

Consortium for Infectious Disease Control

Winnipeg, Manitoba, Canada December 14, 2023

A neutral, third party platform supporting infectious disease projects, providing continuing medical education, coordinating initiatives, and undertaking research

Vaccination Series:

Understanding the Different Types of Pneumococcal Vaccines for Adults



Presenter:
George Zhanel, PharmD, PhD, FCCP, FCAHS

Professor and Associate Head: Department of Microbiology/Infectious Diseases, Max Rady College of Medicine, University of Manitoba

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

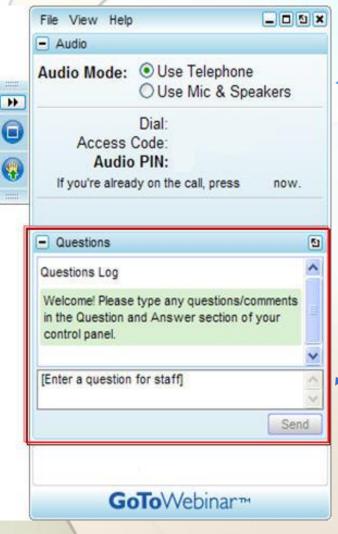
Founding Chair: International Indigenous HPV Alliance

This educational program is made possible through the support of **Merck Canada Inc.**The opinions expressed in this program are those of the presenter(s) and do not necessarily reflect the views of CIDC or its partners

Webinar Objectives

- Describe the burden of adult invasive & non-invasive pneumococcal disease in Canada
- Summarize the epidemiology of invasive pneumococcal disease in adults
- Review adult pneumococcal vaccines in Canada
- Discuss the value of adult-specific conjugated pneumococcal vaccines

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-Adult-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
- Assistant Professor, Dept of Family Medicine
- Co-Director, Practical Problems in Pediatrics, and Immunization and Prevention conferences

Presenter



George Zhanel, PharmD, PhD, FCCP, FCAHS

 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 PIONE

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Understanding the Different Types of Pneumococcal Vaccines for Adults



George G Zhanel (Microbiologist/Pharmacologist)

Professor and Associate Head: Department of Medical Microbiology/Infectious Diseases, Max Rady College of Medicine, University of Manitoba

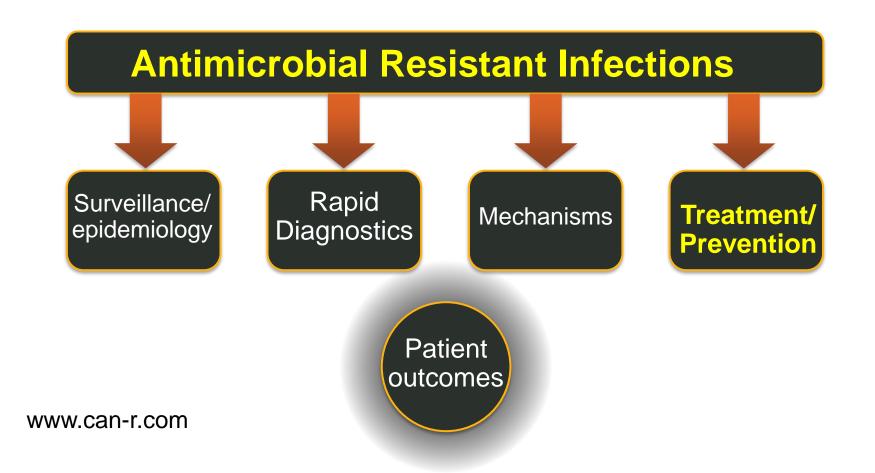
Director: Canadian Antimicrobial Resistance Alliance (CARA www.can-r.com), Max Rady College of Medicine, University of Manitoba, Winnipeg, Canada ggzhanel@pcsinternet.ca



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



Canadian Antimicrobial Resistance Alliance (CARA)



CANADIAN ANTIMICROBIAL RESISTANCE ALLIANCE

HOME

ABOUT US

CURRENT STUDIES

PAST STUDIES

SLIDE GALLERY

RECENT RESEARCH

EDUCATION

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 efection for national CANWARD endy
- Surveillance of online bia esists in C WARD
- Antimicrob us e ta
- Act and feetige all as new antimicrobials
- vrent earch presented at major conferences
- Republications 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 comproviders, and the media in understanding the rise antimicrobial resistance in Canada at how it is bear managed.

No V Stary N 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.





CANWARD



Research Funding/Conflicts

NIH/CIHR/NSERC CFI

Health Canada

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

OBJECTIVES UNDERSTANDING THE DIFFERENT TYPES OF PNEUMOCOCCAL VACCINES FOR ADULTS

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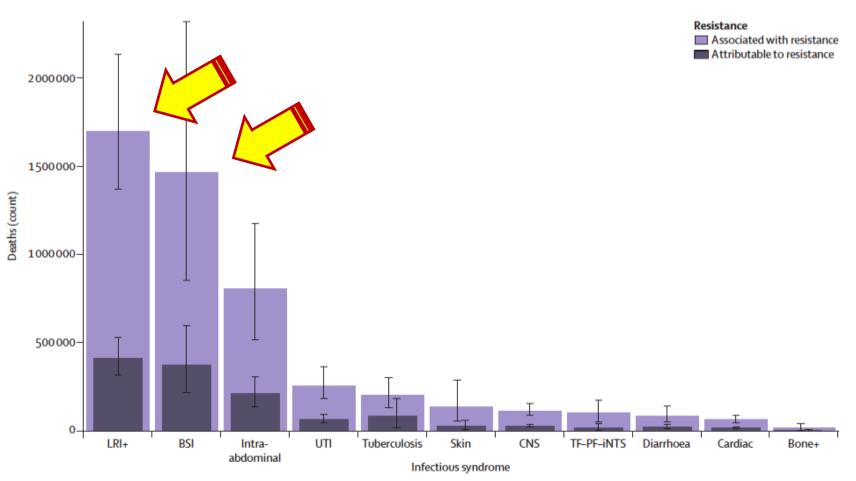
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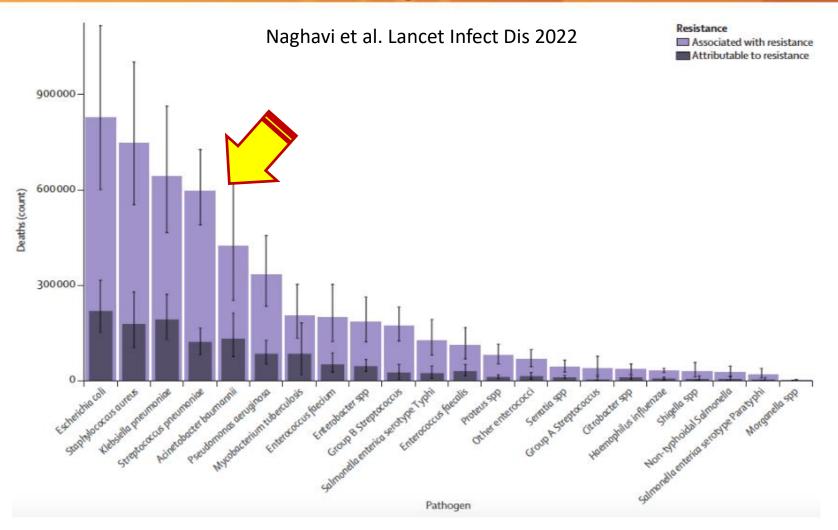
Worldwide Deaths Attributable/Associated With Antimicrobial Resistant Infections (By Infectious Syndrome – 2019)

Naghavi et al. Lancet Infect Dis 2022





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



Journal of Antimicrobial Chemotherapy

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

Journal of Antimicrobial Chemotherapy

<u>Streptococcus pneumoniae</u> serotyping and antimicrobial susceptibility: <u>assessment for vaccine efficacy in Canada after the introduction of PCV13</u>

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

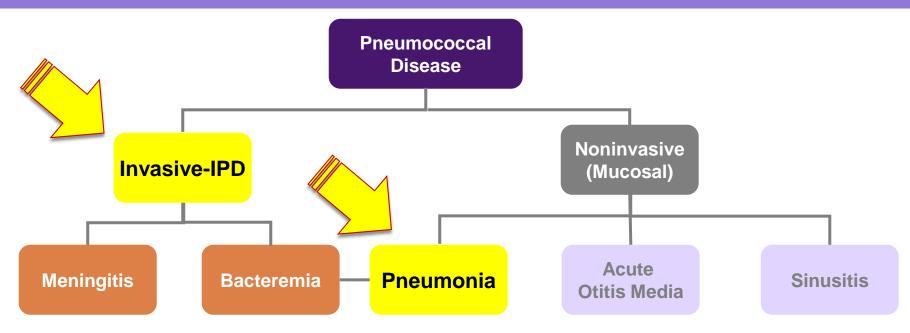


Streptococcus pneumoniae ("the pneumococcus") ...

the most important respiratory bacteria

A Health Canada Pathogen of Interest

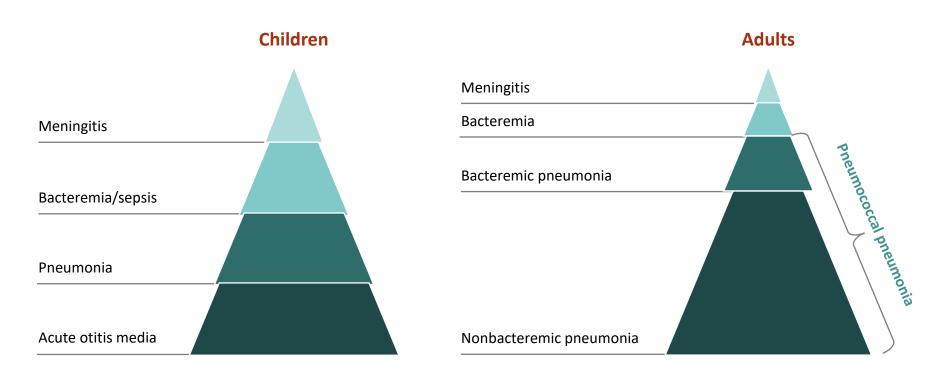
Common Clinical Forms of Pneumococcal Disease



- 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.

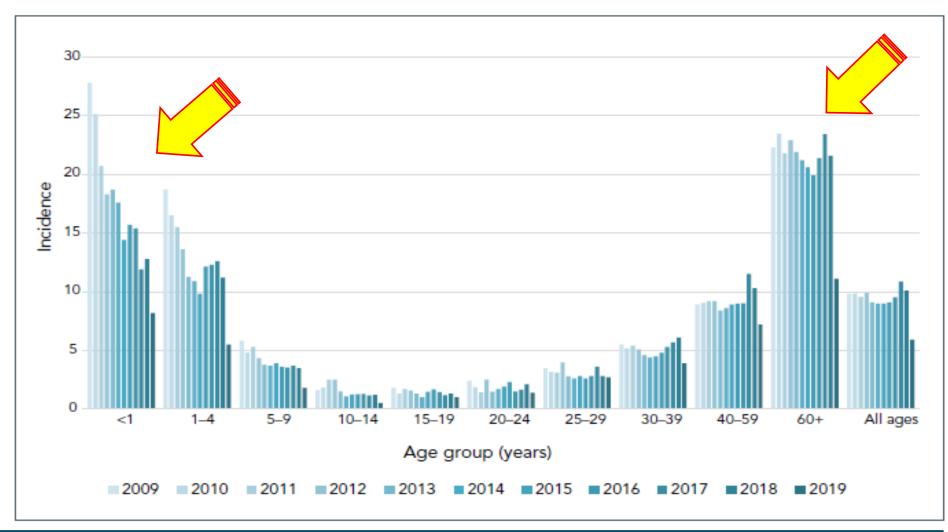
The Burden of Pneumococcal Disease in Adults

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.

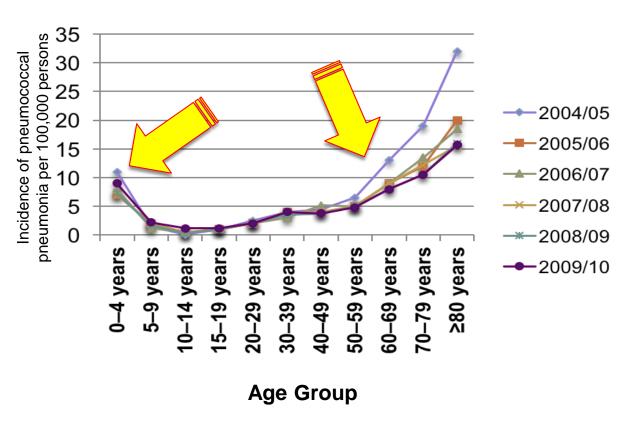


Golden AR, et al. Can Commun Dis Rep 2022;48(9):396–406. https://doi.org/10.14745/ccdr.v48i09a04; PHAC [Internet]. 2022; Available from: https://www.canada.ca/en/publichealth/services/publications/vaccines-immunization/2019-highlights-childhood-national-immunization-coverage-survey.html;



Hospitalization due to Pneumococcal Pneumonia increases with age

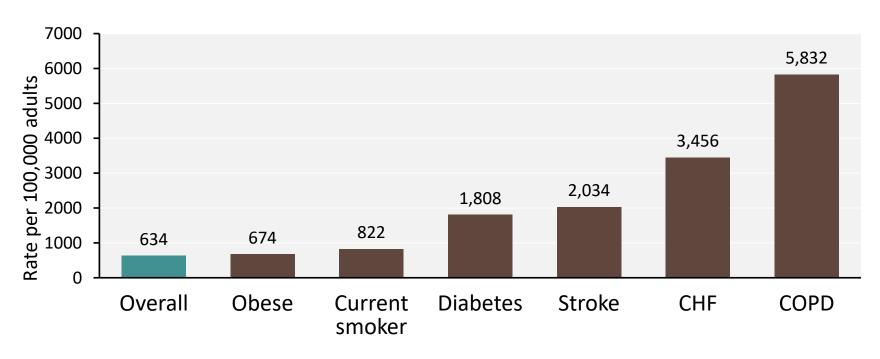
CIHI DAD annual incidence of hospitalizations in Canada 2004/05 to 2009/10 due to pneumococcal pneumonia by age and year



McNeil S, Gray S, Zanotti G, et al. Clinical and economic burden of hospitalization due to Streptococcus pneumoniae pneumonia in Canada, 2004 to 2009 [Presented at the 8th Annual International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD), Iguaçu Falls, Brazil, 11–15 March 2012]. 2012.

Comorbidities Influence the Prognosis of Community-acquired Pneumonia

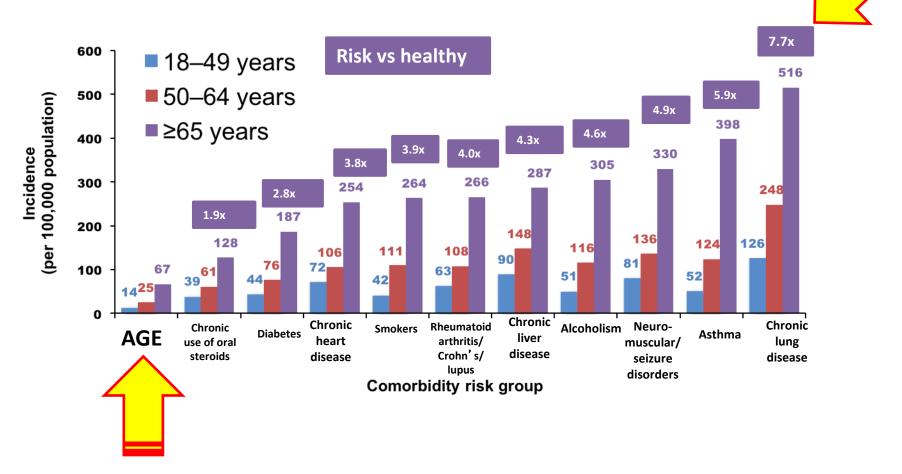
Adults hospitalized with CAP, June 2014 to May 2016



Ramirez JA et al. Clin Infect Dis. 2017.



Age and Comorbidities increase Pneumococcal Pneumonia *Risk* in Adults



AT RISK Adults Hospitalized with Pneumococcal Community-Acquired Pneumonia (pCAP) Equals a <u>Bad Outcome</u> (Canada 2010-2015)

Age	Patients with 1+ Comorbidity (%)	Patients Admitted to ICU (%)	Patient Mortality (%)
16-49	68.3	26.8	3.8
50-64	89.5	35.2	6.3
65+	97.4	26.6	12

LeBlanc JJ et al. BMJ Open Resp Res. 2020.



Risk Factors for Pneumococcal Disease in Adults

Chronic comorbidities

 Heart disease, lung disease, diabetes, functional or anatomic asplenia, liver disease, cerebrospinal fluid leaks, cochlear implants, renal failure

Immunocompromised status

• HIV infection, cancer, solid organ transplantation, immunosuppressive therapy, primary immunodeficiencies, autoimmune diseases

External factors

• Socioeconomic (e.g., homelessness), environmental, preceding viral respiratory infection (e.g., influenza), smoking, alcohol abuse, illicit drug use

Age

• ≥ 65 years



Torres A et al. Thorax. 2015.

What Do I Want You to Know?

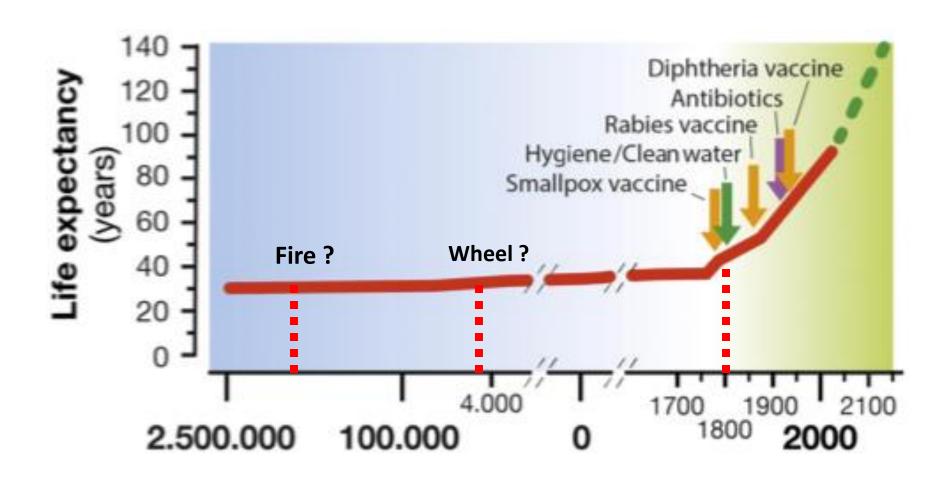
- 1. Pneumococcal Infection is Associated With a Lot of Morbidity and Mortality
- 2. The Majority of the Morbidity and Mortality in <u>Adults</u> Occurs in:
 - Patients ≥ 65 (with or without co-morbidities)
 - Immunocompromised of any age
 - 50-64 years with ≥ 1 co-morbidity

OBJECTIVES UNDERSTANDING THE DIFFERENT TYPES OF PNEUMOCOCCAL VACCINES FOR ADULTS

A. Describe the **burden** of adult invasive & non-invasive pneumococcal disease in Canada

- B. Summarize the **epidemiology** of invasive pneumococcal disease in adults
- C. Review adult pneumococcal vaccines in Canada
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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 (US Data)

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%
Haemophilus influenzae	20,000 (est.)	31 [§]	>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

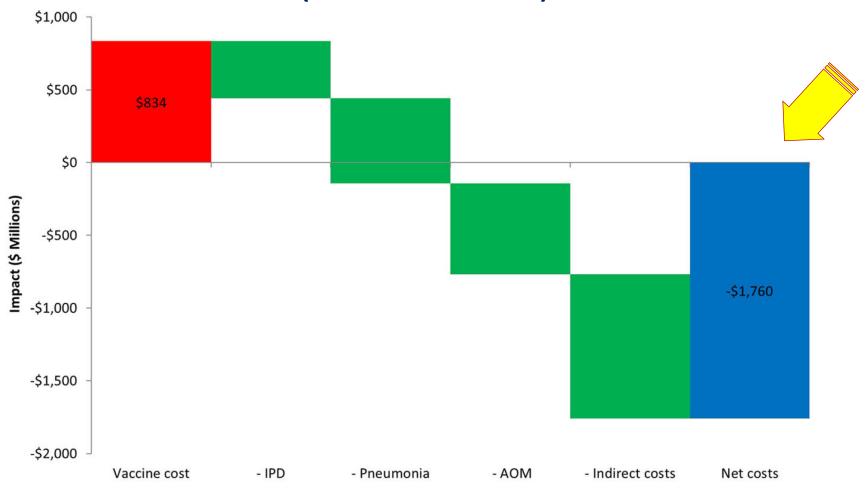
Vaccination Is A Cost-effective Way to Save Lives

Immunization program	Cost saving per \$1 spent	
Influenza for adults ≥ 65 years of age	\$45	
Measles, mumps, rubella for children	\$16	
Pneumococcal polysaccharide for adults ≥ 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

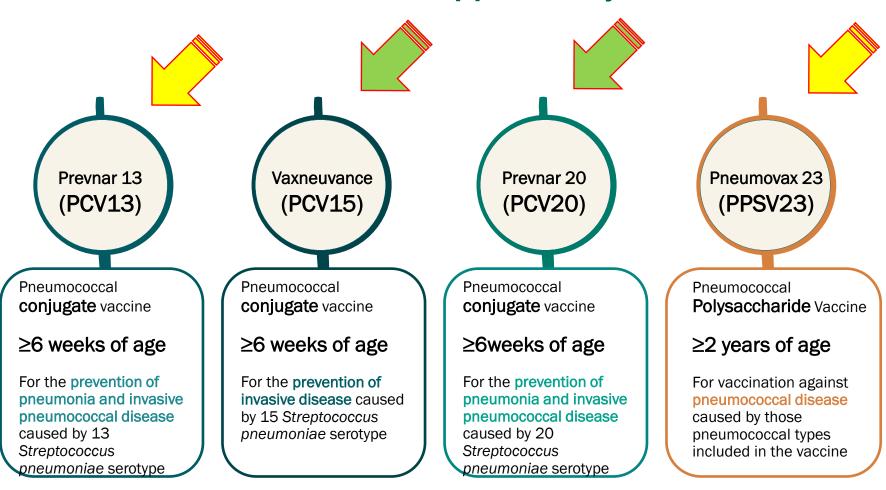
Wilson MR et al 2020 Infect Dis Ther; https://doi.org/10.1007/s40121-020-00294-6

Polling Question

What is your comfort level with recommending specific pneumococcal vaccines to <u>ADULT</u> patients based on their age, comorbidities, and previous vaccine history?

- A. Very comfortable
- B. Moderately comfortable
- C. Comfortable
- D. Somewhat comfortable
- E. Not at all comfortable

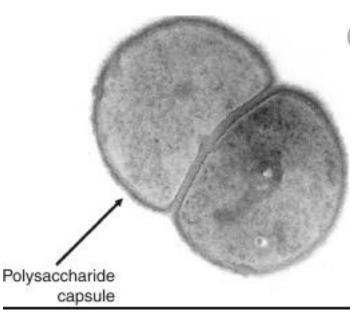
Pneumococcal Vaccines Approved by Health Canada



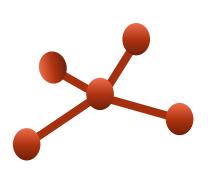
Adapted from Zhanel et al JAC 2023.

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)



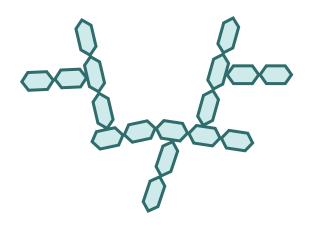
There Are Two Different Types of Pneumococcal Vaccines



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. <a href="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



An Advisory Committee Statement (ACS)

National Advisory Committee on Immunization (NACI)

Public health level recommendations on the use of pneumococcal vaccines in adults, including the use of 15-valent and 20-valent conjugate vaccines

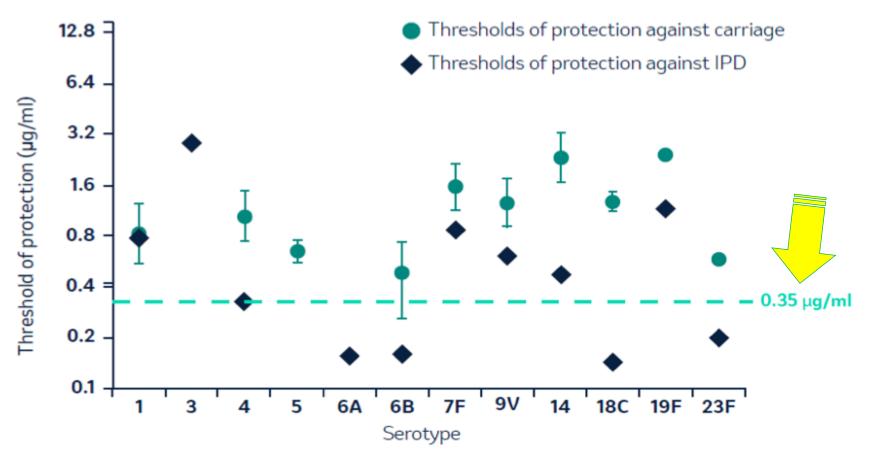
NACI 2023.

PCV-15 and PCV-20 in Canada

- Currently **no efficacy or effectiveness data** available
- **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 additional in relation to PCV-13 vaccine
- Immunogenicity measured by:
 - total antibody levels (IgG to serotype)
 - functional (neutralizing) antibody levels (OPA)

The Role of Immunogenicity in SPN Vaccine Development

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

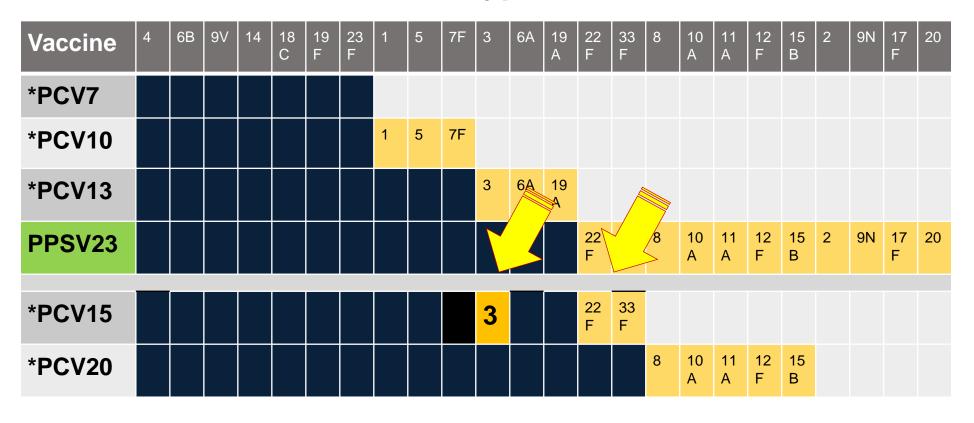


^a Studies conducted in Europe included Denmark, Czech Republic, Finland, France, Germany, the Netherlands, Poland, Slovakia, Spain, and Sweden. Studies conducted in Asia included India, Japan, Malaysia, Nepal, the Philippines, and Singapore. For Africa, studies were conducted in Mali and Nigeria and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

1. Pollard AJ, Bijker EM. Nat Rev Immunol. 2021;21(2):83-100; 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/ 6. WHO. https://www.who.int/publications/i/item/WHO-IVB-13.01 7. Siber et al. Vaccine. 2007;25(19):3816-26.; 8. Andrews et al. Lancet Infect Dis. 2014;14(9):839-846.; 9. Voysey et al. Clin Infect Dis. 2018;66(6):913-920.

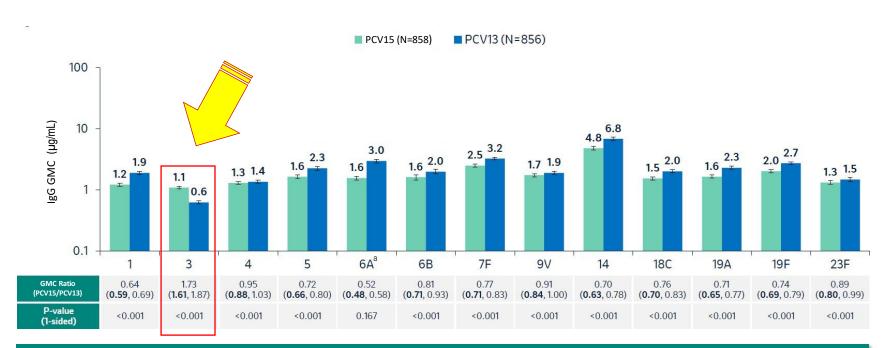
Conjugated* Pneumococcal Vaccines in Canada

Serotype



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

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

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

Banniettis 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

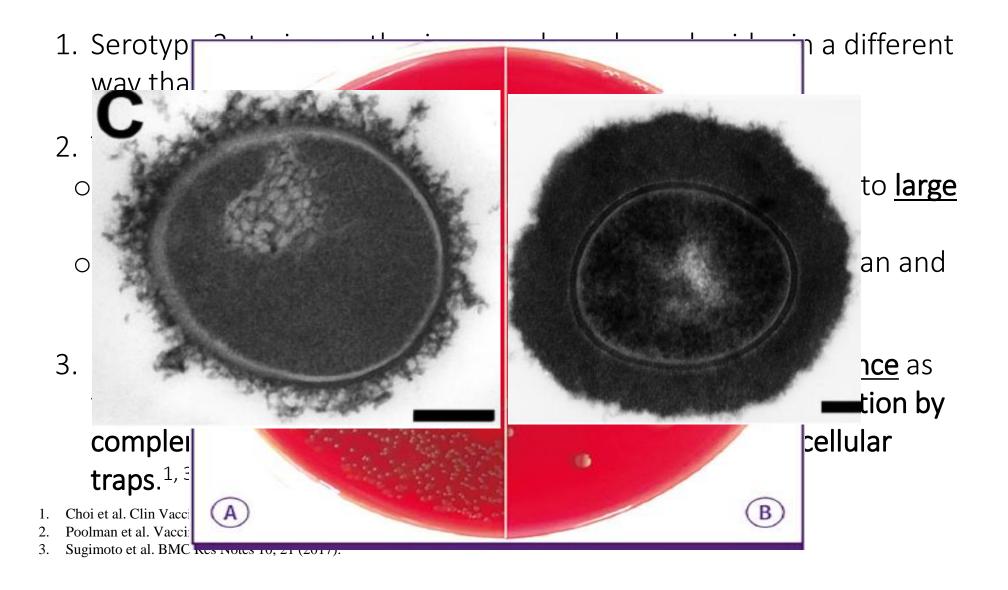
Serotype 3 in Canada, 2010-2018

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%

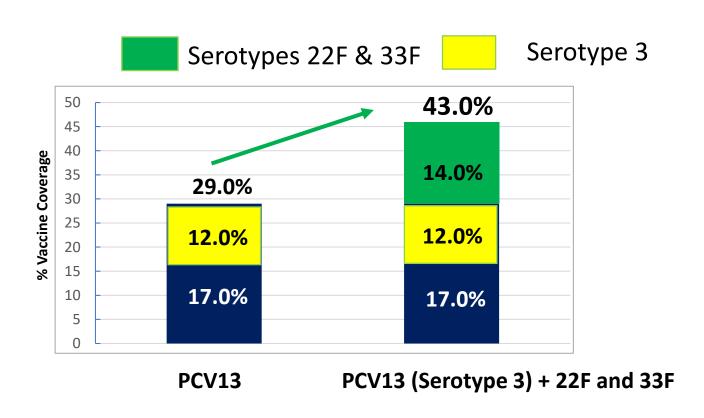
Adapted from: Public Health Agency of Canada. National laboratory surveillance of invasive streptococcal disease in Canada. Annual Summary 2018 and 2014. IPD incidence rates: from Public Health Agency of Canada, Notifiable Disease online charts: https://dsol-smed.phac-aspc.gc.ca/notifiable/charts?c=cc

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

Serotype 3...The Sugar Coated Killer!

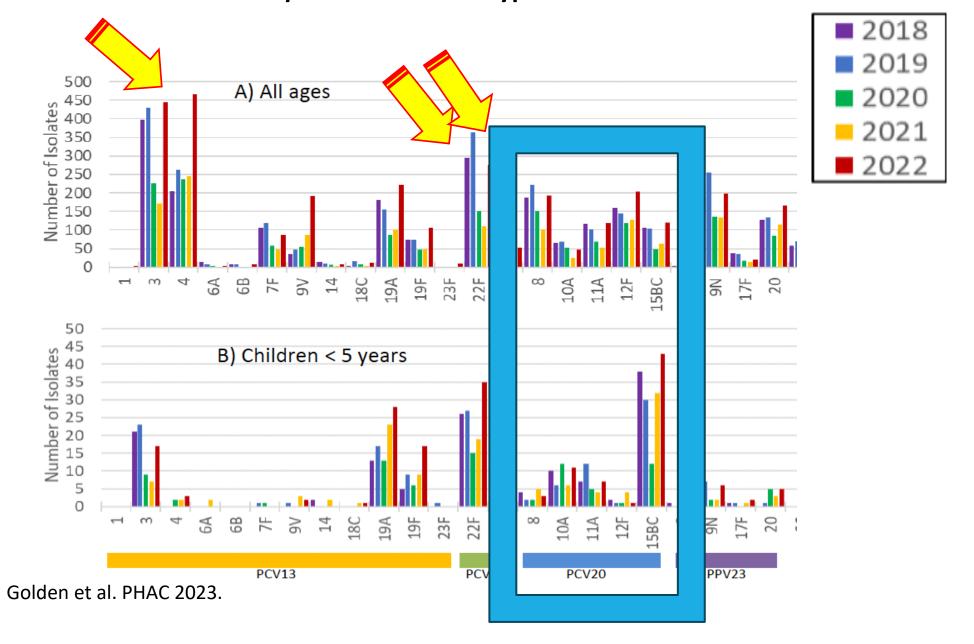


IPD of Serotypes 22F, 33F and Serotype 3 (2019)

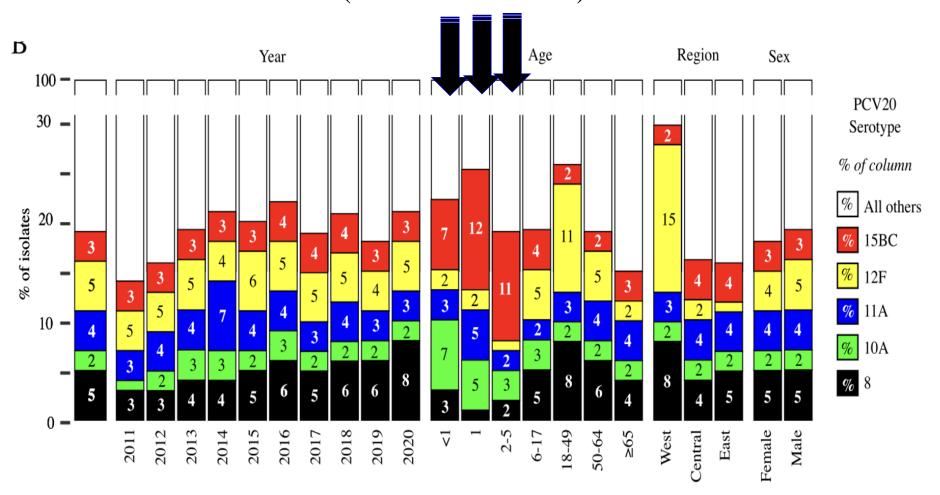


Adapted from Public Health Agency of Canada. 2019 Annual Summary.

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



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



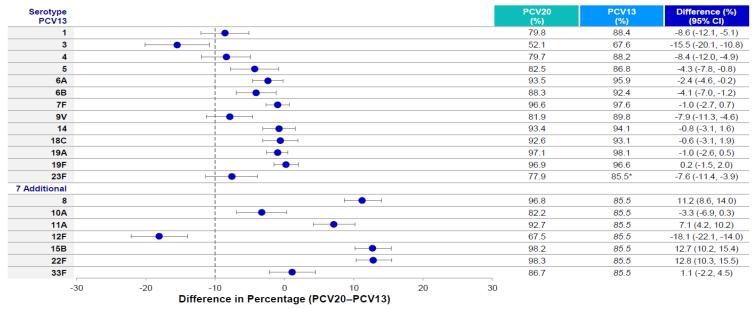
Schellenberg et al. JAC 2023.

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





^{*}The 7 additional serotypes are compared to the percentage for serotype 23F after Dose 3 (lowest in PCV13 group, excluding serotype 3).

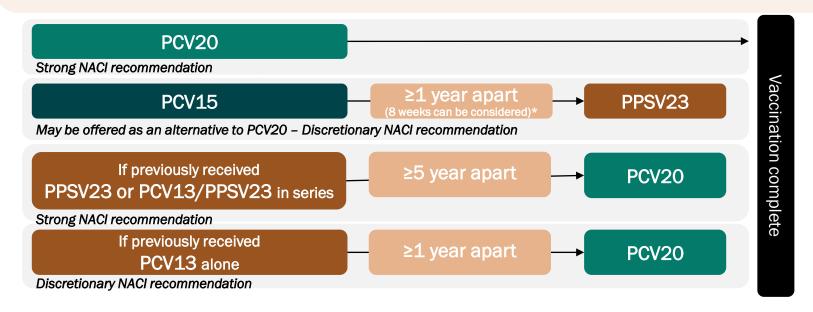
Predefined IgG concentration – ≥0.35 μg/mL for all serotypes except ≥ 0.23 μg/mL, ≥0.10 μg/mL and ≥ 0.12 μg/mL for serotypes 5, 6B and 19A respectively.



NACI <u>2023</u> recommendations for pneumococcal vaccines in adults

For adults **not previously vaccinated pneumococcal** vaccine or whose status is
unknown, **NACI recommends routine administration of PCV20 for:**

- All adults ≥65 years
- Adults who are immunocompromised
- 50-64 years living with risk factors



^{*}For adults 18-64 living with immunocompromising conditions.

Note: NACI supports the continued use of PCV13 and PPSV23 in adults only when PCV15 and/or PCV20 are unavailable or inaccessible.

1. Public health level recommendations on the use of pneumococcal vaccines in adults, including the use of 15-valent and 20-valent conjugate vaccines. An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI). October 2022.



NACI Recommends in 2023 that You...

Give a single dose of PCV-20 to:

- All adults ≥ 65 years of age and older
- Adults 50-64 years with underlying medical conditions and/or other risk factors that place them at high risk of IPD
- Adults ≥ 18 years who are immunocompromised

... alternative PCV-15 followed by PNEU-P-23

NACI 2023.



Priya – Age ≥ 65 years

- 66 years old
- Had a chest infection and was briefly hospitalized in the past year
- Hypertension (on ACEi)
- Obese

Would you recommend a pneumococcal vaccine for her?



ACEi, angiotensin-converting enzyme inhibitor

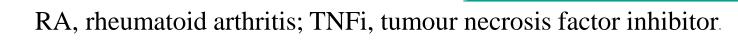


Joanna - Immunocompromised

- 54 years old
- Diagnosed with RA when she was 48
- Has been on prednisone (25 mg/day) for the last 3 months
- Has just been prescribed a biologic (TNFi) by her rheumatologist



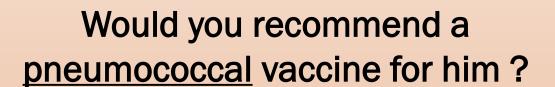
Would you recommend a <u>pneumococcal</u> vaccine for her?

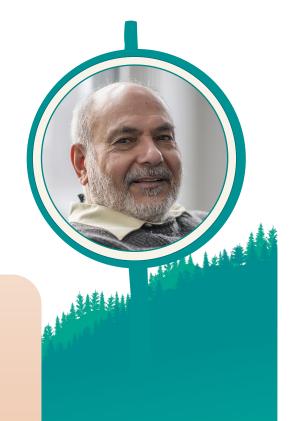




Charlie - ≥ 60 years with co-morbidity

- 62 years old
- Ex-smoker
- BMI 33: pre-diabetic (managed by diet)
- Hypertension (on ARB and thiazide diuretic)
- Dyslipidemia (on statin therapy)





ARB, angiotensin receptor blocker; BMI, body mass index.

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, PCV-20, 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

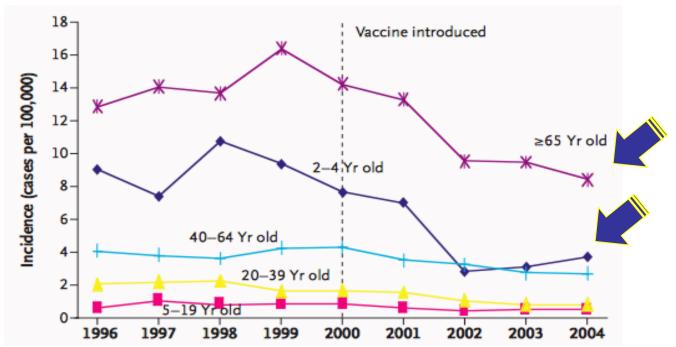
Indirect Effects - Herd Immunity

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

Annual Incidence of Invasive Disease Caused by Penicillin-Nonsusceptible Pneumococci in Persons Two Years of Age or Older, 1996 to 2004









CONCLUSIONS UNDERSTANDING THE DIFFERENT TYPES OF PNEUMOCOCCAL VACCINES FOR ADULTS

- There is a lot of pneumococcal disease in Canada in adults
- Morbidity and mortality increases with age and comorbidities
- NACI says PCV20 ...or PCV15 followed by PPSV23

The Future of Pneumococcal Vaccines

- expanding serotypes in number...sequentially (PCV7,10,13,15, 20 etc)
- expanding serotypes...**non-sequentially** (eg. V116...PCV21)
- conserved pneumococcal targets (eg. PspA, pneumolysin, pneumococcal surface protein C and pneumococcal surface adhesin A)
- adjuvants
- microparticles and nanoparticles
- routes of administration ... IM vs. oral vs. nasal vs. mucosal

Serotype Composition of V116 (Conjugated PCV21)



	Serotype Composition																															
PCV13	4	6B	9V	14	18C	19F	23F	1	3	5	6A	7F	19A																			
PCV15	4	6B	9V	14	18C	19F	23F	1	3	5	6A	7F	19A	22F	33F																	
PPSV23	4	6B	9V	14	18C	19F	23F	1	3	5		7F	19A	22F	33F	2	8	9N	10A	11A	12F	15B	17F	20								
PCV20	4	6B	9V	14	18C	19F	23F	1	3	5	6A	7F	19A	22F	33F		8		10A	11A	12F	15B										
V116									3		6A	7F	19A	22F	33F		8	9N	10A	11A	12F		17F	20A	15A	15C	16F	23A	23B	24F	31 3	5B

PCV13	PCV15	PCV20	PPSV23	V116
4 shared serotypes: 6A, 7F, 19A)	6 shared serotypes: (PVC13 + 22F, 33F)	10 shared serotypes: (PCV15 + 8, 10A, 11A, 12F)	12 shared serotypes: (PCV20 (-6A) + 9N, 17F, 20A)	8 unique serotypes

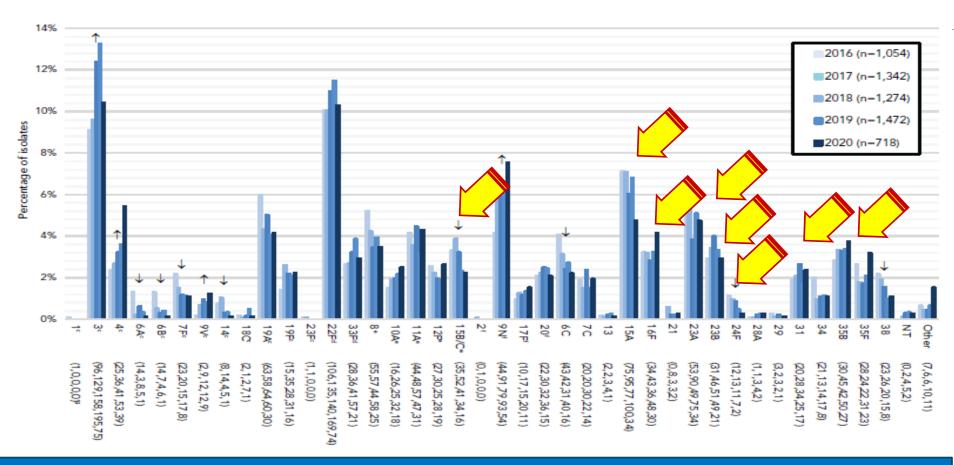


^{*15}C is denoted here to represent the serotype protection proposed with deOAc15B as the molecular structures for deOAc15B and 15C are similar

^{*}Jones C, Lemercinier X. 2005. Full NMR assignment and revised structure for the capsular polysaccharide from Streptococcus pneumoniae type 15B. *Carbohydr Res* 340:403–409.)

Pneumococcal Serotype Evolution in Canada Adults 65+

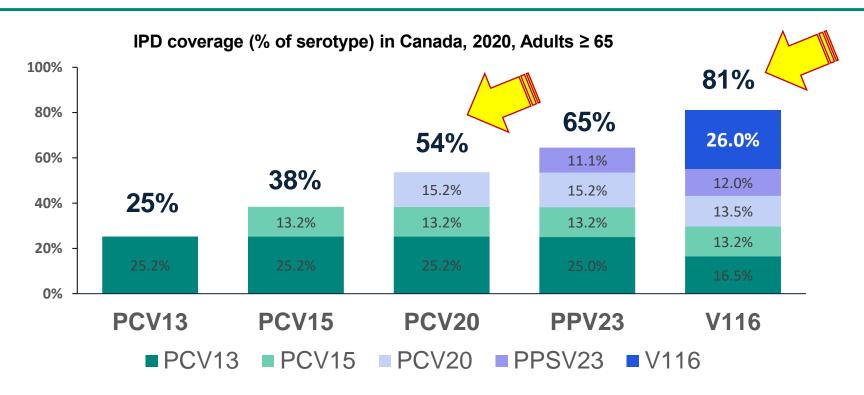
8 unique serotypes in V116 represent ~26% of serotypes



Serotypes in V116 are Responsible for the Majority of Residual IPD in Canadian <u>Adults 65+</u>



Serotypes in V116 are responsible for ~81% of IPD in 2020, underscoring the role not just for expanded <u>valency</u>, but for <u>selection of serotypes</u> based on epidemiologic data

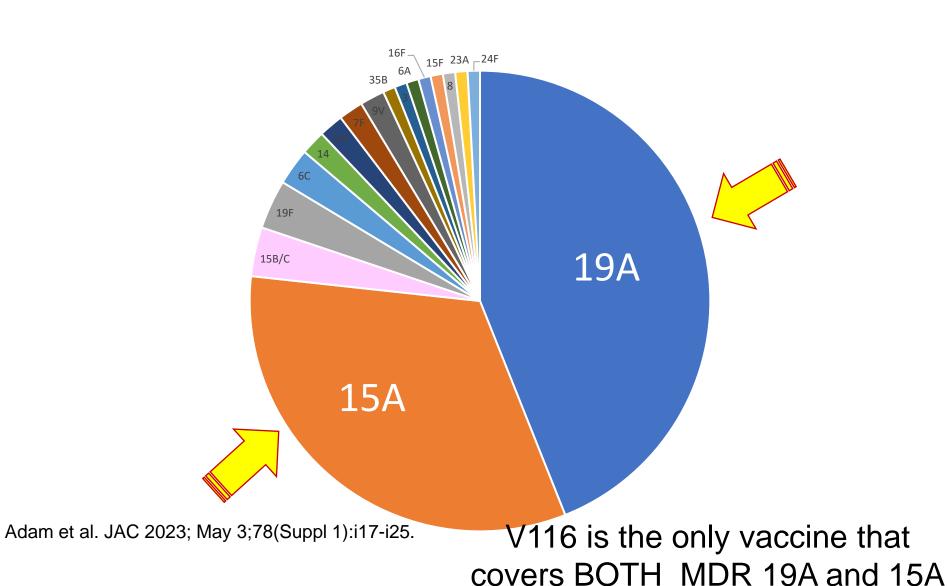


Golden AR, et al. Invasive pneumococcal disease surveillance in Canada, 2020. Can Commun Dis Rep 2022;48(9):396–406. https://doi.org/10.14745/ccdr.v48i09a04



Serotype distribution of MDR invasive *S. pneumoniae* isolates in Canada (SAVE study in 2011 – 2020)





A phase 3 study to evaluate the safety, tolerability, and immunogenicity of V116, a pneumococcal conjugate vaccine designed for adults (STRIDE-3)

Study objectives and methods

Primary immunogenicity

In adults ≥50 years:



Demonstrate that V116 is noninferior to PCV20 for 10 common serotypes

Lower bound of the 2-sided 95% CI of the OPA GMT ratio (V116/PCV20) to be >0.5a



Demonstrate that V116 is superior to PCV20 for 11 unique serotypes

Lower bound of the 2-sided 95% CI of the OPA GMT ratio (V116/PCV20) to be >2.0a

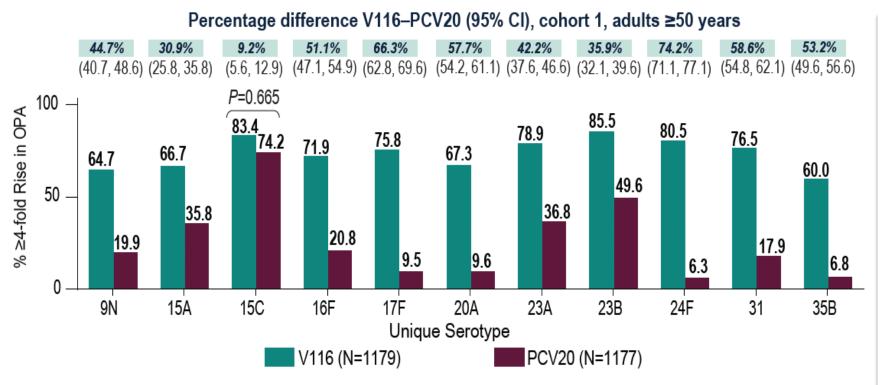
2-sided 95% CI of the differences (V116 – PCV20) between the proportions of participants with a ≥4-fold rise to be >10%^b



Demonstrate V116 immunobridges to adults 50-64 years of age for 21 serotypes in V116

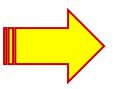
World Vaccine Congress West Coast (WVCWC); Santa Clara, CA, USA; November 27-30, 2023.

Figure 7. Superiority testing for unique serotypes: percentage with ≥4-fold rise in OPA day 1 to day 30



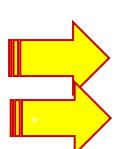
The P-values for serotypes 9N, 15A, 16F, 17F, 20A, 23A, 23B, 24F, 31 and 35B were P<0.001. N=number of participants randomized and vaccinated.

Conclusions



Safety

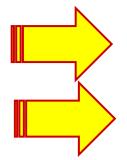
 V116 is well tolerated with an overall safety profile generally comparable to PCV20 and consistent with reported data for licensed pneumococcal vaccines



Immunogenicity

In adults 50 years of age and older, OPA GMT responses in the V116 group at day 30 are:

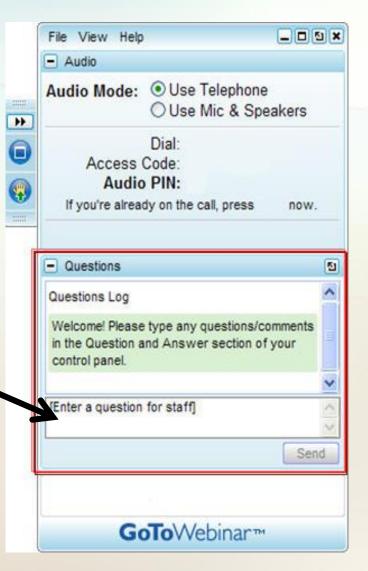
- Noninferior to PCV20 for the 10 common serotypes
- Superior to PCV20 for 10 of the 11 serotypes unique to V116 (all except 15C)
 - Assessment of immune responses for serotype 15C in V116 impacted by responses to 15C observed in the PCV20 group, attributed, likely, to cross-reactive immune responses to serotype 15B
 - V116 induced robust functional immune responses to 15C
- V116 immunobridged immune responses in recipients aged 18-49 years compared to aged 50-64 years
- This pivotal study supports the use of V116 as a novel population-specific PCV for the prevention of PD in adults



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



Vaccination Series:

Understanding the Different Types of Pneumococcal Vaccines for Adults

Evaluation: https://bit.ly/CIDC-Adult-Pneumo-Vaccines

Or https://docs.google.com/forms/d/1CE1LUrj_Z9vK5e5TGMuCQuBuuYkj55muY1zoGqf-J-g

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

Add info@CIDCgroup.org to your contact list to ensure you receive upcoming program notices

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