

Vaccinating Our Children: Focus on pneumococcal vaccines in Canada



Presenter:

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Director: Canadian Antimicrobial Resistance Alliance (CARA www.can-r.com)



Moderator:

John Yaremko, MD

Pediatrician: Montreal Children's Hospital

Associate Professor: McGill University



Organizer: George Wurtak BSc, BEd, MEd

Executive Director: Consortium for Infectious Disease Control

Director: Canadian Network on HPV Prevention

Founding Chair: International Indigenous HPV Alliance

Webinar Objectives

- Discuss the burden of pneumococcal disease in Canada
- Review the history of childhood pneumococcal vaccine options in Canada
- Discuss the importance of childhood pneumococcal vaccination
- Outline current pneumococcal vaccines for children

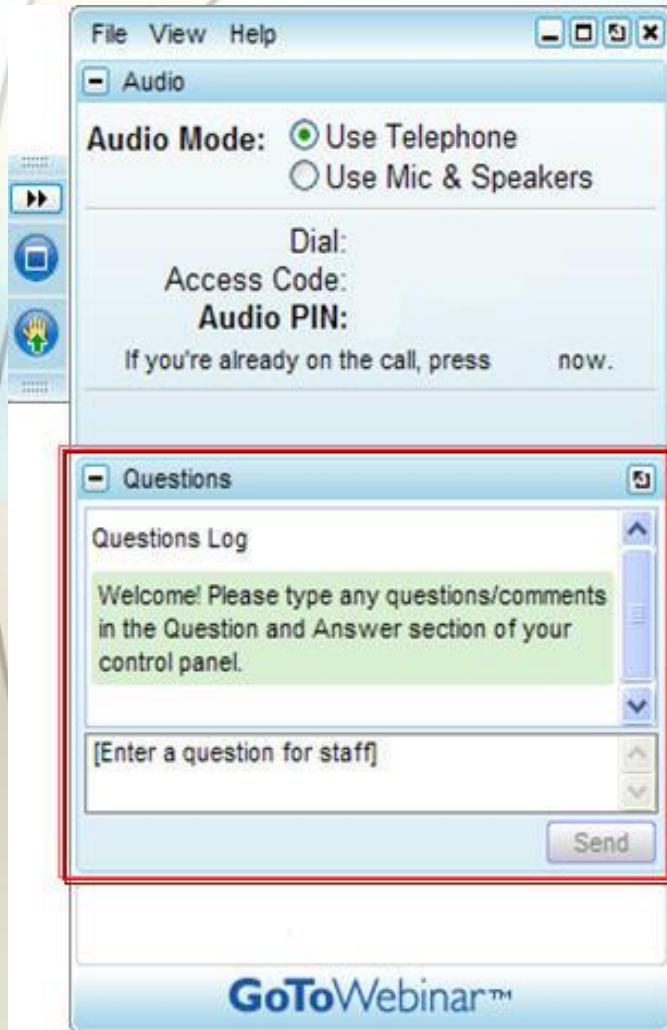
Administrative Information

How to participate:

- You can hear the audio for today's webinar via your computer by selecting "Use Mic & Speakers"
- Submit questions at any time by typing in the "Questions" pane on the control panel & click 'Send' button
- Questions will be answered at the end of the presentation

NOTE: For **mobile device** users:

- To open the questions pane, tap on the "?" or "Questions"
- To change your audio setting, tap on the "Settings" icon



Note: A recording of the presentation will be made available at www.CIDCgroup.org

Recording and Evaluation

Slides and Video Recording

The webinar **Slides and Recording** will be archived at:
www.CIDCgroup.org

Complete the Evaluation Survey at:
<https://bit.ly/cidc-ped-pneumo-vaccines>

Completion of survey is requested to receive a certificate of participation

– all registered participants will receive an email with this link

Moderator



Moderator: John Yaremko, MD

- Pediatrician, Montreal Children's Hospital
- Associate Professor, McGill University

Presenter



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- **Professor and Associate Head**

Max Rady College of Medicine, Medical Microbiology and Infectious Diseases, University of Manitoba, Winnipeg, Canada

- **Director**, Canadian antimicrobial resistance alliance-CARA

ADVENTURER EXPLORER ADVENTURER TRAILBLAZER REBEL PIONEER CREATOR EXPLORER REBEL PIONEER

PIONEER CREATOR EXPLORER DEFENDER TRAILBLAZER REBEL PIONEER EXPLORER ADVENTURER TRAILBLAZER REBEL EXPLORER PIONEER DEFENDER TRAILBLAZER CREATOR

Vaccinating our Children: Focus on pneumococcal vaccines in Canada



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(Microbiologist/Pharmacologist)

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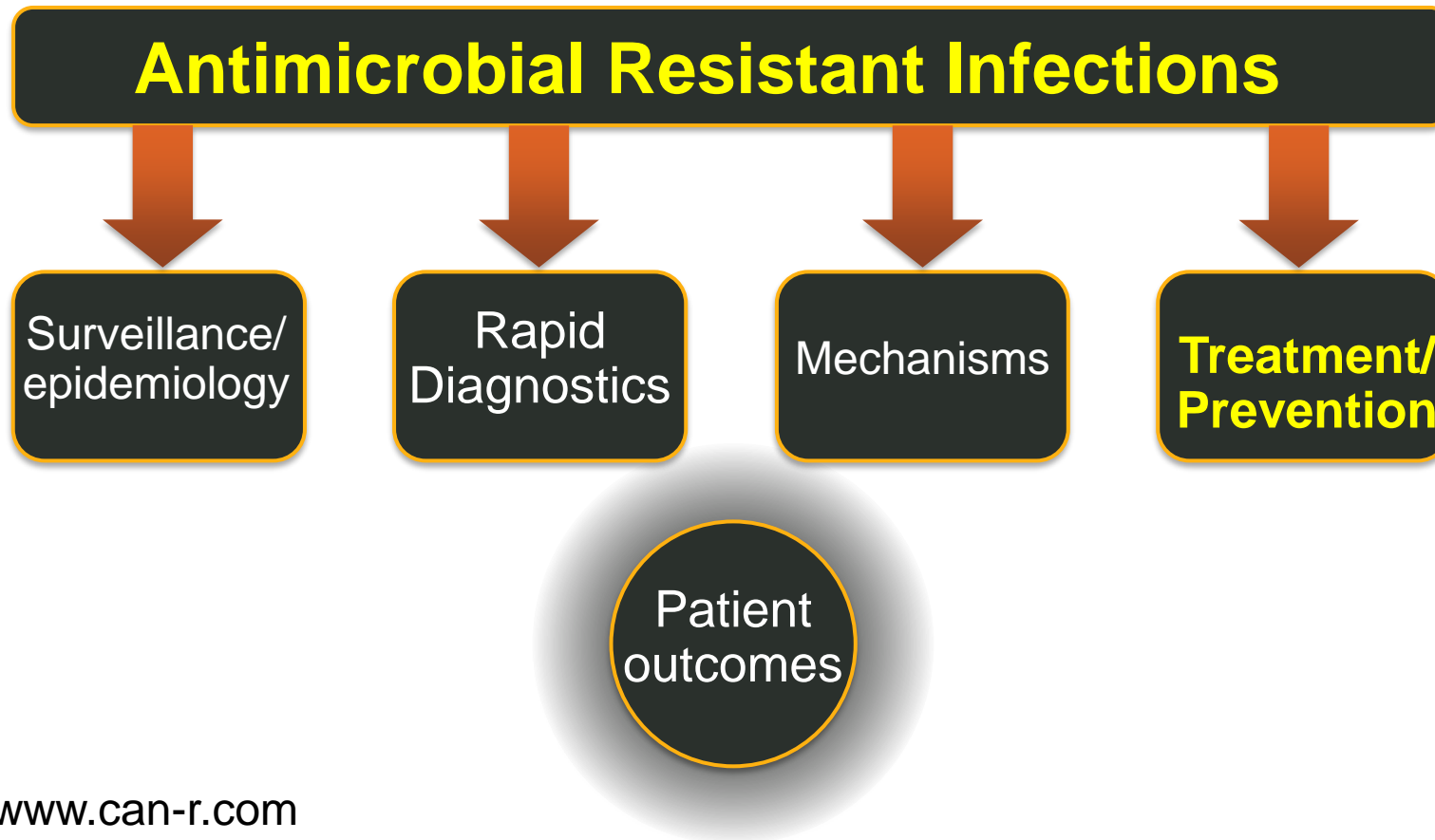
Winnipeg, CANADA



**Rady Health Sciences Center/Max Rady College of Medicine/
National Microbiology Lab, University of Manitoba, Winnipeg, Canada**



Canadian Antimicrobial Resistance Alliance (CARA)



Welcome

The Canadian Antimicrobial Resistance Alliance (CARA) launched a website in early 2007, CAN-R (www.can-r.ca). The site is an online research portal designed to aid and educate Canadian healthcare providers on the escalating issue of antimicrobial resistance in Canada.

Providing current and comprehensive information, the site includes a variety of features and tools on antimicrobial resistance in Canada including:

- Surveillance of pathogens and infections from the national CANWARD study
- Surveillance of antimicrobial resistance in CANWARD
- Antimicrobial susceptibility data
- Activity of novel and new antimicrobials
- Current research presented at major conferences
- Publications from evidence-based medical literature
- Videos: antimicrobial mechanisms of action and resistance (see EDUCATION)

Who will benefit from CAN-R

CAN-R is a useful tool for researchers, medical providers, and the media in understanding the rise of antimicrobial resistance in Canada and how it is being managed.

New Study Now Available: SAVE 2013

In 2011, CARA, the University of Manitoba, and the National Microbiology Laboratory began a collaboration to assess changes in antimicrobial resistance patterns of *S. pneumoniae* serotypes annually, as part of the SAVE (*Streptococcus pneumoniae* Serotyping and Antimicrobial Susceptibility: Assessment for Vaccine Efficacy in Canada After the Introduction of PCV-13) study. The data collected from the SAVE study are **NOW AVAILABLE** as an interactive experience. Antimicrobial susceptibility/resistance data can be reviewed by serotype, patient age or a combination of the two parameters.

Please select on the search most recent antimicrobial resistance data.



www.can-r.com

Research Funding/Conflicts

NIH/CIHR/NSERC

CFI

Research Manitoba

MMSF

Industry

Achaogen

Allergan

Astellas

Avir/HIKMA

Basilea

Cipher

Daiichi

Ferrer

Galderma

Iterum

Janssen Ortho/Ortho

McNeill

Industry

Merck/MSD

Nabriva

Novartis

Orbital Diagnostics

Paladin

Paratek

Pfizer

Red Leaf Medical

Sandoz

Sanofi Pasteur

Shionogi

Sunovion

Tetraphase

Theravance

Venatorx

Verity

Zambon

Zoetis

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- C. Discuss the **history** of pneumococcal **vaccines** in Canada
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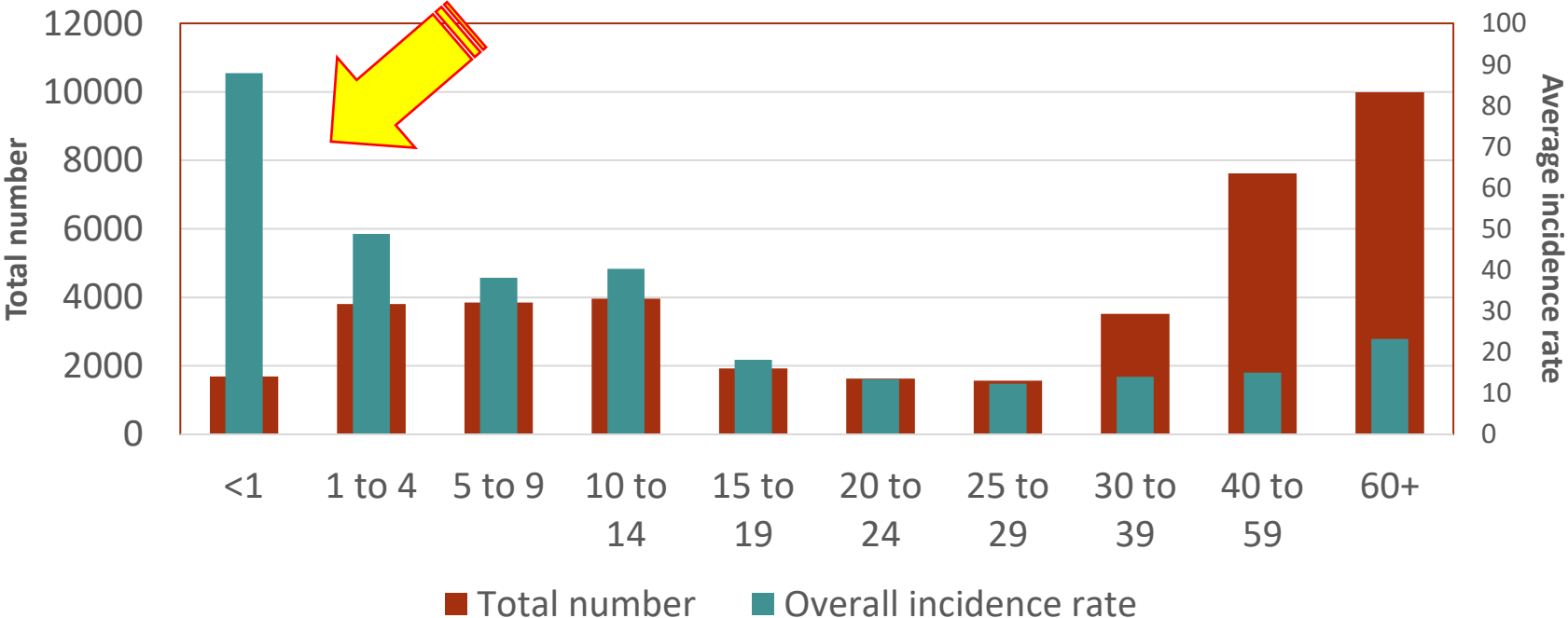
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Burden of Vaccine-preventable Diseases in Canada

Total number and average incidence rates (per 100,000 population) of reported vaccine preventable disease cases in Canada by age group, 2015 to 2019 (n=39,546)¹



¹ Public Health Agency of Canada. Vaccine Preventable Disease: Surveillance Report to December 31, 2019. Published May 20, 2022. Accessed April 19, 2023. <https://www.canada.ca/en/public-health/services/publications/healthy-living/vaccine-preventable-disease-surveillance-report-2019.html>





J Antimicrob Chemother 2023; **78** Suppl 1: i2–i7
<https://doi.org/10.1093/jac/dkad064>

***Streptococcus pneumoniae* serotyping and antimicrobial susceptibility: assessment for vaccine efficacy in Canada after the introduction of PCV13**

George G. Zhanel^{1*}, Joseph P. Lynch III² and Heather J. Adam^{1,3}



academic.oup.com/jac

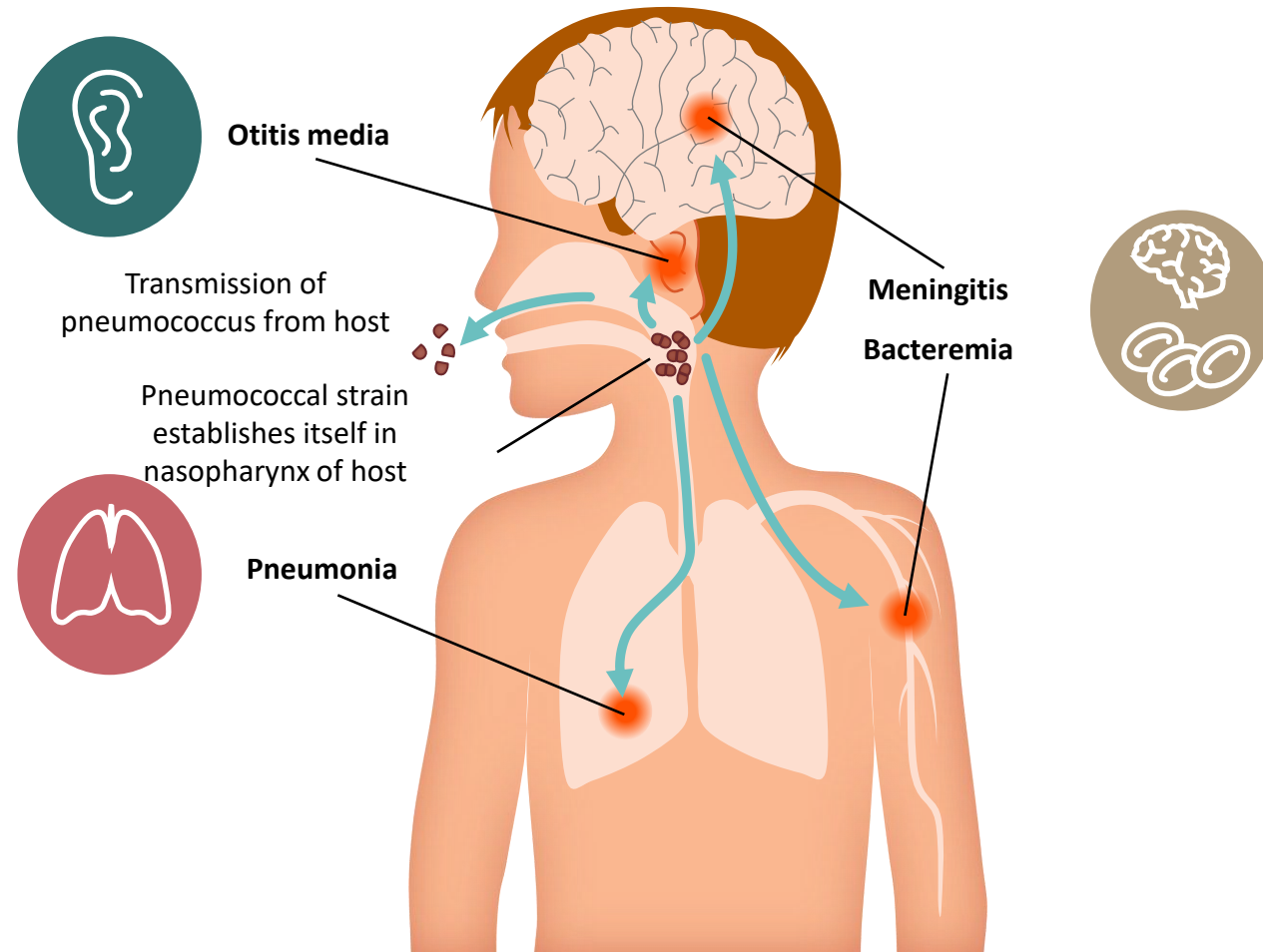


Streptococcus pneumoniae (“the pneumococcus”) ...

the most important respiratory bacteria

A Health Canada Pathogen of Interest

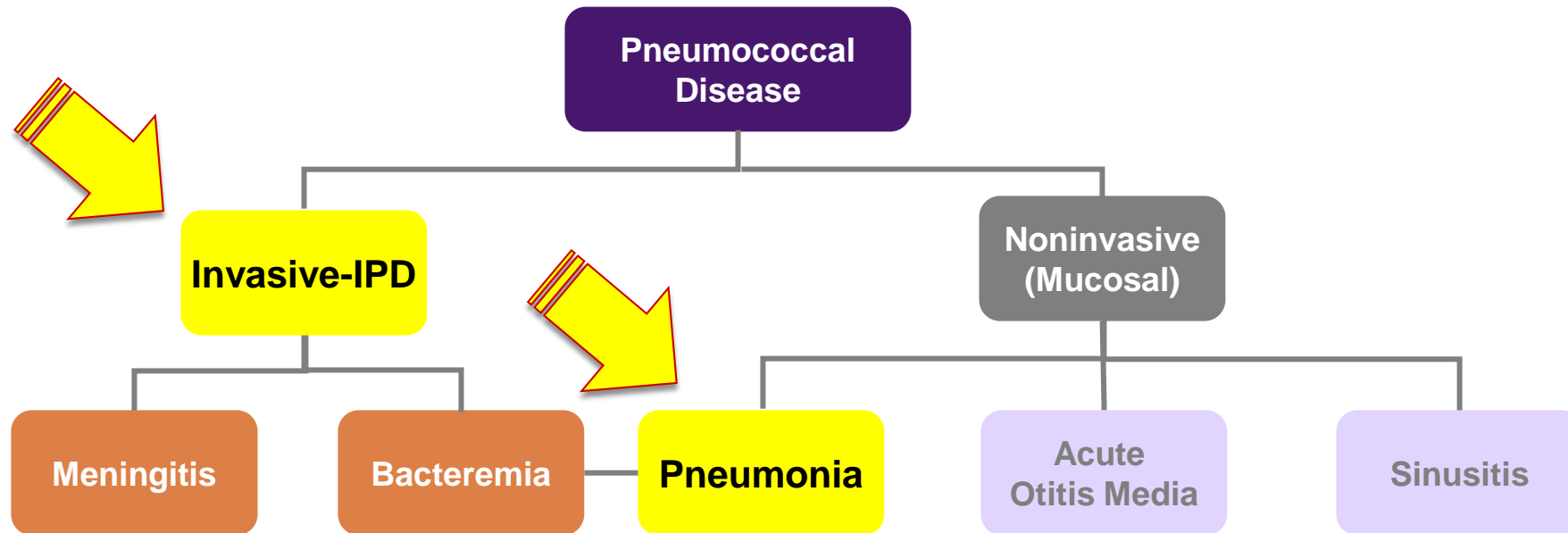
Pneumococcal Infection: Pathogenesis



¹Henriques-Normark B et al. Cold Spring Harb Perspect Med. 2013; ²Larry SM et al. Infect Dis Clin Pract. 2004.



Common Clinical Forms of Pneumococcal Disease



- Pneumococcal disease is broadly grouped into **invasive** disease and noninvasive (also termed *mucosal*) disease
- Noninvasive forms of disease may become invasive (eg, **pneumonia** when accompanied by bacteremia)
- **Serotype** is associated with disease severity and invasiveness

1. Zhanel et al. JAC. 2023; May 3;78(Suppl 1):i2-i7.

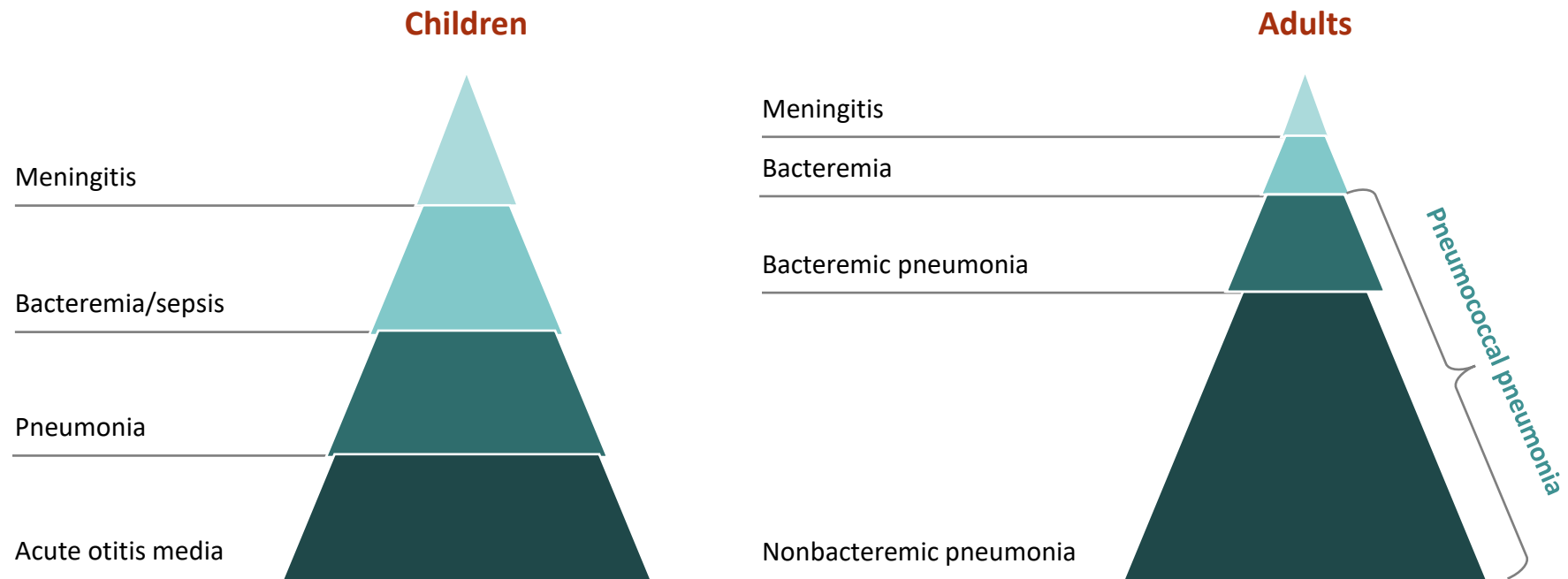
2. CDC. *Epidemiology and prevention of vaccine-preventable diseases*. 11th ed. 2009;217-230.

3. Jansen AG et al. *Clin Infect Dis*. 2009;49:e23-e29.

4. Lynch and Zhanel. *Curr Opin Pulm Med*. 2010 May;16(3):217-25.

The Burden of Pneumococcal Disease in Children

Clinical manifestations of pneumococcal disease differ in children and adults



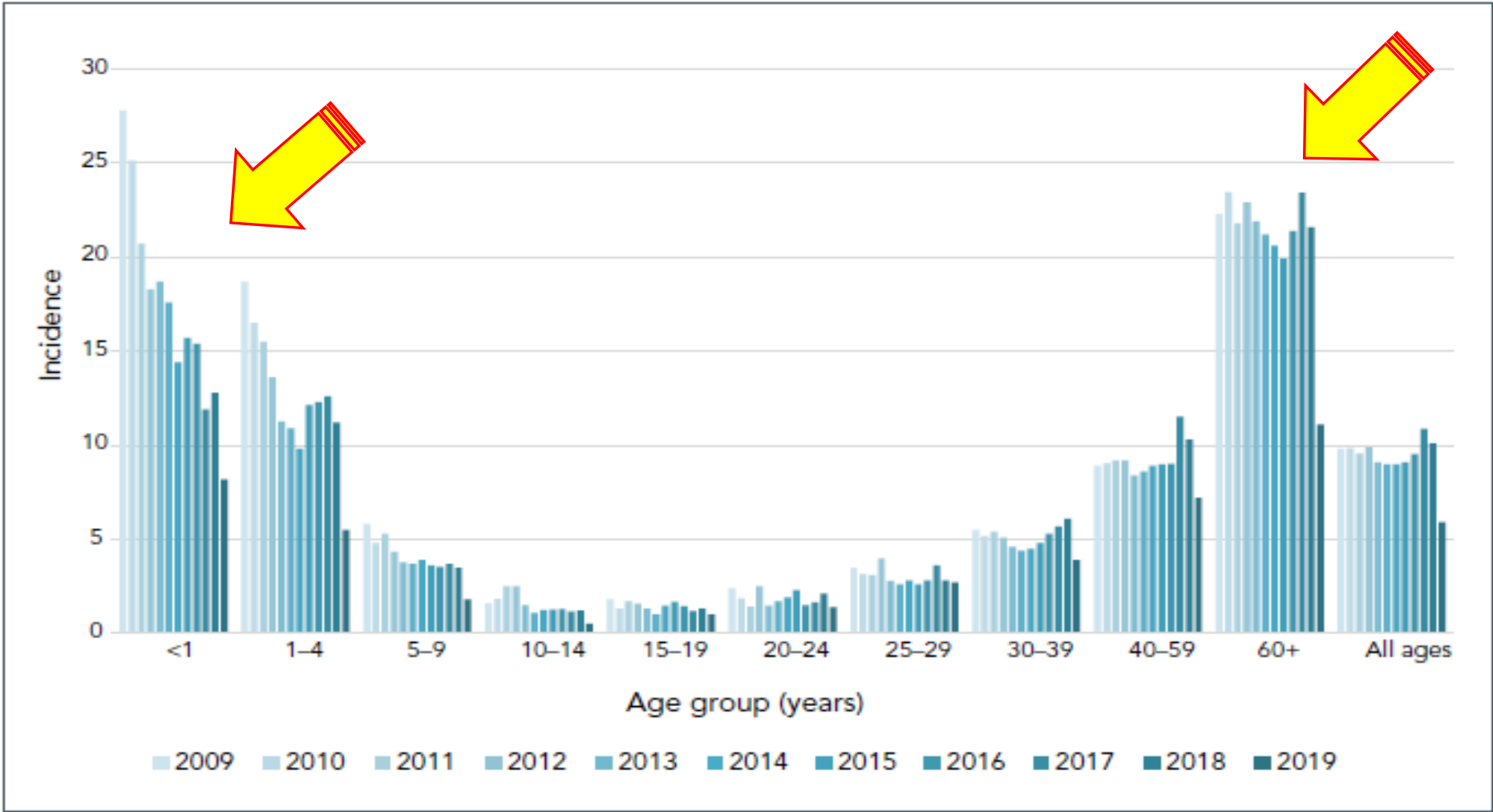
¹ Public Health Agency of Canada. Pneumococcal vaccine – Canadian Immunization Guide. Updated March 22, 2023. Accessed May 6, 2023.

<https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-16-pneumococcal-vaccine.html>;

² Public Health Agency of Canada. Invasive Pneumococcal Disease.



Annual incidence (cases/100,000) of **IPD** cases in Canada by age group, 2009–2020*

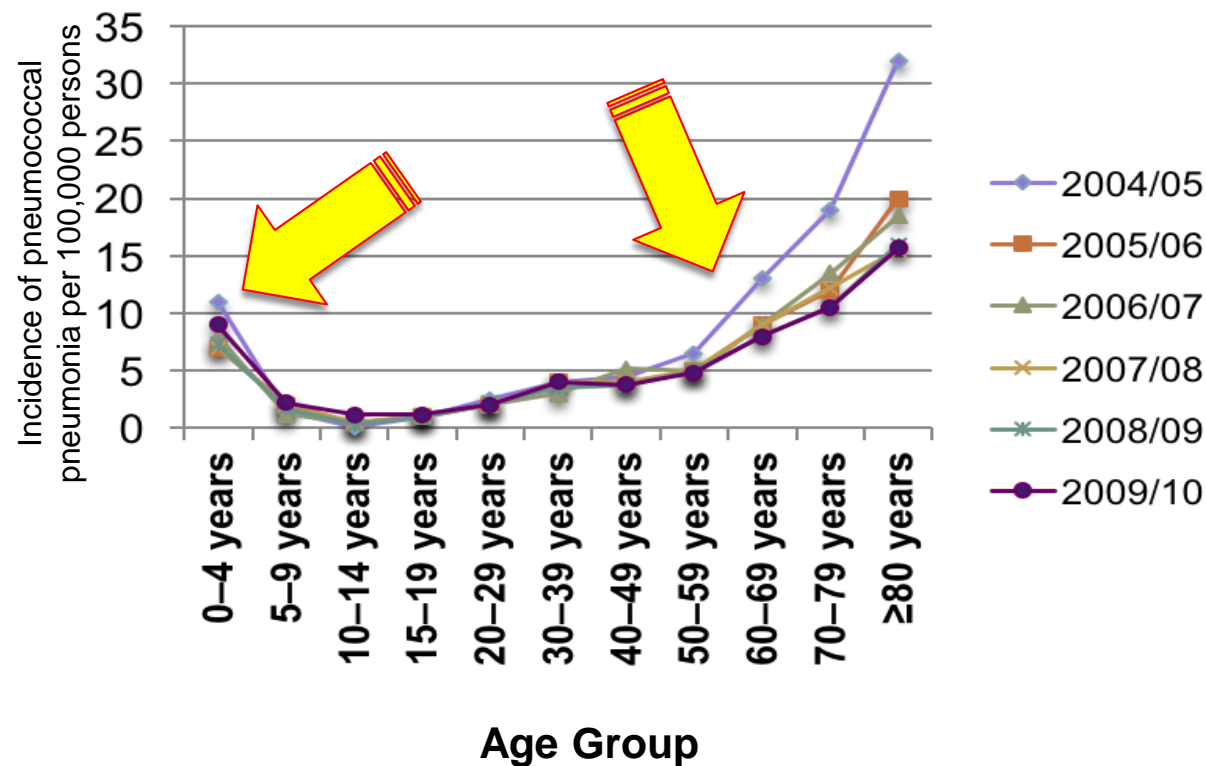


Can Commun Dis Rep 2022;48(9):396–406. <https://doi.org/10.14745/ccdr.v48i09a04>;
PHAC [Internet]. 2022; Available from: <https://www.canada.ca/en/publichealth/services/publications/vaccines-immunization/2019-highlights-childhood-national-immunization-coverage-survey.html>;



Hospitalization due to Pneumococcal Pneumonia increases with age

CIHI DAD annual incidence of hospitalizations in **Canada** 2004/05 to 2009/10 due to pneumococcal pneumonia by age and year

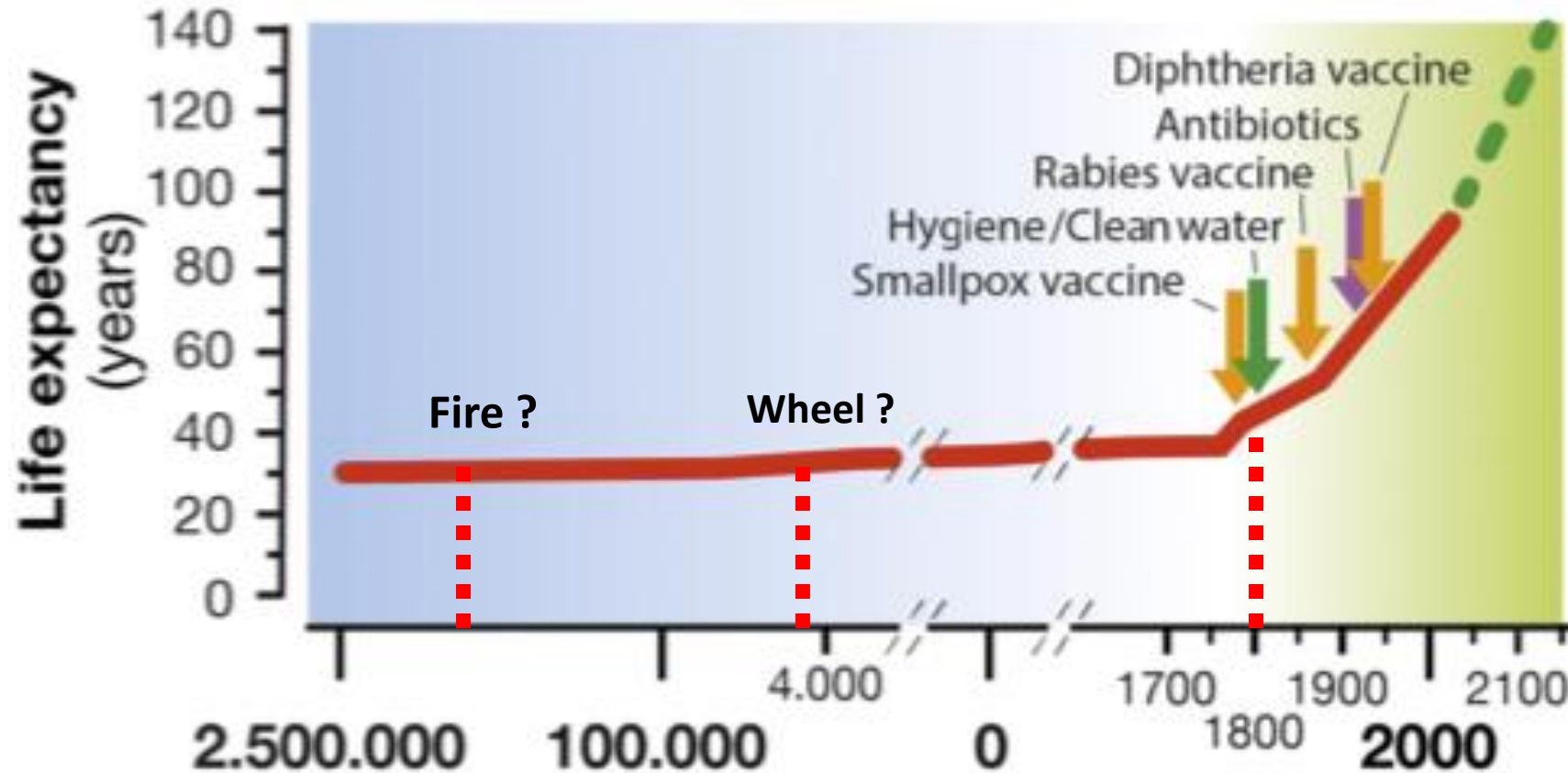


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Vaccines, Antibiotics and Hygiene Increase Life Expectancy



Rosini et al. Front Immunol 2020.

The Success of Vaccines in the 20th century

Disease	20 th Century Annual Morbidity	2013 Reported Cases	% Decreases
Smallpox	29,005	0	100%
Diphtheria	21,053	0	100%
Pertussis	200,752	28,639	86%
Tetanus	580	26	96%
Polio (paralytic)	16,316	1	>99%
Measles	530,217	187	>99%
Mumps	162,344	584	>99%
Rubella	47,745	9	>99%
Congenital Rubella Syndrome (CRS)	152	1	99%
<i>Haemophilus influenzae</i>	20,000 (est.)	31 ^s	>99%

Appendix E: Impact of Vaccines in the 20th and 21st Centuries. Available at:
<http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/E/impact.pdf>

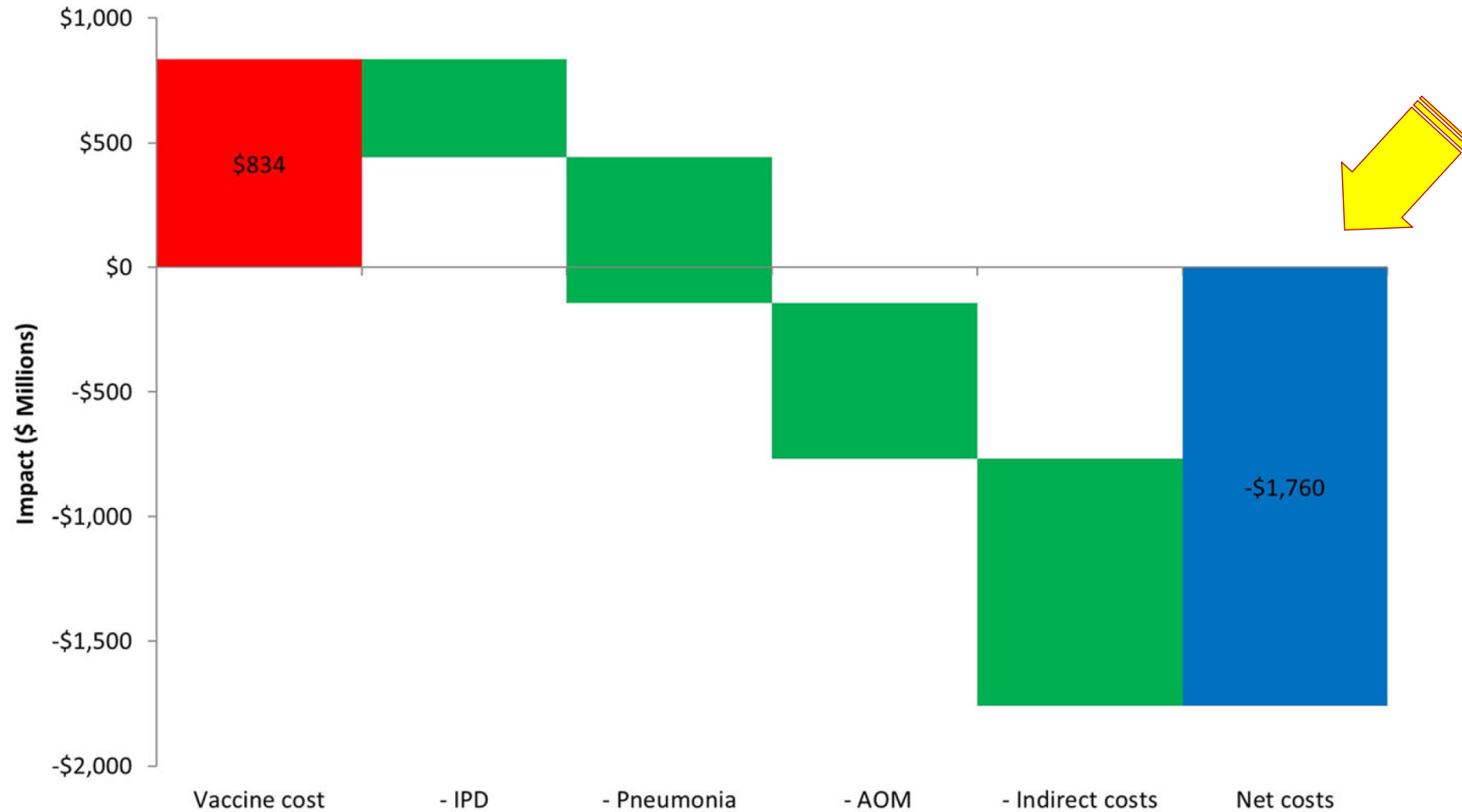
Vaccination Is A Cost-effective Way to Save Lives

Immunization program	Cost saving per \$1 spent
Influenza for adults \geq 65 years of age	\$45
Measles, mumps, rubella for children	\$16
Pneumococcal polysaccharide for adults \geq 65 years of age	\$8
Diphtheria, pertussis, tetanus for children	\$6

Public Health Agency of Canada. Canadian Immunization Guide. Cost Benefit of Vaccines. Updated September 1, 2016. Accessed April 19, 2023. <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-1-key-immunization-information>



Conjugate Pneumococcal Vaccination is Cost-Effective (Canada 2005-2015)

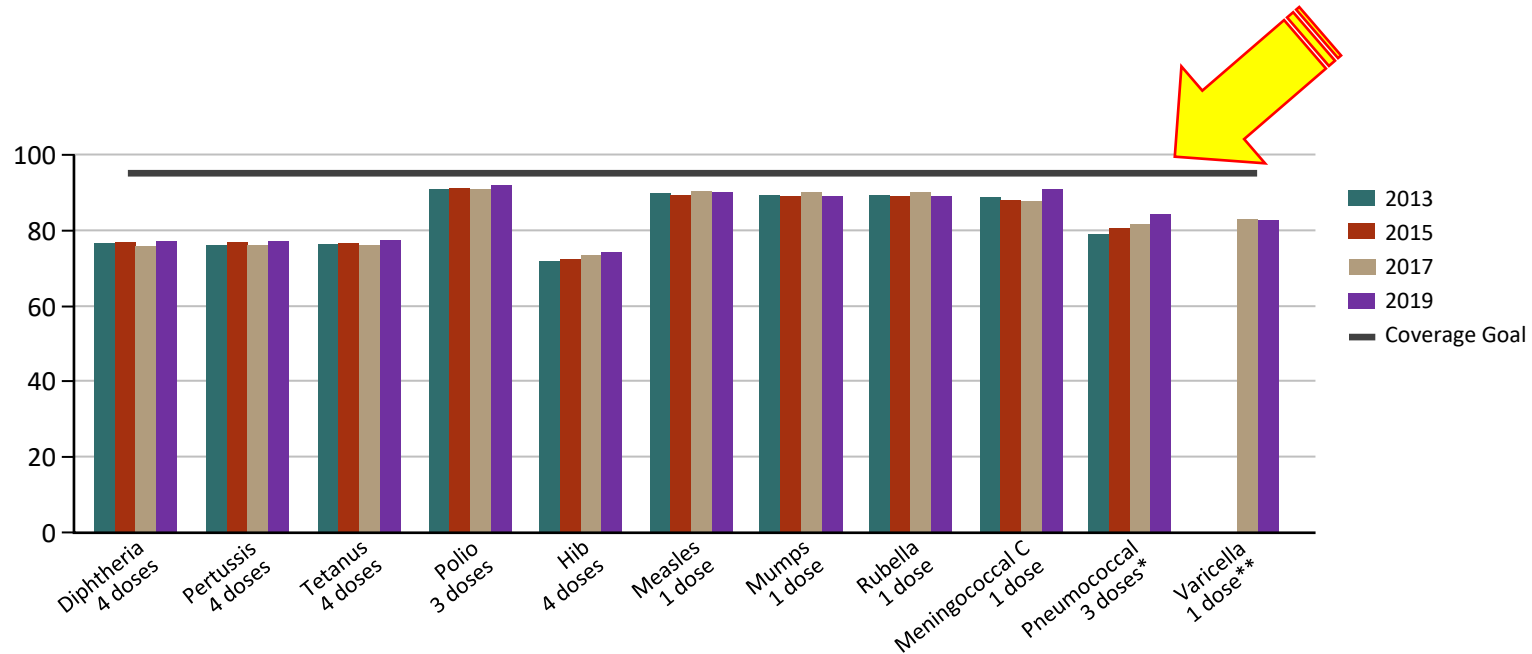


PCV use in Canada is estimated to have saved ~\$1.8 Billion dollars over 11 years[‡]

[‡] Between January 2005 and December 2015 inclusively

Vaccination Coverage Among 2-year-old Children in Canada

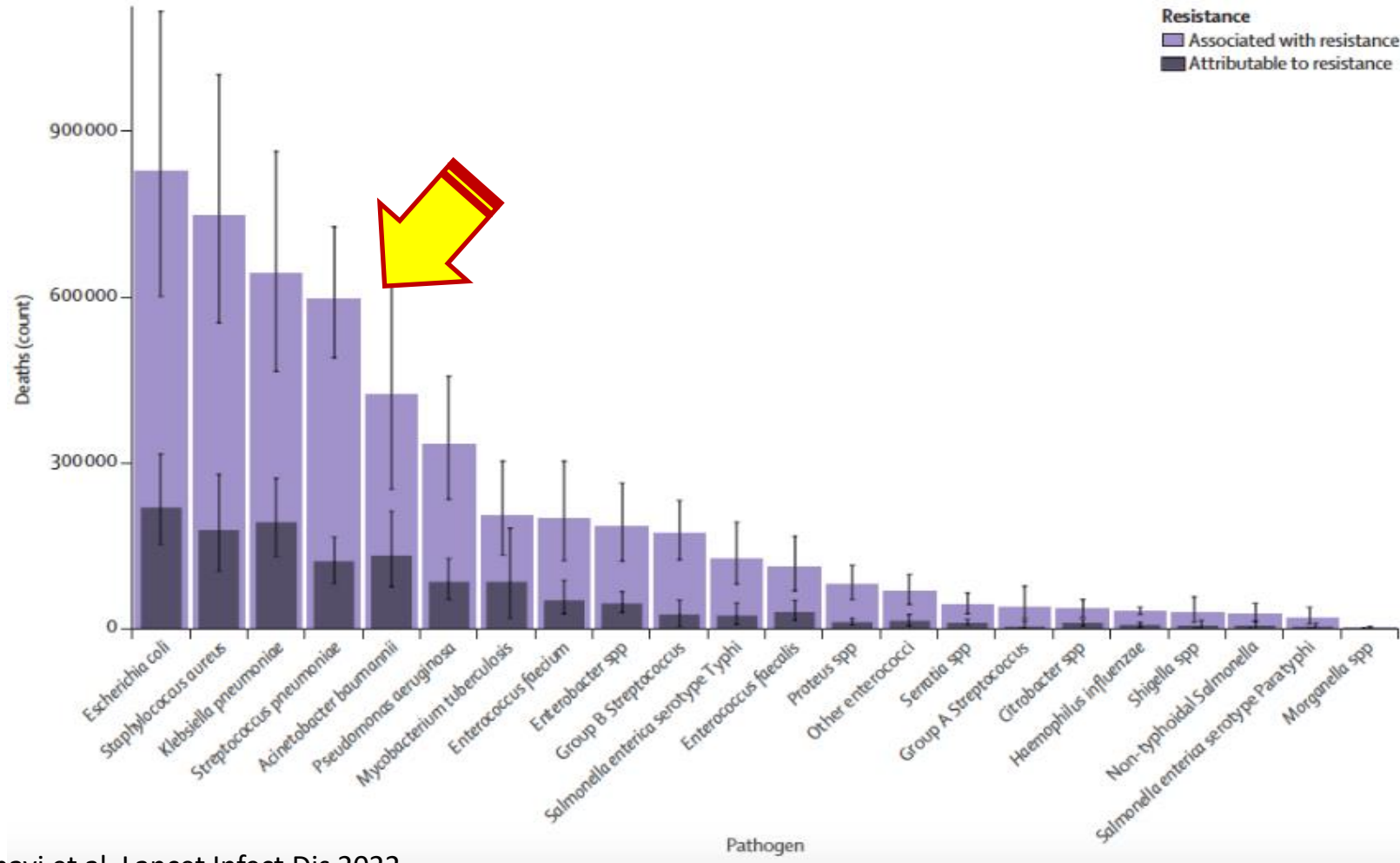
Percentage of 2-year-old children vaccinated before their second birthday, childhood National Immunization Coverage Survey, 2013, 2015, 2017 and 2019



Estimates for the varicella vaccine are not shown for 2013 and 2015 due to data quality concerns.
Public Health Agency of Canada. Highlights from the 2019 childhood National Immunization Coverage Survey (cNICS). Published December 22, 2020.



Worldwide Deaths Attributable/Associated With Antimicrobial Resistant Infections (By Pathogen - 2019)



Naghavi et al. Lancet Infect Dis 2022

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Pneumococcal Vaccines: What We're Preventing

Canadian retrospective study from 1991 to 1998

(before introduction of the first conjugate pneumococcal vaccine in 2001)

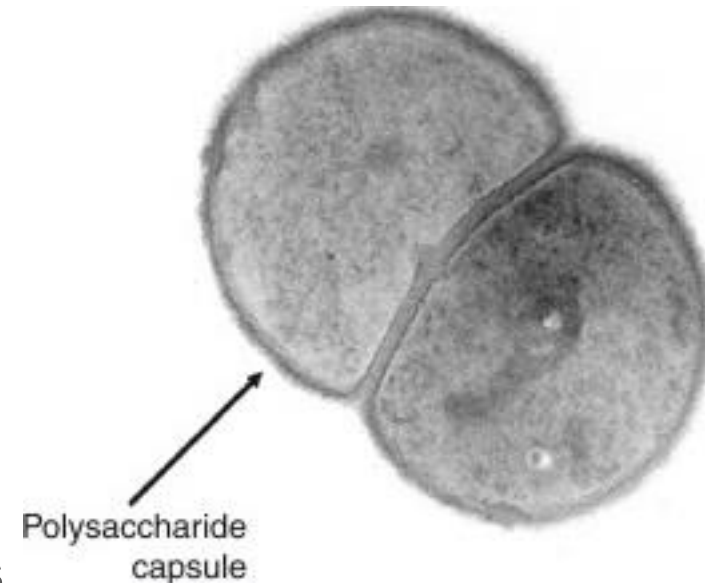
- **2040** IPD cases in children
 - **71% in children <3 years of age**
- In children 6–11 years of age
 - Incidence rate of pneumococcal meningitis: 19.4/100,000
 - Incidence rate of pneumococcal bacteremia: 94.8/100,000
 - Incidence rate of pneumococcal pneumonia requiring hospitalization: 2.5/1000
- Annually, average 15 IPD-related deaths in children > 5 years of age

McClure CA et al. Can J Infect Dis Med Microbiol. 2006.



***S. pneumoniae* and Capsules**

- **Capsules** aid in **colonization** and avoid the immune response
- **Antibodies** can be raised using capsular antigens and are the basis for classification (**serotyping**)
- **> 100 pneumococcal serotypes** are known
 - a subset causes the majority of disease
- **Vaccines** target the most common serotypes causing invasive pneumococcal disease (IPD) and pneumococcal related diseases (pneumonia)



Conjugated* Pneumococcal Vaccines in Canada

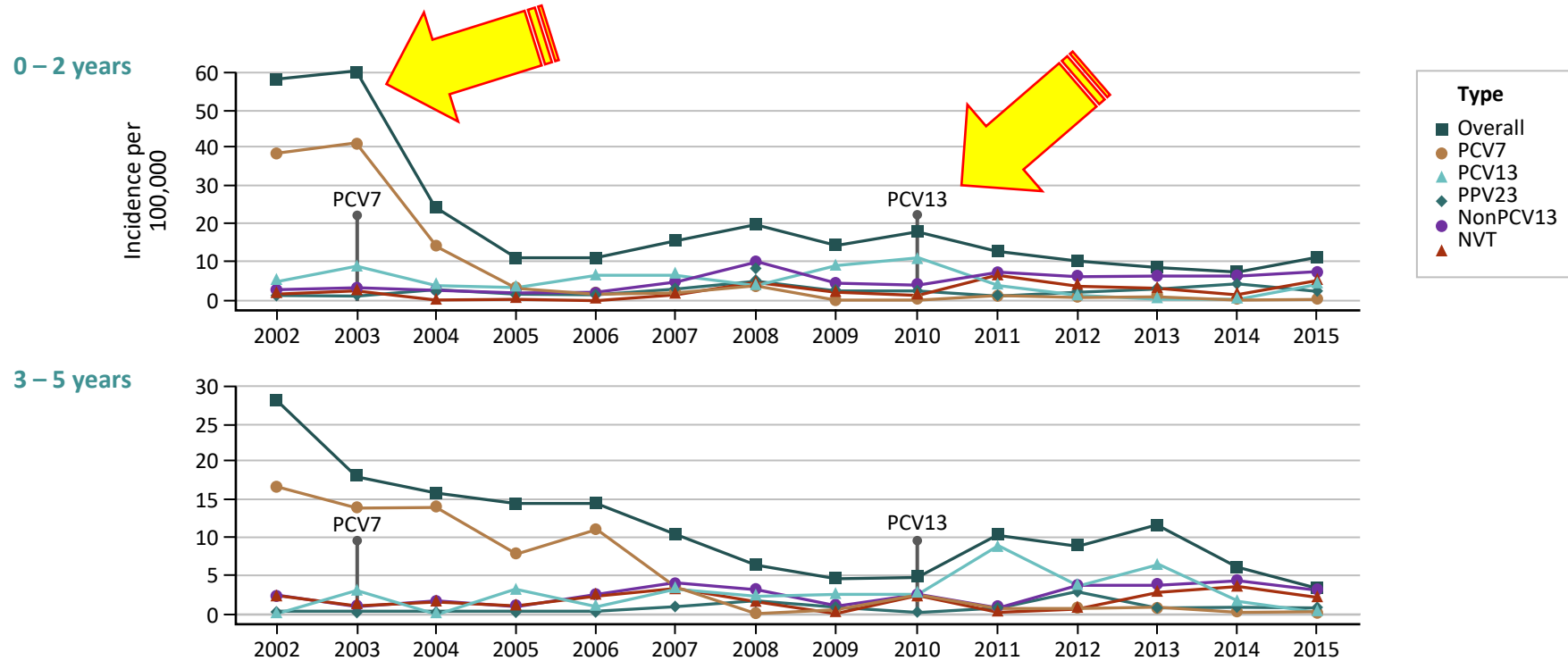
Serotype

Vaccine	4	6B	9V	14	18 C	19 F	23 F	1	5	7F	3	6A	19 A	22 F	33 F	8	10 A	11 A	12 F	15 B	2	9N	17 F	20	
*PCV7																									
*PCV10								1	5	7F															
*PCV13											3	6A	19 A												
PPSV23														22 F	33 F	8	10 A	11 A	12 F	15 B	2	9N	17 F	20	
*PCV15														22 F	33 F										
*PCV20																8	10 A	11 A	12 F	15 B					

Zhanel et al. JAC 2023;78 (Suppl 1):2-7.

Incidence of IPD in Children After Introduction of PCV7 and then PCV13 in British Columbia

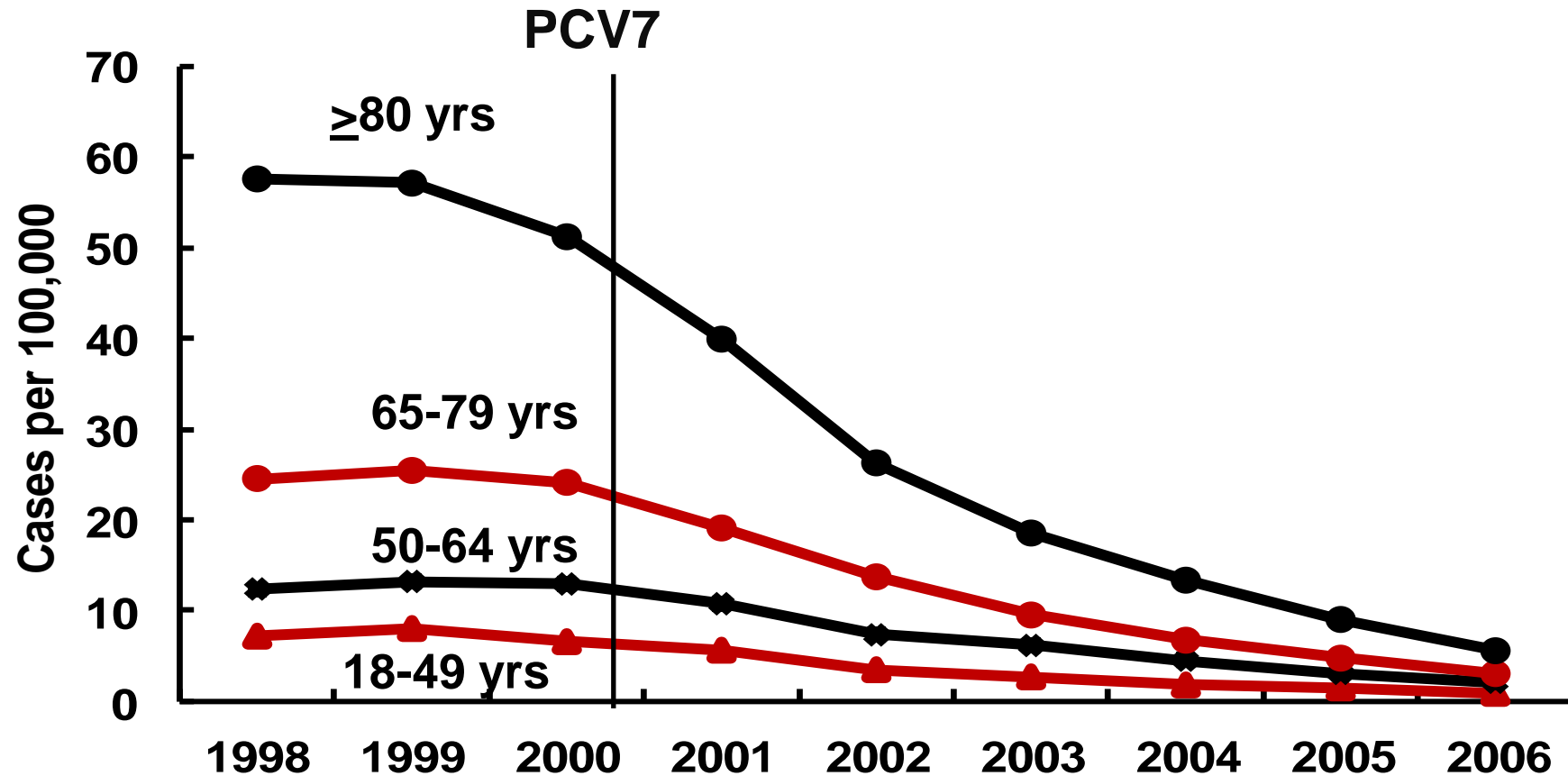
Incidence of IPD in British Columbia from 2002 to 2015 by age



Vadlamudi NK et al. PLoS One. 2020.



Rates of Pneumococcal Conjugate Vaccine (PCV7-type) Invasive Pneumococcal Disease among Adults, US 1998/99-2006



HUMAN VACCINES & IMMUNOTHERAPEUTICS

2018, VOL. 14, NO. 9, 2142–2149

<https://doi.org/10.1080/21645515.2018.1476814>


MINI-REVIEW

The role of vaccines in fighting antimicrobial resistance (AMR)

Kathrin U. Jansen and Annaliesa S. Anderson

How Could Pneumococcal Vaccines Reduce Resistance (PCV-7, PCV-10, PCV-13, PCV-15, PPSV23)

Direct Effects

- reduce pneumococcal infection (co-infection)...patient benefit
 - reduce outpatient/emerg Visits
 - reduce hospitalization
 - reduce mortality (infectious and non-infectious)
- reduce antibiotic Rx –  antibiotic resistance...
“antimicrobial stewardship” ...community benefit

Indirect Effects - Herd Immunity

- reduced spread of resistant serotypes (clones)
...world benefit

Micoli et al. Nat Rev Microbiol 2021;9:287-302.; Buchy et al. IJID 2020;90:188-196.;

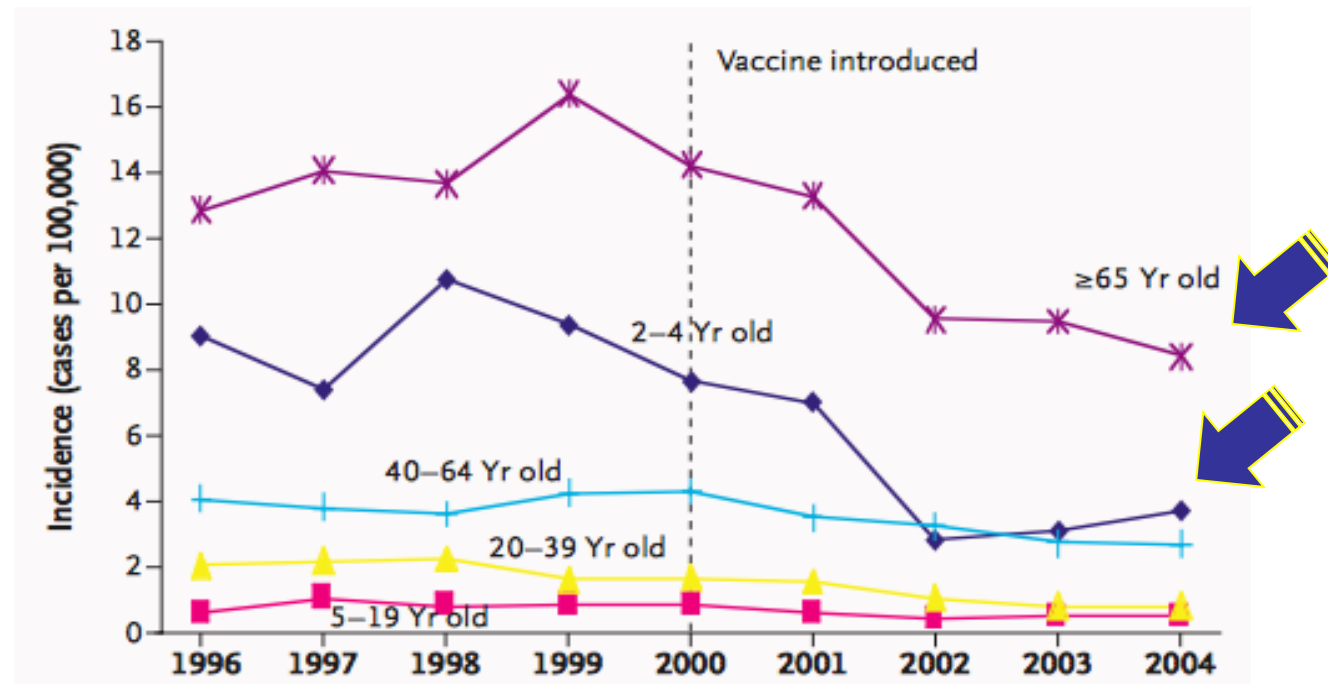
Golden et al. JAC 2019; 74(Suppl 4):39-47.; Jansen. Hum Vaccine Immunother 2018;14(9)2142-2149.

Lipsitch, M. & Siber, mBio 2016; 7, e00428-16.

Annual Incidence of Invasive Disease Caused by Penicillin-Nonsusceptible Pneumococci in

Persons Two Years of Age or Older

US data



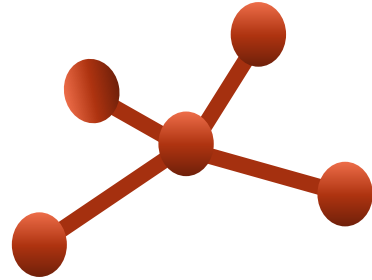
Kyaw MH et al. N Engl J Med 2006;354:1455-1463.

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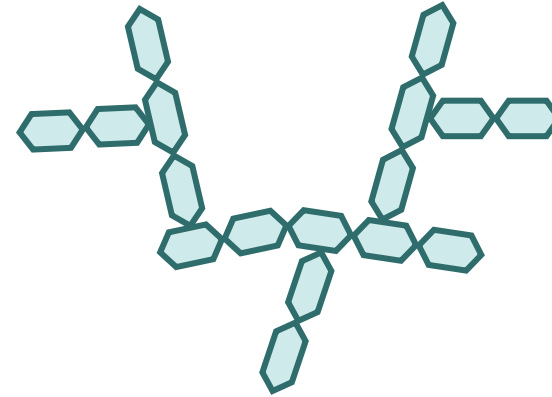
There Are Two Different Types of Pneumococcal Vaccines



Pneumococcal polysaccharide vaccines (PPSV)

Partially purified pneumococcal capsular polysaccharide

PPSV23



Pneumococcal conjugate vaccines (PCV)

Pneumococcal capsular polysaccharides
conjugated to a protein

PCV7, PCV10, PCV13, PCV15, PCV20

¹ Public Health Agency of Canada. Pneumococcal vaccine: Canadian Immunization Guide. Updated March 22, 2023. Accessed April 19, 2023. <https://www.canada.ca/en/public-health/services/publications/healthy-living/canadian-immunization-guide-part-4-active-vaccines/page-16-pneumococcal-vaccine.html>; ² Summary of National Advisory Committee on Immunization (NACI) Statement of February 2023: Public Health Level Recommendations on the Use of Pneumococcal Vaccines in Adults, Including the Use of 15-Valent and 20-Valent Conjugate Vaccines. Published February 24, 2023. Accessed April 19, 2023. <https://www.canada.ca/en/public-health/services/immunization/national-advisory-committee-on-immunization-naci/public-health-level-recommendations-use-pneumococcal-vaccines-adults-including-use-15-valent-20-valent-conjugate-vaccines>



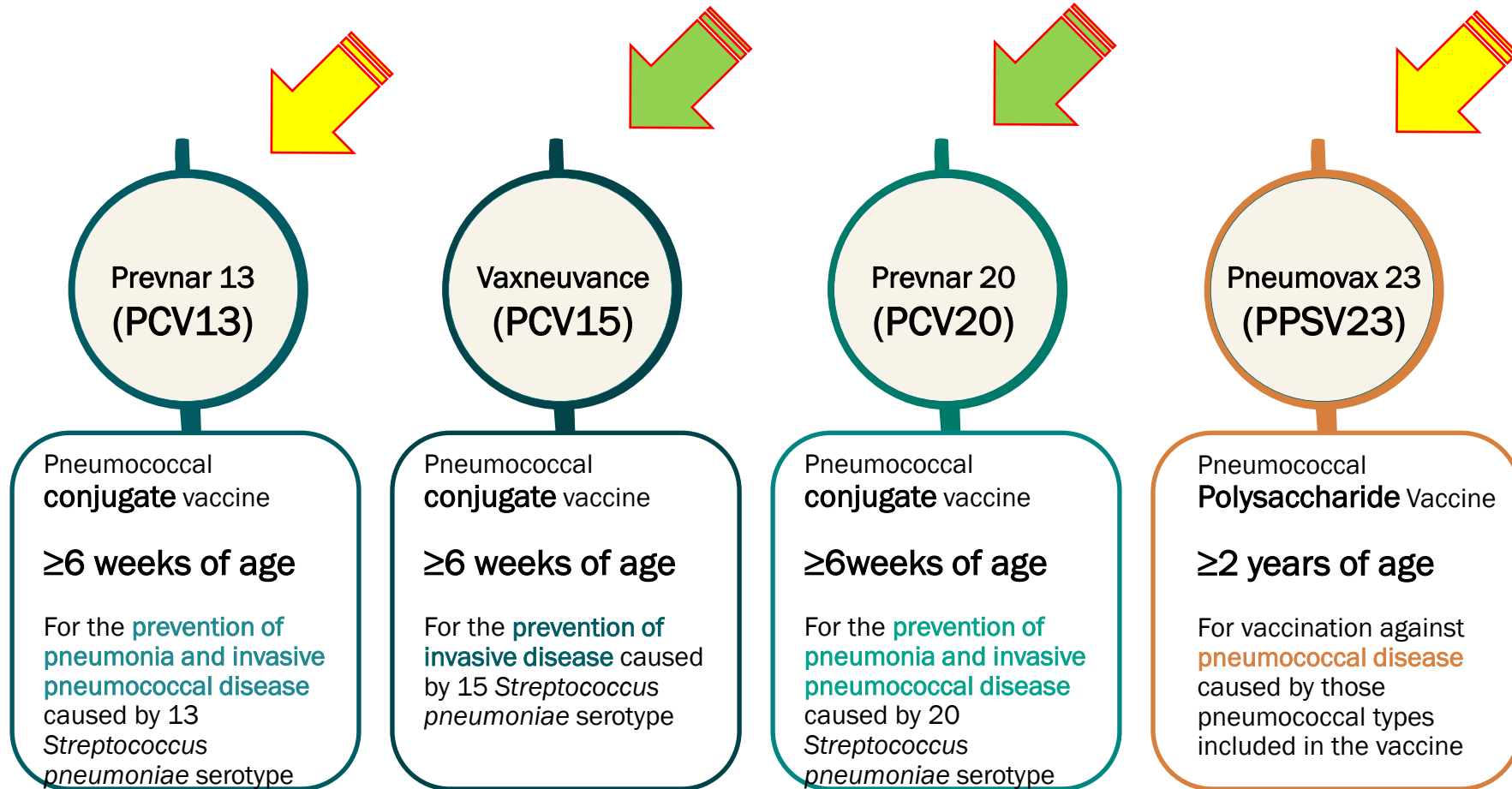
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*PCV15												3			22 F	33 F								
*PCV20																	8	10 A	11 A	12 F	15 B			

Zhanel et al. JAC 2023;78 (Suppl 1):2-7.

Pneumococcal Vaccines Approved by Health Canada



Adapted from Zhanel et al JAC 2023.

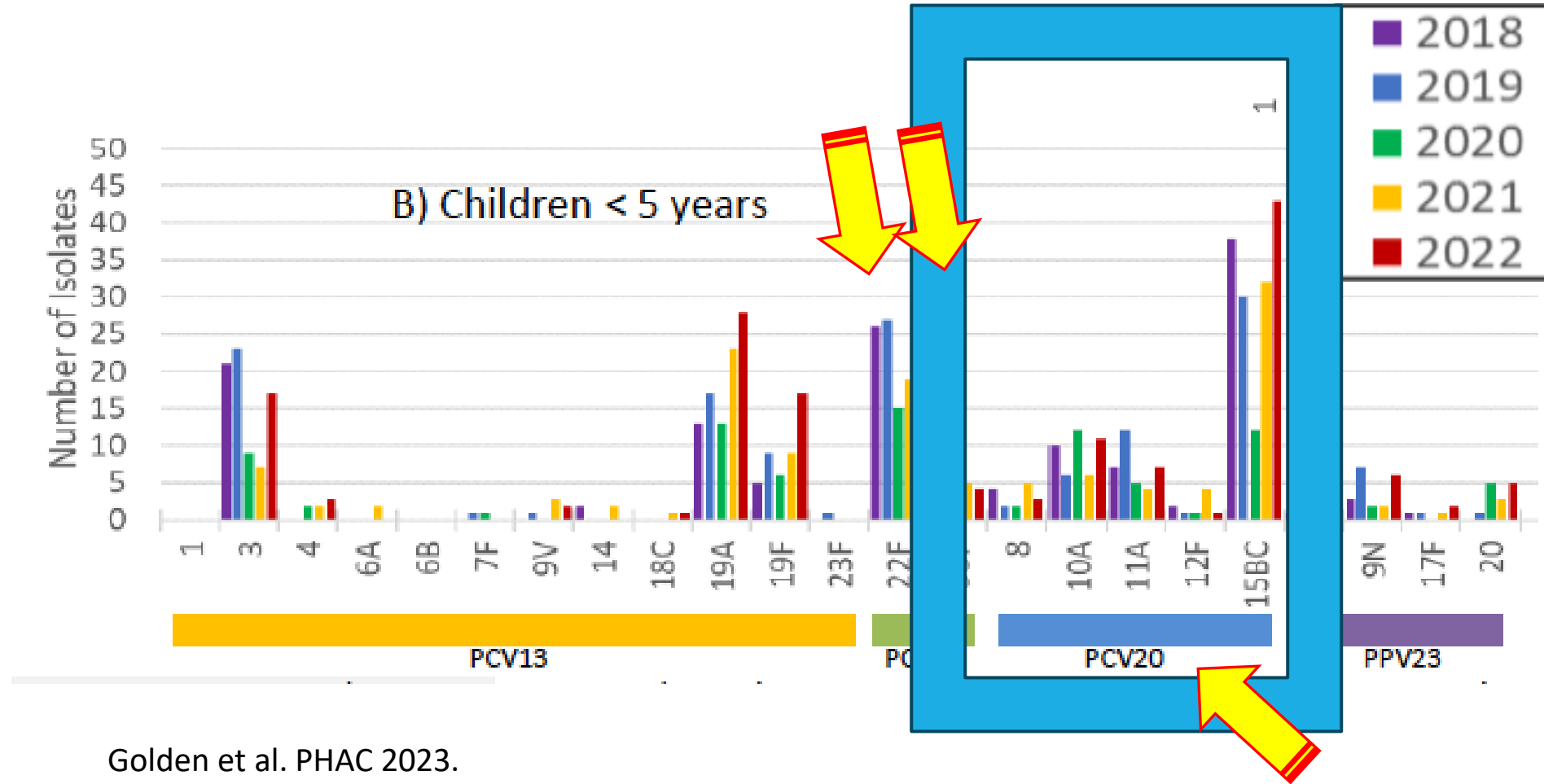
ACIP Recommendation – Parity for PCV15 and 20

TABLE 1. CDC Advisory Committee on Immunization Practices Recommendations for use of PCV in children, June 2023

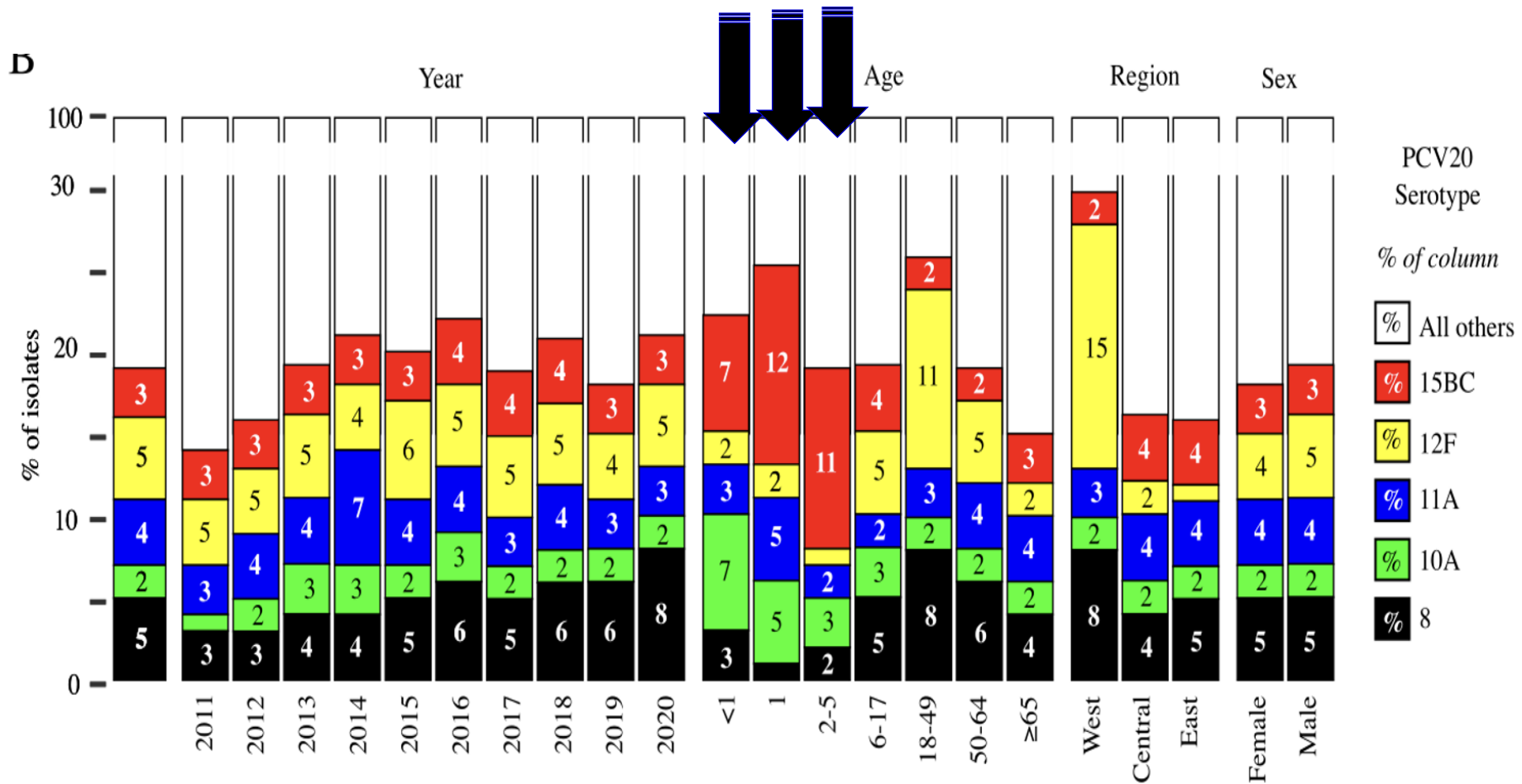
Age and Risk group	Recommendations
Children aged <24 months	<ul style="list-style-type: none"> • Use of either PCV15 or PCV20 is recommended for all children aged 2–23 months according to previously recommended PCV dosing and schedules. • If only PCV13 is available when the child is scheduled to receive a PCV, PCV13 may be given as previously recommended. • If a child started the PCV series with PCV13, the child may complete the series with PCV15 or PCV20 without giving additional doses; the PCV series does not need to be restarted. • For children who have received all recommended dosing and schedules with PCV13 or PCV15, a supplemental dose of PCV20 is not indicated.

*Risk conditions include: cerebrospinal fluid leak; chronic heart disease; chronic kidney disease (excluding maintenance dialysis and nephrotic syndrome, which are included in immunocompromising conditions); chronic liver disease; chronic lung disease (including moderate persistent or severe persistent asthma); cochlear implant; diabetes mellitus; immunocompromising conditions (on maintenance dialysis or with nephrotic syndrome; congenital or acquired asplenia or splenic dysfunction; congenital or acquired immunodeficiencies; diseases and conditions treated with immunosuppressive drugs or radiation therapy, including malignant neoplasms, leukemias, lymphomas, Hodgkin disease, and solid organ transplant; HIV infection; and sickle cell disease and other hemoglobinopathies).

Invasive *S. pneumoniae* serotypes in Canada 2018-2022



Vaccine Coverage of Serotypes Over Time, Age Region and Gender (SAVE 2011-2020)



Schellenberg et al. JAC 2023.

An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI)

Interim guidance on the use of pneumococcal
15-valent conjugate vaccine (PNEU-C-15) in pediatric
populations

NACI March 2023.

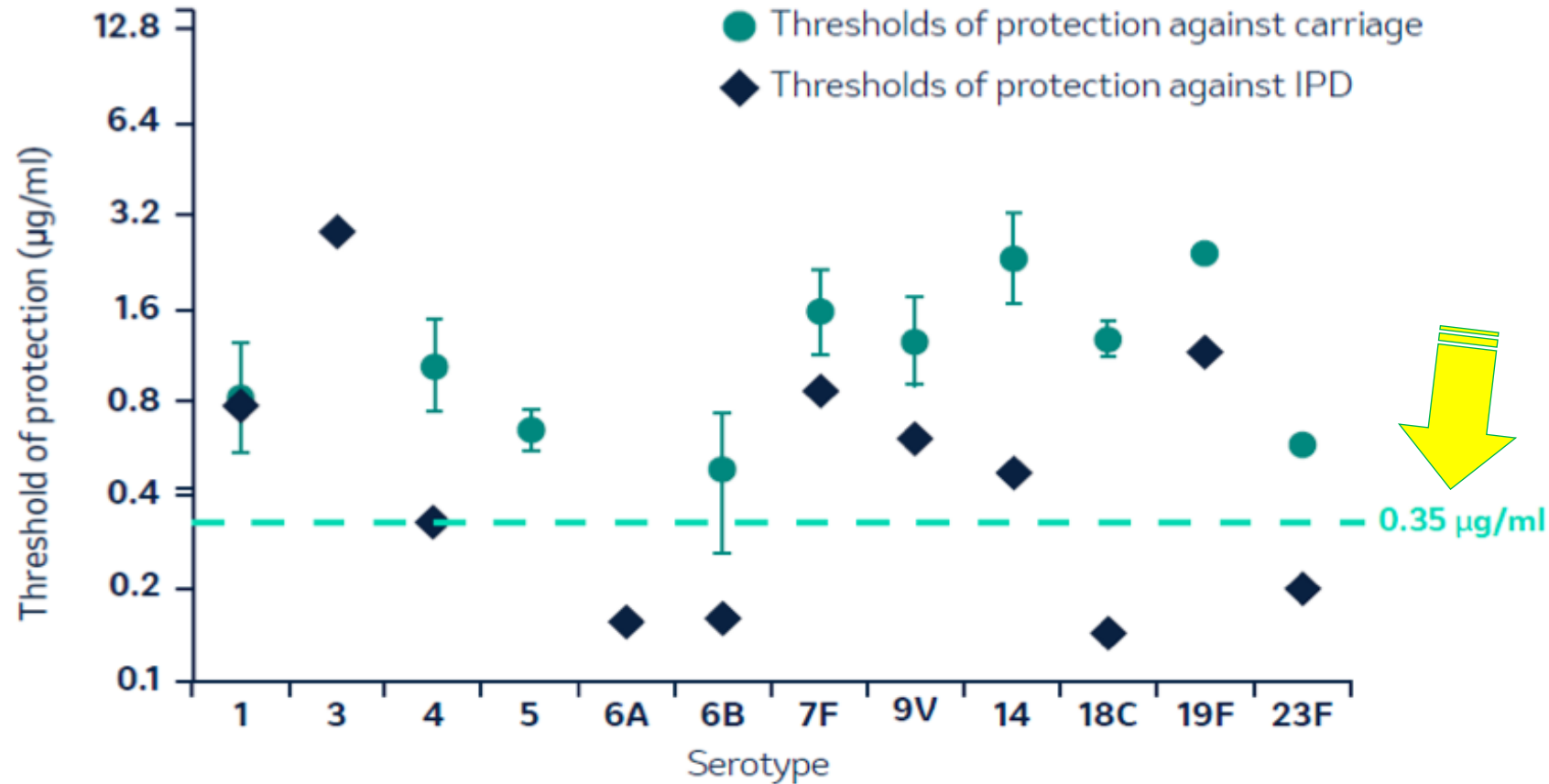
PCV-15 for Pediatrics in Canada

- Currently **no efficacy or effectiveness data** available for PCV-15
- **Immunogenicity used to infer effectiveness** (vs PCV-13)
- Basis for regulatory authorization was the demonstration of comparable **safety** and **immunogenicity** (non-inferiority for serotypes common to PCV-13 and superiority for two additional serotypes **22F** and **33F**) in relation to PCV-13 vaccine
- Immunogenicity measured by:
 - total antibody levels (IgG to serotype)
 - functional (neutralizing) antibody levels (OPA)

NACI 2023.

The Role of Immunogenicity in SPN Vaccine Development

Serotype-specific antibody correlates of protection for infants^{8,9,a}

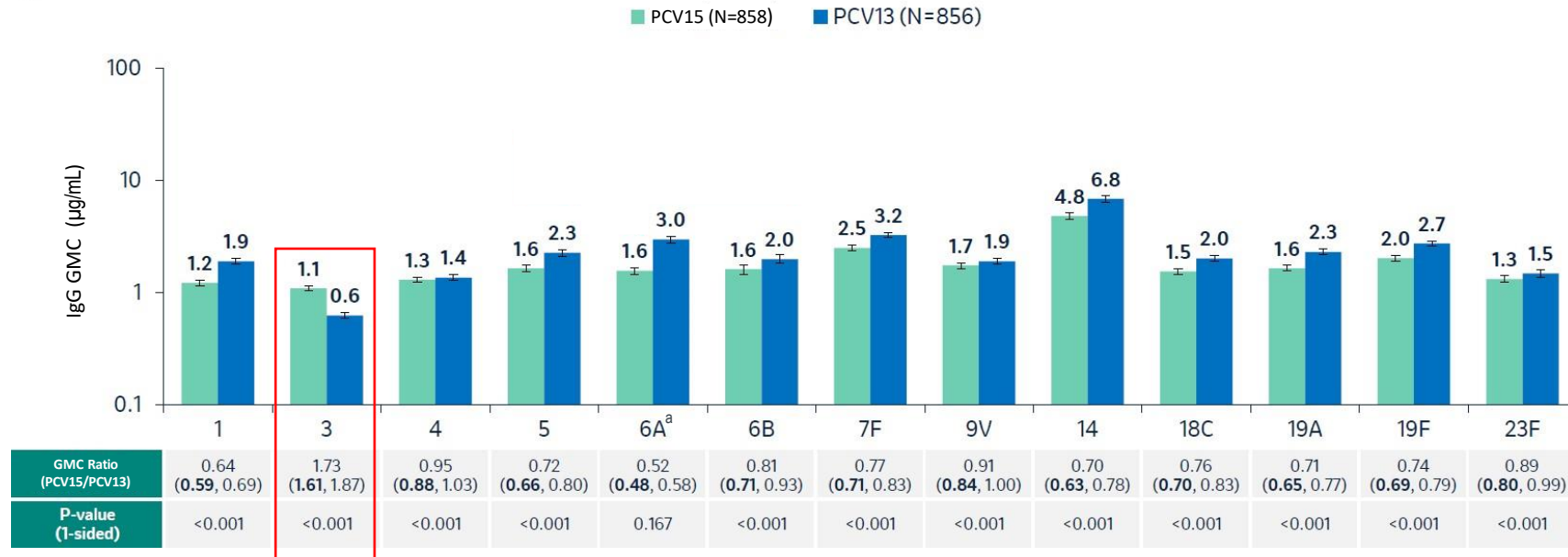


^a Studies conducted in Europe included Denmark, Czech Republic, Finland, France, Germany, the Netherlands, Poland, Slovakia, Spain, and Sweden. Studies conducted in Asia included India, Japan, Malaysia, Nepal, the Philippines, and Singapore. For Africa, studies were conducted in Mali and Nigeria and in Chile for South America.

1. Pollard AJ, Bijker EM. *Nat Rev Immunol*. 2021;21(2):83-100; 2. Plotkin et al. Correlates of protection. In: Plotkin SA, Orenstein WA, Offitt PA, et al. *Plotkin's Vaccines*, 7th edition. Elsevier, 2018;35-38. 3. Song et al. *J Infect Chemother*. 2013;19(3):412-425; 4. Gruber M, Marshall V. Regulation and testing of vaccines. In: Plotkin SA, Orenstein WA, Offitt PA, et al. *Plotkin's Vaccines*, 7th edition. Elsevier; 2018;1547-1565. 5. WHO. <https://www.who.int/publications/m/item/WHO-web-annex-9> 6. WHO. <https://www.who.int/publications/i/item/WHO-IVB-13.01> 7. Siber et al. *Vaccine*. 2007;25(19):3816-26.; al. *Lancet Infect Dis*. 2014;14(9):839-846.; 9. Voysey et al. *Clin Infect Dis*. 2018;66(6):913-920.

PCV 15 Non-inferiority Assessment by IgG GMC Ratio

30 Days Post-dose 3; 13 Shared Serotypes



- Non-inferiority requires the lower bound of the 2-sided 95% CI for IgG GMC ratio (PCV15/PCV13) to be > 0.5 (1-sided p-value <0.025)
- **At 30 days post-dose 3, PCV15 was non-inferior to PCV13 for 12/13 shared serotypes based on IgG GMC ratio**

lnG = Immunoglobulin G; GMC = geometric mean concentration; PCV15 = pneumococcal conjugate vaccine, 15-valent; PCV13 = pneumococcal conjugate vaccine, 13-valent; CI = confidence interval; Error bars indicate 95% Cis ^aNarrowly missed non-inferiority for serotype 6A (lower bound of the 95% CI = 0.48)

Bannietts N. Pneumococcal Polysaccharide 15-Valent Conjugate Vaccine (V114, VAXNEUVANCE): Pediatric Clinical Development Program. Advisory Committee on Immunization Practices; February 24, 2022; Atlanta, GA Vaxneuvance Product Circular. MSD, Hong Kong, 2023

PCV-15 for Pediatrics in Canada

Conclusion (PCV-15 vs PCV-13):

- The available evidence suggests that the vaccines had **comparable immune responses** for the **13 shared serotypes**
- The immune response to the two additional serotypes (**22F, 33F**) and for **serotype 3** (2 fold) was **higher** after PCV-15 compared to PCV-13
- **Safety** profile comparable
- Studies reviewed by NACI showed that PCV-15 **can be administered concurrently** with other routine pediatric vaccines

NACI 2023.

NACI Summary

- NACI recommends that PNEU-C-15 vaccine may be used ***interchangeably*** with PNEU-C-13 vaccine in children less than 18 years of age
- A pneumococcal vaccine series may be started or completed with ***either*** vaccine

NACI 2023.

Serotype 3 in Canada, 2010-2018

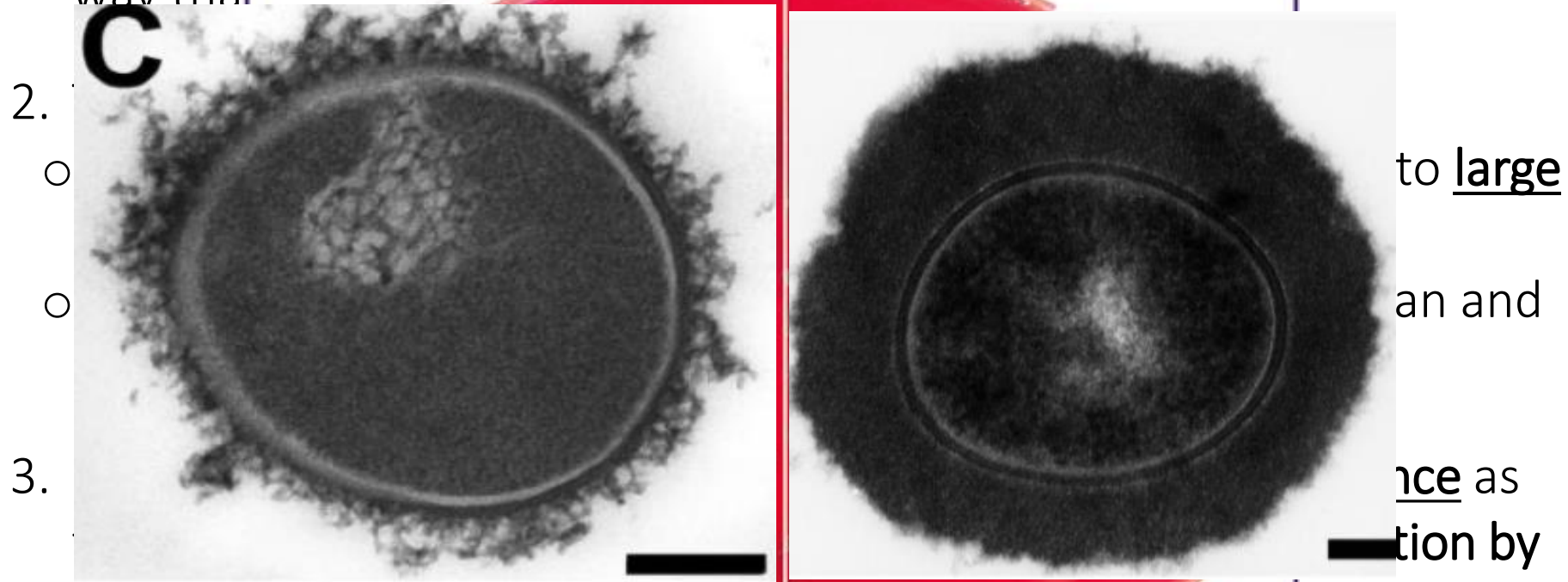
Age Group (PHAC 2019)	Serotype 3
All ages	12%
< 2 years	7.5%
2-4 years	11.2%
5-14 years	9.0%
>= 65 years	13%

Adapted from: Public Health Agency of Canada. National laboratory surveillance of invasive streptococcal disease in Canada. Annual Summary 2018 and 2014.
IPD incidence rates: from Public Health Agency of Canada, Notifiable Disease online charts: <https://dsol-smed.phac-aspc.gc.ca/notifiable/charts?c=cc>

Hammerchmidt et al. Infect Immun.2005;73(4653-4667).

Serotype 3...The Sugar Coated Killer !

1. Serotype 3...in a different way that



comple
traps.^{1, 3}

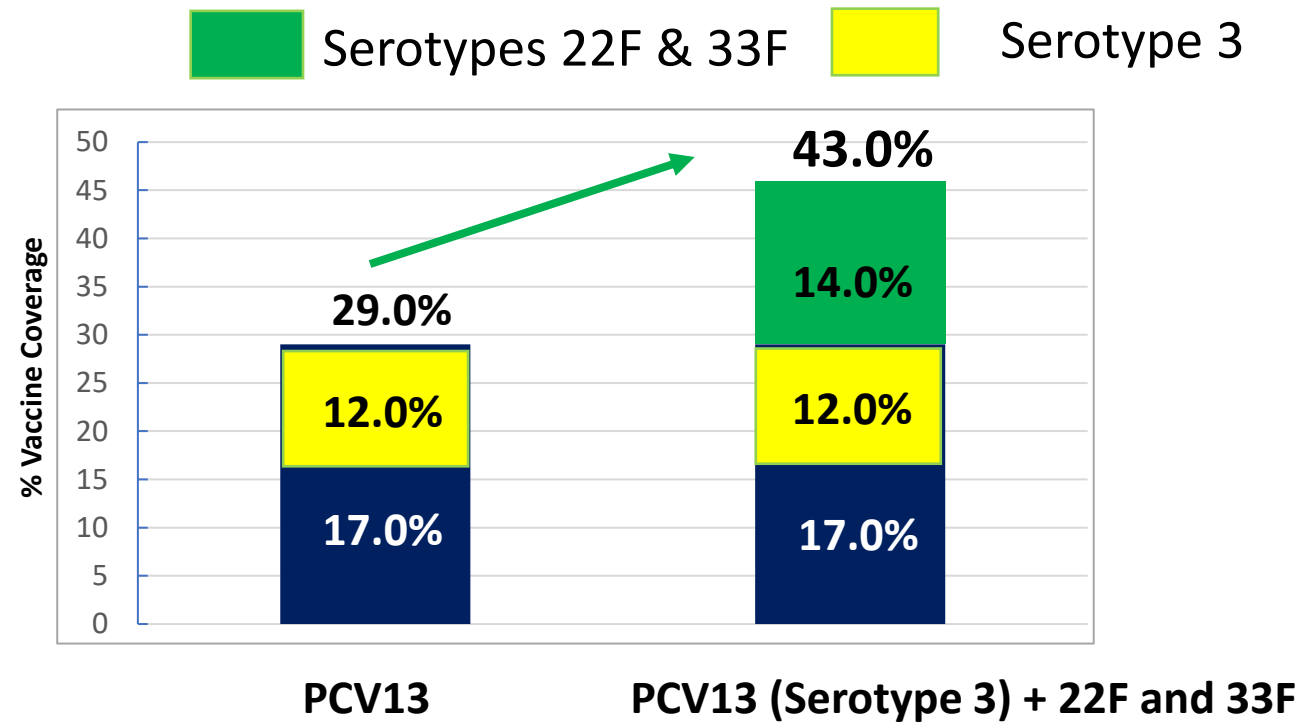
cellular

(A)

(B)

1. Choi et al. Clin Vaccine Immunol. 2010 Dec 18;18(12):1921-7.
2. Poolman et al. Vaccine. 2009 May 21;27(24):3213-22.
3. Sugimoto et al. BMC Res Notes 10, 21 (2017).

IPD of Serotypes 22F, 33F and Serotype 3 (2019)

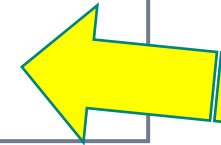


Adapted from Public Health Agency of Canada. 2019 Annual Summary.

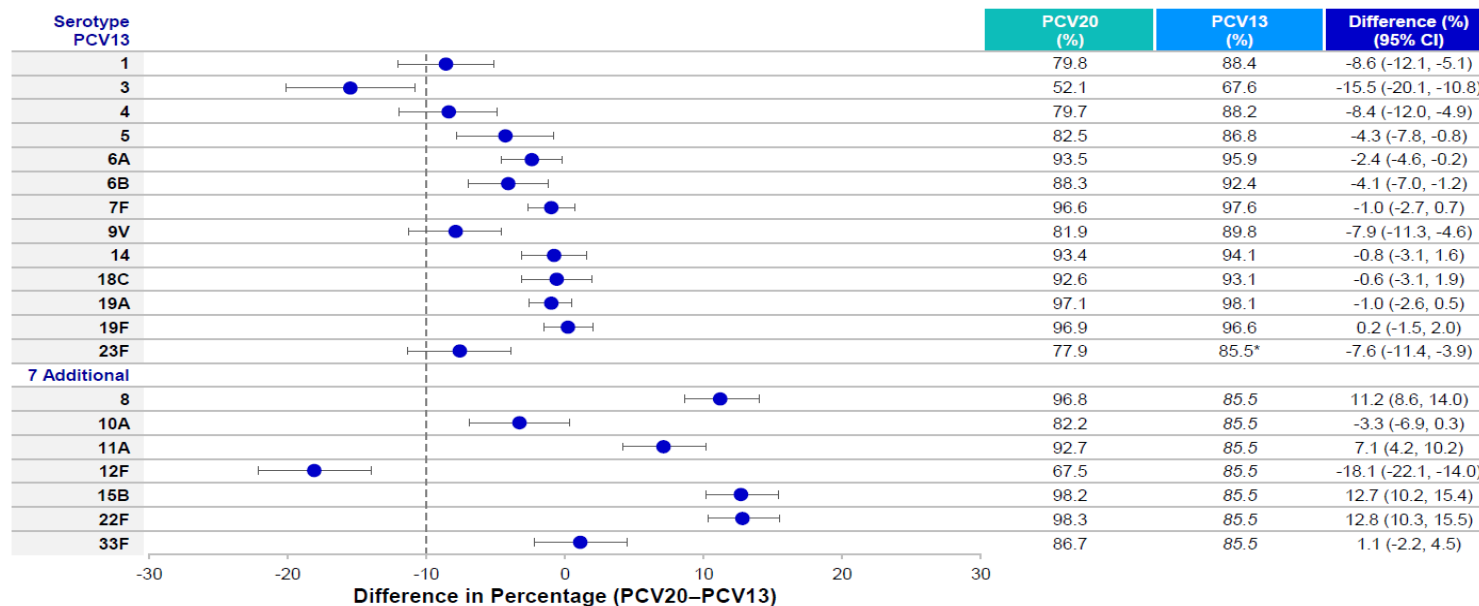
Infants & Children on **3+1** Dosing Regimen: PCV20 vs PCV13

14 Serotypes met non-inferiority in PD3 in terms of responder %

Missed 6 serotypes: Serotypes 1, 3, 4, 9V, 23F, 12F



Post Dose 3: Percentage with Predefined IgG Concentrations 14 Serotypes Met Noninferiority (Difference in %)



*The 7 additional serotypes are compared to the percentage for serotype 23F after Dose 3 (lowest in PCV13 group, excluding serotype 3).
Predefined IgG concentration – $\geq 0.35 \mu\text{g/mL}$ for all serotypes except $\geq 0.23 \mu\text{g/mL}$, $\geq 0.10 \mu\text{g/mL}$ and $\geq 0.12 \mu\text{g/mL}$ for serotypes 5, 6B and 19A respectively.

CONCLUSIONS

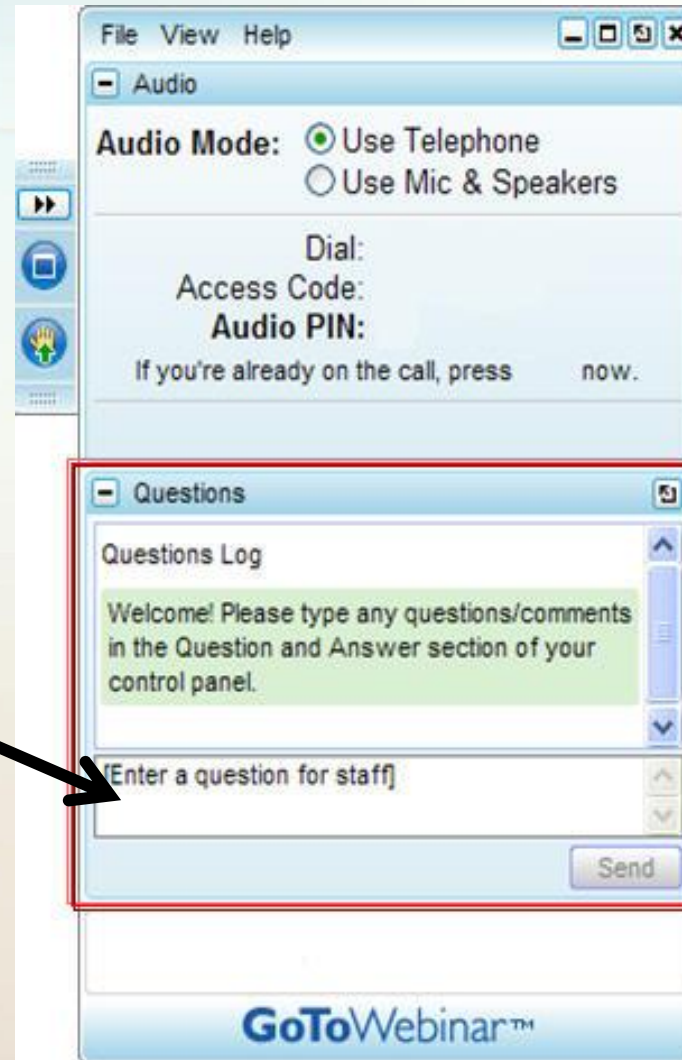
VACCINATING OUR CHILDREN: FOCUS ON PNEUMOCOCCAL VACCINES IN CANADA

- A. Pneumococcal disease burden is high in Canadian children
- B. Both PCV15 and PCV20 offer advantages vs PCV13
- C. PCV15 covers 22F and 33F and also increased immunogenicity versus serotype 3
- D. PCV20 provides ~ 20% greater coverage than PCV15
- E. NO current NACI recommendation...ACIP says use either one

Question & Answer Period

On a computer, submit your text question using the Questions pane

NOTE: On a mobile device, tap on the “?” or “Questions” to open the questions pane



Vaccinating Our Children: Focus on pneumococcal vaccines in Canada

Evaluation: <https://bit.ly/cidc-ped-pneumo-vaccines>

Or https://docs.google.com/forms/d/1gkyvQ0wa4TzAJLUtPYbkVIDzwe3xNA1xyIn_WswhOTk

Slide Set, Video recording at: www.CIDCgroup.org

Thank you for participating!

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