

# A Perspective on the 1976 Swine Influenza Experience: Lessons Learned



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# 5 Major Lessons for Regulators

Lesson 1: Expect the unexpected from the vaccine(s) and their manufacturing

Vaccine yields may be low, mishaps occur, and production timelines likely to lengthen

Different vaccines and different viral strains may behave differently in terms of safety or immunogenicity

Similar vaccines from different manufacturers may behave differently

Safety and immunogenicity may differ between the young and old (whole virus vaccines and children)

Actions: Estimates should allow adequate time for production, try to obtain appropriate data in different age groups pre-pandemic, do a careful and independent regulatory review, update as needed as new information is developed

Share information & know-how internationally

# **5 Major Lessons: continued**

- **Lesson 2: Actions and potentially high risk short-cuts that may be appropriate and needed in an emerging crisis or actual emergency may not be appropriate prior to one**
- **Action: Solve problems pre-pandemic, take special care with new manufacturers, processes and/or facilities, build in redundancy prior to emergency**

# 5 Major Lessons: continued

- **Lesson 3: Unexpected adverse events will occur, whether coincidental or vaccine related, and anxiety and panic may result. Similarly, efficacy will not be well known before a pandemic.**
- **Actions:**
- **Put in place robust rapid detection systems using health care databases (e.g., FDA/CDC joint effort)**
  - Where possible know population background rates of relevant serious potential events (e.g., GBS, other neurologic disease, common ailments such as MI, sudden death)
  - Pre-position for international information sharing
  - Pre-position for efficacy assessments

# 5 Major Lessons: cont.

- Lesson 4: Clear communication re: all benefits/risks of vaccine critical
  - Includes balanced communication of uncertain risk of pandemic as vaccine benefit depends on it
  - Includes uncertainties about vaccine safety and effectiveness
  - Recognize different audiences
- Safety concerns and expectations important and significant (even more today) and can affect, even derail, vaccination plans
- Confidence in vaccines, governments, industry and public health systems will be on the line

# 5 Major Lessons: cont.

- Actions:
  - Utilize outside advisors where feasible/helpful to vet policy and help communicate
  - Have cross-agency and international communications plans and processes in place.
  - Where possible address dissent and differences
  - Develop clear, consistent messages ahead of time
  - Be candid about information gaps – internally and externally
  - Utilize experienced spokespersons and media
- Be prepared for adverse events and product problems – be confident in quality control in lot release and manufacturing, have rapid surge testing capacity, and inspectional ability available if needed

# 5 Major Lessons

- Lesson 5: Success is possible
  - The US successfully produced and administered a large amount of flu vaccine rapidly in 1976
  - Our capacity and knowledge is greater today
- Actions: Build high quality and flexible vaccine manufacturing capacity, assess vaccines carefully pre-pandemic, be prepared to monitor closely in use, learn the lessons of 1976, but without paralysis.
- It may be possible, with adequate warning of human to human transmission, or with priming/pre-vaccination approaches, to greatly reduce the morbidity, mortality, and costs of a future pandemic