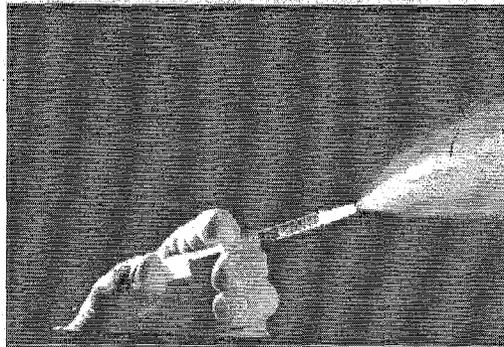


Aviron



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FluMist
(CAIV-T, LAIV)

An Influenza Vaccine
For Use in Healthy Children and Adults
Age 1 – 64

Introduction

Harry Greenberg, MD
Aviron

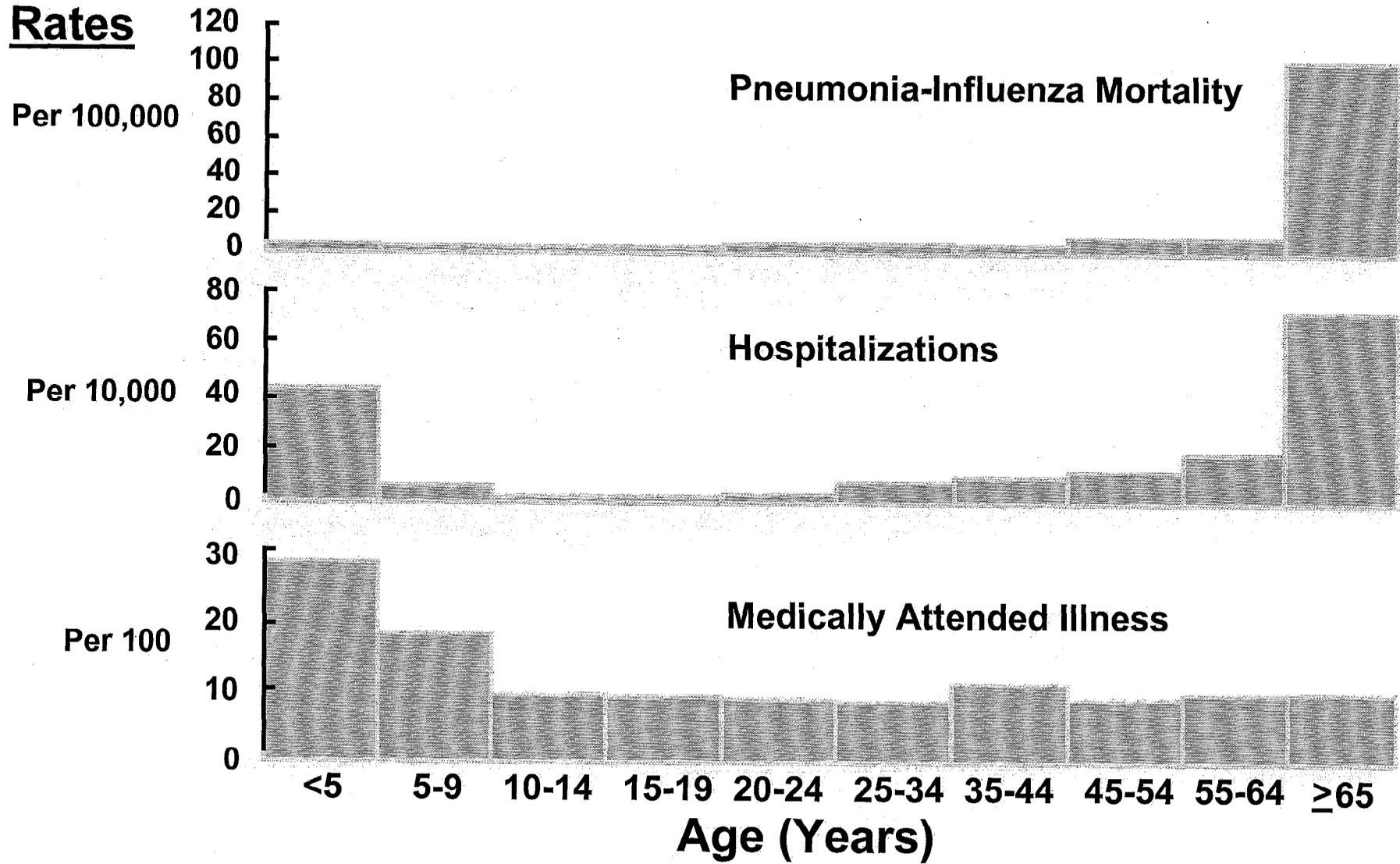
Proposed Indications

- **Annual immunization for prevention of influenza in:**
 - **Healthy children 1 - 17 years of age**
 - **Two doses (one month apart) for previously unvaccinated children < 9 years of age**
 - **One dose for previously vaccinated children and children ≥ 9 years of age**
 - **Healthy adults 18 - 64 years of age**
 - **One dose**

Not Proposed for Use in:

- **High risk children and adults**
- **People with a history of allergy to chicken eggs**
- **Children or adolescents receiving aspirin**
- **Pregnancy**
- **Concurrent vaccination**

Influenza-related Morbidity and Mortality



Glezen WP. Emerging infections: pandemic influenza. *Epidemiol Rev.* 1996; 18(1),64-76.

Limitations of Current Influenza Vaccine Program

- **150 million healthy people currently not vaccinated**
 - Vaccination rate in healthy children less than 10%
 - Vaccination rate in healthy adults less than 30%
- **Need already outstrips supply**
- **Annual injection required**
 - Not delivered to mucosal surface

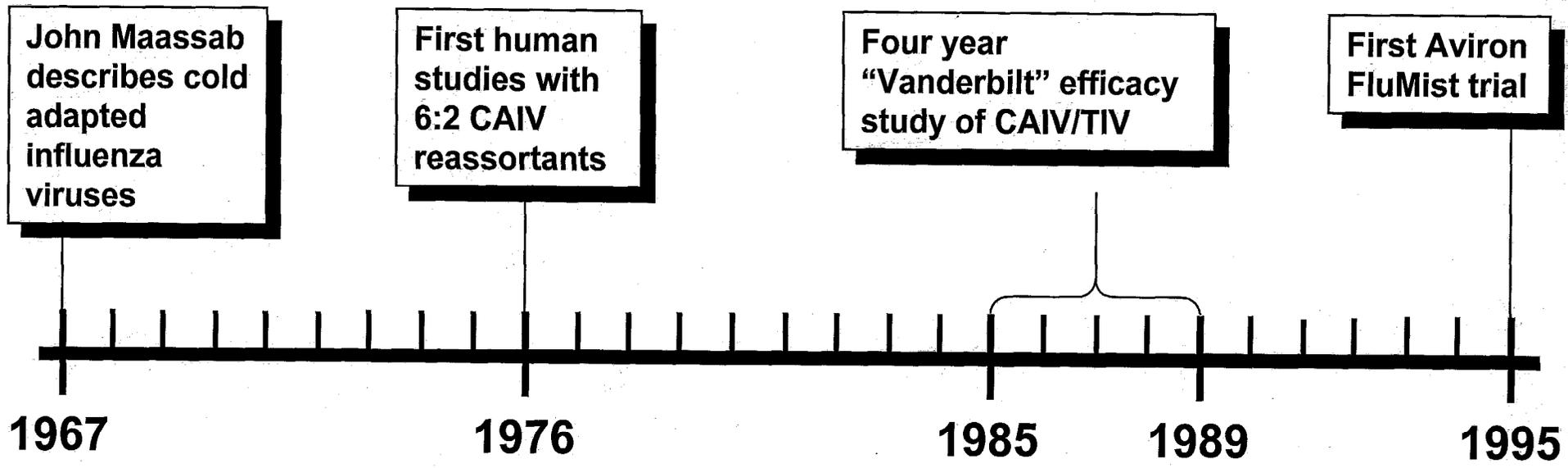
FluMist

- Contains HA and NA gene segments of current epidemic influenza viruses and remaining 6 gene segments from attenuated Master Donor Virus
- Manufactured in specific pathogen-free eggs
- No thimerosal, stored frozen
- Trivalent (H1N1, H3N2, B), containing 10^7 TCID₅₀ of each strain / 0.5ml dose
- Administered by nasal sprayer as a large particle mist (60 μ average diameter) .25ml / nostril

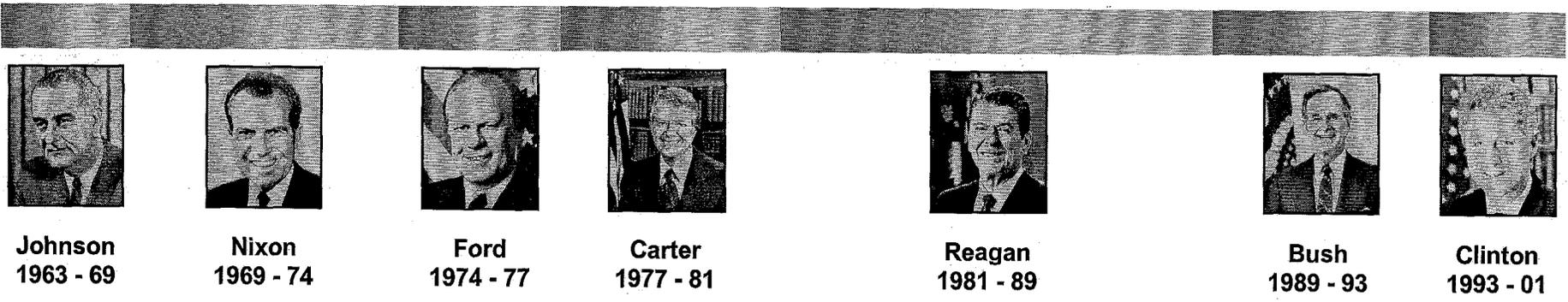
Vaccine Administration



Live Influenza Vaccine Milestones: The First Three Decades



By 1995, 19 separate influenza strains in over 8,000 people tested as CAIV reassortants



Differences between FluMist and Historical Experience with CAIV

- **Trivalent composition**
- **Annual update of strains**
- **Consistent dose in children and adults**
- **Consistent 6:2 genotype**
- **Large particle mist administration**
- **Multiple large scale clinical trials in children and adults**

Presentations

- **Large Scale Safety in Children - The Kaiser Study**
Steven B. Black, MD
Northern California Kaiser Permanente
- **Safety in Children and Adults**
Paul M. Mendelman, MD, Aviron
- **Efficacy and Effectiveness in Adults**
Kristin L. Nichol, MD, University of Minnesota and
The Minneapolis VA Medical Center
- **Efficacy and Effectiveness in Children**
Robert B. Belshe, MD,
Saint Louis University Medical Center
- **Conclusions**
Harry B. Greenberg, MD, Aviron