HYPING VACCINES: AN INVESTIGATION

Chickenpox, Lyme, Rotavirus, And A Highly Revealing Analysis Of Flu Statistics

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Years ago, the description of diseases used to be accurate. Smallpox was a very dreaded, serious, and often fatal illness. Certainly, no parent wished smallpox on his children. Chickenpox on the other hand was a relatively benign illness: a low-grade fever, an itchy rash and a week out of school. Like all childhood illnesses, it was worse in adults and parents were actually hoping that their children could "catch chickenpox" and be finished with it for the future.

In 1995, chickenpox suddenly became a major health problem. Six children were reported to have died from chickenpox; frequent and repeated TV coverage lasted for weeks without anyone mentioning that two of the six children had leukemia and the others were on cortico-steroids. Concurrently, chickenpox became a major economical disaster that was gravely impacting the United States economy, as working mothers stayed home to give their children Aveeno baths and syrup to relieve itching. A short time later, the chickenpox vaccine was cheerfully and successfully launched.

Historically, epidemics have occurred in cycles. Experts in infectious diseases could often predict them. The number of unvaccinated children increased during several successive years of low spread and when the reservoir was full, an outbreak, an epidemic or a pandemic occurred. Children then developed a solid immunity that was boosted successfully during subsequent outbreaks. Recently, in the United States, a new epidemiological trend has become very evident: MBAs and Marketing Directors predict epidemics that are then orchestrated to occur, on cue, when a new vaccine is due to be launched.

A flurry of interest about Lyme disease started in the Northeast and Upper Midwest in 1996-97. It promptly snowballed into a major news campaign in the targeted areas, where indeed there were increasing numbers of cases, many with serious long-term complications. In 1998, the LYMErix vaccine received conditional approval by the FDA and was welcome in the geographical locations where the disease was common and often devastating. Unfortunately, it was soon discovered that the vaccine itself had major side effects and doctors became disenchanted with its use. Since the manufacturer discontinued production of the vaccine, the newspaper articles, experts' interviews and television "health minutes" on Lyme disease have completely stopped. It is almost as if the disease has totally disappeared, when it obviously has not.

Years ago, we did not talk much about the rotavirus. Most people did not even know the name and some thought that it was "RotoVirus", because it kept spreading "around and around" nursery schools. We were happy to tell the parents the baby had "some kind of a virus", that penicillin was not going to help, that we were seeing many children with the same symptoms, and that they improved after a few days. We then suggested liquids and a limited diet and the reassured parents left with their little ones, to stop at their neighborhood drugstore for Pampers and Pedialyte. We obviously were immensely more alarmed when a child had salmonella, shigella, cholera, pathogenic E. Coli and staphylococcus gastro-enteritis.

Rarely, the babies with rotavirus infections became dehydrated. They were then brought to a holding unit at the hospital, given intravenous fluids and discharged before 23 hours. Officially, they had not been actually "admitted" to the hospital.

Suddenly, in 1998, every newspaper and every TV news program started continuous reporting on the rotavirus. Overnight, the rotavirus became a household name and the most common cause of diarrhea. It also killed thousands of babies. The fact that the deaths occurred in Third World countries was rarely, if ever, mentioned. In addition, the news programs warned that the economy of the United States was once more in dire danger, that HMOs were almost bankrupt trying to keep up with the rising costs of hospitalizations and that millions of hours were lost in the workplace during the rotavirus season; after all, mothers of affected children had to stay out of work to care for them and could not drop them off, as usual, at schools and day-care centers. In the midst of that intense "information" campaign, the rotavirus vaccine "Rotashield" was released to the joy and relief of The Centers for Disease Control and Prevention (CDC), pediatricians and parents. Because three doses were needed, the delight of the manufacturer and stockholders was tripled. One could almost imagine them visualizing a set of gorgeous blond triplets singing "Triple the Doses, Triple the Dough" using the old and proven tune of "Double the Mint, Double the Fun".

And then, something went wrong, very wrong. It became quickly evident that some infants who received the vaccine developed intussusception, a form of intestinal obstruction and that a few died. The CDC, to its credit, acted promptly and suspended the administration of the Rotashield in July 1999, just a few months after it was released. In October 1999, it issued a detailed statement that started with the following two paragraphs: *"The Advisory Committee on Immunization Practices (ACIP) decided that Rotashield, the only U.S.-licensed rotavirus vaccine, should no longer be recommended for infants in the United States. This action was based on the results of an expedited review of scientific data presented to the ACIP by CDC in cooperation with the FDA, NIH, and Public Health Service officials, along with Wyeth-Lederle. Data from the review indicated a strong association between Rotashield and intussusception (bowel obstruction) among some infants during the first 1-2 weeks following vaccination. Use of the vaccine was suspended in July pending the data review by the ACIP. Parents should be reassured that their children who received rotavirus vaccine before July and remain well are not at increased risk for intussusception now.*

Rotavirus is a severe diarrheal illness in childhood that accounts for more than 500,000 physician visits and approximately 50,000 hospitalizations each year among children less than 5 years of age. Symptoms include fever, an upset stomach and vomiting followed by diarrhea, which may lead to dehydration. This results in $264 million in direct medical costs and $1 billion in total costs to society.

The rotavirus media blitz came to a screeching halt and for four years, interest in the "designer diarrhea" has ranged between nil and minimal. Children with the disease had once again "some kind of a virus."

However, this is due to change AGAIN. Yes indeed, very soon, we will be undoubtedly bombarded once more with a barrage of relentless rotavirus propaganda, diarrhea will become extremely serious in the United States and the cost to the National economy will become even more staggering as the launching of the "new, safe, effective and improved" rotavirus vaccine is carefully orchestrated. This second vaccine has been developed for years and has been ready to go. If rotavirus disease is so serious, the new formulation should have been released already "to save lives". But it was probably felt that releasing it too soon after the first fiasco would not have been a good business move and as it happens sometimes, when it comes to the care of children, MBAs may overrule MDs. So everyone involved had to wait patiently for the opportune time. Indications are that 2004 will be the year.

For years, the inactivated flu vaccine has been recommended for the elderly. It was also recommended for children and adults at risk, mainly those with chronic debilitating conditions. Recently, annual vaccination of all children aged 6 to 23 months and older children and adolescents in their household was recommended. Because of parental concerns over thimerosal, a "preservative-free" pediatric flu vaccine was expressly produced for the 2003-2004 season. Marketing experts decided that the description of the product as "preservative-free" was less controversial than "mercury-free".

A live intranasal flu vaccine, FluMist, was also recently licensed. As per the manufacturer: "*Before you get the flu, ask your health care professional about new FluMist — the first nasal flu vaccine that helps prevent the flu where the flu virus typically enters your body — your nose. FluMist helps prevent the flu for the entire season. FluMist is indicated for active immunization for the prevention of disease caused by influenza A and B viruses in healthy children and adolescents, 5 to 17 years of age, and healthy adults, 18 to 49 years of age. FluMist is not indicated for immunization of individuals less than 5 years of age, or 50 years of age and older.*"

It is not exactly clear why suddenly healthy infants, children and adults under the age of 50 needed to be vaccinated.

As expected, an outbreak of flu occurred in the fall of 2003. A massive barrage of "information" was orchestrated and news programs were saturated except for two days after the capture of Saddam Hussein. There was special emphasis on pediatric cases and particularly pediatric deaths.

According to the 2003 "Red Book" of the American Academy of Pediatrics (AAP), the Report of the Committee on Infectious Diseases and the pediatrician's reference on the subject, par excellence: *"Influenza classically is characterized by sudden onset of fever, often with chills or rigors, headache, malaise, diffuse myalgia, and a nonproductive cough. Subsequently, the respiratory tract signs of sore throat, nasal congestion, rhinitis, and cough become more prominent. Conjunctival injection, abdominal pain, nausea and vomiting can occur. In some children, influenza can appear as an upper respiratory tract infection or as a febrile illness with few respiratory tract signs. In young infants, influenza can produce a sepsis-like picture and occasionally can cause croup, bronchiolitis or pneumonia. Acute myositis characterized by calf tenderness and refusal to walk may develop after several days of influenza illness…"* (p. 382)

Epidemiology and Prevention of Vaccine-Preventable Diseases is an important CDC publication that is often used as a resource. The following is from page 249 of the 5th Edition: *"The severity of influenza illness depends on the prior immunologic experience with antigenically related virus variants. In general, only around 50% of infected persons will develop the classic clinical symptoms of influenza.*

'Classic' influenza disease is characterized by the abrupt onset of fever, myalgia, sore throat, and non-productive cough. The fever is usually 101-102°F, and accompanied by prostration. The onset of fever is so abrupt that the exact hour is recalled by the patient. Myalgias mainly affect the back muscles. Cough is believed to be the result of tracheal epithelial destruction. Additional symptoms may include rhinorrhea (runny nose), headache, substernal chest burning and ocular symptoms (e.g. eye pain and sensitivity to light.)"

All of us who have had the flu remember the aches and pains, and how much our eyes hurt when we moved them. We remember the cough and the fever and the sick stomach. We remember how we felt tired and fatigued for a long while. We actually remember our flu encounters so well that we feel sick all over again watching that great commercial with the poor actor looking so miserable and enumerating all his symptoms.

MMWR

For years, the *Mortality and Morbidity Weekly Report* published by the CDC has been the most reliable source of accurate information on diseases. The CDC was so careful about every statement and figure that it included the following disclaimer in every report on the Internet: *All MMWR HTML versions of articles are electronic conversions from ASCII text into HTML. This conversion may have resulted in character translation or format errors in the HTML version. Users should not rely on this HTML document, but are referred to the electronic PDF version and/or the original MMWR paper copy for the official text, figures, and tables. An original paper copy of this issue can be obtained from the Superintendent of Documents, U.S. Government Printing Office (GPO), Washington, DC 20402-9371; telephone: (202) 512-1800. Contact GPO for current prices*

The MMWR of December 19, 2003 [/ 52(50);1232-1234] covers the period between **December 7 and 13.**

Important portions will be copied verbatim and footnotes will be inserted between brackets, immediately after the corresponding statements for clarity (italics). My comments will appear in bold.

Influenza activity in the United States continued to increase during December 7--13, 2003. [* Provisional data reported as of December 17] The proportion of patient visits to sentinel providers for influenza-like illness (ILI)[†] overall was 7.4%, which is above the national baseline[§] of 2.5%. [[†] Temperature of >100.0° F (>37.8° C) and cough and/or sore throat in the absence of a known cause other than influenza] [[§] Calculated as the mean percentage of visits for ILI during non-influenza weeks, plus two standard deviations. Wide variability in regional data precludes calculating region-specific baselines and makes it inappropriate to apply the national baseline to regional data.]* **The above symptoms are not flu symptoms. They are certainly not those listed in the Red Book and the quoted CDC publication and they are certainly not those that the average person attributes to the flu. A child or an adult with just such a low-grade fever and a cough <u>or</u> a sore throat can hardly be said to have Influenza. The bar has been substantially lowered if the CDC includes such cases in the national flu statistics, whatever the intention. Similarly, one must wonder why and how the 2.5% baseline for low-grade fever, sore throat or cough was decided on. Certainly every primary physician and nurse practitioner will easily assert that year-round, patients with such symptoms amount to a greater percentage of visits. The unrealistic 2.5% figure lowers the bar further.**

During the reporting week of December 7--13, World Health Organization (WHO) and National Respiratory and Enteric Virus Surveillance System (NREVSS) laboratories reported testing 3,814 specimens for influenza viruses; 1,365 (35.8%) were positive. Of these, 262 were influenza A (H3N2) viruses, 1,080 were influenza A viruses that were not subtyped, and 23 were influenza B viruses.

Since September 28, WHO and NREVSS laboratories have tested 32,854 specimens for influenza viruses; 9,464 (28.8%) were positive. Of these, 9,395 (99.3%) were influenza A viruses, and 69 (0.7%) were influenza B viruses. Of the 9,395 influenza A viruses, 2,113 (22.5%) have been subtyped; 2,112 (>99.9%) were influenza A (H3N2) viruses, and one (<0.1%) was an influenza A (H1) virus. All 50 states have reported laboratory-confirmed influenza this season. **The fact that only 1/3 of the submitted specimens were positive is of some concern and may suggest that most of the patients tested may not have had the flu. A more careful clinical diagnosis, based on more appropriate criteria, would have yielded reasonable incidence figures and higher**

confirmation rates. One can only imagine the uproar if surgeons performed appendectomies on patients who vomited once, had a low-grade fever and a vague tummy ache.

*Of 269 influenza viruses collected by U.S. laboratories since October 1 and characterized antigenically by CDC, 265 were influenza A (H3N2) viruses, two were influenza A (H1) viruses, and two were 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. Of the 265 influenza A (H3N2) isolates that have been characterized, 62 (23%) were similar antigenically to the vaccine strain A/Panama/2007/99 (H3N2), and 203 (77%) were similar to a drift variant, A/Fujian/411/2002 (H3N2)**. Both influenza B viruses characterized were similar antigenically to B/Sichuan/379/99. [** Although vaccine effectiveness against A/Fujian /411/2002-like viruses might be less than that against A/Panama/2007/99-like viruses, the current U.S. vaccine probably will offer some cross-protective immunity against the A/Fujian /411/2002-like viruses and reduce the severity of disease.]* **It is imperative to point out that 77% of the cultures antigenically identified by the CDC did not match the strain in the flu vaccine this year. In addition, one must question the first statement in the footnote "***Although vaccine effectiveness against A/Fujian/411/2002-like viruses might be less than that against A/Panama /2007/99-like viruses***". The use of the word "might" seems inappropriate. The vaccine effectiveness against A/Fujian/411/2002-like viruses is definitely less than that against A/Panama/2007/99. The bar has been lowered further. The authors were wise to use the word "probably" in the following sentence:** *the current U.S. vaccine probably will offer some cross-protective immunity against the A/Fujian/411/2002-like viruses and reduce the severity of disease***. Commenting on that possibility, an infectious disease specialist said in an interview:** *"The available flu vaccine will prevent death".*

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On December 19, 2003, a MMWR Dispatch was also published by the CDC (52:1-2). Reported by J Wright, DVM, A Likos, MD, N Bhat, MD [EIS officers, CDC], it was entitled **Update: Influenza-Associated Deaths Reported Among Children Aged <18 Years --- United States, 2003--04 Influenza Season.**

Since October, 42 influenza-associated deaths among children aged <18 years have been reported to CDC. All patients had influenza virus infection detected by rapid antigen testing or other laboratory testing methods. **The fact that all 42 deaths, according to the authors, were "influenza-associated" does not mean that the cause of death was the influenza, of course. The second sentence serves to "reinforce" the first and to convince anyone with doubts. But it cannot change the fact that detection of influenza viral infection in the laboratory does not prove that "The Flu" was the cause of death.**

Among the 42 reported deaths, 20 (48%) patients were male, and 21 (50%) were female; the sex of one patient was not reported. Twenty-three (55%) of the children were aged <5 years, and 13 (31%) were aged 6--23 months. The median age was 4 years (range: 9 weeks--17 years). Seventeen (40%) of the children had underlying chronic medical conditions; the previous medical status for four (10%) children was unknown. Among the 21 patients who had no underlying chronic medical condition, five had invasive bacterial co-infections, including three caused by methicillin-resistant Staphylococcus aureus (MRSA), one by Streptococcus pneumoniae, and one by Group A streptococcus. Three children with underlying chronic medical conditions had invasive bacterial co-infections, including one caused by MRSA, one caused by Streptococcus pneumoniae, and one caused by Neisseria menigitidis. **One must wonder why in a review of national importance, an effort was not made to identify the sex of one child and the past history of four others. The underlying chronic conditions (some children had more than one) were: Lupus 1, cerebral palsy 2, chromosomal abnormality 1, hypothyroidism 1,**

gastroesophageal reflux 1 and biliary atresia 1. Two children were developmentally delayed and 2 had mental retardation. Three children had asthma, one had received a heart transplant, 3 had seizure disorders, one had Pierre Robin Syndrome and the last one had the syndrome of Cornelia de Lange. The available information is not enough to determine the role of the influenza infection in the demise of these children. Eight (19%) of the 42 children had fulminating systemic infections. At least in these, influenza was not the primary cause of death. [The immediate cause of death is listed first on a death certificate. To its right, the physician must enter the interval between onset and death. In the following three lines, underlying and associated causes are listed in order of significance with the intervals between onset and death.]

What may be tragic is the fact that, because of the continuous bombardment with reports of the "epidemic", some parents, believing that their children just had the flu, may have waited too long to seek medical advice for meningitis, septicemia or pneumonia. Similarly, a busy ER physician seeing a multitude of children brought by parents concerned about the "major flu epidemic" going on, may have thought that the child he was sending home, simply had the flu, like all the others. Symptoms of early bacterial meningitis are easily mistaken for the flu. This was evident in New Hampshire around Christmas when an 18-year old co-ed was seen in an Emergency Room, diagnosed with the flu and discharged without further testing only to die of meningococcal meningitis a short time later. The cases of the 5 children in the MMWR report, who died of invasive bacterial illnesses, and who had no underlying condition, should be thoroughly investigated. The fact that they "tested positive for the flu" may be etiologically irrelevant.

Influenza vaccination status was available for only seven patients; five (aged 1 year, 14 months, 20 months, 3 years, and 8 years) were not vaccinated; two (aged 21 months and 5 years) received 1 dose of influenza vaccine; however, their previous vaccination history was unknown. Influenza A viruses were isolated from 11 (26%) patients; 29 (69%) infections were detected by rapid diagnostic testing or by direct fluorescent antibody testing of respiratory specimens. In two (5%) patients, evidence of influenza A virus infection was solely by immunohistochemical staining (IHC) of postmortem tissue specimens at CDC. Five cases that were positive by rapid antigen testing of respiratory specimens also were tested by IHC; all five also had influenza A viral antigens detected *in bronchial epithelium tissues obtained at autopsy. CDC continues to work with state health departments to collect additional information on all cases.* **The lack of information on the vaccination status of 83% of the deceased children is disturbing and indicates a further lowering of the bar. Positive viral cultures are more definitive proofs of viral presence. The fact that viral cultures were positive in only 26% of cases is important. On the other hand, a positive viral culture is not absolute proof that influenza is the cause of death; without more details, its significance is hard to determine.**

Lastly, the fact that the events that followed vaccination of seven children were not made available for review is also of concern.

Before December 2002, there were 12 reports to the Vaccine Adverse Events Reporting System (VAERS) of children under 10, who expired shortly after receiving the inactivated flu vaccine. It is accepted that only a small percentage of actual reactions are ever reported to VAERS. In 11 cases, the flu vaccine was the only vaccine administered. All children had serious underlying chronic illnesses. Five children died within 24 hours of vaccination and 2 within 72 hours.

* * *

Influenza outbreaks are usually widespread and of uniform intensity. So, was the flu a global emergency this past fall, as it seemed to be in the United States? Specifically, what was the situation worldwide during the week of December 7 to 13?

According to a December 23, 2003 report of the World Health Organization (WHO) entitled "**Widespread influenza activity persists in northern hemisphere - update 5" Disease Outbreak Reported that covered Week 50, 7 December – 13 December 2003:** *" Influenza activity associated with influenza A(H3N2) viruses continues to increase in Africa (Tunisia), Europe (Czech Republic, Denmark, Finland, Italy, Norway, Russia, Switzerland, Russia Federation and Ukraine) and North America (the United States), and persists in France and some parts of Canada. In other European countries (Portugal, Spain and the United Kingdom) and most parts of Canada, activity has declined.*

Most influenza infections this season have been attributed to influenza A(H3N2) viruses. The majority of viruses antigenically characterized so far have been shown to be A/Fujian /411/2002-like; the rest have been A/Panama/2007/99-like. There have been few reports of influenza A/Fujian/411/2002-like virus detections from Asia …

An avian influenza A(H5N1) outbreak in poultry in a chicken farm in the Republic of Korea was reported on Tuesday 16 December. The outbreak was recognized by the death of about 19 000 chickens. Surviving chickens in the affected farm were slaughtered. As of Monday 22 December 2003, nine poultry farms in 4 provinces were found to be infected by avian influenza. About one million chickens and ducks are to be culled. The A(H5N1) strain isolated is being examined to determine its relation to other influenza A(H5N1) viruses, which emerged in Asia recently. So far no human A(H5N1) cases have been reported.

It is not unusual for flu outbreaks to be increasing in the second week of December. It is unusual that this outbreak was already decreasing in Spain, Portugal, the United Kingdom and most of Canada. In fact, the British vaccine authorities were so sure the flu season was over that they were happy to sell their leftover stock of flu vaccines to the CDC. Over all, it should be reassuring to note that a shorter paragraph was needed to summarize the influenza activity globally in the week in question (December 7 to13) than to describe what happened in chicken farms in Korea.

Over here, the CDC was publishing on December 11, a long and detailed report entitled **Flu Vaccine Supply—2003-04 Season** which started with the following statement: *"The strong consumer demand for influenza vaccine this year will likely exceed the consumer demand seen in previous flu seasons. Some healthcare providers have used — or may use —- all of their supplies of influenza vaccine. In past years, supply has generally been sufficient to meet demand. This year, however, a strong demand has continued for longer than usual into the month of December. At a time when flu vaccination clinics are typically winding down, people are still seeking vaccination.*

That certainly says it all.

The early reports of vaccine shortage resulted in sustained greater demand. People who had never been interested in previous flu vaccination programs, when the vaccine supply was plentiful, were lining up this past fall before the "vaccine ran out". To its credit, the CDC was able to provide vaccines for anyone who wanted to be vaccinated. Vaccine supplies were redistributed to areas with increased demands and more stock was imported from abroad. People lined up in clinics on a first come first serve basis and in certain sites, had to pick up little pink numbered tickets like those used at delicatessen counters. The vaccine was also administered in drugstores and senior centers.

The owners of a retail chain considered distributing FluMist in their stores but changed their mind when they realized that Christmas shoppers may not be too thrilled if they were sneezed upon and showered with live viruses from vaccinated folks. Computer-literate folks searched on eBay.

In New York, two entrepreneurs without medical or nursing training, rented space in an apartment

building and started administering the flu vaccine to anyone who could afford it. [They were arrested]. In Florida, thousands of doses of an unapproved vaccine almost found their way to the people.

Some HMO's became convinced that the flu was a National Emergency and decided that distribution of the vaccine was the patriotic duty of all healthcare providers. This resulted in payments that were less than the cost of the product and its administration forcing some physicians to refer their private patients to clinics.

Earlier in the season, the makers of FluMist were concerned about the limited popular interest and offered $25 refunds to stimulate sales. Recovery was quick when the shortage of the inactivated vaccine was publicized. The perfect example of a win-win situation was the recent offer by the CDC to purchase a substantial number of doses of FluMist at $20 a dose.

Over all, the sales of flu vaccines exceeded everyone's expectations. Large bonuses must have certainly been distributed and everyone in flu vaccine companies must have had wonderful holidays. That was indeed a very good year and it would not be surprising if textbooks for Business 101 were rewritten to include a chapter entitled: "The Marketing of an Epidemic: The Flu of 2003".

Some of the following questions have been asked. Many more should be.

How effective is the inactivated flu vaccine? Is it safe? Does it still have serious side effects? Does it cause long-term problems? Do the benefits outweigh the risks for everyone including debilitated children and adults? Should preservative–free products be developed for adults and particularly the elderly? How are the strains for the upcoming season vaccine really chosen? Do MDs get vaccinated yearly? How about the owners of the company that manufactures the vaccines?

How good is the live flu vaccine? Will it be considered "safe and effective" after a few years? Do we really need to vaccinate every one?

How serious was this Flu Epidemic?

Why is Medicine changing so much?