Editorial

Needed: A more sensible flu prevention

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Abstract

In the spring of 2004, the CDC published new recommendations in regards to Influenza vaccination. During the summer, the flu vaccine manufactured by Chiron in its British plant and intended for the 2004-2005 season was banned for use in the United States. The CDC had already mounted an intense publicity campaign to support its new recommendations when it was faced with the "perceived" shortage. The "threatening" epidemic never materialized and the flu season was one of the mildest. Many lessons were learned: (1) hype and propaganda do not necessarily result in better vaccination rates; (2) unexpected and new virus strains may appear during the season; (3) some of the "at risk-groups" may not benefit from vaccination; (4) Influenza A virus is becoming increasingly resistant to anti-viral medications; (5) avoiding exposure remains the ideal prophylaxis; (6) appropriate and selective vaccination should be closely monitored.

Keywords: Flu vaccine, Influenza A, effective therapy

1. Introduction

Last fall, the poor old folks of Florida had not recovered from back to back hurricanes, in the worst season in a quarter century, when they were thrust into another alarming situation.

The flu vaccine manufactured in a British plant was contaminated with Serratia *Marcescens* and its importation into the United States was banned. As a result, the Country was faced with a "shortage" of 50 million doses of vaccine. The fate of a million doses from the same plant that had already been shipped to the US in July—before the ban—remains unknown.

Maybe like the MMR in *Vive La Difference* [1], they found their way to South America.

Maybe they didn't.

Starting in October, the CDC promulgated serial recommendations and priority lists. There were frequent Press releases and warning bulletins that further frayed the nerves of people of all ages and particularly the elderly.

The News Outlets reported the "crisis" around the clock and had their own "experts" for interviews and advice. Long lines half-way around the block, formed everywhere. In the south, the scared old people stood with their big straw hats in the scorching sun, their water bottles in hand. In the north, because of an unusually cold fall, people lined up on sidewalks, bundled up in heavy overcoats, shivering and waiting.

Those who "got the shot" went home very happy as if they had just won at Bingo. The others went home tired and disappointed but determined to start very early, the following morning, in another line somewhere.

A lottery system was even proposed by some. For the poor old people, these were threatening times? Would they be so lucky to find a dose of vaccine somewhere—some day soon? Will they make it to Christmas? Or will they be among the 36,000 people who die every year from the flu as they have heard?

2. First recorded death of the flu season

On October 13, a 79-year old lady in Lafayette, California collapsed after standing in line, outside a supermarket, in the heat, for four hours. She hit her head and died the following day.

A couple of days later, in Concord, another East Bay community, two women ages 76 and 83, also collapsed from heat exhaustion, after patiently waiting in a long slow line outside a discount store. They were treated on the scene and then transported to a nearby hospital where they were admitted for a couple of days [2].

As expected, the shortage brought out the worst in people and $85 vials of flu vaccine were suddenly available—for $700. This did not please Attorney Generals in several states, who slammed charges of price gouging on the guilty drug distribution companies. [3].

3. The panic

The panic remained carefully and relentlessly orchestrated: Scaring people out of their wits is easier than trying to convince them that the flu vaccine is needed, safe and effective. For an eighty year old, hearing that 36,000 Americans die every winter from the flu can be very unsettling - even when there are very few cases of "Influenza like Illness" (ILI) around.

Obviously, 36,000 Americans don't really die from the flu each year. No one really knows where that figure came from. It was suddenly floated a few years ago and simply stuck. What is certain is that it is doomed to increase. There was a hint already in the July-August 2004 issue of the American College of Physicians' Observer: "The flu leads to 300,000 hospitalizations and kills 36,000 to 40,000 Americans every year."

In fact, according to the CDC's official figures, the actual number of influenza deaths during the years 1997-2002 varied

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from a low of 257 (6 positive cultures) in 2001 to a high of 1,765 (60 positive cultures) in 2000, when the population of the United States was 281,421,906 [4].

4. Antiviral therapy

On November 3, 2004, in spite of the slow start of the flu season, the CDC published its *Interim Chemoprophylaxis and Treatment Guidelines for the 2004-2005 Season:* Amantadine or Rimantadine were recommended for chemoprophylaxis and Oseltamivir or Zanamivir for treatment of Influenza "as supplies allow."

People at "high risk" were to have priority in case of shortage. Details about both treatment and prophylaxis with the antiviral medications were carefully outlined [5].

The document also made reference to the *Strategic National Stockpile* and offered reassurance that **"**Efforts are underway by Health and Human Services to procure additional supplies of antiviral medications. Some of the supply was to be held in reserve in the event of an influenza pandemic. However, some of the supply was made available to States and Territories for use in outbreak settings, as might occur in a hospital or long term care facility."

In a separate document [6], the CDC listed the side effects of the four recommended antiviral drugs and warned about drug interactions. Noteworthy was the statement about their use during pregnancy: "No clinical studies have been conducted regarding the safety or efficacy of amantadine, rimantadine, zanamivir, or oseltamivir for pregnant women; only two cases of amantadine use for severe influenza illness during the third trimester have been reported. However, both amantadine and rimantadine have been demonstrated in animal studies to be teratogenic and embryotoxic when administered at substantially high doses. Because of the unknown effects of influenza antiviral drugs on pregnant women and their fetuses, these four drugs should be used during pregnancy only if the potential benefit justifies the potential risk to the embryo or fetus (see manufacturers' package inserts)."

For the sake of brevity, only reactions occurring after Amantadine (brand name: Symmetrel), will be listed [7]. Amantadine is only effective against Influenza and is only used to "prevent" the disease. It is therefore not intended for treatment. (Amantadine is also used in the treatment of Parkinson's disease and drug-induced extra-pyramidal reactions).

The adverse reactions reported in up to 10% of patients taking the recommended dose of Amantadine are dizziness, insomnia and nausea.

Up to 5% of the patients on the medication complained of or exhibited agitation, anxiety, confusion, depression, diarrhea, dry mouth, dry nose, hallucinations, headache, hypotension, irritability, fatigue, loss of appetite, nervousness and peripheral edema.

Less than 1% of patients reported: congestive heart failure, difficulty breathing, eye/optic nerve pathology with vision problems, hyperkinesia, hypertension, psychiatric difficulties, skin rashes, slurred speech, urinary retention etc

Convulsions and suicidal tendencies/suicide were very rarely reported (<1:1000).

Interestingly, a study published in the August 28, 2004 issue of *The Lancet* described emerging resistance of the Influenza type A virus to Oseltamivir [8], one of the two drugs recommended for treatment.

According to the authors, some children were still infectious after five days of treatment and some 18% of the treated children developed mutant drug-resistant viruses as early as four days after therapy with Oseltamivir was initiated.

5. The dollar factor

Vaccine and antiviral drug manufacturers were not the only industries hoping to cash in on the "crisis". Makers of antibiotics were also getting ready to have their piece of the pie.

The division vice-president of investor relations of a leading pharmaceutical company told analysts that the shortage of flu vaccine could provide "some incremental positive impact." The reason was that the sales of broad-spectrum antibiotics are affected by the severity of the flu season as those antibiotics are used to treat secondary infections and complications such as pneumonia and bronchitis. The analysts were reassured that as the severity of the flu season "ramps up", secondary infections will increase and the demand for the company's main broad-spectrum antibiotic, and its sales, will also increase.

During the fourth quarter of 2003 that included much of last year's flu season, the broad-spectrum antibiotic in question generated $225 million in US sales, a 21.4% increase over the fourth quarter of 2002 [9].

6. The ripple effect of the "shortage"

The vaccine "shortage" resulted in unique situations and events.

In early December, a licensed practical nurse in surgical scrubs walked calmly into a hall at a college in Minneapolis, set up a table and started administering "flu shots" to students. Things went well and she returned to her chosen spot the following two mornings.

At least 38 students were vaccinated and each gladly paid the $20 fee charged for the injection [10].

It was later revealed that this nurse worked for a healthcare service that held flu vaccination clinics nationwide. Her supervisors had asked her to dispose of partially used vials of vaccine rather than return them to the company headquarters. According to her attorney, she decided instead to sell the leftover vaccine to raise money for the American Heart Association. Apparently a contest to raise funds for the Heart Association was being held at the school that her daughter attended and stuffed animals were promised to those students who collected the most donations. The lawyer assured the investigating authorities that indeed all generated income from the make-shift clinic had been turned over to the gym teacher in charge of the contest.

The American Heart Association immediately denied any involvement or even knowledge of the incident and a Health Department spokesperson reassured everyone that the used vaccine appeared legitimate.

The College apologized to the students, reviewed the existing security measures and released a new recommendation: All

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vendors will have to display their permits. The vaccinated students in turn graciously accepted the apologies.

In New Jersey, a stranger event took place. A man walked into a hospital and calmly offered flu vaccine for sale. The hospital administrator just as calmly contacted the authorities and agents from U.S. Immigration and Customs Enforcement intercepted the shipment at John F. Kennedy International Airport on November 16 and seized 8,000 doses of vaccine. [11].

The vaccine had been shipped from the French drug company Aventis Pasteur to Saudi Arabia and then sent by air via commercial carrier to New York. A federal official was reassuring: "There is no evidence pointing to a conspiracy or organized effort to smuggle flu vaccine."

New Jersey reported its first confirmed case of influenza in the end of November.

7. More vaccine to the rescue

In early December, U.S. health officials approved the importation of up to 4 million doses of Fluarix™, the influenza vaccine made by GlaxoSmithKline (GSK) bringing the total to 65 million doses of vaccine for the season [12].

Because of the "crisis situation" and the fact that the FDA had not yet approved Fluarix™, it was decided to release it as an "investigational drug". On December 6, the CDC Director told an AMA briefing session "since these vaccines are investigational they will require informed consent." Upon further questioning, the Director added that "a standard medical consent will be required."

Health and Human Services Secretary Tommy Thompson was jubilant: "With the latest purchase we will be able to protect more high-risk Americans this flu season in communities across the country".

The following day, N. J. Burkett, of *ABC – Eye Witness News*-New York reported: "Strange Turn in Flu Shot Shortage: City Has a Surplus; Concern about High Risk Patients Rises, as Clinics Sit Empty [13]."

On December 10, *NBC News*-San Diego reported that there was indeed no shortage of flu vaccine in the sunny city; one clinic had over 18,000 doses of pediatric flu vaccine and no takers. "We have a quarter million dollars in vaccine sitting in the refrigerator that we won't be able to use by the end of flu season" said a spokesman for the clinic who added, "We've seen the war zone of about 6,000 people a day trickle down to about 50 people a day [14]."

Three days later, *CNN* announced that there was now a surplus of vaccine in many areas. Long waiting lines had disappeared and employees in vaccination centers were in total disbelief.

In Mid-December at a Seattle grocery store, there were more people waiting at the express checkout lane than at the vaccination line.

A spokesman for the Texas Department of State Health Services describing the situation said, "It's one of those things like Beanie Babies or something … if you can't get something you've got more people wanting them."

Always optimistic, the public health officials said that they were hoping that the demand was dwindling because "the people who need flu vaccine the most: babies, the aged and the infirm had been vaccinated." But they also realistically acknowledged that may be frustration and apathy had become a problem: "Being told they can't get a desired immunization is an unfamiliar and unwelcome sensation for most Americans."

8. CDC pediatric recommendations

The recommendation to vaccinate babies under age 2 was partially based on a CDC-funded retrospective study of some 30,000 children enrolled in a Colorado health plan. The enrolled children were not randomly assigned to receive the flu vaccine or a placebo and the study was never published in a peer-reviewed journal but simply reported in the CDC on-line MMWR (Morbidity & Mortality Weekly Report). When asked about adverse events following vaccination, the lead investigator stated that "Hospital admissions were not tracked, and the parents were not interviewed [15]."

In the past, the flu vaccine had been recommended for children with chronic illnesses and specifically those with asthma (Reactive Airway Disease) in order to protect them not only from the flu but also all its complications.

A study from Strong Children's Research Center in Rochester, published in August 2004, compared outcomes in vaccinated and unvaccinated children, as regards to their asthma symptoms and complications. The results were clearly not those expected by the investigators. After adjusting for other variables, the vaccine group had a significantly increased risk of asthma related clinic and emergency room visits (odds ratios 3.4 and 1.9, respectively).

The authors concluded, "This study failed to provide evidence that the influenza vaccine prevents pediatric asthma exacerbations [16]."

Though strange, that conclusion is understandable.

9. The survey

In December, the CDC published "Estimated Influenza Vaccination Coverage among Adults and Children—United States, September 1 to November 30, 2004 [17]."

To assess the use of influenza vaccine and the primary reasons reported for not receiving vaccine, questions were added to the ongoing Behavioral Risk Factor Surveillance System (BRFSS) survey.

The following information was based on data collected between December 1 and 11 on self-reported vaccination during a 3-month period (September 1 to November 30, 2004). There were in all 16,713 interviews conducted in 48 states and the District of Columbia. Data for Nevada and New Mexico were not available.

The median response rate for states/areas for the preceding month (November 2004) was 52.3% (range: 23.2%-76.8%). For 2003, the last year for which yearly response rates are available, the median response rate for states/areas was 53.2% (range: 34.4%-80.5%).

Among adults in all priority groups, 34.8% reported receiving an influenza vaccination between September 1 and November 30. Coverage was highest (51.1%) among persons aged >65 years, followed by health-care workers with patient contact (34.2%) and high risk adults (19.3%). The percentage of per-

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sons reporting that they obtained an influenza vaccination during this period was smaller in each of these groups than the percentage that said they obtained a vaccination during the previous influenza season, September 1, 2003 to March 31, 2004.

Among persons aged >65 years who reported receiving influenza vaccine during the 2003-04 influenza season, 71.7% reported also being vaccinated during the 2004--05 influenza season. Among adults in priority groups who had not yet received influenza vaccine, 23.3% reported that they attempted to obtain vaccination but could not; among persons aged >65 years, the proportion was 32.5%. Among adults in priority groups, 10.0% of adults said they were saving the vaccine for others, and 6.5% thought that they were not eligible to receive the vaccine.

36.6% of children aged 6-23 months and 26.8% of children aged 2-17 years with high-risk conditions were vaccinated. 51.6% of children with high-risk conditions aged 2-17 years who were vaccinated during the 2003-04 influenza season received the vaccine this year.

62.9% of respondents with an unvaccinated child aged 6-23 months said that they believed that the vaccine was not needed. 8.4% reported that they tried but could not obtain any vaccine. 38.4% of respondents with an unvaccinated child aged 2-17 years with a high-risk condition reported that they thought vaccination was not needed and 14.4% reported that they tried but could not secure a vaccination.

So, by the end of November 2004 and in spite of the most intense publicity campaign ever:

- The 36.6% vaccination rate among 6-23 month-old children is still better than last year's rate of 7.4%.
- Almost two thirds of the adults in the priority group had not been vaccinated.
- Almost half of the elderly, two thirds of the health-care workers and 80% of the "high risk" adults had not also received their "shot".
- Fewer adults in all groups had received the flu vaccine when compared to 2003.
- Over 70% of children at high risk had not been vaccinated.
- Only half of the high-risk children vaccinated during the 2003-04 season had been revaccinated.
- Over 60% of parents of unvaccinated infants and toddlers believed that the flu vaccine was needed.
- Almost 40% of parents of unvaccinated older children in the "high risk" category remained firmly unconvinced that vaccination against the flu was necessary or useful.

The optimistic and unidentified editor of the report did not seem concerned with the results. As expected, he/she was elated about the half-full glass:

- Because of the survey limitations, the results were probably better than they appeared.
- Persons in the priority groups are receiving vaccine at higher rates than those in non-priority groups.
- Because vaccine coverage is below par, efforts should continue "as vaccine becomes available."
- Because (62.6%) of respondents with unvaccinated 6-23 month-old children did not think vaccination was needed, further efforts are needed to educate the public about the new influenza vaccination recommendation for young children.
- The 36.6% vaccination rate among 6-23 month-old children is still better than last year's rate of 7.4%.

Obviously the editor failed to mention that it was only in April 2004 that the Advisory Committee on Immunization Practices recommended the vaccination of 6 to 23 months-old children.

10. The viral studies

Influenza activity in the United States peaked during February 2005 then quickly declined. On March 24, 2005, influenza was listed last on the CDC home page.

10.1 Viral Identification

A total of 108,800 specimens were submitted for viral testing between October 3, 2004 and March 12, 2005. Of these, 17,840 (16.4%) were positive and 81.2% (14,479) of those were Influenza A viruses. Four thousand seven hundred forty-seven (32.8%) of the 14,479 influenza A viruses were sub-typed and 4,734 (99.7%) were influenza A (H3N2) and 13 (0.3%) were influenza A (H1) viruses.

10.2 Antigenic Characterization

Five hundred and twenty seven influenza viruses were antigenically characterized in all: 4 influenza A (H1) viruses, 344 influenza A (H3N2) viruses, and 179 influenza B viruses. The hemagglutinin proteins of the influenza A (H1) viruses were similar antigenically to the hemagglutinin of the vaccine strain A/New Caledonia/20/99.

One hundred forty-five (42%) of the 344 influenza A(H3N2) isolates were antigenically similar to A/Wyoming/3/2003, which is the A/Fujian/411/2002-like (H3N2) component of the 2004-05 influenza vaccine.

One hundred ninety-nine (58%) influenza A(H3N2) isolates had reduced titers to A/Wyoming/3/2003 and were most closely related to a recent reference strain, A/California/7/2004 (H3N2).

In summary, during this season, 58% of patients who had antigenically-characterized Influenza A isolates, had a viral strain that was ***not*** included in the 2004-2005 vaccine. This is almost 3 times more than the 20% reported in public.

11. The pediatric population

Laboratory-confirmed influenza-associated pediatric hospitalizations are monitored in two population-based surveillance networks: the Emerging Infections Program (EIP) and the New Vaccine Surveillance Network (NVSN).

The available and more detailed EIP data for the period of October 3, 2004 to March 5, 2005 show a preliminary influenza-associated hospitalization rate of 1.5 per 10,000 for chil-

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dren 0–4 years old and 0.2 per 10,000 for children aged 5-17 years. The overall hospitalization rate reported by EIP for children aged 0-17 years was 0.7 per 10,000.

The 2003-04 end of season hospitalization rate for EIP was 7.8 per 10,000 children 0-4 years and 0.8 per 10,000 for children aged 5-17 years.

There were 18 "influenza-associated" pediatric deaths reported to CDC this season. Details of the underlying conditions and the actual cause of death were not available for review.

During the 2003-04 season 152 influenza-associated deaths in U.S. residents younger than 18 were reported from 40 states. All patients had influenza virus infection detected by rapid antigen testing, viral culture, or other laboratory methods and most had serious underlying conditions. Several died of bacterial sepsis including one child who had Serratia *Marcescens* bacteremia.

12. The latest news

Towards the end of the season it was revealed (*San Francisco Chronicle*, February 9, 2005) that a new strain of Influenza A virus, dubbed A/California/7/2004, had made a rapid emergence in the western states causing a surge in the number of cases. According to the CDC, the new A/California strain, first cultured in Santa Clara accounted for 20 percent of the Influenza A viruses tested [18].

As mentioned above, 58% of tested influenza A(H3N2) isolates were most closely related to A/California/7/2004.

During the more sever flu season of 2003-2004, the available vaccine did not contain the prevailing Influenza A strain either.

On February 10, 2005, a panel of influenza experts met at the World Health Organization headquarters in Geneva and recommended inclusion of the California strain (A/California /7/2004 (H3N2) in next season's vaccine. The panel usually meets twice a year to formulate vaccines for the two hemispheres.

In a telephone interview, the WHO top influenza expert said that the panel has been wrong only once in the last 10 years [19].

In Mid-February, a new study from the National Institute of Allergy and Infectious Diseases (NIAID) was published in the "Archives of Internal Medicine" [20]. Lone Simonsen, Ph.D., the lead investigator and a senior epidemiologist at the Institute reviewed thirty three consecutive flu seasons (1968 to 2001) and reported that although vaccination rates in the elderly had increased remarkably over the years, the mortality rate had not changed much.

In an interview, Dr. Simonsen discussed the 1997-1998 flu season when the strains included in the vaccine were totally different from those cultured in the fifty states. Over 60% of the eligible elderly were vaccinated during the season obviously without any benefit. There were approximately 5,000 fewer excess deaths in this age group than there were the following flu season, when the same percentage of people were vaccinated with the correct strains.

According to VAERS reports, ten people died shortly after receiving the flu vaccine in the fall of 1997.

The CDC immediately criticized the NIAID study and reassured everyone that no policy change was contemplated because of it.

On Saturday February 26, 2005 *News 4* Georgia reported that "a flu outbreak at a Berrien County nursing home has claimed the lives of 11 elderly patients since Tuesday [21]." All residents of the 63-bed facility who had qualified for a flu vaccine had been vaccinated and standard precautions to prevent airborne contamination had been in effect. Many of those who died had other health problems.

A State health official was quoted as saying that the outbreak showed exactly how unpredictable and easily transmissible influenza can be. Considering that 17% of the vaccinated nursing home population died in 4 days, that was the most remarkable understatement of the whole flu season.

13. The future

The Advisory Committee on Immunization Practices (ACIP) influenza working group has created a tiered system of recommendations for the influenza vaccine to roll out during a vaccine shortage "that can be expected." Keiji Fukuda, MD, MPH, chief of the epidemiology section of the Influenza Branch at the CDC explained the plan by saying, "In a sense, I think that this tiering represents an attempt both to provide some level of granularity that was being requested but also trying to keep people focused on the fact that in many ways it was very, very difficult but not impossible to [categorize] gradations in terms of risk."

The working group proposed that state and local health officials vaccinate groups in tier 1A before all other groups when vaccine supply is "extremely limited." "In normal supply years, tiers 1A, 1B and 1C are considered equal," Fukuda said, "and should be vaccinated simultaneously."

The FDA Center for Biologics Evaluation and Research's Vaccine and Related Biological Products Advisory Committee (VRBPAC) met and endorsed the World Health Organization Global Influenza Program recommendation. The 2004-2005 influenza vaccine for use in the United States will include the A/New Caledonia/20/99(H1N1)-like strain, an A/California/7/ 2004(H3N2)-like strain and a B/Shanghai/361/2002-like virus strain. The inclusion of patients with respiratory capacity compromise, such as those with neuromuscular disorders in the high risk category was recommended.

14. VAERS Reports

Twenty one deaths occurring shortly after flu vaccination were reported to the Vaccine Adverse Events Reporting System from October 1 through December 31, 2004. Seven of those cases were from Missouri alone and four received a dose of flu vaccine from the same lot (U1478AA) on 10/14/2004 and were reported to VAERS on 10/28/2004 in succession (Cases 228345, 228346, 228347 and 228348). Two other elderly persons from Missouri who received a dose from the same U1478AA lot also died: Case 22712 was vaccinated on October 7, 2004 and case 228895 on October 13, 2004.

Seven patients died within 24 hours from vaccination.

Seventeen patients were elderly.

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A 4-year old girl with Tay-Sach disease from California (Case 231627) had a cardiac arrest 3 days after vaccination.

An 8-month-old boy from Ohio (Case 228987) who was a dwarf and microcephalic received a dose of flu vaccine on 10/18/2004 and developed a fever the following day. He later had convulsions and expired on 10/23/2004.

A 5-month-old normal and healthy girl (Case 228504) from New York received DTAP, IPV, Prevnar and Flu vaccine (lot U1407AA) on 10/18/2004. She was found dead in her crib the following morning and was suspected of having had an acute brain syndrome and acute liver damage. Being younger that six months of age, she should NOT have received the flu vaccine.

A healthy 37-year old man from California (Case 231755) received a dose of flu vaccine (lot U1519AB) on November 17 and reacted the following day. He developed an encephalopathy, went into coma and expired on November 23.

The first two disabled children were in all likelihood housebound. Whether anyone discussed the vaccination risk-benefit with their parents is unknown.

The last two cases are tragedies. The vaccine was probably ineffective in the case of the man from California and was clearly contraindicated for the poor 5 month-old from New York.

There were in all six reports to VAERS with lot number 1407AA and 15 other reports with lot number U1519AB.

15. Discussion

In the past, annual flu vaccination was advised for high risk individuals and at-risk health workers, a population of about 185 million people. In spite of the severity of the 2003-2004 flu season less than half that number were actually vaccinated (around 83 millions).

In February 2004, it was revealed that the CDC was considering Universal Flu Vaccination. The recommendation to vaccinate all Americans every year "would improve overall vaccination rates, boost vaccine supply and prepare the public health system for mass vaccinations if a flu pandemic strikes [22]."

In the spring of 2004, the CDC recommended that just about everyone older than six months should receive the flu vaccine—even those who had "never needed" the vaccine in the past.

The CDC spent a lot of time, effort and money during the fall of 2004 on what was called the "flu vaccine crisis".

In retrospect, even after the Chiron vaccine ban there was enough influenza vaccine available for those who needed and wanted it.

When the Chiron situation surfaced and it became clear that the available vaccine supply would not be enough for "everyone the CDC was hoping to vaccinate," the recommendation was changed. Healthy children and adults were to forgo the vaccination so that those individuals "who really needed it"—the elderly and those at high risk, could get it.

When it became clear that actually a large vaccine surplus existed, the CDC changed its recommendation again and offered the vaccine to anyone who "wanted" it.

Administering flu vaccine yearly to children with underlying health problems had been supported and accepted. The 2004 recommendation to vaccinate all children older than 6 months raised eyebrows and prompted questions not only because it was not felt that vaccination was needed but also because most of the available vaccine contained thimerosal.

For the same reasons, the recommendation to administer the flu vaccine to pregnant women caused disbelief and intense concern [23].

The promised flu epidemic for 2004-2005 never came.

16. Parting Questions

1. Is the flu vaccine safe and effective?
2. Do pregnant women and healthy adults, infants and children really need it?
3. Why is the USA the only country where the vaccine is universally recommended?
4. When will the CDC launch the next flu scare?

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