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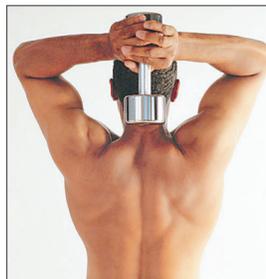
HEALTH

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TUESDAY, OCTOBER 25, 2005

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THIS WEEK IN HEALTH



Moving Crew

Back Off General exercise, not a back-specific workout program, works better to relieve low-back pain. F3

Claim Check

Ahhhh, Youth What a concept: Mouth sprays to make you younger, sexier, thinner. What a scam, says the Federal Trade Commission. F3

My Time

When Spouse Retires, Real Work Begins Some couples are better equipped to handle the lifestyle change than others. F2

KidLife

Nightly Menu Filling up together on family history builds self-esteem and self-knowledge. F2

Quick Studies

The latest on Herceptin for breast cancer, inhaled insulin for diabetes, injections of a rheumatoid arthritis drug to treat psoriasis. F6

LEAN PLATE CLUB

Sally Squires

Healthy Treats? No Big Trick

In less than a week, tens of millions of children will put on costumes and go trick-or-treating in search of candy and other goodies.

At a time when childhood obesity has reached epidemic proportions, Halloween poses some special challenges. Doling out handfuls of high-calorie snacks can seem inappropriate. But dropping baby carrots into trick-or-treaters' bags doesn't seem quite right, especially if you want to avoid having your house wrapped in toilet paper.

"I always want to keep Halloween fun," notes registered dietitian Elisa Zied, a spokeswoman for the American Dietetic Association (ADA) and the mother of two young children. "I eat the candy, too. I just don't eat a lot of it."

Here are some giveaway ideas that kids will consider a treat rather than a trick but that also deliver slightly more nutrition than the rest of the stuff they're likely to collect. By offering them, you may even wind up introducing kids to snacks they'll choose themselves later on.

Introduce dark chocolate. Most kids already love milk chocolate, but fewer have acquired the taste for this darker and less-sweet flavor. Rich in antioxidants, dark chocolate also contains the healthy fat stearic acid and iron, of which most children need more. Studies suggest that stearic acid may not only be good for the heart, but also could help to control blood

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One's zero sugar; one's zero fat.



Joe Huff and his wife, Joy, left, shown with two of their seven children — Ben, 11, and Nicole, 13 — joined a Christian health plan to save on medical bills.

Seeking Divine Protection

By SANDRA G. BOODMAN
Washington Post Staff Writer

When his wife spent a week in Georgetown University Hospital's intensive care unit last year recovering from life-saving brain surgery, Joe Huff never worried about who would pay her \$120,000 hospital bill, even though his family has no health insurance.

Huff, a 52-year-old Laytonville real estate agent, said he trusted that a bill-sharing cooperative of evangelical Christians he joined 10 years ago — and to which he faithfully mailed a \$346 monthly check — would come through, just as it had when the youngest of the couple's seven children was hospitalized with spinal meningitis two years ago.

After a \$250 deductible, Huff said, Christian Care Medi-Share paid for everything. "We also got about 20 cards and letters from people saying they were praying for us," he added.

Huff and his family are among the 60,000 members of Medi-Share, the largest of a little-known group of nonprofit organizations that market themselves as faith-based alternatives to health insurance. The half-dozen plans,

Some Believers Put Faith in Church Plans Instead of Standard Health Insurance

which claim a total membership of more than 120,000 Americans, are especially popular in the South.

The appeal of these "church plans," as they are known in the insurance industry, is both economic and religious. Because their monthly cost is roughly half that of conventional health insurance premiums, they appeal to those who find medical insurance difficult or impossible to afford. And because their membership is strictly limited to evangelical Christians certified as regular churchgoers by their pastors, they cater to people opposed to "subsidizing high-risk, sinful lifestyles," in the words of Medi-Share's Web site.

"A nonbeliever doesn't have an obligation to follow through" by sending a check each month, said James K.

Lansberry, executive vice president of the 35,000-member Samaritan Ministries International of Peoria, Ill.

All three of the largest plans — Medi-Share, Samaritan and the Christian Brotherhood Newsletter, headquartered in Barberton, Ohio — impose strict limits on treatment, restrictions that would be illegal under regulations that apply to conventional insurance.

Tobacco use, immoderate drinking, homosexuality and extramarital sex are strictly forbidden, and anyone caught violating these proscriptions can be expelled. The plans don't pay for abortion, or treatment of sexually transmitted diseases or HIV that was not, as Samaritan puts it, "contracted innocently." While each plan's rules differ, most exclude coverage of preexisting conditions, as well as treatment related to cancer recurrence, serious heart disease, obesity, psychiatric disorders or vision problems.

"Our [members'] greatest sin is racing down to the buffet after the sermon," quipped E. John Reinhold, a former insurance executive who is the founding chairman of Medi-Share, a subsidiary of the American Evangelistic Association, based in Melbourne, Fla.

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HEALTHY SKEPTICISM | Flu Vaccination



Seniors lined up last year for flu shots, which were restricted to high-risk groups. Some in poor health waited hours.

A Shot of Fear

Flu Death Risk Often Exaggerated; So Is Benefit of Vaccine

By STEVEN WOLOSIN, LISA M. SCHWARTZ AND H. GILBERT WELCH
Special to The Washington Post

Medical research often becomes news. But sometimes the news is made to appear more definitive and dramatic than the research warrants. This series dissects health news to highlight some common study interpretation problems we see as physician-researchers and show how the research community, medical journals and the media can do better.

For years, the public health community has used fear as one strategy to promote the flu vaccine. A vaccination poster distributed by the U.S. Centers for Disease Control and Prevention (CDC), for example, emphasizes that "36,000 Americans die of flu-related illnesses each year,"

implying that the vaccine could prevent many of these deaths.

When it became aware of the vaccine shortage last October, the federal government changed course and tried to reassure Americans that going without a shot was no big deal. "We all need to take a deep breath. This is not an emergency," CDC director Julie Gerberding advised the public.

Instead of urging vaccination for everyone age 50 and older, as they had been doing, government officials recommended shots only for people 65 and older, and those in selected high risk groups. The public's response was predictable: People were upset and confused. Our local television news played a story in which a pharmacist was called "a murderer" when his vaccine supply ran out. Ironically, the crisis mentality led some to engage in be-

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■ INSIDE Does vaccination reduce flu deaths?

Enough Vaccine to Go Around

Clinics Expect to Meet Demand This Flu Season

By GREGORY MOTT
Washington Post Staff Writer

If you're looking for a flu shot this season, you shouldn't have much trouble finding one.

As Washington area residents begin lining up in grocery stores, pharmacies and workplaces, federal officials and others monitoring the situation say they don't foresee a repetition of last year's vaccine shortfall, which resulted from the shutdown of an English factory manufacturing drugs for California-based Chiron Corp.

"We don't anticipate a shortage, although there might be a delay" in getting vaccine to doctors who have ordered it, said Norman H. Edelman, chief medical officer for the American Lung Association, which offers a flu shot locator on the Web at <http://www.flucliniclocator.org>. (Maxim Health Systems offers similar information at www.findaflushot.com.)

Shot providers like Giant, CVS and others whose clinics turn up on the shot finder Web sites tend to get their supplies earlier than individual medical practices and public health clinics because they purchase vaccine in large quantities and often have contracts that require early delivery.

The reassurance came after Chiron's announcement last week that its vaccine production for the 2005-06 flu season will fall short of its previously projected 18 million to 26 million doses. The company did not reveal how much of the drug it will be able to make.

Chiron is one of four companies — up from

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As Vaccination Rates Rise, Flu Deaths Little Changed

VACCINE, From F1

haviors that probably increased their risk. Frail elderly people, some with oxygen tanks, stood in long lines in the cold, waiting for the vaccine. Others crowded clinics and doctors' offices, increasing their chance of exposure to flu and other infectious agents.

With uncertainties about this year's vaccine supply, the CDC again recommended that highest-risk people get priority for flu shots, at least until late October. But last year's flu season may have left people confused about essential points: Just how risky is the flu? And just how effective is the vaccine? The answers to these questions may surprise readers.

How Risky Is the Flu?

First, a caveat: The risk calculations we analyze here describe typical flu seasons only. We don't consider here what the picture would be in the event of a deadly flu pandemic — a worldwide outbreak of a new, highly virulent flu strain, the potential for which has recently drawn considerable media attention. No one really knows how likely such an outbreak is, but the risk profile would certainly change. A pandemic is a fundamentally different situation: The risk of death would be substantially higher, and untested strategies (including new treatments, quarantine and a new vaccine) would need to be implemented rapidly.

We deal here with what is known about typical flu seasons, based on data that form the basis for the federal government's flu-risk figures.

By choosing to highlight the annual number of flu deaths, the CDC employed an attention-grabbing tactic often used by public health and disease advocacy groups. It's a tactic readers should be inoculated against if they want a clear picture of the risks they face. (See "Research Basics: Understanding How Big a Risk Is," right.)

In fact, it is very difficult to know how many people die from any given disease because there is often much uncertainty in determining the cause of death. This is particularly true for the flu. That's because it shares symptoms with so many other diseases, and because people most likely to die a flu-related death are also at high risk for many other causes of death.

Flu deaths are probably undercounted because doctors do not routinely test for the flu, and because some deaths that should be



BY M. SPENCER GREEN — ASSOCIATED PRESS
In Chicago this year, Darrvelle Levin draws a dose of flu vaccine.

attributed to the flu are given other diagnoses. For example, someone who dies from a heart attack because they are debilitated by the flu might not get counted as a flu death. Some overcounting of flu deaths also occurs: Clearly not all winter pneumonia deaths are caused by the flu.

According to the CDC, 90 percent of flu-related deaths occur among people age 65 years and older. Based on this information and the age distribution of the population, the chance of a flu-related death for people in that age group is about one in 1,000. Another way of saying this is that the chance of *not* dying from flu for those 65 and older is about 999 out of 1,000. (For context, the chance of a flu-related death is slightly lower than the chance of dying from a fall or other accident.)

For people younger than 65 (including children), the chance of a flu-related death is much smaller — about one in 100,000. Of course, adults and children might be concerned about flu-related problems besides death, such as being hospitalized or just suffering with unpleasant symptoms (typically three to seven days of fever, muscle aches, headache, weakness, dry cough and runny nose). As you might guess, counting the number of flu-related hospitalizations or the number of people experiencing symptoms from the flu is even more difficult than counting flu deaths.

How Good Is the Vaccine?

Getting a shot does not guarantee you will not get sick from the flu or die from it. Recently, the Cochrane Collaboration, an international group that evaluates the evidence for various medical interventions, reviewed the medical

literature on the effectiveness of the flu vaccine in preventing death.

Unfortunately, the evidence on how well the vaccine works to prevent death in the elderly is limited. Few of the existing studies are randomized trials — considered the gold standard for medical evidence. Instead, most data are from observational studies — studies in which scientists simply count up outcomes (here, the number of deaths that occur among people who did or did not get the vaccine).

But drawing conclusions about cause and effect from such observations is fraught with problems.

For example, a 2003 study published in the *New England Journal of Medicine* observed that the flu vaccine was associated with a 50 percent reduction in the overall death rate (that is, death from heart disease, stroke, cancer and all other causes combined). To attribute an effect of this magnitude solely to the flu vaccine is ludicrous: Flu-related deaths make up less than 2 percent of all deaths. If the claim were accurate, the vaccine's power would dwarf that of any other medical intervention. There is, however, a much more likely explanation: People who choose to get a flu shot are much healthier — and therefore already at much lower risk of death — than people who do not.

Only five randomized trials have examined the effectiveness of the flu vaccine. In these studies, patients were randomly assigned — a selection technique equivalent to the flip of a coin — to get either a flu vaccine or a placebo injection. But none of these studies looked at whether the vaccine prevents death. Instead, the scientists measured who developed a flu-like illness. For a summary of the findings of these studies, see "How Well Does the Vaccine Work in the Elderly?" below.

In the absence of good randomized trial data, it is still possible to gauge the effectiveness of vaccination by looking at time trends in flu vaccine rates compared with flu-related deaths in the elderly. As more people get vaccinated, you would expect the flu-related death rate to decline — if the vaccine is effective. But, as the graph below, titled "A Widening Gap," shows, despite a dramatic increase in vaccination among the elderly, deaths from the flu and pneumonia have hardly budged. (The calculations have taken into account the aging of the population.)

For younger adults, flu-related death is so rare that it has not been reliably studied: Doing so would require a trial of millions of people.

Of course, the flu shot may have benefits besides reducing the chance of death. Many get flu shots simply to avoid getting sick. The Cochrane Collaboration identified more than 20 randomized trials addressing this question. The overall chance of developing "clinical" flu (we'll explain in a minute) was 19 percent in those chosen, again by chance, to receive the recommended flu vaccine vs. 23 percent in the control groups.

The careful reader may notice that these percentages are substan-

Research Basics: Understanding How Big a Risk Is

"On average, the flu kills 36,000 people each year in the U.S."

This statement, from the Centers for Disease Control and Prevention's Web site, uses a common strategy to highlight — really exaggerate — risk. The message begins with an attention-grabbing large number, but it provides no information to put the number into context.

To understand this number, readers first need to know "out of how many?": that is, the size of the population at risk. The number of people who could die of flu-related illness is the entire U.S. population. In 2002, the 36,000 flu-related deaths occurred among approximately 288 million people. (The U.S. population today is estimated at about 297 million, but this article and the table below use data from 2002 — the most recent national death data available.)

By highlighting the numerator (the number of deaths) without mentioning the denominator (the total number at risk), the government focuses attention on a large number instead of a small proportion. Explicitly providing this denominator would probably change how readers perceive their risk of dying from a flu-related illness. A clearer expression of the reader's risk might say: This year 0.01 percent of Americans (one in 10,000) will die of a flu-related illness. For most people, the message feels even less threat-

ening when stated as follows: "Out of 10,000 Americans, 9,999 will not die of a flu-related illness this year."

Since 90 percent of flu-related deaths occur among people 65 and older, it is helpful to think about the risks according to age. For people younger than 65, the chance of a flu-related death is about 1 in 100,000. For people 65 and older, the chance is about 1 in 1,000.

Second, once you know the size of risk, it is important to have information to put the risk in context. One way to do this is to compare the risk of flu-related death to death from other common diseases — like heart disease. For the U.S. population, the risk of dying from heart disease in a given year is 0.24 percent — more than 20 times more common than death from flu. Another way to put the 36,000 in context is to compare it to the 2.4 million deaths that occur annually in the United States — so flu-related deaths make up only 1.5 percent of all deaths that occur each year.

The chance of flu-related death this year — like any statistic — can be stated in a variety of ways. We think the most useful way is to present the annual risk (that is, divide the numerator by the denominator) as shown in the table below.

— Steven Woloshin, Lisa M. Schwartz, H. Gilbert Welch

How Big a Killer Is the Flu?

	Flu	Heart disease	All causes
Number of U.S. deaths in a typical year	36,000	703,000	2,443,000
Number who could have died	288,357,000 total U.S. population	288,357,000 total U.S. population	288,357,000 total U.S. population
Annual risk	$\frac{36,000}{288,357,000} = 0.01\%$ (1 out of 10,000)	$\frac{703,000}{288,357,000} = 0.24\%$ (24 out of 10,000)	$\frac{2,443,000}{288,357,000} = 0.85\%$ (85 out of 10,000)

SOURCE: 2002 FEDERAL DEATH CERTIFICATE DATA (AVAILABLE AT [HTTP://WONDER.CDC.GOV/MORTSQ.HTML](http://wonder.cdc.gov/mortsq.html)); ESTIMATE OF FLU DEATHS COMES FROM THOMPSON ET AL. JAMA 2003; 289:179-186.

tially higher than those reported for the elderly. (See "How Well Does the Vaccine Work in the Elderly?") This is because clinical flu is defined as a set of non-specific symptoms including fever, cough and muscle aches — symptoms shared by many non-flu illnesses like the common cold. These non-flu illnesses may be especially common in younger adults because of their exposure to other people, particularly children. To try to isolate the effect of the vaccine, scientists sometimes use laboratory tests to confirm the activity of flu virus in the blood. Using this measure, the chance of flu in the vaccine group is 2 percent vs. 7 percent in the control group.

Studies have also measured another outcome: how vaccination affects days lost from work. On average, there are about 0.16 fewer days lost from work per person vaccinated. Another way of saying this is that about 5 percent of those vaccinated avoid missing about three days of work because of the flu. (That is, 0.16 days divided by the 5 percent who benefited from vaccination equals 3.2 days.) The other 95 percent vaccinated got no bene-

fit.

Take-Home Messages

To promote vaccine use, many in the public health community have overstated the risk of flu-related death and the effectiveness of the vaccine in preventing it. While the flu vaccine may have some important benefit (less flu-related illness), we really do not know whether it reduces the risk of death. For younger individuals — for whom the chance of flu-related death is extremely small — any death-protection benefit can only be very modest (and it is unlikely we will ever reliably know whether it even exists). However, we do know that the vaccine reduces the risk of being sick and time lost from work. But because the effect is small, individuals will have to judge for themselves whether it's worth the bother.

We are not suggesting that Americans forgo flu vaccines. We simply want to help people make informed decisions.

For many people, getting the vaccine is a reasonable choice. And many may reasonably choose not to

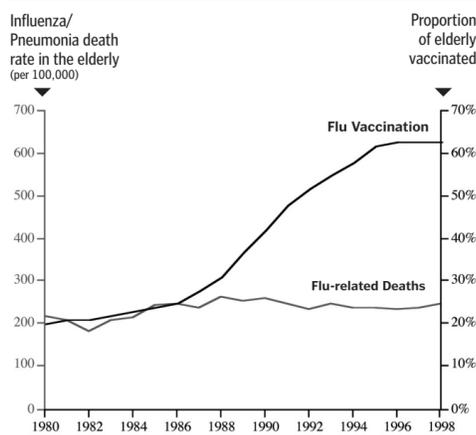
get it. (Consequently, the use of flu vaccination rates by Medicare and others to measure health care quality probably does not make sense.) Regardless, public health officials should not exaggerate risks or benefits to promote vaccination. Exaggeration carries a price: Not only do some people get scared and engage in behaviors that increase their risk (like waiting in a crowded clinic for a flu shot). They may also grow cynical and end up ignoring health messages that really matter.

Steven Woloshin, Lisa Schwartz and Gilbert Welch are physician-researchers in the VA Outcomes Group in White River Junction, Vt., and faculty members at the Dartmouth Medical School. They conduct regular seminars on how to interpret medical studies. (See www.vaoutcomes.org.) The views expressed do not necessarily represent the views of the Department of Veterans Affairs or the United States Government. To respond to this article, send e-mail to health@washpost.com.

A Widening Gap

Despite a rapid rise in vaccination among the elderly between 1980 and 1998, the death rate from flu-related illness in this population has remained flat. One implication: The vaccine is not all that effective in lowering the risk of death.

Trends in use of flu vaccine and mortality from influenza and pneumonia for Americans age 65 and older, 1980-1998.



*Age-adjusted death rates are from federal death certificate data (available at <http://wonder.cdc.gov/mortsq.html>); Vaccination rates in the elderly are from national survey data reported in the CDC publication, *Morbidity & Mortality Weekly Reports*.

How Well Does the Vaccine Work in the Elderly?

Despite 64 published studies over the past 35 years, we really don't know how well the flu vaccine works to prevent serious illness and death in the elderly. How is this possible? The answer has to do with how the studies were done.

Fifty-nine of the 64 studies were observational; that is, studies where scientists simply count up outcomes (e.g., the number of flu-like illnesses among people who did or did not get the vaccine). Observational studies cannot prove cause and effect. And

findings that are encouraging — for example, fewer deaths observed among those vaccinated — may not mean the vaccine works. Rather, such results may simply reflect that the people who get vaccinated are generally healthier than those who do not.

The five remaining studies were randomized trials — the gold-standard experiments most trusted in science. None of the five looked at the vaccine's effect on flu-related death; what they looked at instead was the vaccine's effect on getting the flu or a

What was an elderly person's chance of having a flu-like illness in a flu season?

	placebo group	vaccine group
Nursing Home		
Study 1 (Russia)	13%	5%
Study 2 (U.S.)	15%	6%
Community		
Study 3 (Netherlands)	4%	2%
Study 4 (Britain)	9%	5%
Study 5 (U.S.)	4%	2%

SOURCES: LANCET ONLINE COCHRANE REVIEW 2005 AND ORIGINAL JOURNAL ARTICLES

flu-like illness. The results suggest that flu shots have a larger ef-

fect in nursing homes than in the community at large.

Officials Predict Ample Flu Shot Supply This Season

FLU, From F1

three — producing flu vaccine for the U.S. market, the Food and Drug Administration (FDA) said in a news release after the company's announcement, adding that the government has been working with producers to ensure "an adequate, safe and effective supply of vaccine" for this year.

A new injectable vaccine, GlaxoSmithKline's Fluorix, has been approved by the FDA for use in people age 18 and older, joining Chiron's Fluvirin, Sanofi Pasteur's Fluzone (the U.S. market leader) and the nasal vaccine FluMist from Gaithersburg-based MedImmune. The Centers for Disease Control and Prevention (CDC) had indicated before Chiron's announcement that 80 to 100 million doses of flu vaccine might be available

nationwide this season; 61 million doses were available last season.

Edelman said matching supply to demand is an annual problem for those distributing the vaccine, "because you don't know what the demand will be."

Another issue, he said, is the growing acknowledgement among public health experts that elderly people — who make up a large portion of the high-risk population given priority for flu shots — in many cases get little or no benefit from the vaccine. "Some of them have immune systems that are just not responsive enough and vaccine just doesn't elicit an appropriate antibody response," Edelman said.

New attention is being focused lately on how the illness is spread. "Everyone agrees that the vectors — the Typhoid Marys of the system — are school-age children,"

said Edelman. "The American Lung Association has said in its public statements that the CDC has to really rethink its strategy, and I think an optimal strategy would be one that encourages all kids to get vaccinated."

The CDC's definition of high-risk is those groups considered to be most likely to develop flu-related complications — people 65 years of age and older, residents of long-term-care facilities, people with chronic cardiovascular or metabolic diseases, children 6 to 23 months of age, pregnant women, health care workers involved in direct patient care and those in regular contact with children under 6 months of age.

Edelman and other health experts say everyone who wants flu protection should get vaccinated and that the government should

play a larger role in making vaccine available and getting people to use it. But evidence suggests that even universal availability and access would have limited impact on immunization rates. In the Canadian province of Ontario, which offers free flu shots to every person who lives, works or attends school there, less than half the population got vaccinated last year, according to Dan Strasbourg, a spokesman for the Ontario Ministry of Health and Long-Term Care.

While there is general agreement that vaccination is the cheapest, best and most effective means of preventing the flu, there are plenty of things people can do to lessen their likelihood of contracting the illness this season. The CDC offers this advice:

■ Avoid close contact with those

who are sick, and stay away from others when you are sick, which means staying away from work, school and errands to avoid spreading illness; and

■ Cover your mouth and nose with a tissue while coughing or sneezing, wash your hands often and avoid touching your eyes, nose or mouth.

Tamiflu (oseltamivir), which has drawn attention as a possible weapon against avian flu, is one of four prescription antiviral drugs — Symmetrel (amantadine), Flumadine (rimantadine) and Relenza (zanamavir) are the others — that have been approved as treatments for those who do get the flu. If taken within two days of contracting the illness, these drugs can shorten the duration of illness by a day or two and make a person with the flu less contagious.

Three of the antiviral drugs — all except Relenza — have also been approved for use in preventing the flu in healthy adults. But Edelman said they are generally not regarded as alternatives to the vaccine, which "is simple, totally safe and much less expensive, especially than Tamiflu."

The antiviral drugs might be useful alternatives for people who cannot receive flu vaccine because they are allergic to eggs, Edelman said. The Lung Association strongly encourages people with asthma to get flu shots, but Edelman points out that those people should not use FluMist, which he said has been shown to trigger asthma attacks in some cases.

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