

2011 Military Health System Conference

H1N1 Preparedness and Recent Lessons Learned

The Quadruple Aim: Working Together, Achieving Success

COL Wayne Hachey, DO, MPH
Executive Secretary
Defense Health Board
Skyline 1, Suite 1100
5205 Leesburg Pike
Falls Church, VA 22041

Diana D. Jeffery, Ph.D.
Director, Center for Health Care
Management Studies
TRICARE Management Activity
Skyline 5, Suite 510
5111 Leesburg Pike
Falls Church, VA 22041

Mark F. Gentilman, O.D. CEM, FACCP
Dep Director, Civil Military Medicine
Force Health Protection & Readiness
TRICARE Management Activity
Skyline 4, Suite 403
5113 Leesburg Pike
Falls Church, VA 22041



January 24, 2011

Office of the Assistant Secretary of Defense (Health Affairs)

Report Documentation Page

Form Approved
OMB No. 0704-0188

Public reporting burden for the collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to a penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number.

1. REPORT DATE 25 JAN 2011	2. REPORT TYPE	3. DATES COVERED 00-00-2011 to 00-00-2011			
4. TITLE AND SUBTITLE H1N1 Preparedness and Recent Lessons Learned		5a. CONTRACT NUMBER			
		5b. GRANT NUMBER			
		5c. PROGRAM ELEMENT NUMBER			
6. AUTHOR(S)		5d. PROJECT NUMBER			
		5e. TASK NUMBER			
		5f. WORK UNIT NUMBER			
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Military Health System, TRICARE Management Activity, 5111 Leesburg Pike, Skyline 5, Falls Church, VA, 22041		8. PERFORMING ORGANIZATION REPORT NUMBER			
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)		10. SPONSOR/MONITOR'S ACRONYM(S)			
		11. SPONSOR/MONITOR'S REPORT NUMBER(S)			
12. DISTRIBUTION/AVAILABILITY STATEMENT Approved for public release; distribution unlimited					
13. SUPPLEMENTARY NOTES presented at the 2011 Military Health System Conference, January 24-27, National Harbor, Maryland					
14. ABSTRACT					
15. SUBJECT TERMS					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT unclassified	b. ABSTRACT unclassified	c. THIS PAGE unclassified	Same as Report (SAR)	43	

The Quadruple Aim



This briefing supports the aim of:

Readiness

Ensuring that the total military force is medically ready to deploy and that the medical force is ready to deliver health care anytime, anywhere, in support of the full range of military operations, including humanitarian missions.



Outline



- Pandemic Preparations and Response – Dr. Hachey
- 2009 H1N1 After Action Report – Dr. Gentilman
- Impact on the Military Health System – Dr. Jeffery

Before the Pandemic



- DoD had been actively planning and preparing for an influenza pandemic since 2002
- Policies in place: vaccines, antivirals, ethical and clinical practice guidelines
- Materials stockpiled: H5N1 vaccine, antivirals, antibiotics, PPE
- Compared to many other U.S. Government agencies we were well prepared

2009 H1N1

Formally Known as Swine Flu



- Early April: A novel swine origin influenza A (H1N1) virus was identified from two unlinked patients in the US
- DoD surveillance assets identified the first four cases in the US - two cases each in California and Texas
 - Out of the first 8 cases in the US, DoD identified 5
- At the same time widespread influenza-like illness (ILI) was noted in Mexico
 - Unusual ILI had been occurring in Mexico since December 2008
- Disease then spread across the US and internationally
- Scramble to find a name that would not cause the pork industry to crash – 2009 H1N1 or pH1N1

2009 H1N1 Timeline



- Pandemic Declaration by WHO 11 June 2009
- Southern Hemisphere flu season – 2009 H1N1 was the predominant virus, low attack rates in elderly, no change in virulence, no significant genetic drift
- Northern Hemisphere flu season – 2009 H1N1 also became the predominant virus, still spared the elderly, no change in virulence, no significant genetic drift

2009 H1N1



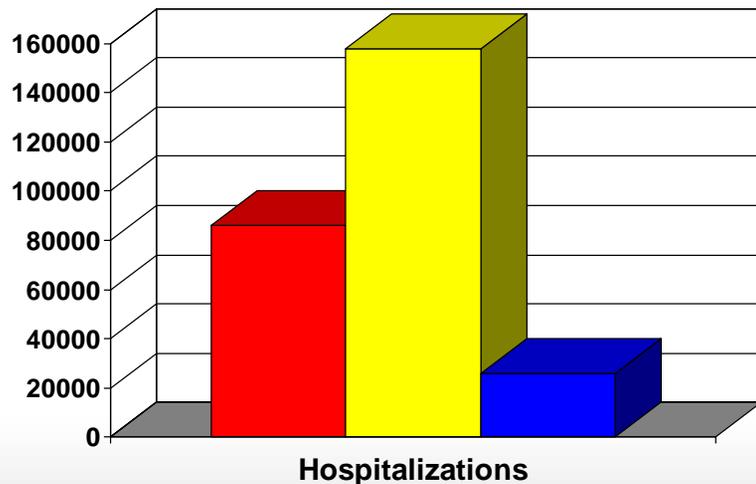
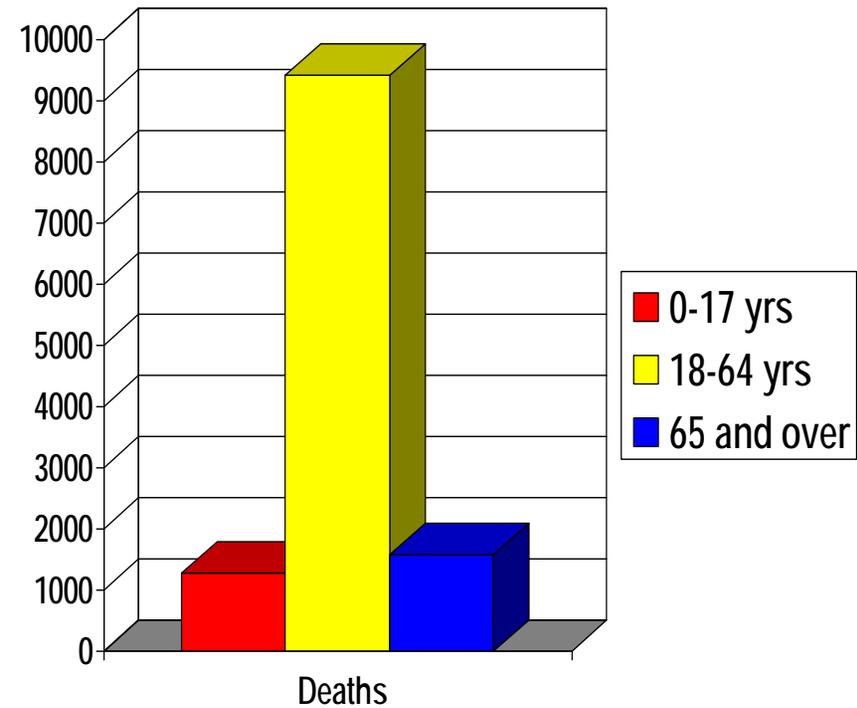
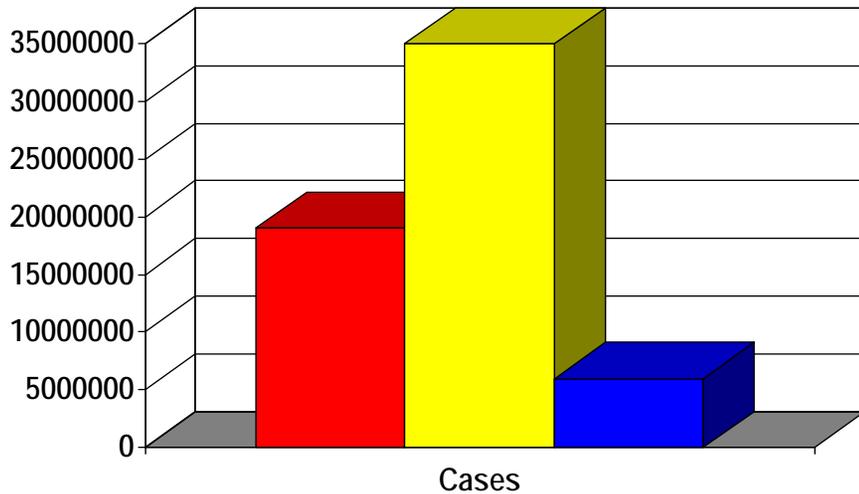
- Sensitive to Oseltamivir & Zanamivir
 - Rare Oseltamivir resistance identified ~ 1%
- No protection from seasonal influenza vaccine per CDC but
 - DoD data suggests vaccine effectiveness up to 50% for seasonal influenza vaccine against pandemic strain – age dependent
- 33% of people born before 1951 had cross reactive antibodies – unknown degree of actual protection

2009 H1N1 U.S. Impact



- Compared to previous pandemics Novel H1N1 spread in weeks vs. months
- CDC estimates (April 2010)
 - 43 million to 88 million cases
 - 192,000 to 398,000 hospitalizations
 - 8,720 to 18,050 deaths
- Although deaths were within the seasonal flu range – years of life lost were comparable to 1968 pandemic

Midrange CDC Estimates Cases, Hospitalizations, Deaths by Age



Novel H1N1 – Who Dies?



- US deaths
 - >65% with underlying health conditions
 - 58% of children hospitalized and 65% of pediatric deaths had underlying condition
 - BMI \geq 40 four fold increase in both hospitalizations and death
 - Other high risk conditions included pregnancy, asthma, cardiovascular disease, neuro-developmental delay
 - Compared with seasonal flu:
 - 5 fold increase in deaths in kids
 - 5 fold decrease in deaths in elderly

2009 H1N1 DoD Impact - Deaths



- 2 Active Duty Deaths
 - Previous years:
 - 1 each in 2000, 2003, 2008
 - 2 in 2005
- 6 Family Member Deaths
- 3 Retiree Deaths
 - Last reported influenza associated death was 12 January 2010

Mitigation Measures



- Vaccine
- Antivirals
- Communication

Vaccine Not So Merry-go-round



- Changing projections on how much vaccine DoD would receive and when
- Initial plan included a large allocation to DoD with the initial vaccine release
 - Mild severity caused a shift in National policy
- New guidance was 1M doses early Oct followed by 1.6M doses end of Oct
 - Production capacity overestimated
 - DoD received gradual allocations of vaccine

2009 H1N1 Vaccine Policy



- Mandatory for all uniformed personnel (AD, Guard and Reserve)
- Highly encouraged for all others
- 3 separate vaccine supplies with specific target groups
 - DoD Policy: High risk individuals may receive vaccine from any source

2009 H1N1 Vaccine Programs



- All vaccine allocated by HHS
 - 2.7 M doses purchased by DoD to continue to meet mission requirements in pandemic environment
 - State allocation program – for DoD CONUS dependents (includes Alaska, Hawaii and US Territories and Possessions)
 - 1M doses targeting USG civilian employees (also targeted OCONUS dependents)

2009 H1N1 Vaccination Rates

(10 May 2010)



Service	% Immunized
Army	96
Air Force	98
Marines	86
Navy	97
Total	96

2009 H1N1 Vaccine Safety



- Collaborative effort between the Military Vaccine Agency and the Armed Forces Health Surveillance Center
- Determined baseline rates for potential vaccine related adverse events
- Identified all AD 2009 H1N1 vaccinees
 - Search for recognized vaccine related adverse events
- Rapid cycle analysis of aggregate data comparing pH1N1 with past 3 flu seasons
- **RESULT: NO INCREASE IN VACCINE RELATED ADVERSE EVENTS**

Antivirals



- Oseltamivir represented bulk of DoD stockpile
 - 8M treatment courses
 - 1M @ MTFs
 - 7M @ Depots
- Funding received for
 - More Zanamivir - Will represent 30% of overall stockpile
 - Rimantadine to be added to stockpile
- Antiviral policy mirrored CDC with exception of expanded use to maintain operational capability

Communication



- Policies and guidance revised as national guidance shifted
- All posted on Watchboard (<http://fhpr.osd.mil/aiWatchboard>)
 - Over 8M hits since April 09
- Also used flash message system targeting DoD pharmacists
- Other media
 - Print, TV, web based social media

Pandemic Response Options



DoD 2009 H1N1 After Action Report



- In April 2010, White House directed Departments and Agencies prepare a 2009 H1N1 After Action Report (AAR) which would be a part of a larger Federal report
- DoD AAR is currently at the Under Secretary level for review; other Department reports such as HHS are still outstanding
- DoD AAR
 - Analysis and report done by team of experienced contractors
 - Derived from themes consistently seen in surveys and interviews
 - Non-scientific, i.e., findings based on those who participated
 - Emphasis on Department level findings although findings from single Service or COCOM with Department-wide implications were included

DoD 2009 H1N1 After Action Report



- Over 450 observations were submitted by the COCOMs, Services, the Joint Staff, and OSD
 - Contractor also interviewed key personnel in 8 agencies
- Army had the most observations (102) followed closely by the USAF and COCOMs (95 each)
- Findings were listed as successes, challenges or gaps in four pillars (same as White House's National Framework)
 - Surveillance, Mitigation, Vaccination, Communication/Education
- Analysis revealed 50 observations were the most relevant – these form the basis of the AAR
- Executive Summary will go to the White House; entire report (less interview transcripts) will be posted on the DoD PI Watchboard (**<http://fhpr.osd.mil/aiWatchboard>**)

DoD 2009 H1N1 AAR - Successes



- DoD's influenza and emerging infectious disease surveillance programs seen as highly successful. DoD identified the first cases of 2009 H1N1 seen in the U.S.
- Excellent collaboration was achieved through the standing Pandemic Influenza Task Force (PITF) and the Deputy Secretary of Defense sponsored senior level Pandemic Influenza Working Group (PIWG) which oversaw DoD and Pentagon-specific activities
- Vaccination compliance within DoD was the best observed in five years with over 90% of the active force receiving the vaccine
- Pandemic Influenza Watchboard and the MILVAX web portal were effective communication tools to inform Commanders, DoD stakeholders and beneficiaries

DoD 2009 H1N1 AAR - Challenges



- Initially, confusion between the WHO Phases and Federal Government Response Stages directly impacted pandemic Service and COCOM plan implementation
- Stafford Act was not declared. As a result, DoD was not able to provide support to the states. Only option available to the states (or other Federal agencies) was the Economy Act
- Vaccine distribution not fully ramped up until January 2010. These delays were primarily attributed to HHS allocation of vaccine to DoD. **In the event of another pandemic, DoD must be permitted to purchase its vaccine directly from the manufacturer and distribute it within its own logistics network. This would have likely reduced many of the vaccine challenges experienced during the 2009 H1N1 pandemic.**
- The vaccine distribution policy for non-uniformed personnel overseas outside of CENTCOM lacked clarity.

DoD 2009 H1N1 AAR - Gaps



- There are no practical methods to assess civilian absenteeism real-time nor is there any method to assess absentee trends for contractor personnel
- No funding projected after FY09 for DoD controlled influenza stockpiles of vaccine, anti-virals and Personal Protective Equipment (PPE)
- Vaccination of some service members who received the vaccine from civilian sources (primarily reserve component) were not documented in their military health record
- Confusion lingered in some organizations about where to receive immunizations or other health information relating to 2009 H1N1 pandemic in their local area

DoD 2009 H1N1 AAR - Conclusions



- The authors concluded the Department of Defense met its mission requirements during the 2009 H1N1 pandemic - although improvement is needed in some areas
- The Department was successful in maintaining situational awareness and developing policies to protect the force and its TRICARE beneficiaries
- Surveys and interviews revealed the Department's efforts were substantial under the uncertain conditions experienced during this public health emergency
- COCOMs and Services rapidly modified existing pandemic plans to respond to the new pandemic threat. Experience in pandemic planning since 2005 significantly increased DoD's ability to respond
- Follow-on: OASD(HD&ASA) and OSD(HA) will develop a plan to address the AAR recommendations in collaboration with the Pandemic Influenza Task Force

H1N1 CASE STUDY: Purpose & Methods



Request from Deputy Director, TRICARE Management Activity to conduct a case study to evaluate the effect of 2009-2010 H1N1 on the Military Health System (MHS)

Qualitative review of:

- Existing policy & procedures for pandemic influenza preparedness, surveillance, and response
- Timeline of critical decisions, events and communications
- Receipt and administration of H1N1 vaccine

Quantitative analysis of:

- Health care utilization for all TRICARE beneficiaries with Influenza-like Illness (ILI)
- Cost analysis compared to previous flu season

Case Study: Overall Findings of Qualitative Analysis



- DoD guidance for pandemics response focuses on preventive behaviors, immunization, antiviral use, and surveillance
- DoD policy provides general guidance to local medical commanders who make decisions based on regional needs, served population, and resources
- Most DoD guidance for the 2009-2010 H1N1 pandemic coincided with or followed the increased rates of H1N1 cases

Case Study: Overall Findings of Qualitative Analysis, cont.

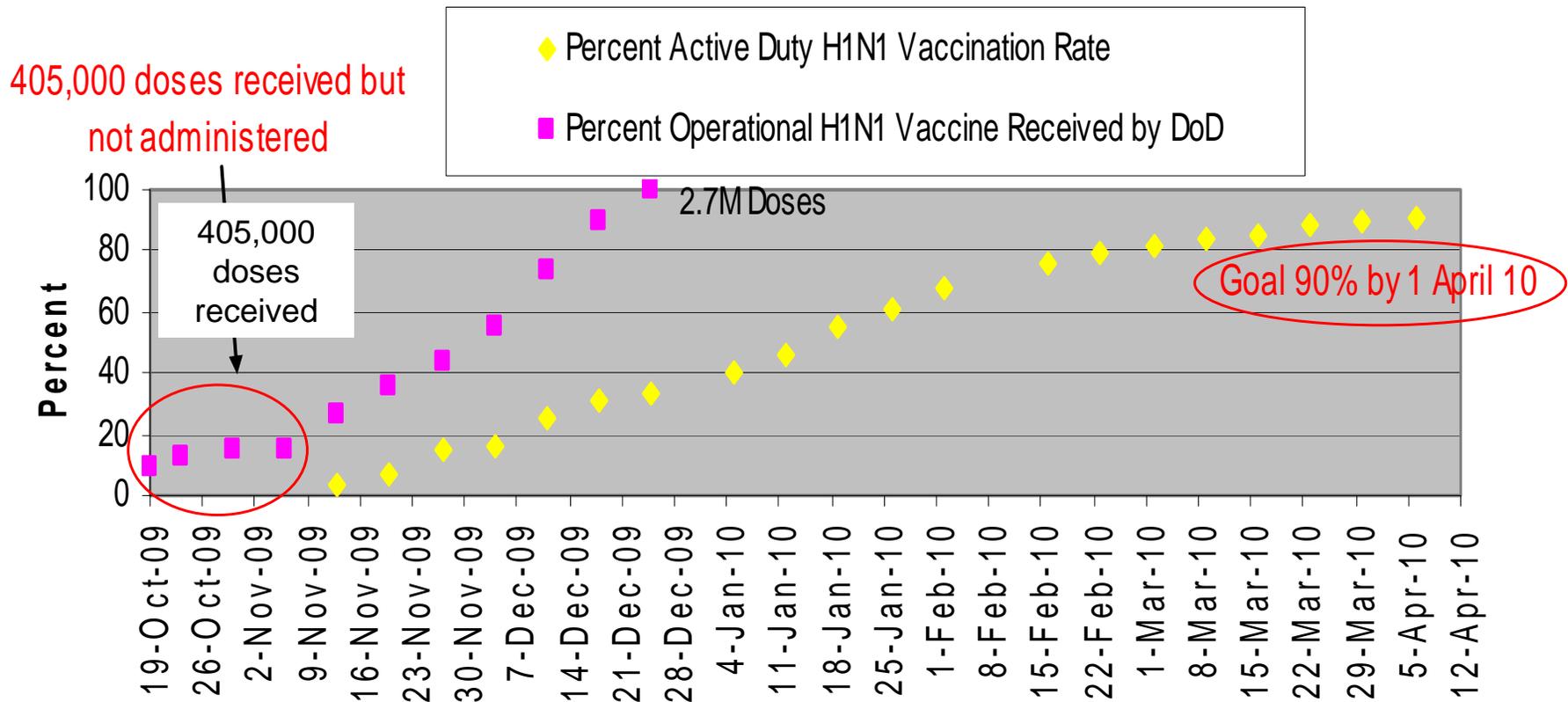


- MHS H1N1-related health care use increased toward end of Oct 2009; H1N1 vaccination began mid-Nov 2009
- DoD Pandemic Influenza Watchboard is the most timely data source for pandemic control compared to all other sources
- The rise of assumed H1N1 cases preceded the majority of H1N1 vaccinations administered to active duty service members

Receipt & Administration of H1N1 Vaccine for Active Duty Service Members



Operational Vaccine Availability & AD DoD Vaccination Rates



Source: Vaccination Rate (AFHSC Weekly Reports and USAFSAM Weekly Reports)
 Vaccine Availability COL Hachey Briefs (3 Mar 2010, 17 May 2010, June 2010)

Receipt & Administration of H1N1 Vaccine for Active Duty Service Members: Findings

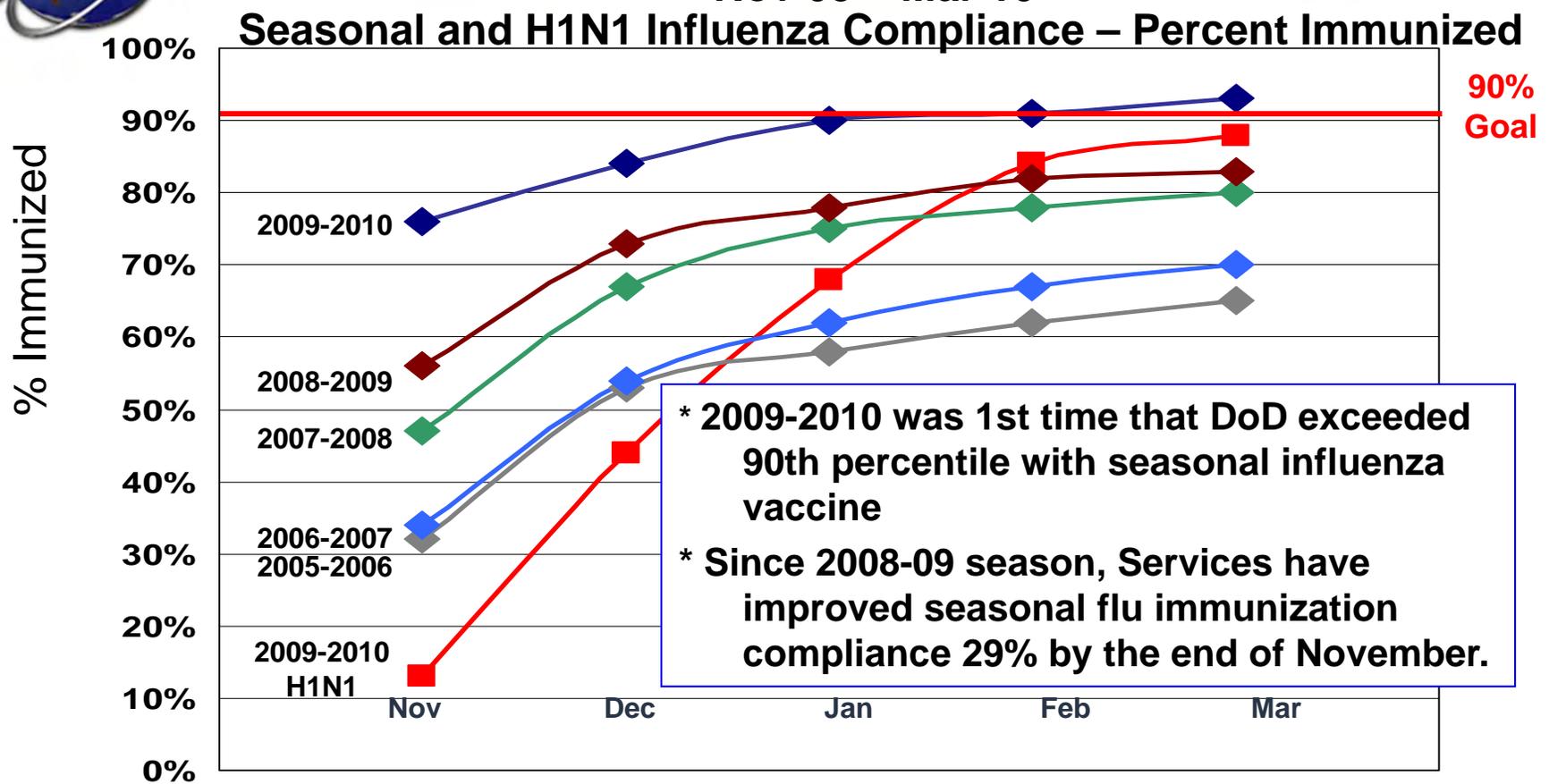


- Immunization began mid-Nov 09
- MILVAX, in collaboration with TriServices, set goal of 90% immunized by 1 Apr 2010
- Air Force goal set as 90% within 1-month of receipt
- Mid-Oct 09 immunization could have slowed transmission by approximately 486,000 people by 1 Nov 09

Seasonal and H1N1 Influenza Vaccine Immunization Program



DoD COMPO 1 INFLUENZA/H1N1 IMMUNIZATION STATUS, Nov 05 – Mar 10



Data Source: Service ITS Nov 08 – Mar 10* and DEERS Nov 05 – Mar 08*

UNCLASSIFIED



Case Study: Overall Findings of Quantitative Analysis

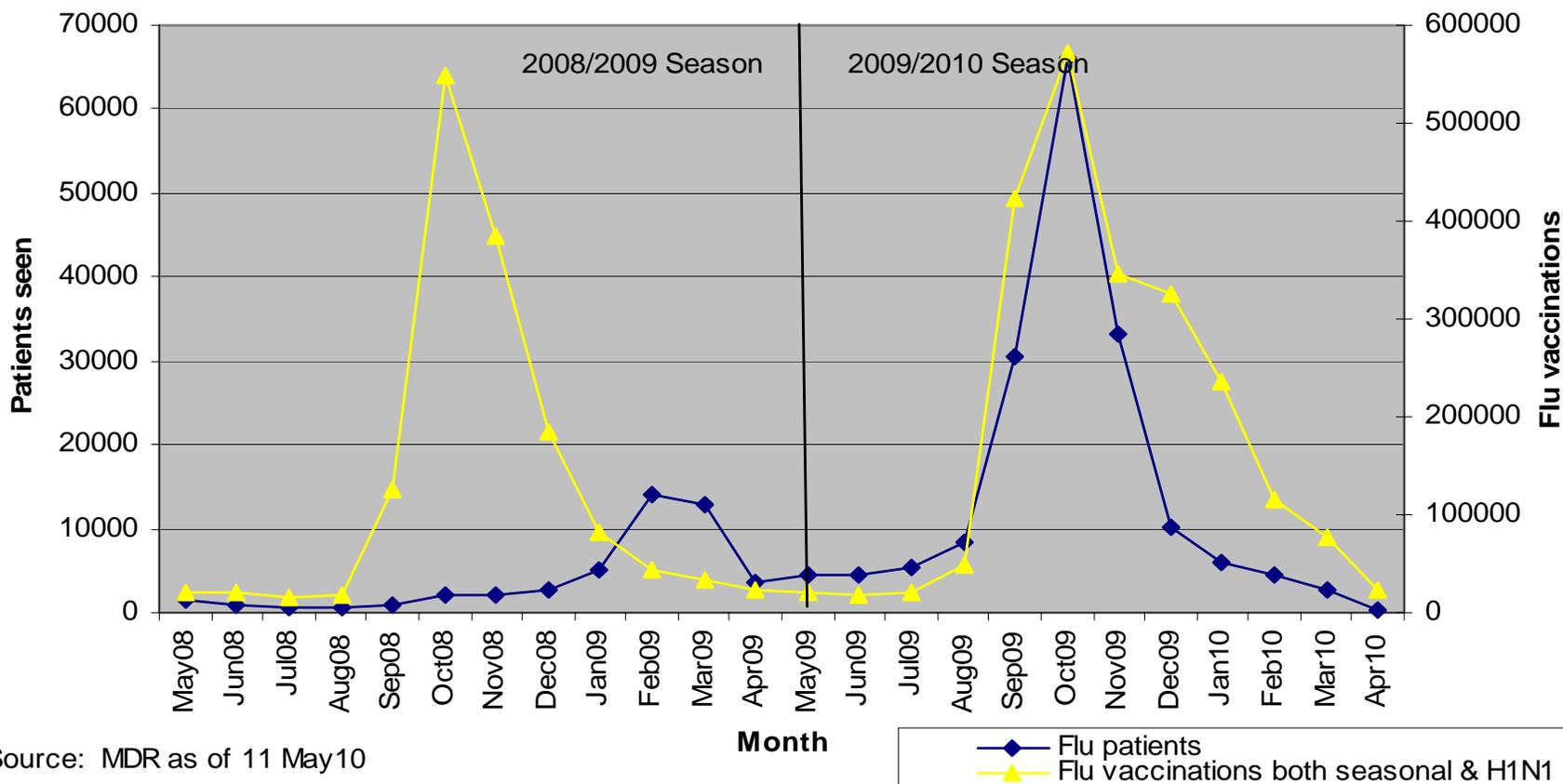


- Compared to the previous flu season, higher ILI healthcare utilization found for 2009/2010 season among all beneficiary subgroups ($p < 0.001$)
 - Number of beneficiaries seeking care was ~ 4x higher
 - Ambulatory visits increased by 5.3x for direct care (DC) and 3.2x for purchased care (PC)
 - ER visits increased 5.2x DC and 8.5x PC
 - Inpatient admissions increased by 5.1x DC and 2.8x PC
- Total estimated cost for ILI July 2009 – January 2010 was \$156.7M
- H1N1 cost DoD ~ \$100M more than expected based on previous flu seasons

Timing of Vaccinations Compared to Number of TRICARE Beneficiaries* Seen for Influenza Symptoms**



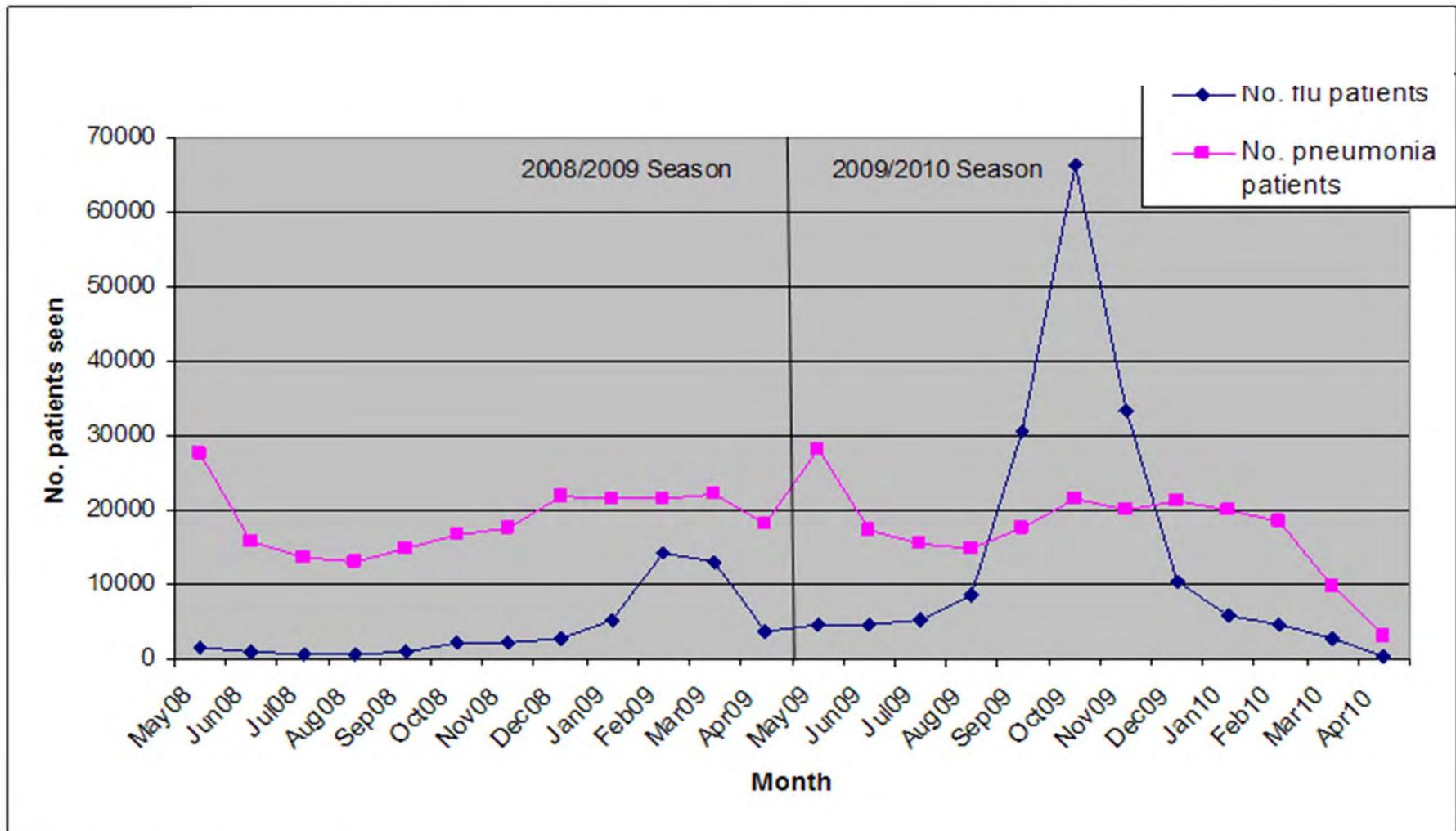
Patients seen by month of initial diagnosis of each flu season plotted against influenza vaccinations



****Services rendered by line assets in the field are excluded;**

****MDR Immunization data used to visualize timing**

Number of TRICARE Beneficiaries Seen for Influenza-like Illness and Pneumonia by Month



Source: [MDR](#) as of 11 May10

2011 MHS Conference



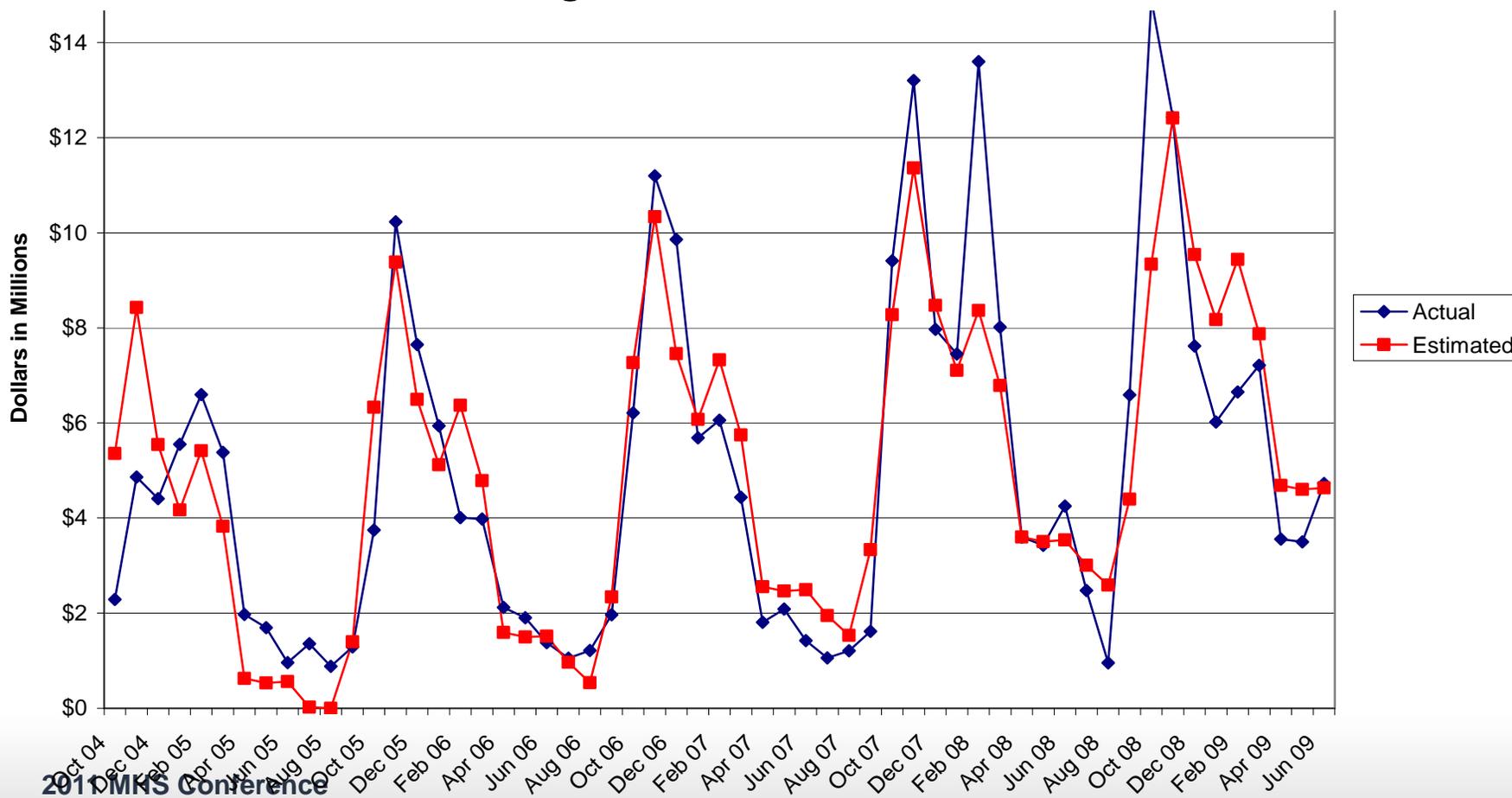
H1N1 Pandemic Costs: Data & Methodology

- Oct 2005 – Jan 2010 MHS data (SIDR, SADR, TED, PDTS, and DEERS) were used to examine costs of flu immunizations and costs of care for TRICARE beneficiaries with ILI
- Costs were calculated with multiple linear regression models for type of care (inpt, outpt, ER, Rx, immunizations) and source (DC, PC) controlling for eligibility, age, beneficiary category, seasonality, and underlying time trend
- The model-projected flu costs were compared to the actual flu costs to isolate the incremental cost of H1N1

The Model Estimates for Normal Flu Compared with Historical Costs



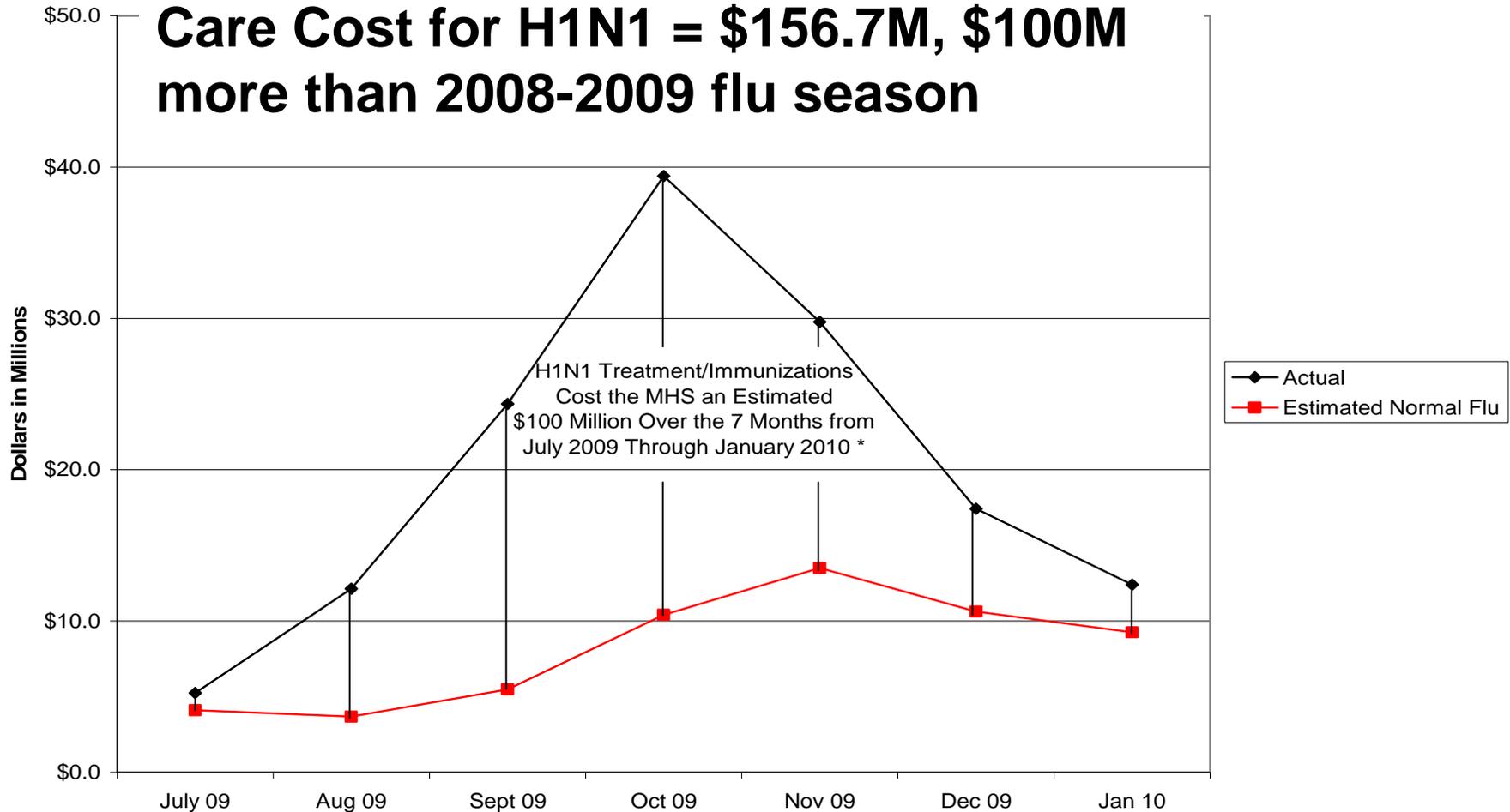
Monthly Total TRICARE Direct Care and Purchased Care Costs Associated with Flu Treatment and Immunizations Occuring Prior to H1N1 Outbreak



H1N1 Financial Impact on TRICARE



TRICARE Direct Care & Purchased Care Cost for H1N1 = \$156.7M, \$100M more than 2008-2009 flu season



Source: MDR as of 11 May 10

H1N1 Financial Impact on All TRICARE Beneficiaries



- 61% of the H1N1 cost impact was for ages 0-24
- 72% of the H1N1 cost impact was for Active Duty and family members
- **Costs do not include:**
 - Services rendered by line assets in the field
 - Costs of preparing for H1N1, i.e., surveillance, stockpiling of medical supplies and drugs, etc.
 - Vaccine costs borne by government
 - Lost work productivity

Lessons Learned



- MHS H1N1 vaccine strategy had limited effectiveness
 - Population already exposed prior to vaccine availability
 - Not effective without lead time to develop vaccine
 - Lag time (weeks) between vaccine receipt and vaccine administration impacts immunity and transmission
- In pandemic situation, DoD needs to be resourced and allowed to purchase vaccines directly from manufacturer to help assure force readiness OR develop a faster process for receipt and distribution of vaccines
- There is no real time source to collate the vaccination rates of all TRICARE beneficiaries

Recommendations



- **Aim for 90% vaccination rate within month of vaccine receipt**
 - Review supply chain at central depot(s) to ensure timely processing and distribution
- **Support information-based decision-making**
 - Use of Pandemic Influenza Watchboard as primary data source for DoD guidance
 - Obtain systematic feedback from the field to help evaluate rates of illness and vaccine coverage
 - Where feasible, develop TRICARE claims coding for type of flu vaccine, flu strain, and flu strain -specific treatment
 - Improve cost accounting for vaccine purchase and administration
 - Monitor TRICARE beneficiaries about receptivity toward flu vaccines

Recommendations, cont.



- **Review and revise pandemic response policies to assure that**
 - All federal agencies recognize and agree upon the necessity for timely distribution of vaccines and other pandemic control measures to FHP as a matter of national security
 - Roles, responsibilities and authority for DoD individuals involved in pandemic planning and response are visible
 - There is standardized guidance based on vaccine availability and population priorities

- **Maintain current efforts to keep TRICARE beneficiaries well-informed about influenza (H1N1, seasonal and others) with respect to**
 - Importance of immunization
 - Immunization priorities for vulnerable populations
 - Availability and access to immunizations (i.e., where and when)

Three “Take-Aways”



1. Overall the Department of Defense was well prepared for an influenza pandemic.
2. Most of the gaps identified in the DoD after action report represented issues outside of the control of the Department of Defense.
3. The 2009 H1N1 pandemic had a significant impact on the Military Health System in terms of increased utilization and increased costs.