

H1N1 Vaccine

Pediatric Disaster Planning and NYC Experience with Novel Influenza A (H1N1)

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September 15, 2009**

Today's Presentation

- H1N1 vaccine recommendations
- H1N1 vaccine distribution
- Seasonal influenza vaccine recommendations
- Influenza vaccine uptake
- Implementation issues
 - Guidance and Challenges
- Resources

H1N1 Vaccine Recommendations*: Priority Groups

- Pregnant women
- Children and young adults 6 months through 24 years of age
- Adults 25 through 64 years of age with underlying medical conditions
- Health care workers and EMS
- Household contacts and care givers of children <6 months of age

* CDC, MMWR August 28,2009/Vol. 58/No. RR-10

H1N1 Vaccine Recommendations :

Priority Groups continued

- Once initial priority group is vaccinated, add:
 - Adults 25 through 64 years of age
- Following group is those 65 and older

H1N1 Vaccine Dosing

- Clinical trials in progress
- Looking at 1 vs. 2 doses
- 7.5 mcg, 15 mcg and 30 mcg
- With and without adjuvant
- Different populations
- Initial results from adult studies released last week
 - Pediatric results pending
- Vaccine licensed by FDA as a ‘strain change’ supplement

Clinical Trial Basic Design Concepts

Licensed Manufacturers

- Monovalent vaccine
- Designed to inform dose, dosing regimen and safety
- Common design communicated to license manufacturers
- Randomized, double-blind, controlled, dose ranging
- 2 doses (0,21d) with post-dose 1 immunogenicity assessment
- Age stratification (6m-35m, $\geq 3-9$ yo, $\geq 18-64$ yo, ≥ 65 yo)
- Adult and pediatric studies concurrent
- Unadjuvanted and adjuvanted arms
- Target for earliest possible clinical trial start
- Clinical trials conducted under IND



Clinical Trial Basic Design

Age range	7.5 μ g HA N	15 μ g HA N	30 μ g HA N	3.8 /7.5/15 μ g HA + adjuvant N
6m-3y	100	100	-	100/antigen dose
\geq 3-9yo	100	100	-	100/antigen dose
\geq 18-64yo	100	100	100	100/antigen dose
\geq 65yo	-	100	100	100/antigen dose

- Are current seasonal dosages sufficiently immunogenic?
- One dose or two?
- Are adjuvants dose-sparing?

Clinical Trial Endpoints

Immunogenicity: 21 days post each vaccination

- Proportion seronegatives with HAI \geq 1:40
- Proportion seropositives with \geq 4-fold rise in HAI (seroconversion rate)

Others: GMT, immunogenicity at earlier time points
(e.g. 14 days after vaccination); microneutralization titers

Safety

- solicited local and systemic events within 7 days of vaccination
- unsolicited adverse events
- serious adverse events (SAEs) documented monthly
- new onset medical conditions documented monthly
- baseline and post-vaccination safety labs
- 6-12 month follow-up period after the last dose of vaccine



Additional H1N1 Vaccine Studies

- Safety and immunogenicity of TIV in pregnant women
- Trials began June 11, 2009
- 2nd and 3rd trimester women
- Antibody responses: HAI
- 52 women enrolled as of end July
- Results pending

H1N1 Vaccine Presentation

- Inactivated and live attenuated intranasal vaccine
- Multidose vials
- Single use vials
- Single dose syringes
- Pediatric 0.25 mg syringes
- Information pending about number of doses of each presentation
- Availability of the different presentations may vary by time of distribution

H1N1 Vaccine Distribution

- Initial vaccine distribution expected sometime between late September to mid-October
- Pro rata basis
- Distribute broadly to have vaccine available as widely as possible
- Will use central distribution mechanism similar to current VFC vaccine distribution
- HHS plans call for enough vaccine to provide 2 doses to all Americans (~600M doses)
 - Requires use of adjuvanted vaccine
 - Final number of doses pending

H1N1 Vaccine Distribution Sites

- Hospitals
 - Health care workers, inpatients and outpatients
- CHCs/FQHCs
- EMS/FDNY
- Private Providers
 - Pediatric vaccinators
 - Adult vaccinators
 - Outreach through medical societies, HAN, vaccine reps, PCIP
 - Ob/Gyns
- Some pharmacies
- Health department clinics

H1N1 Vaccine Distribution Sites: Special Initiatives

- School-based vaccination
 - Focus on elementary schools
 - On site by school nurses
 - Teams
 - SBHCs
- PODs
 - Middle and high schools
 - Community access
- Special groups
 - For example, MRDD providers

H1N1 Vaccine Reporting and Accountability

- All reporting through the CIR
- Already required for children 18 and younger
- Current State law requires consent for 19 and older
- Expect this to be waived through emergency regulations
- Future shipments based on accountability
- Adverse event reporting module in CIR

Influenza Vaccine Uptake

Influenza Vaccine Recommendations 2009-2010

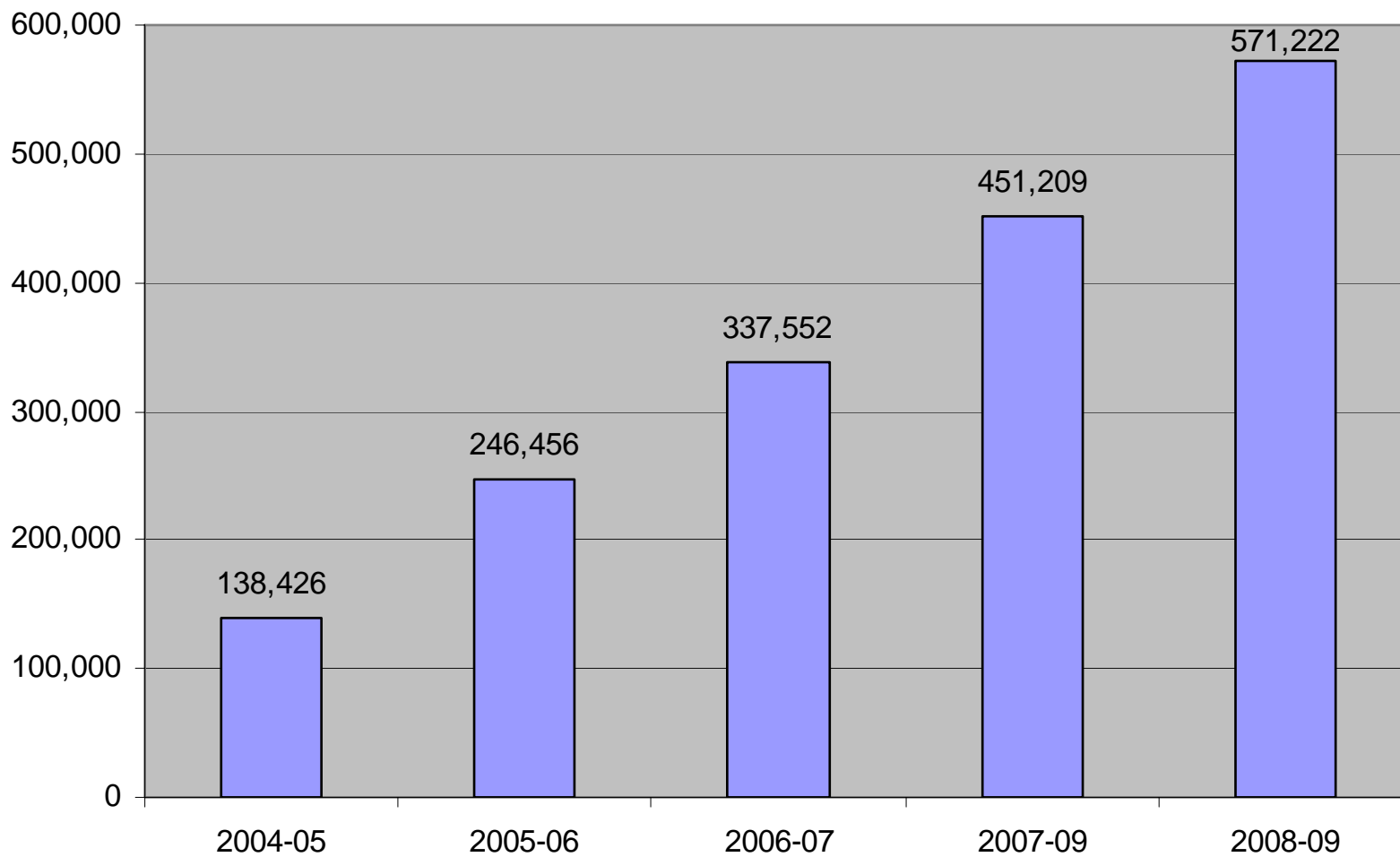
- All persons who want to reduce their risk of influenza
- All children 6 months to 18 years of age
- Women who will be pregnant during the influenza season
- All persons ≥ 50 years of age
- Children on chronic aspirin therapy
- Adults with chronic medical conditions
- Residents of nursing homes and other chronic care facilities
- Persons who live with or care for persons at high risk for influenza-related complications, including healthy household contacts and caregivers of children from birth - 59 months of age
- Health care workers

Influenza Vaccine Recommendations for All Persons with Chronic Illness*

- Heart disease
- Pulmonary disease (e.g., emphysema, asthma)
- Metabolic disease (e.g., diabetes)
- Renal dysfunction
- Any condition that can compromise respiratory function
 - Neuromuscular diseases, seizures, spinal cord injury, cognitive dysfunction
- Hemoglobinopathies
- Immunosuppression
 - HIV/AIDS
 - Medications and other treatments

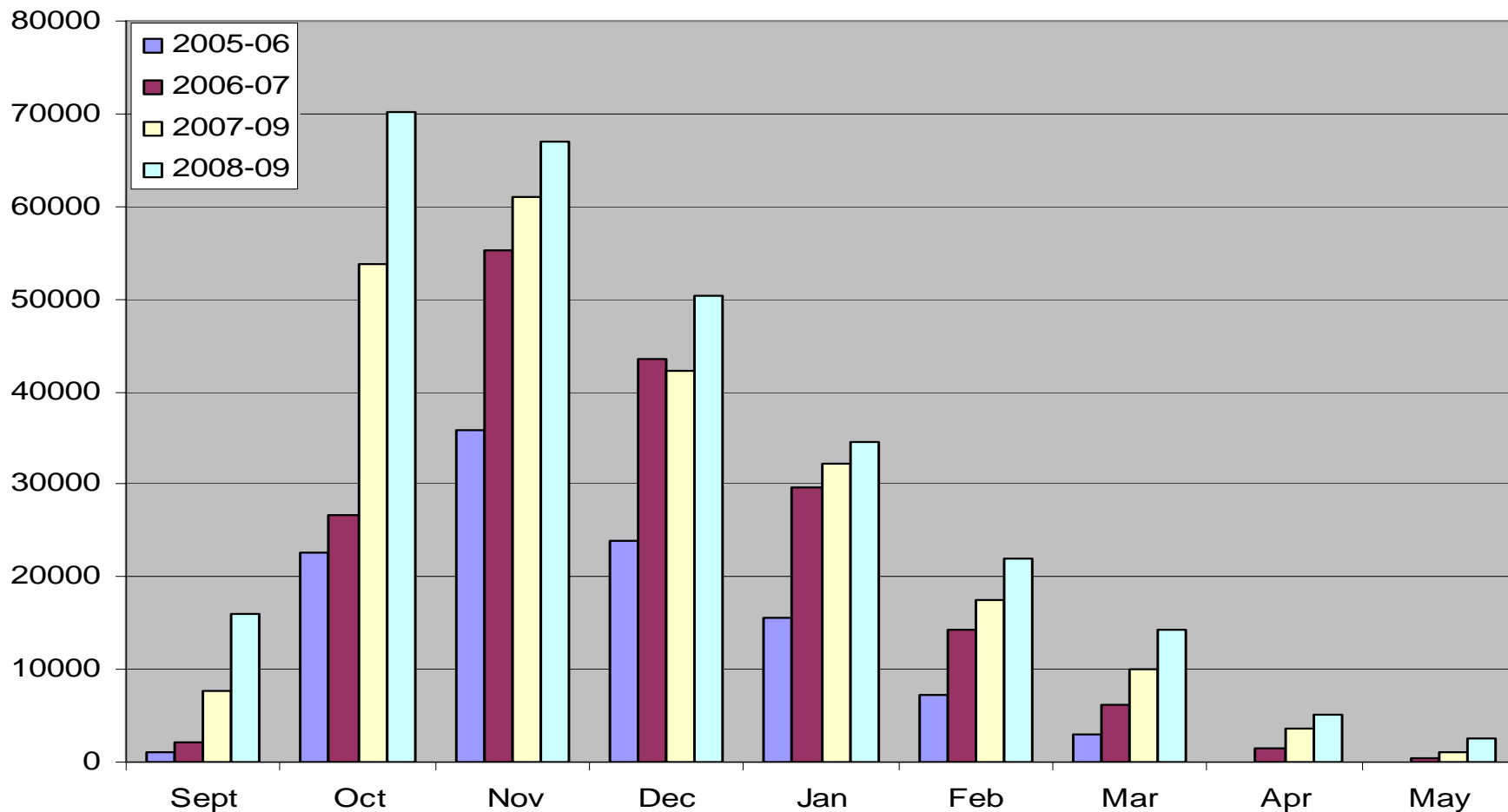
* \geq 6 months of age

Influenza Immunizations Given to Children 6m-18y



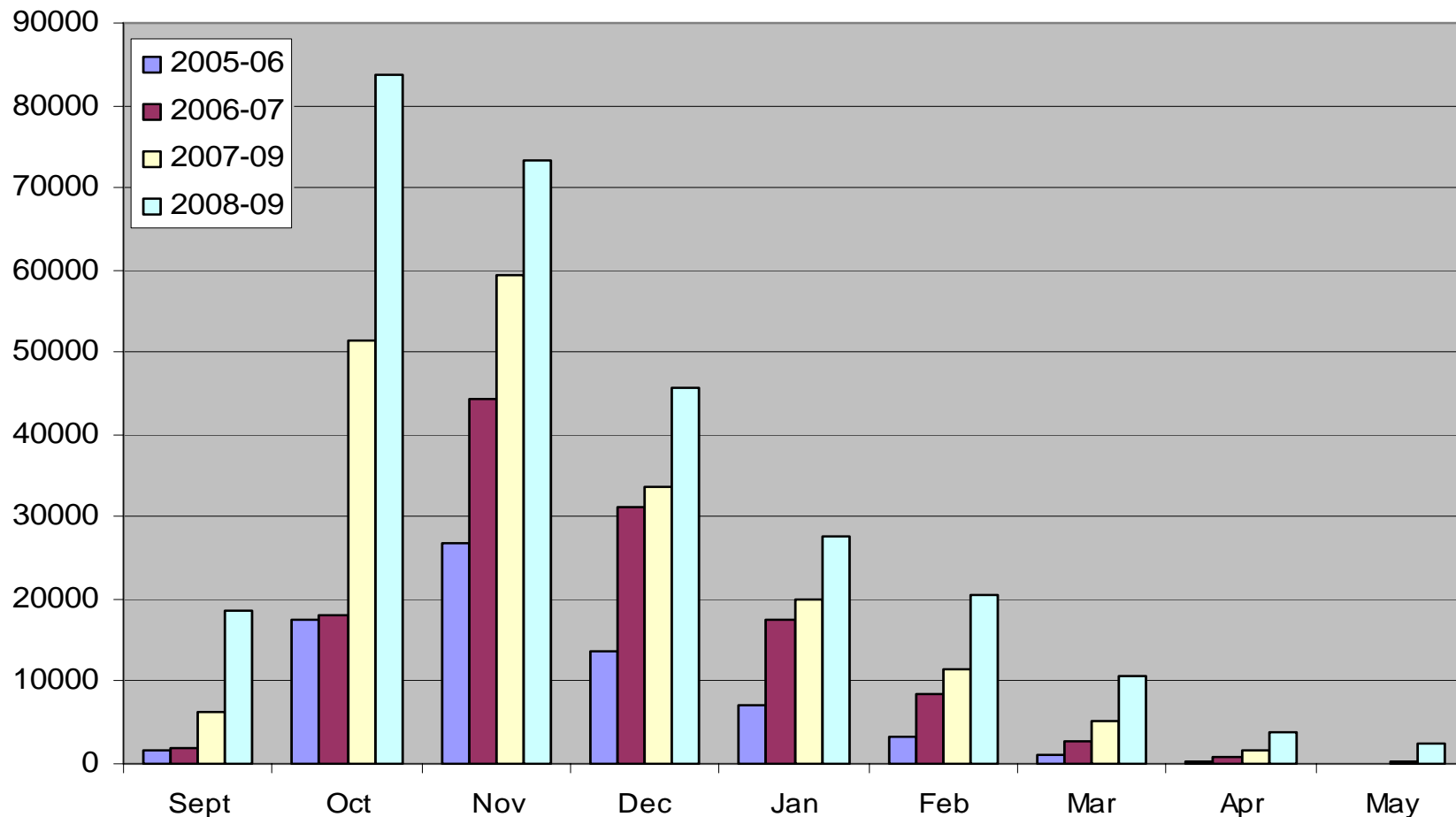
Information reported to CIR as of 6/10/2009

Influenza Immunizations Given to Children Aged 6-59 Months



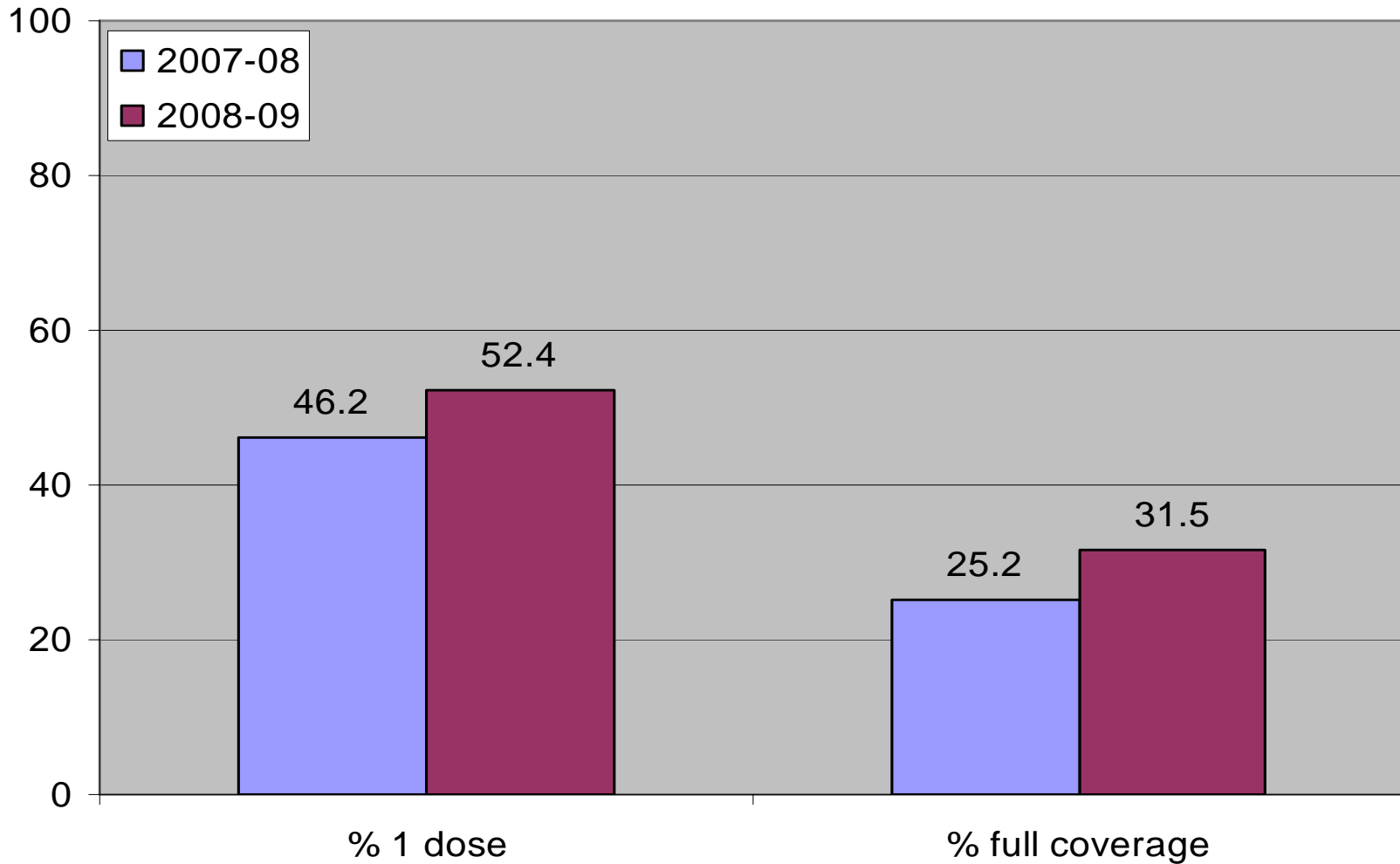
Information reported to CIR as of 6/10

Influenza Immunizations Given to Children Aged 5-18 Years



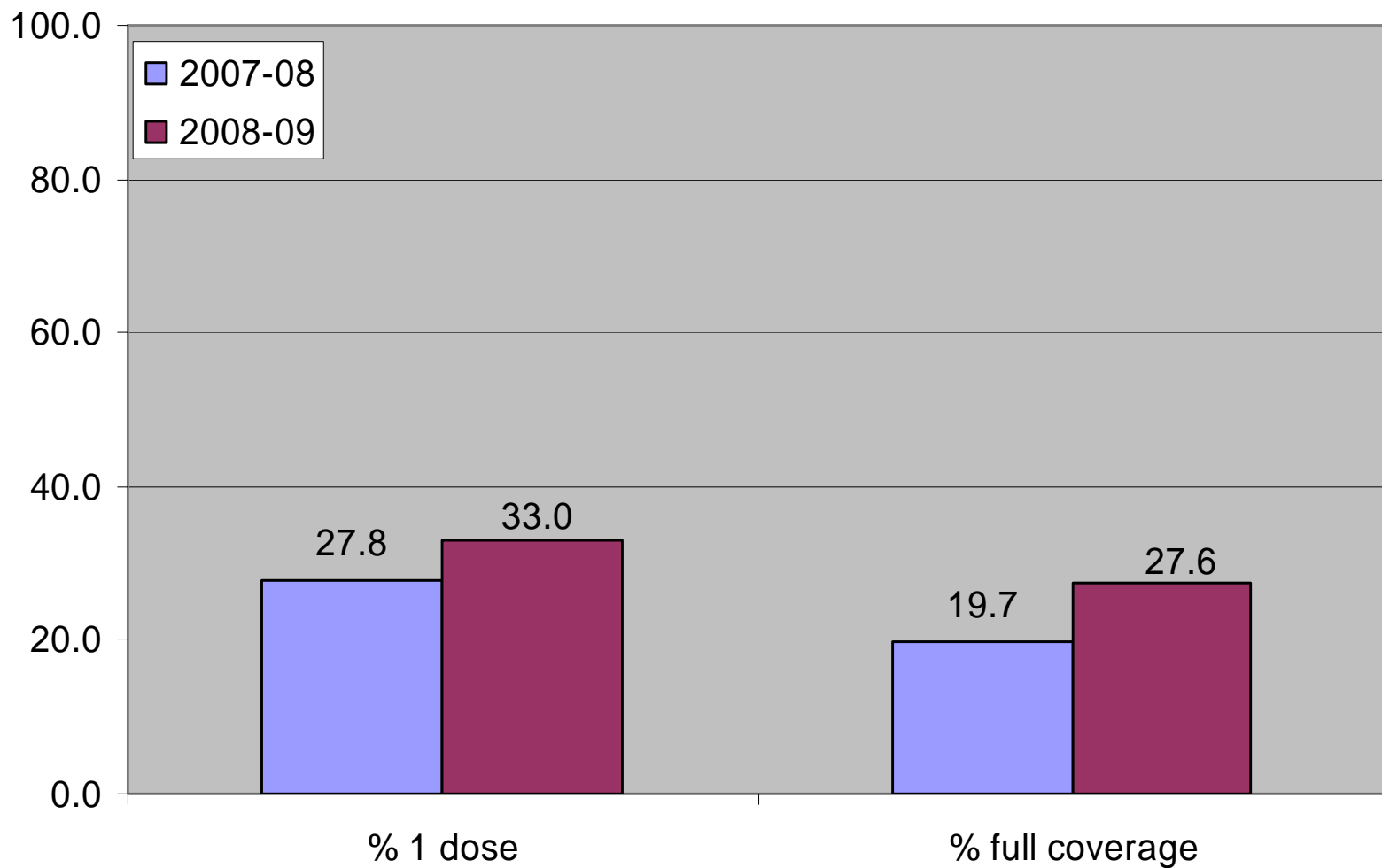
Information reported to CIR as of 6/10

Influenza Coverage: 6-23 m olds



Information reported to CIR as of 6/10

Influenza Coverage: 24-59 m olds



Information reported to CIR as of 6/10

Implementation

Getting Ready for Flu Season

- Order sufficient vaccine
- Vaccinate all office staff
- Develop protocols within the health care setting
 - Have patient information available (posters, flyers)
 - Flag charts of high-risk patients
 - Use standing orders
 - Have special designated vaccination hours
 - Make every encounter an opportunity to vaccinate
 - Use signed declination forms if vaccine refused
- Offer vaccine once available: continue vaccinating into the spring

2009-2010 Influenza Vaccine

- A/Brisbane/59/2007 (H1N1) - like
- A/Brisbane/10/2007 (H3N2) - like
- B/Brisbane/60/2008 – like*

Strains included in the vaccine change every year based on surveillance data

You need this year's flu vaccine to protect against this year's flu!!

Vaccine supply information will be available at www.cdc.gov/flu

* New strain

Timing of Annual Influenza Vaccine

- In the past we would say ‘influenza activity peaks between late December and early March’
- However, we have learned that seasonal flu circulates earlier and longer than previously appreciated
- Optimal time for vaccination programs may be September through November, however, vaccination should continue into the new year
- Persons should be vaccinated against influenza as soon as vaccine is available

Additional Guidance

- Can provide H1N1 and seasonal vaccine at the same time, but at different sites
- Exception is that both LAIVs presentations can not be given together
- Do not hold back second doses
 - There will be sufficient vaccine available for all who want to be vaccinated

Challenges

- Need to provide both seasonal and H1N1 vaccine
- Some young children will require 2 doses of seasonal vaccine plus H1N1 (1 or 2 doses)
- Safety concerns
- Transmission may occur prior to vaccine being available
- Adverse event reporting module in CIR

Implementation Considerations

- Consider expanding access to flu vaccine
- Hold evening, weekend flu clinics
- If a large practice or facility, ensure implementation of non-patient specific standing orders
- Reminder recall/postcards/phone calls
- Distribute education materials
 - Health bulletins
- Display posters in the waiting/exam rooms

Resources

- Nyc.gov/flu
- Nyc.gov/health/cir or 212-676-2323
- CHI
- Cdc.gov/flu
- ACIP
 - Recommendations: August 28, 2009/Vol. 58/No. RR-10
cdc.gov/mmwr/preview/mmwrhtml/rr5810a1.htm?s_cid=rr5810a1_e
 - July 31/vol58/No. RR – 8
cdc.gov/mmwr/preview/mmwrhtml/rr5808a1.htm?s_cid=rr5808a1_e
 - ACIP presentations at:
cdc.gov/vaccines/recs/acip/meetings.htm
- NFID at nfid.org

Questions?