Update: The National Influenza Vaccine Summit 2009 Meeting

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Disclaimer…

The opinions expressed in this presentation are solely those of the presenter and do not necessarily represent the official position of the American Medical Association

The National Influenza Vaccine Summit is…

- Co-sponsored by AMA and CDC
- A partnership of organizational stakeholders, both private and public, in influenza vaccine research, production, distribution, advocacy, and administration
- All committed to achieving the Healthy People 2010 goals for influenza vaccine
- Contact L.J Tan (Litjen.Tan@ama-assn.org) for more information
- All presentations will be available at www.preventinfluenza.org; Executive Summary will be available in two weeks

Summit Creates United Influenza Vaccination Goals

- Improve transparency and communications between partners around influenza vaccine supply and distribution
- Increase awareness about severity of influenza, benefits of vaccination throughout season
- Advocacy to change policy
- Achieve national/local media coverage
- Provide timely communications between Influenza Vaccine Summit stakeholders
  - Email Updates, weekly conference calls
  - Extend communications messages to the grassroots levels

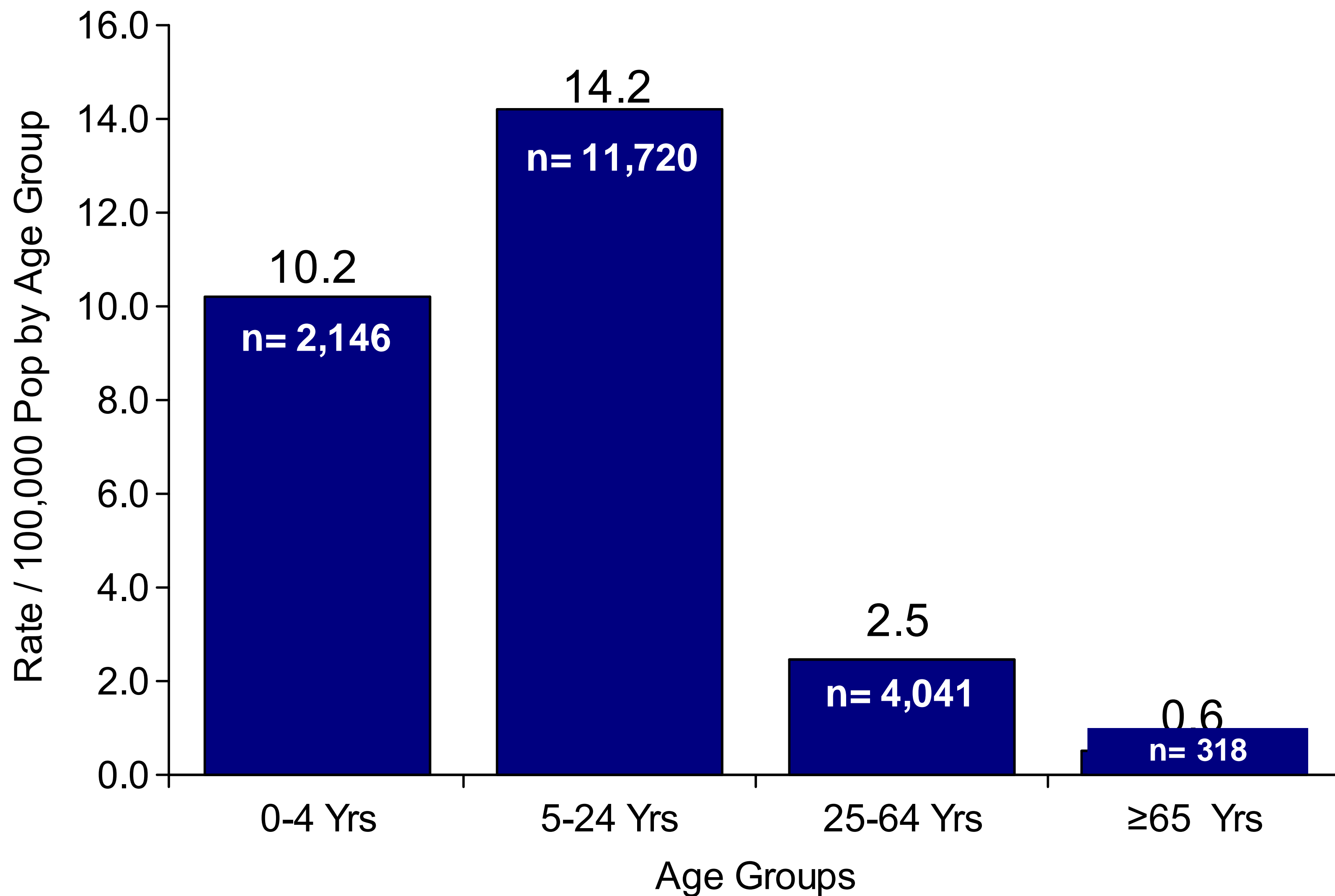
The 2009 National Influenza Vaccine Summit Meeting

- Record attendance – more than 287 registered participants representing 153 organizations covering 30 states and 3 foreign countries!
- Update on influenza – Including pandemic H1N1
- Multiple sessions to provide basis for 2009-2010 action items
  - Real time influenza immunization surveillance data
  - Improving health care worker rates
  - Ensuring influenza vaccination for patients of private providers
  - Communications surrounding influenza vaccination
  - Improving influenza immunization for 18-and-younger
  - Expanding the influenza immunization season

Pandemic H1N1 Influenza

- On April 15, 2009 a novel swine-origin influenza A H1N1 virus was identified in a boy in California
- 27,717 reported cases in US
- 55,000 reported worldwide
- Majority of persons hospitalized and who died had underlying conditions
- Given the rapidly evolving outbreak more cases are expected and transmission will likely continue into the influenza season

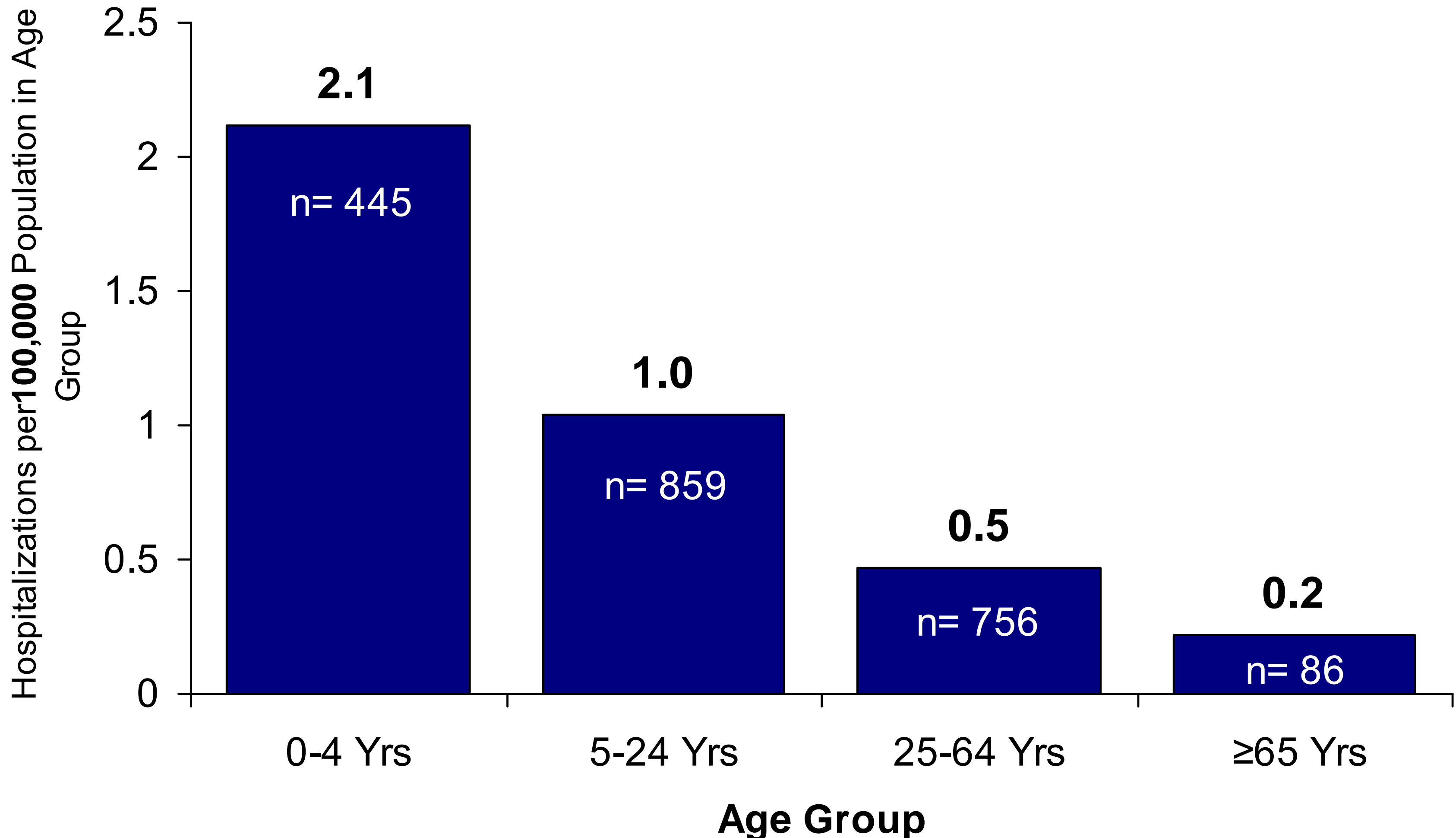
Epidemiology/Surveillance, Pandemic H1N1 Cases Rate per 100,000 Population by Age Group - As of 18 JUN 2009 (n=18,125*)



*Excludes 3,324 cases with missing ages.

Rate / 100,000 by Single Year Age Groups: Denominator source: 2008 Census Estimates, U.S. Census Bureau at: http://www.census.gov/popest/national/asrh/files/NC-EST2007-ALLDATA-R-File24.csv

Epidemiology/Surveillance, Pandemic H1N1 Hospitalization Rates* by Age Group (n=2,228) - As of 18 Jun 2009



*Hospitalizations with unknown ages are not included (n=82)

*Rate / 100,000 by Single Year Age Groups: Denominator source: 2008 Census Estimates, U.S. Census Bureau at: http://www.census.gov/popest/national/asrh/files/NC-EST2007-ALLDATA-R-File24.csv

Hospitalizations

- 3,065 hospitalizations among 27,717 cases
- Detailed clinical data available on ~268 patients
  - 21% admitted ICU
  - 13% mechanical ventilation
  - 17 deaths
- Median time from onset of illness to hospital admission
  - 3 days (range 1-14 days)
- Median length of stay
  - 3 days (range 1-53)

Descriptive Epidemiology

- 128 female (48%), 140 male (52%)
- Median age 22 years (range 21 days-86 years)

Age Groups	Hospitalized No (%) n=268
0-23 months	24 (9)
2-4 years	20 (8)
5-9 years	28 (10)
10-18 years	55 (20)
19-49 years	95 (35)
50-64 years	31 (12)
≥65 years	15 (6)

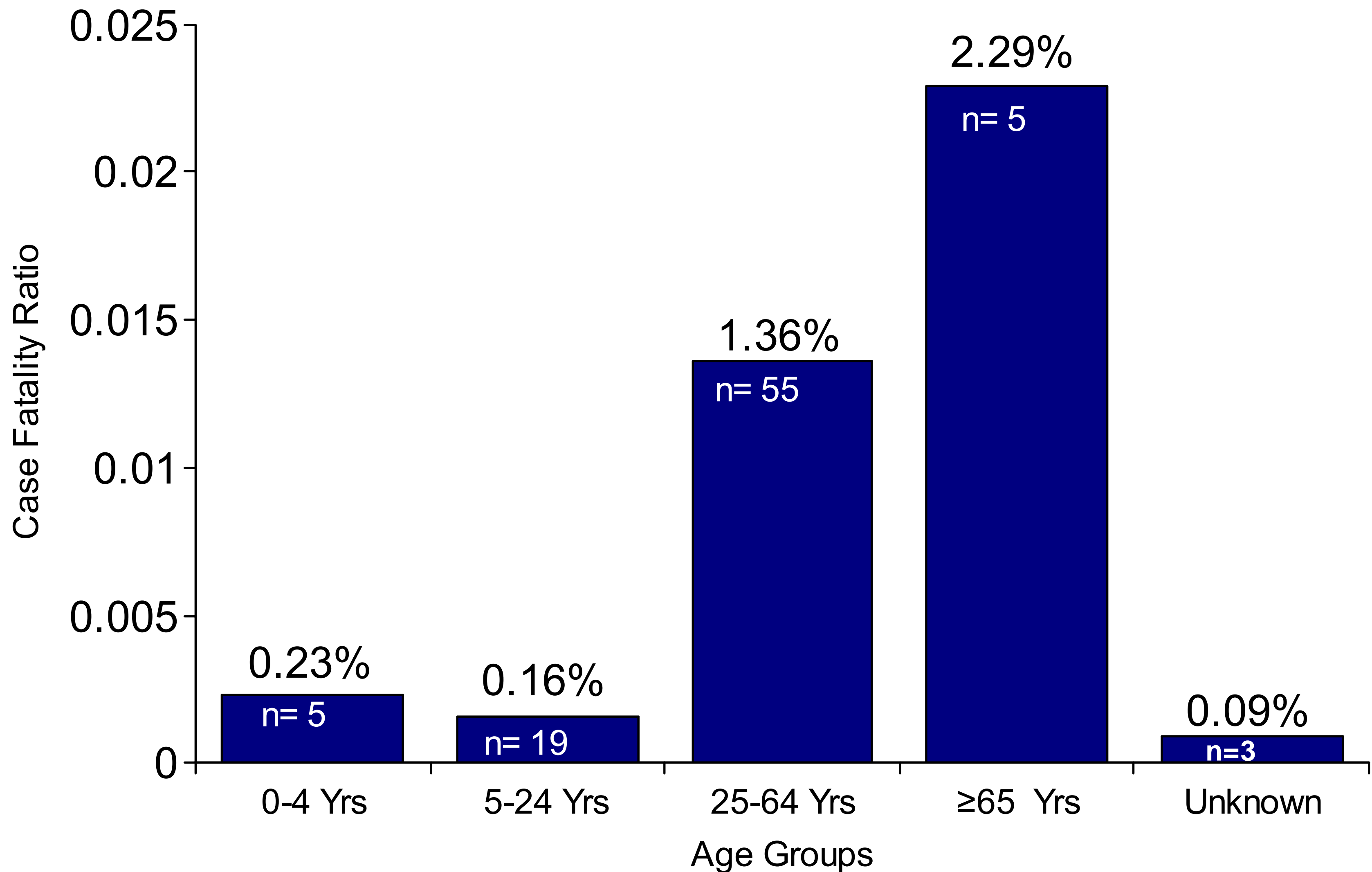
Underlying Conditions

Condition	No (%)
Asthma or COPD	32%
Diabetes	16%
Immunocompromised	12%
Chronic cardiovascular disease**	11%
Neurocognitive disorder	8%
Neuromuscular disorder	8%
Current Smoker	10%
Pregnant	7%
Chronic Renal Disease	8%
Seizure disorder	6%
Cancer	3%

71% with underlying conditions

* 51 people had more than one underlying condition; median 1 (range 1-6)

Epidemiology/Surveillance, Pandemic H1N1 Case Fatality Ratio by Age Group - Data reported as of 18 JUN 2009 (n=87)



Epidemiology/Surveillance, Pandemic (H1N1) Deaths Reported to CDC by States as of 25 JUN 2009

- Limited data available on 99/111 deaths in 20 states
- 49 Female (53%), 44 Male (47%)
- Race/Ethnicity (N=47)
  - 6 non-Hispanic Black (13 %)
  - 19 non-Hispanic White (40%)
  - **19 Hispanic (40%)**
  - 3 Other (6%)
- Median time from illness onset to death
  - 7.5 days (range 0 - 40 days)

Pandemic H1N1 Influenza Epi Summary

- Is the pandemic virus continuing to circulate?
  - Yes
- Are pandemic viruses circulating at same time as other influenza viruses?
  - Preliminarily, yes
- Are viruses changing?
  - Viral surveillance plans in place, existing platform to monitor
- Are epidemiologic parameters changing (e.g., attack rate, incubation period, etc.)?
  - Will be difficult to obtain representative data in most countries
  - Ongoing outbreaks in U.S. also provide data
- Are clinical manifestations changing (e.g., severity, secondary infections)?
  - Difficult given different healthcare parameters
  - Getting viruses from unusual or severe cases feasible
- Are community mitigation interventions working?
  - Perhaps possible to study in several countries, likely won't have lab confirmed outcomes

Rate of Confirmed and Probable Novel H1N1 Cases by State

As of June 24, 2009

District of Columbia

Puerto Rico

Cases per 100,000 Population

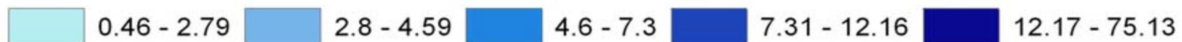
0.46 - 2.79

2.8 - 4.59

4.6 - 7.3

7.31 - 12.16

12.17 - 75.13



Previous pan flu planning assumptions

- Planning centered on influenza A H5N1 virus
- Disease would begin overseas
- Focused on a Pandemic Severity Index 5 scenario (severe, 1918-like)
- Assumed the potential for significant economic and social disruption
- Pre-pandemic influenza vaccine would be available for 20M critical infrastructure and key resources workers at the onset of a pandemic

Previous pan flu planning assumptions cont.

- Priority would be placed on development and production of a pandemic influenza vaccine
- Seasonal influenza vaccine production and vaccination efforts would be curtailed
- Limited number of pan flu vaccine manufacturers
- Pandemic influenza vaccine would be available in limited quantities in ~4-5 months
- Would initially implement a government-managed public sector vaccination program (federal, state and local public health w/public clinics)

Previous pan flu planning assumptions cont.

- **Goal to vaccinate all persons in the U.S. who choose to be vaccinated**

HOWEVER

- **Initial limited supply would necessitate prioritization of vaccine**

Novel Influenza A H1N1

- **Disease began in N. America and was detected towards end of the N. Hemisphere flu season**
- **Epidemiologic picture continues to emerge over the over summer 2009**
- **Vaccination planning must move forward rapidly in the summer to prepare for a fall 2009 vaccination campaign**
- **Necessary to plan for range of pandemic severity scenarios (mild, moderate, severe)**
- **Economic/social disruption may not be extensive**

Novel Influenza A H1N1 cont.

- Initial supply of H1N1 vaccine may be larger than estimates based on previous pandemic planning assumptions (for an H5N1 scenario)
- Vaccine priority groups will be evaluated and revised in the context of the current epi data
- Seasonal flu vaccine supply minimally affected by novel H1N1 vaccine development and production

Novel Influenza A H1N1 cont.

- Potential for confluence of seasonal and pandemic influenza vaccination
- More limited, targeted novel H1N1 vaccination campaign may be appropriate
- Scenario planning around implementation options is necessary

Uncertainties

- Vaccine supply: Amount and timing of availability
- Formulation (unadjuvanted, adjuvanted, combination)
- Priority groups recommended for vaccination
- Severity of illness, and timing of illness in relation to vaccine availability
- Timing of availability of H1N1 and seasonal vaccines
- Demand for an H1N1 vaccine

Challenges: Magnitude of vaccination effort

- Potentially
  - 600 million doses
  - 2 doses per person
- Compares with
  - ~150 million doses annually for all childhood vaccination
  - ~115 million doses maximum for annual flu vaccination
- May be necessary to coordinate with 1,000s of critical infrastructure and key resources sector businesses and organizations

Potential delivery models

- Public health-coordinated effort
- Mixed hybrid model that blends vaccination in
  - Public health-organized clinics
  - Traditional healthcare settings
  - Occupational settings
  - Retail settings

Key issues: Preparation

- Identifying and engaging providers
  - Public, private, community
- Developing payment mechanisms for vaccination
  - Funds to augment staffing for public health vaccination clinics (contracts for LHDs, community vaccinators)
  - Administration fee for private providers
      - Insured and Medicare/Medicaid
      - Vaccines for Children
      - Underinsured or uninsured adults

Key issues: Distribution

Two options

- Manufacturers/distributors ship vaccine to states using established distribution channels
- Centralized distribution (VFC-like program)

Allocation/ordering

Issues

- Need to determine how vaccine will be allocated amongst many potential vaccinating entities
- Provider vaccine need not certain
- Provider inventory capacity limited
- Ordering procedures will differ depending on distribution model

Key issues: Vaccinating

- Recording and reporting doses administered
- Respecting priority groups
- Assuring receipt of second dose
- Emergency Use Authorization (EUA) requirements, if applicable

Need for contingency planning…

- What is reasonable to expect with respect to private sector delivery
- Situation in the fall could be incompatible with private sector administration
- Approach that is not dependant on private sector must also be planned for

Overarching issues

- Coordination between programs at state level, and between state/local and federal levels
- Coordination with the private sector
- Expectation management

Some key activities

- Supplemental funding for accelerated planning and early implementation
- Vaccine Implementation Steering Committee (ASTHO, NACCHO, AIM, Preparedness Directors, CSTE, NPHIC)
- Working with provider organizations, and others
- Distribution planning
- Scenario development to guide planning

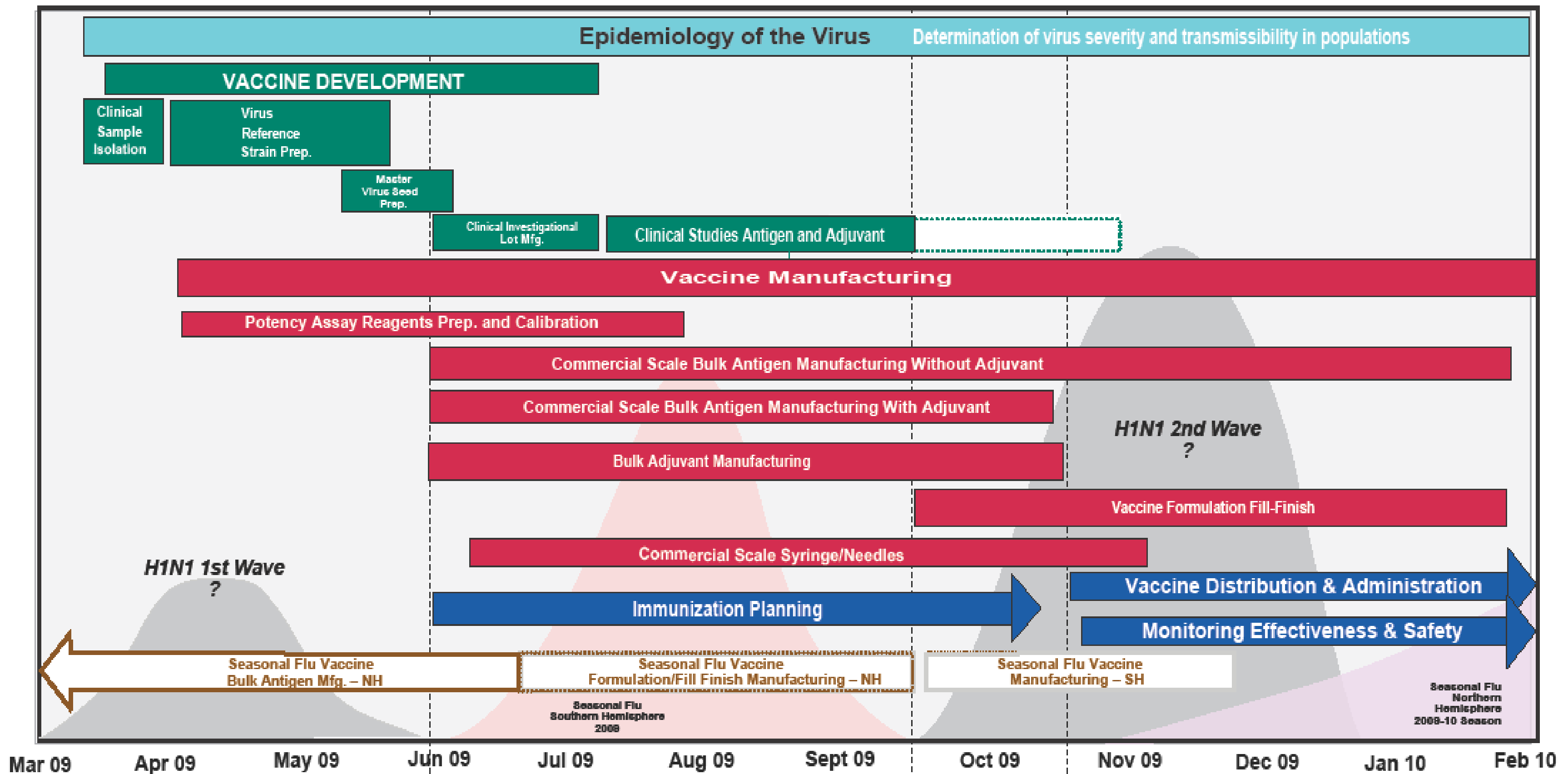
Timely identification of clinically significant adverse events

- Enhanced surveillance through Vaccine Adverse Event Reporting System (VAERS)
- Active surveillance using sequential analytic methods through Vaccine Safety Datalink sites and the Defense Medical Surveillance System
- Special studies: hospital admission/discharge data, neurologist surveys, other
  - Active case finding of incident GBS in multiple areas
  - May be done through EIP sites and/or in collaboration with American Academy of Neurology

Pandemic H1N1 Vaccine Strategy

- Clinical studies will inform vaccine formulation and safety profile
- Strain change: Anticipate licensure of formulations similar to seasonal influenza vaccine (antigen alone)
- Pre-EUA packages in preparation for vaccines with adjuvant
- Scenario-sensitive vaccine production & administration approach
- **Key *vaccine* decision issues:**
  - Vaccine type(s)
  - Preservative (thimerosal)
  - Adjuvant
- **Key *immunization program* issues:**
  - Prioritization of vaccine: Target groups
  - Implementation plans
  - Vaccine safety and effectiveness monitoring
  - Intersection with seasonal influenza vaccine program
  - Communications

US 2009 Pandemic H1N1 Vaccine and Immunization Strategy



FOUO

The Difference between Avian Influenza and Swine Influenza

- The best solution for avian influenza is tweetment!

- The best solution for swine influenza is oinkment!

Update on Influenza: ACIP Directions

- Seasonal Influenza recommendations to be published in MMWR soon
- ACIP Special pandemic H1N1 public session planned for July 29th.
- Some considerations:
  - Recommendations for use of pandemic vaccine based on clinical trials for VE and safety
  - How might a pandemic influenza vaccine program co-exist with a seasonal program?
  - Plan for near simultaneous seasonal and H1N1 vaccine programs

Update on Influenza: ACIP Directions

- Current ACIP guidelines indicate use can begin when vaccine available
  - Provides protection even when early circulation of influenza viruses
  - No evidence for clinically important waning immunity among those vaccinated in late summer and early fall
  - Reduces overlap between pandemic and seasonal vaccine campaigns

ACIP role and plans in pandemic planning

- Review epidemiologic data, vaccine studies, and and program planning
- Develop and review plans for vaccination targeting and early receipt of vaccine
  - Need to reassess existing vaccine prioritization plan
- Suggest ways to reduce impact on seasonal vaccination program
- Begin development of guidance for pandemic influenza H1N1 vaccine use

Novel Real Time influenza vaccination monitoring

- Considerable interest in measuring vaccination rates in real time
  - Affords potential to target populations where uptake is poor
  - Affords subtle shifts in messaging to improve uptake mid season
- RAND Rapid Survey Project
- SDI Medical Claims data analysis and FluSTAR

Novel Real Time influenza vaccination monitoring

- RAND Rapid Survey Project
  - Surveys administered to members of the "Knowledge Panel"
    - 40,000 households recruited with known probability
    - Sample includes non computer users
  - Sampling weights based on US Census data make uptake estimates nationally representative
  - Studies using Knowledge Networks are published in high-quality health journals
  - Coverage rate estimates compare favorably to NHIS

Novel Real Time influenza vaccination monitoring

- RAND Rapid Survey Project
  - Three nationally representative surveys of US adults age 18 and older
    - End-of-season 2007-08 (n=3,043)
    - Midseason 2008-09 (n=3,972)
    - End-of-season 2008-09 (n=5,203)
  - Results available in just over one month, e.g.,
    - Midseason survey fielded November 7-19, 2008
    - Short, peer-reviewed report on RAND's website December 10, 2008

Novel Real Time influenza vaccination monitoring

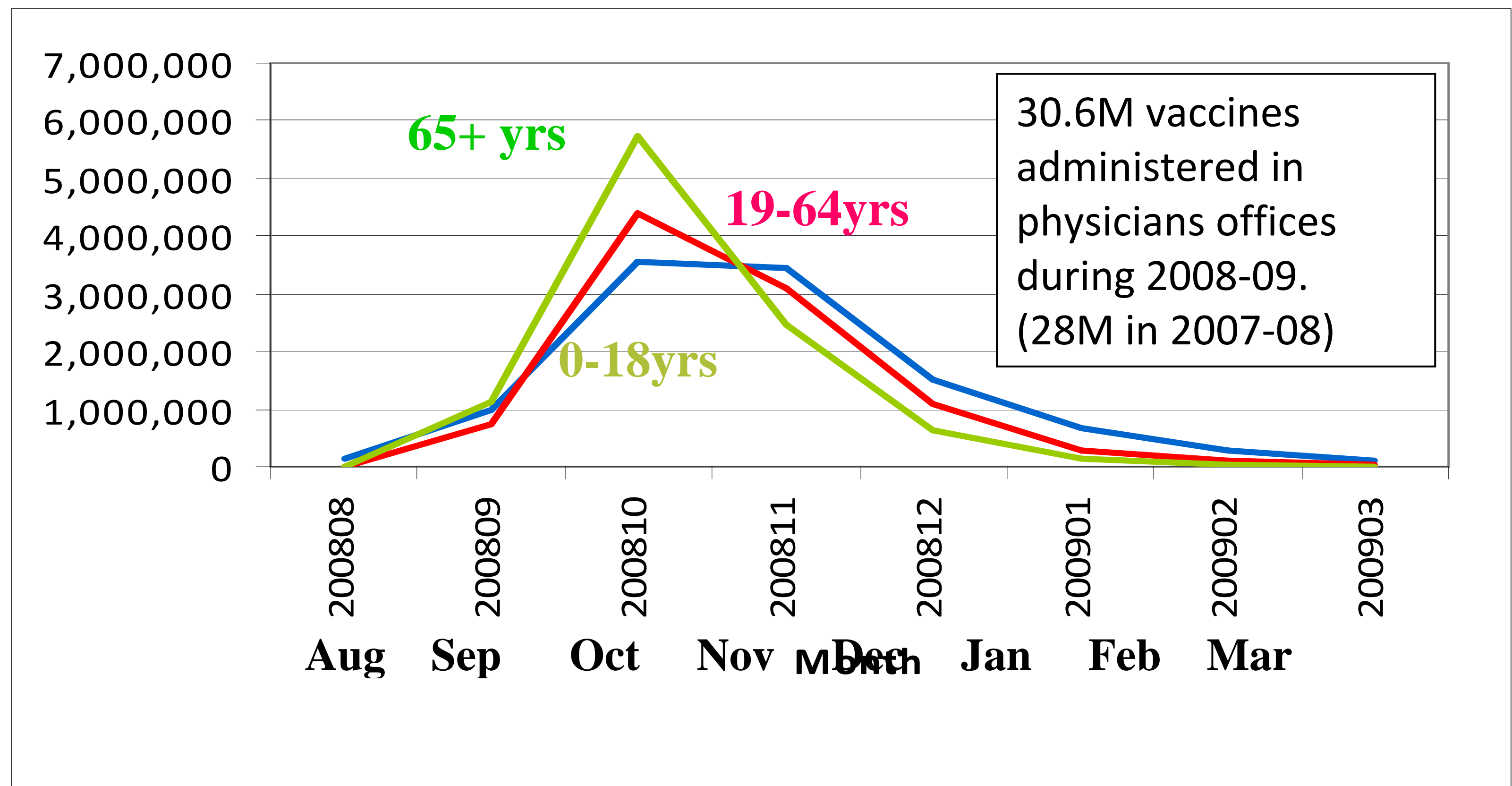
- RAND Rapid Survey Project
  - Just over one-third of adults 18 and older were vaccinated during the 2008-09 season
  - Uptake varied among adults with specific ACIP recommendations
    - Uptake among elderly exceeds that for other recommended groups
  - A substantial proportion of the unvaccinated had no intention of being vaccinated

Novel Real Time influenza vaccination monitoring

- RAND Rapid Survey Project
  - Contrary to conventional wisdom, people appear to accept vaccine late in the season
  - Data highlights importance of recommendations and reminders in achieving current uptake
  - Near-term efforts might target the 7% who intended to be vaccinated, but were not
  - Healthcare workers were more positive about vaccine, but appear somewhat misinformed

Novel Real Time influenza vaccination monitoring

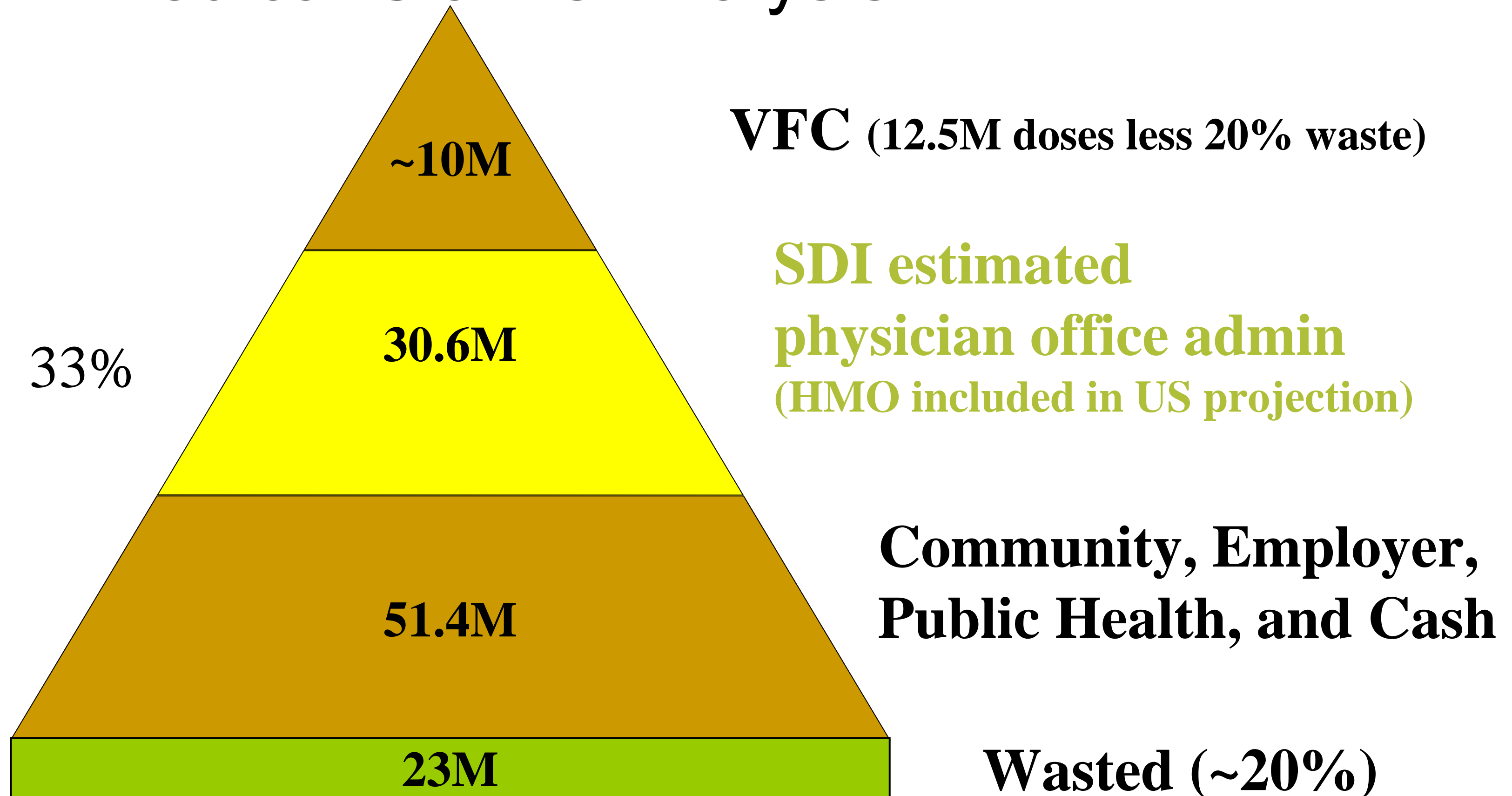
- SDI Medical Claims Analysis



Total US availability in 2008-09: 115M doses

Novel Real Time influenza vaccination monitoring

- SDI Medical Claims Analysis



Total Doses Distributed = 115M doses

Novel Real Time influenza vaccination monitoring

- SDI Medical Claims Analysis
  - Influenza vaccine administered in physician offices for ‘08/09 saw a 8% increase compared with the ‘07/08 season, mostly due to gains in Sept-Oct
  - In 18-and-under, influenza vaccine administered in physician offices for ‘08/09 saw a 7% increase compared with the ‘07/08 season, mostly due to gains in October
  - SDI data thus far compares very favorable with data generated from the NHIS and BRFSS

Influenza immunization among health care workers

- Nationally averaging from 46 -50%
- Despite strong efforts, many facilities find that their rates plateau (~70%)
  - Simply basing programs on the Health Belief Model fails
  - Free vaccine does not improve rates
- Not just a health care worker issue but a patient safety issue
- Must consider an ecological model where organizations, communities, and policy makers to create environments conducive to risk reduction
- Policies requiring HCW vaccination may be necessary to protect HCWs, safeguard communities, and ensure patient safety

Influenza immunization among health care workers

Statement from the Summit…

- Congratulate facilities that have made strong efforts to improve influenza immunization rates
- Emphasize that despite multiple interventions, HCW rates are stagnant. Interventions include:
  - Education
  - Free vaccine and convenient access
  - Positive incentives
- Facilities must try stronger methods, including policy considerations, to improve influenza IZ rates among HCWs
  - To protect the worker
  - To protect the patient

Ensuring vaccination in private provider settings

- Multiple provider panel
  - Influenza immunization is recommended for those with CVD, those who are pregnant
  - Those on chemotherapy will have differing immune responses to vaccination
    - Cocooning those unable to respond important
  - Primary obstacles to immunization are not usually medical: Eg:
    - Costs of vaccine
    - Not responsibility of the specialist/provider
    - Time makes discussion difficult
    - Not always a priority in patient visit

Facilitating Influenza IZ in the 18 and Under

- New Jersey Daycare and Preschool Mandate
  - Multiple challenges were overcome in the 2008-2009 school year
  - For the 2009-2010 Season:
    - After December 31st, unvaccinated students must be excluded from school for the duration of influenza season (through March 31st) or until they receive at least one dose of the influenza vaccine.
    - With the exception of the first year of implementation, no additional grace period will be allowed.
    - Students enrolling after December 31st are still required to receive flu vaccine through the end of flu season.

Facilitating Influenza IZ in the 18 and Under – Matt Daley…

- “Tinkering” with current approaches will fail to achieve adequate vaccination coverage
- Transformational change is needed:
  - Immunization “silos” broken down
  - Close cooperation between primary care, public health, schools
- Health care system must place a higher value on influenza vaccination

NACCHO Partners Meeting - School Settings

- **Key Issue:**
  - Identify and disseminate best practices to give a spectrum of school systems ideas on how to implement and sustain school-located influenza vaccinations
- **Key Solution:**
  - Central database of best practices and peer-to-peer exchange mechanisms
- **Key Concerns:**
  - addressing spectrum of issues related to logistics, communications with parents, schools, principals; consent forms, sustained funding, and working with mass vaccinators

NACCHO Partners Meeting - Healthcare Settings

- **Key Issue:**
  - Expand access points for vaccine: includes not only sites for clinics, but also personnel for running the clinics and identifying additional vaccinators
- **Key Solution:**
  - The target groups identified to accomplish this were mass vaccinators, community partners, and pharmacists
- **Key Concerns:**
  - public misperceptions about the vaccine, missed opportunities, physician buy-in of influenza vaccination in non-medical-home settings, reimbursement, insurance barriers to reimbursement for services outside medical home, improving access and increasing points of access, training needs, safety, liability concerns

NACCHO Partners Meeting - Supply, Distribution, Financing

- **Key issue:**
  - Improved communications between manufacturers and public health re: supply and distribution challenges
- **Key concern:**
  - eliminating insurance/reimbursement barriers for vaccination given outside medical home; improved communications b/n public health and payers

NACCHO Partners Meeting - Final Report

- This report will be formally written an placed on NACCHO's web page at:

  http://www.nacho.org/topics/HPDP/infectious/immunization/index.cfm

Facilitating Influenza IZ in the 18 and Under – Matt Daley…

- “Tinkering” with current approaches will fail to achieve adequate vaccination coverage
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Communications for the Upcoming Season…

Pandemic H1N1 Communications - Key Messages/Themes (1)

- “There are reasons to be worried/concerned when it comes to the pandemic H1N1 influenza virus and the upcoming season”
- “This novel virus warrants aggressive public health actions (e.g., investment in vaccines and vaccination)”
- “Strong actions are taken to protect people from seasonal flu (e.g., production and administration of annual vaccines) – and should be taken in response to this pandemic virus”

Pandemic H1N1 Communications - Key Messages/Themes (2)

- "When it comes to reducing influenza transmission and protecting people from influenza, vaccines are the most important tool available."
- "The pandemic H1N1 flu virus is a reminder of the ever-changing and unpredictable nature of influenza."

Preparing in the Face of Uncertainty

- Use promotion of seasonal flu vaccine as a core which can be expanded and adapted
- Plan for a few key scenarios and be prepared to adapt approach, messages, and materials
- Improve processes and surge
- Identify and train spokespeople

What will we communicate about seasonal flu vaccine? When?

If seasonal flu vaccine is available first:

- Begin promoting seasonal influenza vaccine as soon as first doses become available using our “standard” messages, which include:
  - **“People should begin getting their flu vaccines in September or as soon as vaccine is available”**
  - **“Vaccination should continue throughout the influenza season into March until vaccine runs out”**

Additional messages. . .

- "This new flu is a reminder of the unpredictable nature of influenza, and the importance of prevention."
- "Flu vaccines are the most important step for protecting yourself and your loved ones against this serious disease – vaccination can result in fewer doctor's visits, hospitalizations and deaths."
- "The seasonal flu vaccine is not expected to protect against the pandemic/novel H1N1 flu. A pandemic H1N1 flu vaccine may/will/will not be available soon."

What will we communicate about seasonal flu vaccine? When?

If pandemic/H1N1 and seasonal flu vaccines are available at the same time, there is not widespread severe disease and there is not high demand for pan flu vaccine:

- Use seasonal flu vaccine communication as the core. Promote seasonal influenza vaccine broadly as soon as it becomes available using our "standard" messages, as well as:
  - "The seasonal flu vaccine is not expected to protect against the novel H1N1 flu."
  - "Pandemic flu is a reminder of the unpredictable nature of influenza, and emphasizes the importance of flu prevention."
  - "A separate vaccine is available which prevents novel H1N1 flu and is recommended for the following people for the following reasons…….."
- Conduct targeted outreach to promote pandemic/H1N1 flu vaccine to those for whom it is recommended.

What will we communicate about seasonal flu vaccine? When?

If pandemic/H1N1 and seasonal flu vaccines are available then we see widespread, severe disease, high media coverage, and high demand for novel H1N1 vaccine:

- Broadly communicate about both vaccines with heavy emphasis on:
  - "seasonal flu vaccine is not expected to protect against the novel H1N1 flu"
  - explaining novel H1N1 flu vaccine prioritization/recommendations and rationale behind them

National Influenza Vaccination Week, 2009 – 2010 Season

- Scheduled for December 6 to 12, 2009
  - Children’s Vaccination Day
    - Tuesday, December 8, 2009
  - Healthcare Worker Vaccination Day
    - Thursday, December 10, 2009
  - Senior Vaccination Day
    - Friday, December 11, 2009

2009 -2010 Seasonal Vaccine Supply

- 119M million doses are predicted by the manufacturers this year. 90% shipped by November 1st.
  - Sanofi – 50M doses
    - 50% by end of August, completed in October
  - GSK – 20M doses, production impacted by B strain growth
    - 1M by end of July, 80% by end of August
  - Novartis – 30M doses
    - 33% by end of August, complete by end of September
  - MedImmune – 10M doses
    - All shipping in August
  - CSL Biotherapies – 8M doses

General Outcomes from the June 29 – July 1 2009 Meeting

- Must deal with what we know will happen; H1N1 vaccine supply and disease is uncertain, seasonal influenza vaccine supply and disease is fairly certain
- As of today, expecting >51M doses of seasonal vaccine by end of Aug. 119M total doses, 90% by end of Oct.
- Begin seasonal flu vaccination consistent with messages from previous seasons but recognize that we will have to overlay pandemic vaccination later!
  - Need to improve immunization of 18-and-under; high risk in private provider settings

General Outcomes from the June 29 – July 1 Meeting

- Begin seasonal influenza vaccination as soon as vaccine is available, vaccinate through the season until vaccine runs out
- Healthcare worker flu IZ rates are still poor; facilities need to push strong programs to improve rates
- Increasingly looking like pandemic H1N1 will circulate along with seasonal flu in the fall
- Pandemic vaccination will be overlap with seasonal vaccination, Summit will update as info becomes known!
  - That does not mean stopping seasonal vaccination efforts!

Next Steps…

- Summit Executive Committee will look at the notes from the Summit's discussions and distill out salient, impactful action steps for implementation in the 2009-2010 season
  - Pandemic H1N1 will dominate discussion but seasonal efforts must continue
- All presentations and the agenda are posted on the Summit website:

  www.preventinfluenza.org
  - Also available are multiple resources for influenza immunization

THANK YOU!!