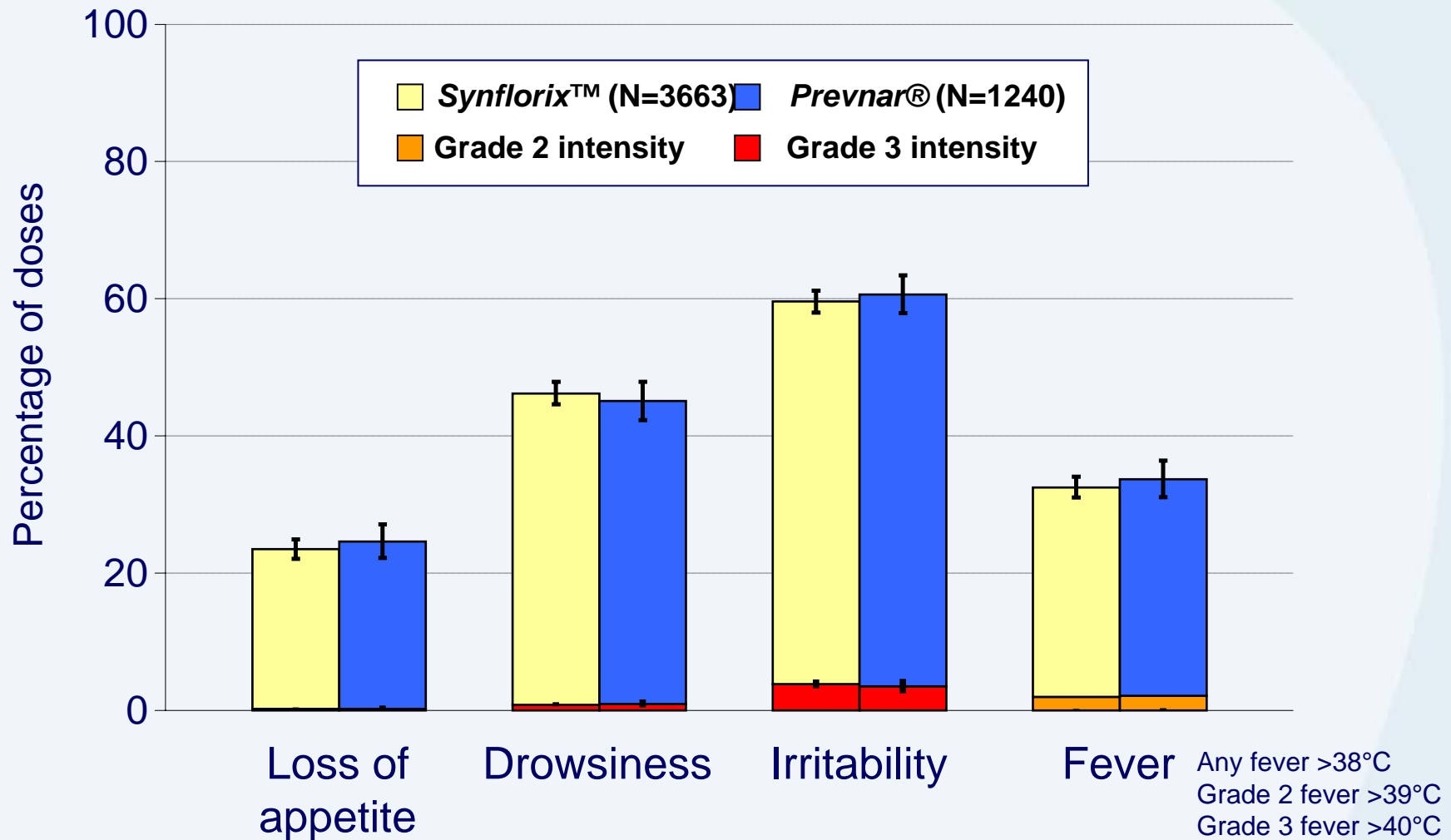
Safety/Reactogenicity

Solicited local symptoms post-primary



Grade 2 redness/swelling >20mm
Grade 3 redness/swelling >30mm

Solicited general symptoms post-primary



Stability

- ***Synflorix*TM vaccine should be administered immediately after being removed from the refrigerator.**
- ***Synflorix*TM vaccine remains stable and can be administered in case the vaccine has been stored outside the refrigerator up to three (3) days between 8°C and 25°C or up to one (1) day between 25°C and 37°C. These data are not recommendations.**
- **Discard vaccine if exposed to temperatures > 37°C.**



Summary



Thank you

Additional reading:

1. Vesikari et al., PIDJ 2009:28:S66
2. Wysocki et al., PIDJ 2009:28:S77
3. Bernal et al., PIDJ 2009:28:S89
4. Knuf et al., PIDJ 2009:28:S97
5. Synflorix™ Product Monograph