# Current Trends in the Research Pipeline for AMR-Related Vaccines and Diagnostics

Kent E. Kester, M.D.

# Disclosures

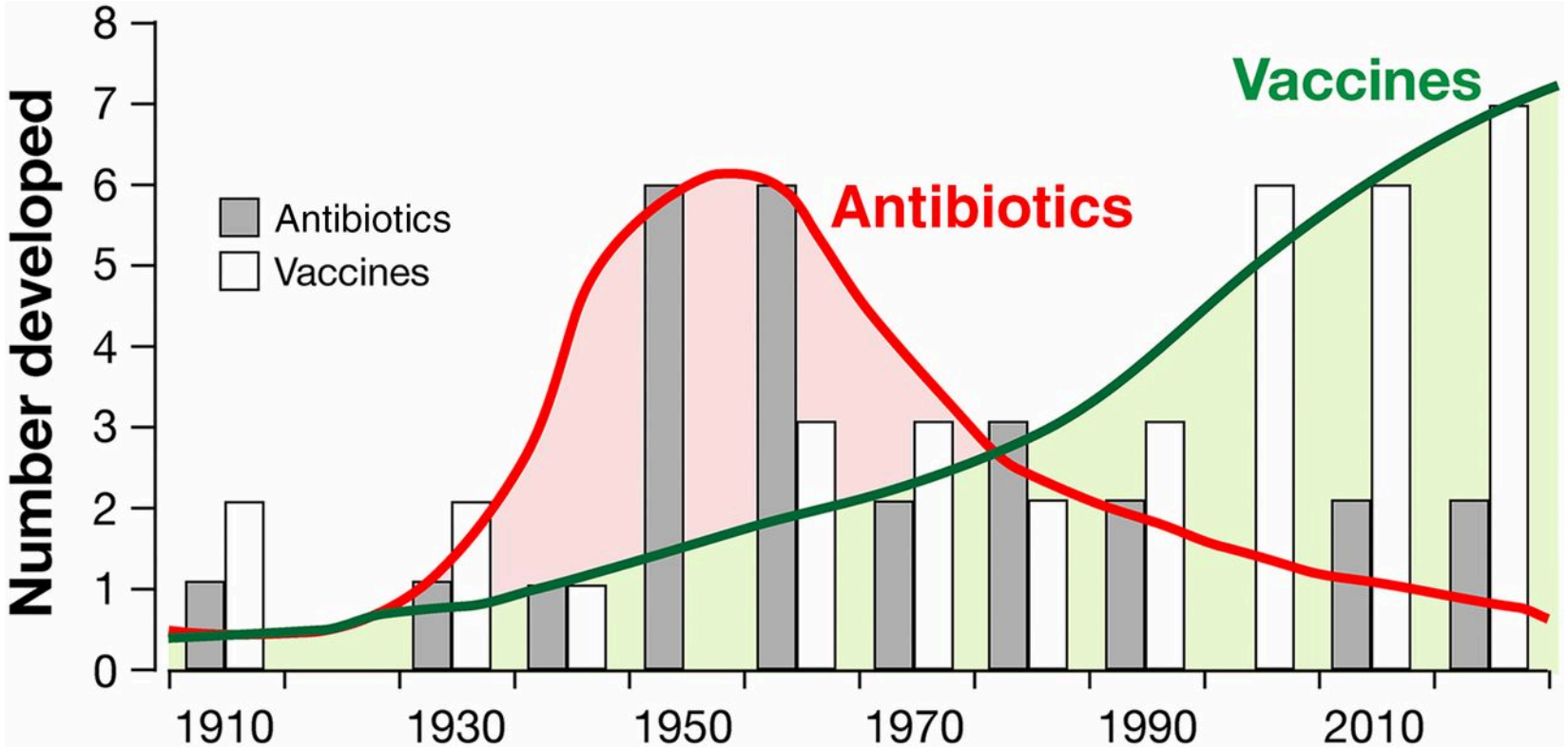
- Employee of Sanofi Pasteur, Inc.

- All presentation topics are my own opinion and do not reflect the official policy of my employer.

# The Role of Vaccines and Diagnostics in Antimicrobial Resistance

- Vaccines
  - Vaccines to protect against infection from bacteria that have a propensity for antibiotic resistance (e.g., *Pseudomonas*, *Acinetobacter*, etc.)
  - Vaccines for viral respiratory pathogens whose syndromes may be mistaken for a bacterial infection or bacterial pathogens for which antibiotic administration can be curtailed
    - Successful vaccine prevents the viral infection and thereby reduces inappropriate antibiotic prescribing
- Diagnostics
  - Diagnosis (rapid) of antibiotic resistance in clinical isolates (e.g., blood, sputum, urine, etc.)
  - Assessment of bacterial isolates for susceptibility against new antibiotics

**Vaccines and antibiotics licensed during the last century, showing the golden era of antibiotics in 1950s, the present golden era of vaccines, and the limited pipeline of new antibiotics during the last decades.**




David E. Bloom et al. PNAS 2018;115:51:12868-12871

# Vaccine Pipeline

- A challenging environment for pathogen-specific vaccines owing to commercial considerations (e.g., cost of development and anticipated market)
- New technologies being exploited (e.g., mRNA, new adjuvants, new expression systems, systems biology, reverse vaccinology, structural vaccinology, bioconjugates)—regulatory pathway not always clear
- NIAID: continued AMR research support
  - Establishment of four Cooperative Research Centers focused on developing vaccines to prevent sexually transmitted infections
- CARB-X: investments in *S. aureus*, Group A streptococcal, and *Klebsiella* vaccines

# Bacterial Vaccine Pipeline

- *Pseudomonas* (CF)
- *E. coli* (UTI)
- *Klebsiella*
- *A. baumannii*
- Non-typable *H. influenzae/M. catarrhalis* (COPD)
- *C. difficile*
- Pneumococcal
- *N. gonorrhoeae*
- *S. aureus*/MRSA
- Group B streptococci (neonatal sepsis)

- Academic/Biotech
- Academic/Biotech
- Academic/Biotech
- Academic/Biotech
- Biotech/Large Industry

- Biotech/Large industry
- Large Industry
- Government/Academic/Biotech
- Academic/Biotech/Large Industry (?)
- Nonprofit/Large Industry

# Viral Vaccine Pipeline

- Improved Influenza Vaccine (“Universal Influenza Vaccine”)
- RSV (infants and elderly)
- Human Metapneumovirus

- Government/Academic/Biotech/ Large Industry
- Government/Academic/Biotech/ Large Industry
- Biotech

# Diagnostics Pipeline

- Multiplicity of new technologies relevant for diagnostic purposes
  - In some cases, the technology is moving faster than the regulatory processes
- Molecular amplification, sequencing, imaging technology, detection of VOCs, etc.
- Cost is a major issue
  - Acquisition and support of new diagnostic platforms
  - Reimbursement/payers impact on hospital adoption of new technologies
- NIAID AMR support
- CARB-X investment in innovative technologies

# Examples of New AMR-Related Diagnostic Approaches

- Direct from specimen diagnostics for more rapid testing of bloodstream infections
- Single cell biometric analysis
- Optical bacterial imaging
- Sensor arrays to detect VOCs in blood culture samples
- Molecular-based POC testing for chlamydia/GC directly from a patient sample

# Pipeline Outlook

- Vaccines can clearly play a role in the fight against AMR
  - Lots of innovative approaches to vaccine development
  - Cost of development and commercial factors will continue to be of concern
  - Novel approaches may have regulatory complexities

- Wealth of innovative technologies relevant for AMR-related diagnostics
  - Cost factors (especially related to reimbursement) are a significant barrier for expensive new diagnostic platforms

Thank You.