GVIRF 2018 Workshop 3: Pneumococcal Vaccines: Lessons Learned and the Road Ahead	
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Session Outline	**Chair**: David Durrheim (Professor, University of Newcastle) **Presentations:** *2018 Status of PCV Use and Impact*, Kate O'Brien (Executive Director, International Vaccine Access Center, Johns Hopkins Bloomberg School of Public Health) *Rollout of Pneumococcal Conjugate Vaccine (PCV) in India,* Narendra Arora (Executive Director, The INCLEN Trust International), and Pradeep Haldar (Ministry of Health and Family Welfare, Government of India) *The Future of PCVs,* Keith Klugman (Director, Pneumonia Program, Bill & Melinda Gates Foundation)
Objectives of the session	*To discuss:* • Lessons learned on access to pneumococcal conjugate vaccines (PCVs) and the impact achieved thus far • Ways to improve the utility of PCV towards achieving the SDGs
Main outcome	• Pneumococcal vaccines are being rolled out globally and showing substantial impacts on pneumococcal deaths and other serious outcomes • In settings where community-wide immunity can be maintained, PCV immunization schedules must be optimized to maximise herd protection while reducing program costs for improved sustainability
Summary	Pneumococcal disease caused an estimated 335k deaths in 2015, particularly impacting the poor. PCV has now been introduced in 134 countries, but global coverage lags well behind that of older vaccines such as DTP because large countries such as China and Indonesia have not yet introduced PCV and because coverage is incomplete in some countries. PCV has driven a decline in pneumococcal deaths, averting an estimated 250k deaths globally from 2000 to 2015. In a high income setting, a full quantification of PCV value including impact on invasive pneumococcal disease (IPD), pneumonia, acute otitis media, upper respiratory tract infections, and associated treatment costs showed that preventing less severe outcomes contributes substantially to cost savings from the vaccine.[a] Two PCVs are currently available, differing in the number of serotypes contained (10 valent vs. 13 valent), carrier proteins, shelf life and price. Data to date suggest that they are interchangeable and do not show consistent differences in impact on IPD and mortality. Limited serotype replacement has been observed: non-vaccine-type IPD has increased after PCV introduction, but these increases are small in comparison to the impact against vaccine-type disease and stabilize in about 5 years. Overall PCV gives a net decline in IPD in all age-groups.[b] The full impact of the vaccine, extent of serotype replacement and optimal dosing remain to

	be completely understood, while simultaneously needing to drive country adoption and high PCV coverages. In India, PCV introduction began in 2017 in the context of two major challenges: a large birth cohort of 26.7M children and simultaneous introduction of rotavirus and measles/rubella vaccines. PCV rollout is being conducted in phases, with annual targets taking Gavi support levels and vaccine supply constraints into consideration. Explicit criteria have been used to prioritize States for rollout, taking into account potential impact, development needs, and readiness for introduction. A national rollout plan has been established, leveraging the National Nutrition Mission (NNM) as a catalytic opportunity for expanding the PCV program. This plan is helping to ensure vaccines and financing will be available when required. Through this transparent, data-driven program, India will be vaccinating its entire birth cohort with PCV by 2020. Future directions in pneumococcal vaccination include optimizing the number of doses and their schedule to improve sustainability while maintaining impact and developing new vaccines that expand protection and address serotype replacement. Current data suggest that a 2+1 or potentially a 1+1 regimen could provide better herd protection than current 3+0 schedules. Additional studies are underway to evaluate alternate dosing regimens and inform policy recommendations.[c,d] New vaccines are in development that promise to improve affordability and supply security in the PCV market, including higher valency PCVs that address as many as 20 serotypes, and protein or whole cell vaccines that could have broad coverage for all serotypes and prevent serotype replacement. Impact on nasopharyngeal carriage is a key requirement for novel pneumococcal vaccines.
Key references or quotes	a. Palmu AA, Jokinen J, Nieminen H, Rinta-Kokko H, Ruokokoski E, Puumalainen T, Moreira M, Schuerman L, Borys D, Kilpi TM, Vaccine-preventable disease incidence of pneumococcal conjugate vaccine in the Finnish invasive pneumococcal disease vaccine trial, Vaccine, Volume 36, Issue 14, Pages 1816-1822 (2018) https://doi.org/10.1016/j.vaccine.2018.02.088. b. Feikin DR, Kagucia EW, Loo JD, Link-Gelles R, Puhan MA, et al., Serotype-Specific Changes in Invasive Pneumococcal Disease after Pneumococcal Conjugate Vaccine Introduction: A Pooled Analysis of Multiple Surveillance Sites, PLOS Medicine 10(9): e1001517. (2013) https://doi.org/10.1371/journal.pmed.1001517 c. Goldblatt, D et al., Pneumococcal conjugate vaccine 13 delivered as one primary and one booster dose (1 + 1) compared with two primary doses and a booster (2 + 1) in UK infants: a multicentre, parallel group randomised controlled trial, The Lancet Infectious Diseases, Volume 18 , Issue 2 , 171 – 179 d. O'Brien, KL, When less is more: how many doses of PCV are enough?, The Lancet Infectious Diseases , Volume 18 , Issue 2 , 127 - 128