

Novel Influenza A (H1N1) Outbreak and Response:

Vaccine Safety Monitoring

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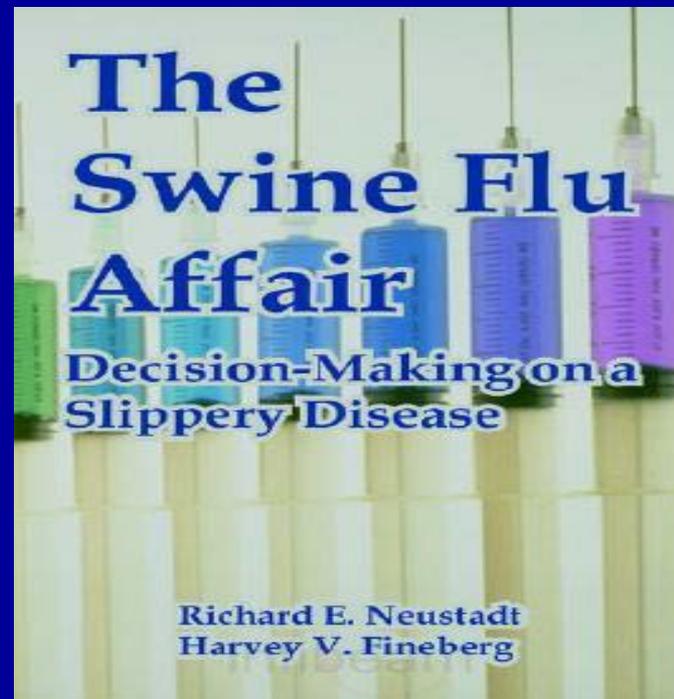
National Vaccine Program Office

Department of Health and Human Services



Importance of Monitoring H1N1 Vaccine Safety

Lessons from the 1976 mass vaccination
campaign



Importance of Monitoring H1N1 Vaccine Safety

- Lessons from the 1976 mass vaccination campaign
- New vaccine, potential new adjuvant
- Limited pre-use data
- Special populations may be given the vaccine early in the campaign
- Public trust and confidence



Monitoring H1N1 Vaccine Safety

What is Needed?

- Identify AEFI and quickly evaluate if caused by vaccine
 - GBS in 1976
- Quickly address spurious associations
 - Pregnant women



Example: Background Rates in Subpopulations

- Pregnant women are listed in Tier 1 in current guidance for vaccine allocation
 - 6 million clinically recognized pregnancies in the US each year
 - 15% end in a clinically recognized spontaneous abortion
 - 900,000 clinically recognized spontaneous abortions each year
 - 2,466 clinically recognized spontaneous abortions each day
 - **With 50% vaccine coverage, @1,200 spontaneous abortions within 24 hours of vaccination**



Monitoring H1N1 Vaccine Safety

What is Needed?

- Identify AEFI and quickly evaluate if caused by vaccine
 - GBS in 1976
- Quickly address spurious associations
 - Pregnant women
- Ability to distinguish between the two



Brief Review of Current Safety Monitoring

- Passive Surveillance – VAERS
- Active Surveillance – VSD
- Clinical Assessment – CISA
- DoD
- VA



VAERS

- Co-administered by CDC and FDA
- Accepts reports from physicians, other HC providers, and the public
- Limitations
 - Under reporting
 - Incomplete data
- Designed for detecting signals or generating hypothesis
 - Can not assess causality



VSD

- Large linked database of 8 MCOs administered by CDC
 - @ 2% of pop. < 18 yrs.
 - @ 1.5% of pop. > 18 yrs.
- Includes exposure data (vaccine history), outpatient, ER, hospital and laboratory
- Hypothesis testing



CISA

- Investigate pathophysiologic mechanisms and biologic risks for adverse reactions
- Review VAERS reports
- Develop clinical guidance



DoD

- Use VAERS system
- Reportable Medical Events system – mandatory for AEFI that result in missed duty or hospitalization
- Spontaneous reporting to Vaccine Health Care Network (VHCN)
- Clinical data repository – Defense Medical Surveillance System (DMSS)
 - Links vx with military health care interactions
- Electronic medical record database
 - Includes lab, imaging, specimen, pharmacy records
- Military Vaccine Reporting System (MVRS)
 - Active surveillance of vaccinated to solicit AEFI
 - Allows request to be contacted by HC provider
- VHCN repository



Dept. Veterans Affairs (VA)

- Passive surveillance through VA ADERS
- Active surveillance of influenza and pneumococcal vaccines in collaboration with FDA
- Developing Rapid Cycle Analysis



A COMPREHENSIVE REVIEW OF FEDERAL VACCINE SAFETY PROGRAMS AND PUBLIC HEALTH ACTIVITIES

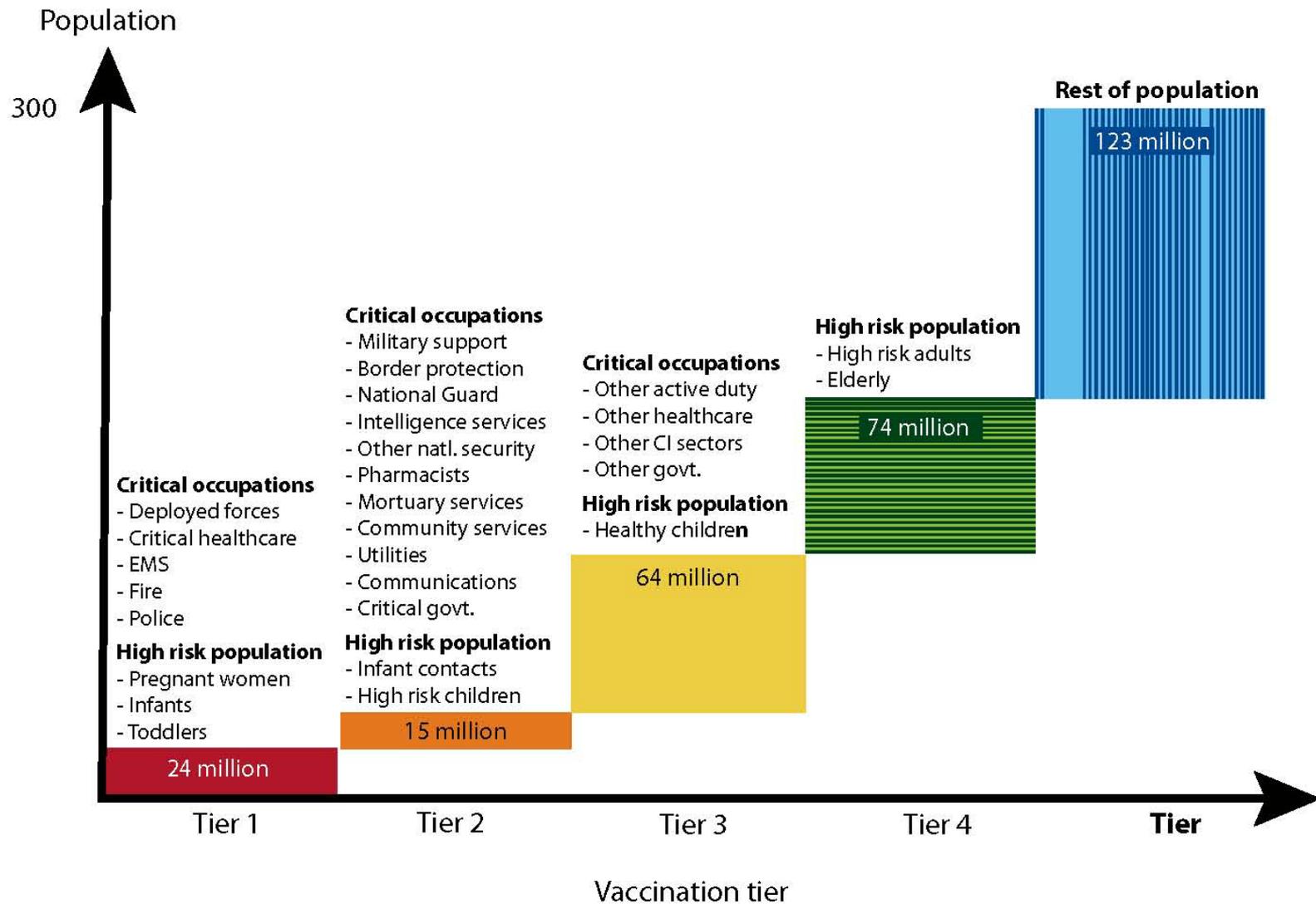
[http://www.hhs.gov/nvpo/nvac/documents/
vaccine-safety-review.pdf](http://www.hhs.gov/nvpo/nvac/documents/vaccine-safety-review.pdf)



H1N1 Vaccine Uncertainties Relating to Safety Monitoring

- Vaccine(s)
 - Formulation?
 - Adjuvant?
 - Number of doses?
- Distribution
 - Who will get the vaccine first?
 - Are those who first receive the vaccine captured under current surveillance systems?
 - Through what sector will the vaccine be delivered?





<http://www.pandemicflu.gov/vaccine/allocationguidance.pdf>



Challenges

- Linking exposure (receipt of vaccine) data and outcomes data
 - Linking maternal immunization to outcomes in the infant
- More than one vaccine may be used
- Identifying lot-specific issues
- Active surveillance, particularly of high priority groups
- Background rates
- Linking with States' plans and data

