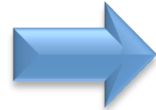


Product Development for Vaccines Advisory Committee

Highlights from 2015 year for Vaccine Development

**110
pathogens**



Pipeline Analyses
List will change each
year
Emerging pathogens
included in 2015



**577
candidate
vaccine
approaches**

24 pathogens

Pathogens screened this year

- | | |
|-------------|----------------------------|
| Viral | • Chikungunya |
| | • Dengue |
| | • EV71 |
| | • HIV |
| | • HSV |
| | • Influenza (Universal) |
| | • RSV |
| | • MERS |
| | • Nipah |
| • Norovirus | |
| Gram + | • Group A Streptococcal |
| | • Group B Streptococcal |
| | • Streptococcus pneumoniae |

- | | |
|-----------|----------------------------|
| Gram - | • Campylobacter |
| | • ETEC |
| | • Non-typhoidal salmonella |
| | • Shigella |
| | • Paratyphoid fever |
| Parasitic | • TB |
| | • Chagas disease |
| | • Hookworm |
| | • Leishmaniasis |
| | • Malaria |
| | • Schistosomiasis |

WHO RSV vaccine consultation held March 2015

- Pathway for 3rd trimester maternal immunization agreed
- Pilot case definitions for severe/very severe RSV LRI for LMIC trials agreed
- Global epidemiology/disease burden group has agreed to pilot these case definitions
- WHO is strengthening RSV surveillance
- Comparisons of candidate reference reagents for RSV neutralising antibody underway (ECBS)

Data now available from clinical trials in pregnant women

Group B streptococcal vaccines:

Group B Strep highlighted as:

- a pathogen area with substantial disease burden,
- part of a maternal immunization agenda,
- likely technical feasibility to development a vaccine,
- two large manufacturers engaged

***First WHO GBS vaccine consultation planned
March 2016***

Group A streptococcal vaccines:

- Group A Strep with likely technical feasibility to develop a vaccine, but suboptimal industry engagement
- Lack of clarity about priority indications/use scenarios, and regulatory pathways to achieve them
- PDVAC suggested the field would benefit from development of a dual market investment case – pharyngitis/invasive disease in high income countries & ARF/RHD/PSGN in parts of Africa, Asia & Australasia
- An area where greater engagement from industry would be very beneficial
- Disease burden very substantial
- Could also fit into agenda for prevention of over-use of antibiotics/ antimicrobial resistance

Norovirus

- Fairly advanced candidate in Phase 2 with Takeda
- Large gaps in disease burden knowledge in LMIC – potentially over 100,000 deaths per year in children
- Plans to explore whether to add norovirus to rotavirus surveillance network (for discussion Nov 2015 at Network meeting)

New enteric vaccine technologies

- ETEC possibly progressing to Phase 3 by 2017.
- Presently unclear whether Phase 3 will be ETEC alone, ETEC/Shigella or ETEC/rotavirus combination

PDVAC will continue to track and may provide guidance on best practices for trial design by 2017 or so.

HSV vaccines

- Global roadmap for development of vaccines against sexually transmitted infections (STIs) in 2014
- HSV vaccines: Both prophylactic and therapeutic candidates in clinical development
- Roadmap progress, 2015: Global HSV-2 & HSV-1 estimates, HSV vaccine impact modelling consultation, work plan for comprehensive business case
- PDVAC supports building business case and roadmap, esp:
 - Better data on neonatal herpes in LMICs (e.g., via CHAMPS network)
 - Updated assessments of role of HSV in HIV epidemics

For 2016:

- Continuing work in RSV: note For information agenda item in April 2016. Example whereby PDVAC has informed SAGE agenda
- Scoping activities in Group B Strep
- Supporting development of investment case for Group A Strep
- Consideration of strengthening of norovirus surveillance
- Developing workplan related to ETEC/Shigella

Lessons from Ebola for PDVAC

- Ring Vaccination Design
- Still early to be clear what broader implications will be for Vaccine Development
- Emerging pathogen agenda to be included
- Preclinical assays and models to be within scope