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Are US flu death figures more PR than science?

US data on influenza deaths are a mess. The Centers for Disease Control and Prevention (CDC) acknowledges a difference between flu death and flu associated death yet uses the terms interchangeably. Additionally, there are significant statistical incompatibilities between official estimates and national vital statistics data. Compounding these problems is a marketing of fear—a CDC communications strategy in which medical experts “predict dire outcomes” during flu seasons.

The CDC website states what has become commonly accepted and widely reported in the lay and scientific press: annually “about 36 000 [Americans] die from flu” (www.cdc.gov/flu/about/disease.htm) and “influenza/pneumonia” is the seventh leading cause of death in the United States (www.cdc.gov/nchs/fastats/lcod.htm). But why are flu and pneumonia bundled together? Is the relationship so strong or unique to warrant characterising them as a single cause of death?

David Rosenthal, director of Harvard University Health Services, said, “People don’t necessarily die, per se, of the [flu] virus—the viraemia. What they die of is a secondary pneumonia. So many of these pneumonias are not viral pneumonias but secondary [pneumonias].” But Dr Rosenthal agreed that the flu/pneumonia relationship was not unique. For instance, a recent study (*JAMA* 2004;292:1955-60) found that stomach acid suppressing drugs are associated with a higher risk of community acquired pneumonia, but such drugs and pneumonia are not compiled as a single statistic.

CDC states that the historic 1968-9 “Hong Kong flu” pandemic killed 34 000 Americans. At the same time, CDC claims 36 000 Americans annually die from flu. What is going on?

Meanwhile, according to the CDC’s National Center for Health Statistics (NCHS), “influenza and pneumonia” took 62 034 lives in 2001—61 777 of which were

attributed to pneumonia and 257 to flu, and in only 18 cases was flu virus positively identified. Between 1979 and 2002, NCHS data show an average 1348 flu deaths per year (range 257 to 3006).

The NCHS data would be compatible with CDC mortality estimates if about half of the deaths classed by the NCHS as pneumonia were actually flu initiated secondary pneumonias. But the NCHS criteria indicate otherwise: “Cause-of-death statistics are based solely on the underlying cause of death... defined by WHO as ‘the disease or injury which initiated the train of events leading directly to death.’”

In a written statement, CDC media relations responded to the diverse statistics: “Typically, influenza causes death when the infection leads to severe medical complications.” And as most such cases “are never tested for virus infection... CDC considers these [NCHS] figures to be a very substantial undercounting of the true number of deaths from influenza. Therefore, the CDC uses indirect modelling methods to estimate the number of deaths associated with influenza.”

CDC’s model calculated an average annual 36 155 deaths from influenza associated underlying respiratory and circulatory causes (*JAMA* 2003;289:179-86). Less than a quarter of these (8097) were described as flu or flu associated underlying pneumonia deaths. Thus the much publicised figure of 36 000 is not an estimate of yearly flu deaths, as widely reported in both the lay and scientific press, but an estimate—generated by a model—of flu-associated death.

William Thompson of the CDC’s National Immunization Program (NIP), and lead author of the CDC’s 2003 *JAMA* article, explained that “influenza-associated mortality” is “a statistical association between deaths and viral data available.” He said that an association does not imply an underlying cause of death: “Based on modelling, we think it’s associated. I don’t know that we would say that it’s the underlying cause of death.”

Yet this stance is incompatible with the CDC assertion that the flu kills 36 000 people a year—a misrepresentation that is yet to be publicly corrected.

Before 2003 CDC said that 20 000 influenza-associated deaths occurred each year. The new figure of 36 000 reported in the January 2003 *JAMA* paper is an estimate of influenza-associated mortality over the 1990s. Keiji Fukuda, a flu researcher and a co-author of the paper, has been quoted as offering two possible causes for this 80%

increase: “One is that the number of people older than 65 is growing larger... The second possible reason is the type of virus that predominated in the 1990s [was more virulent].”

However, the 65-plus population grew just 12% between 1990 and 2000. And if flu virus was truly more virulent over the 1990s, one would expect more deaths. But flu deaths recorded by the NCHS were on average 30% lower in the 1990s than the 1980s.

If passed, the Flu Protection Act of 2005 will revamp US flu vaccine policy. The legislation will require CDC to pay makers for vaccines unsold “through routine market mechanisms.” The bill will also require CDC to conduct a “public awareness campaign” emphasising “the safety and benefit of recommended vaccines for the public good.”

Yet this bill obscures the fact that CDC is already working in manufacturers’ interest by conducting campaigns to increase flu vaccination. At the 2004 “National Influenza Vaccine Summit,” co-sponsored by CDC and the American Medical Association, Glen Nowak, associate director for communications at the NIP, spoke on using the media to boost demand for the vaccine. One step of a “Seven-Step ‘Recipe’ for Generating Interest in, and Demand for, Flu (or any other) Vaccination” occurs when “medical experts and public health authorities publicly... state concern and alarm (and predict dire outcomes)—and urge influenza vaccination” (www.ama-assn.org/ama1/pub/upload/mm/36/2004_flu_nowak.pdf). Another step entails “continued reports... that influenza is causing severe illness and/or affecting lots of people, helping foster the perception that many people are susceptible to a bad case of influenza.”

Preceding the summit, demand had been low early into the 2003 flu season. “At that point, the manufacturers were telling us that they weren’t receiving a lot of orders for vaccine for use in November or even December,” recalled Dr Nowak on National Public Radio. “It really did look like we needed to do something to encourage people to get a flu shot.”

If flu is in fact not a major cause of death, this public relations approach is surely exaggerated. Moreover, by arbitrarily linking flu with pneumonia, current data are statistically biased. Until corrected and until unbiased statistics are developed, the chances for sound discussion and public health policy are limited.

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PERSONAL VIEWS

The UK flu vaccine shortage—who is at fault?

It is a very British thing to do: when people complain, someone must be at fault. Recently the health secretary, Patricia Hewitt, suggested that general practitioners might have been giving flu vaccine to the “worried well” rather than to those patients who are most at risk and thus recommended for vaccination, resulting in a shortage. The suggestion led GPs’ leaders to defend their profession and to blame the shortage on heightened public awareness of avian flu and the threat of a human pandemic, increasing public demand for the vaccine, which has outstripped supply. The debate has now moved on to the issue of whether GPs and the government ordered enough vaccine from the suppliers to ensure that all those recommended for vaccination received it (<http://news.bbc.co.uk/1/hi/health/4456876.stm>), as well as the issue of some vital doses being not only given to the worried well but also siphoned off by private companies as perks for their employees.

At the heart of the problem has been our inability in the past in Britain to effectively estimate and target those most at risk and recommended for vaccination. Some 20 years ago flu and its prevention by vaccination were given low priority by the government and the health professions alike. Flu itself was seen as an inevitable consequence of winter, and we just muddled through, again in a very British way.

Between 2000 and 2005 the amount of flu vaccine used in this country doubled

Vaccination on the other hand was seen as a marginal pursuit in general practice for small financial gain. This climate of apathy led to only 1.5 million doses of vaccine being given, mostly to the worried well, while those who would benefit most—sick and elderly people—were left unprotected.

Studies that I and others carried out in the early and mid-1990s (for example, *BMJ* 1997;315:1069-70) showed that over half of all vaccine was given to the worried well and that less than half of those who would most benefit from it received it, despite the fact that vaccine delivery had risen to more

than four million doses. Even by 2000, when the UK government had introduced an age based policy of vaccinating everyone aged 75 years or over (revised in subsequent winters to 65 or over), we as a nation were still protecting fewer than six million of our citizens. In one hospital included in our studies less than a third of the patients at high risk who were admitted to hospital with complications of flu had received vaccine that winter.

The introduction of an aged based policy should have addressed the two important factors in vaccine delivery—who we should target, and how much vaccine we

need—at least among elderly people. Target payments in England and item of service fees in Wales and elsewhere should have created an incentive for GPs to target people recommended for vaccination. So has the system worked? Or is it in as much chaos as the media coverage in the last couple of weeks would have us believe? Using data derived from GP computer systems, I and others estimated some years ago that to vaccinate everyone aged 65 or over and younger people with high risk conditions we would need to have available enough vaccine for 23% of the UK population, or about 14 million doses, the amount this year ordered by GPs from manufacturers (*Lancet* 1999;353:208-9).

In the years since the introduction of an aged based policy and target payments to GPs a number of positive changes have occurred. Primary care professionals’ previous reactive behaviour to each autumn’s flu

vaccine campaign has been replaced by a systematic approach to preventing a lethal disease. This has been shown in two ways: firstly, in the number of complaints from the worried well saying that in previous years they always used to be vaccinated but now their GPs are refusing to inject them; and

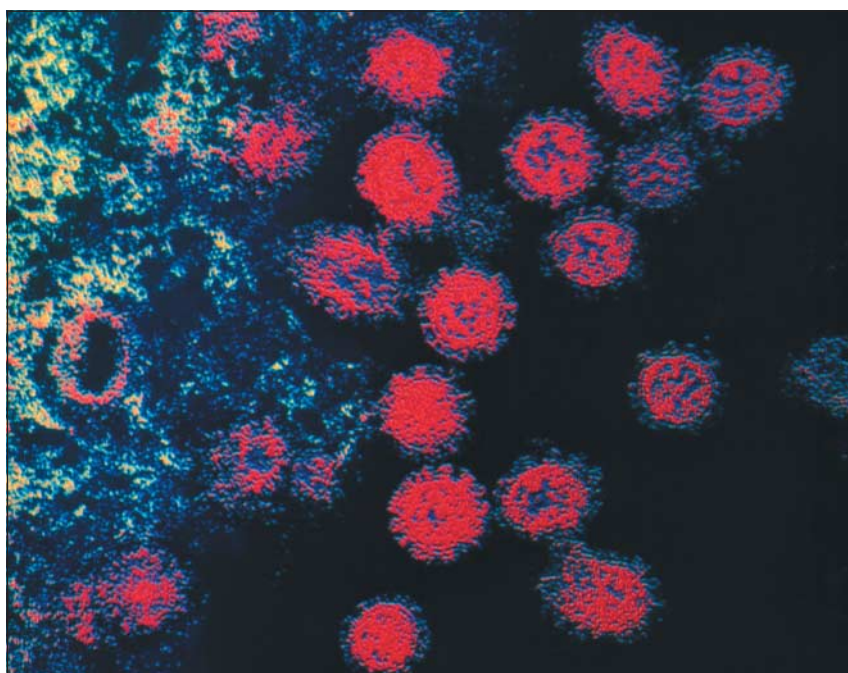
secondly, in the rise in the uptake of vaccine across the UK, overall and in specific groups. Between 2000 and 2005 the amount of flu vaccine used in this country doubled, to reach 14 million doses this year. A study we carried out across England and Wales, looking at outpatients with high risk conditions that would make them eligible for vaccination, found that vaccine uptake was more than 90% in all the hospitals surveyed.

Rather than arguing about who is to blame, we as a nation should be congratulating ourselves that in five short years we have increased our vaccine use such that enough vaccine is available for everyone who is eligible and that more of these people have been protected than ever before. The real question now is whether the government is going to take the brave step of lowering the age of eligibility further to 55, as in the United States, or go for universal coverage, as Ontario has done. This second policy would serve not only to protect more citizens but also to increase vaccine production capacity so as to meet any emerging threat of a pandemic.

Is the government going to take the brave step of lowering the age of eligibility to 55?

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Competing interest: JW has on occasion been a scientific adviser to Wyeth, Chiron, and Sanofi Pasteur MSD.



DR GOPAL MURTHI/ISPL

A public enemy: but what's the best way to fight it?

Business sector shuns tobacco companies

The World Health Organization's current estimate of the global number of deaths caused by tobacco use each year is 4.9 million. That's nearly four deaths a second, and about half of these people die before their working life ends. The great majority of these preventable, often wretched and painful early deaths occur among cigarette smokers. And the great majority of these smokers are the best, most loyal customers of multinational tobacco companies such as British American Tobacco (BAT) and Philip Morris.

All four companies said they had not known that BAT was the headline act... all four rapidly withdrew

So imagine yourself as the chief executive of a company haemorrhaging customers in this way: BAT, with 15.4% of the global market share, loses 754 600 customers a year; Philip Morris, with 16.4%, contributes 803 600 dead customers. Acres of your embarrassing internal memos have caused you to give up decades of denial that your products cause all these deaths. You're not going to throw in the towel, so the only way forward is to use the device of informed consent—you sell risk. It's almost interesting. Could this approach even be spun as "corporate social responsibility"?

Last month the organisers of a Sydney "master class" on corporate social responsibility showed the door to BAT, originally one of the event's draw cards. The Ark Group had advertised a session featuring BAT, the law firm Minter Ellison, the ANZ Bank, and Vodafone. After successful advocacy initiatives in Hong Kong and Sydney in 2004, where tobacco companies had been withdrawn from similar conferences (*Tobacco Control* 2004;13:445-7), Action on Smoking and Health Australia wrote to the other companies on the programme, inviting them to reflect on whether they felt comfortable sharing the stage with a company whose products killed 50% of those who used them on a long term basis. Minter Ellison replied that they supported free speech. The others did not reply.

While all this was happening, a delegate sent me the brochure for another conference on corporate social responsibility, slated for March 2006 in Sydney and organised by the International Quality and Productivity Centre (IQPC). This time BAT

had gone to the top of the tree as the featured act, with its head corporate social responsibility official from London heading the bill in what the programme promised would "leverage corporate responsibility to guarantee business sustainability" (doubtless translated in the tobacco industry as how to exploit talk about corporate responsibility to keep people smoking).

Were the other featured companies comfortable with this? I contacted a former senior WHO official with impeccable business contacts. Within minutes this official went right to the top of two of these companies: Pfizer, one of the world's largest drug companies, which makes products to help people stop smoking, and McDonald's. I contacted two others listed on the programme: Beyondblue, a prominent lobby group that seeks action to help people with depression, and the head of community and environment at IAG, an insurance group that has taken the concept of corporate social responsibility seriously and as a result is near the top of the St James Ethics Centre's corporate responsibility index.

All four said they had not known that BAT was the headline act when they signed up to speak on the programme. All four rapidly withdrew. Fearing that its conference was going down the plughole, IQPC then withdrew BAT's invitation to speak. Ronald McDonald House, which withdrew, helps children with cancer. The person at Pfizer who was due to speak had worked at

the New South Wales Cancer Council for over 10 years. Was this all just bad luck for BAT? Or was it simply that nearly everyone these days has a friend or relative who has been affected by a tobacco related disease?

Nearly everyone these days has a friend or relative who has been affected by a tobacco related disease

Health groups were the first in Australia to shun the tobacco industry. Then a conga line quickly formed of sporting and cultural groups that refused tobacco sponsorship, before it was eventually banned in Australia in 1994. Most Australian universities do not want tobacco companies' money (<http://tobacco.health.usyd.edu.au/site/supersite/resources/pdfs/UnivTobPolicies.pdf>), and all political parties except the Liberal-National coalition now refuse donations from the tobacco industry. As far back as 1994, a spokesman for a leading executive recruitment agency, Bain and Company, said, "I don't think there's any doubt that it's harder to get enthusiasm for tobacco companies. If you have 10 qualified candidates and you tell them it's a tobacco company, five might say they don't want the job" (*Australian Financial Review* 2 Sep 1994:44).

David Davies, a senior executive at Philip Morris, told the Australian National Press Club in March this year without blinking that his company fully supported Australian government policy "to prevent the uptake of smoking and to encourage and assist as many smokers as possible to quit as soon as possible" (www.philipmorrisinternational.com/PMINTL/pages/eng/press/speeches/DDavies_20050323.asp). All tobacco companies repeatedly say they don't want children to smoke, but none have returned a cent of the estimated \$A18.7m (£8m; \$14m; €12m) in "unwanted profits" they earned in Australia this year from the children's market (*Aust N Z J Public Health* 2003; 27:360-1).

The business community is now dissociating itself from the tobacco industry. As the US health agency the Campaign for Tobacco Free Kids put it in a 2002 poster: "No matter how often a snake sheds its skin, a snake is still a snake."

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Image problem: are tobacco company tactics falling flat?

The nursing profession's coming of age

There has been much coverage in the media recently of the proposed extension of nurses' prescribing rights so that from next spring they will be authorised to prescribe all drugs apart from controlled drugs.

BMA spokespeople have voiced concerns (*BMJ* 2005;331:1159) that patients' safety might be compromised if nurses who have done only a relatively short period of training are able to prescribe a wide variety of drugs. This is nonsense: nursing is a three year undergraduate or diploma level course, and nurse prescribers are highly trained and experienced nurses with many years of post-graduate and often specialist education.

I am a nurse practitioner working in a large general practice in West Yorkshire, where I am a salaried partner. Nurse practitioners have evolved as a distinct nursing discipline over the past 20 years in the United Kingdom, and yet few people know we even exist. Our emergence has in effect been a silent revolution in the delivery of health care. Our own regulatory body has finally agreed to regulate the role and to form a separate part of the nursing register for the "advanced nurse practitioner," so that a uniformly high standard will be defined and only those nurses who have reached that competence may call themselves by that title.

Nurse practitioners are highly experienced nurses who have taken further education—often to master's level—to be able make diagnoses and treat patients with undifferentiated complaints. The further education that nurse practitioners undertake grounds them in advanced clinical examination skills as well as in the underlying sciences, such as pathophysiology and pharmacology, so that they can work safely and effectively. In response to the BMA's comments on our "limited education," I added up all my years of training since starting as a nursing student. I have had 12 years of education, including an MSc in health science and my postgraduate diploma in autonomous nursing practice.

My job as a nursing practitioner in general practice and an extended nurse prescriber means that I work alongside the GPs and offer patients an alternative health-care practitioner to consult. I improve access to medical services and am authorised to order all sorts of investigations, including radiography, and can refer patients for consultant opinion or even admit them as acute patients to hospital if need be. This all sounds like a traditional medical role, but we nurse practitioners are more than this: we inhabit a nursing ethos of which the essence is the therapeutic relationship. This allows us

to connect with our patients and to understand their experience of their illness and to respond to their needs. Our critics say we are being mini-doctors, but actually we are maxi-nurses, and this is not mere semantics: the difference is important. There is much research evidence to show that in comparison with doctors we deliver safe and effective health care, but with a difference: patients often prefer consulting nurses because of our communication skills and because our approach centres on the whole patient.

I was not surprised that the BMA responded so negatively to nurses having enhanced responsibilities. A power struggle is going on. Historically nursing was a docile and predominantly female profession, but now we are challenging doctors on their own territory. In an emotive and defensive response last year the Royal College of General Practitioners said that the proposed expansion of nurse prescribing meant that the role of GPs was being eroded by nurses and would result in GPs being made redundant.

It is sad that instead of trying to enhance the care of patients and to develop better working between professional groups some doctors focus on protecting their turf. Fortunately most doctors do not share the limited view of their representative bodies and have generously pledged nurses their support and have full confidence in our ability to work autonomously in these expanded roles. To function most effectively, and for the good of patients, nurses and doctors need each other. The two professions have a symbiotic relationship, and I suspect it will ever be thus.

The distinction between medicine (diagnosis and cure) and nursing (care) has become increasingly blurred. Medicine and nursing are parts of a continuum, and where you are on that continuum—whether you are a doctor or a nurse—changes depending on what the patient needs from you at any one time.

In 2005 we have nurse practitioners as full profit sharing partners in general practice. Some practices are even nurse led—it is the nurses who employ the GPs, and patients are formally registered with the practice, not the doctor. It behoves us all to remember that professionals—nurses and doctors—should serve society. The practice of nursing is whatever the patient and nurse together agree it is. The only aim to consider is that we respond safely, sensitively, and effectively to our patients' needs.

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SOUNDINGS

Dentures and deep time

The only thing I really remember about "Harold" was that he would keep his dentures in different sets of jars in the laboratory marked "Best Pair," "Reasonable Pair," and "Not So Good." Quite often he would do without them altogether, and then he looked like Harold Steptoe from the 1970s UK television sitcom about rag and bone men.

Harold was not what you would call an inspirational teacher, but on this occasion he passed around a small black rock with shiny crystals on the surface. It was heavy and about twice the size of a golfball.

The students passed it around perfunctorily with a conspicuous lack of interest and mild distaste in case it had come into contact with the dentures. It returned rapidly to Harold who pocketed it, and then droned on about x ray diffraction patterns for 45 minutes.

Through the dusty windows of the Victorian lab we could see a summer afternoon beckoning and our lives drifting away. At the end we were all getting up to leave when someone asked him what the rock was.

It was, he said, the oldest thing you will ever touch. It was a meteorite formed over four and half billion years ago—before the earth or the sun had formed. It was a third of the age of the universe, he said, older than most of the stars in the sky. We asked if we could look again, but he shook his head, rattling his second best pair of dentures.

That was my first experience of "deep time."

My second experience was a couple of years ago. It was 2 am on a crystal clear, starlit night, and from the makeshift observatory at the bottom of our garden I saw the Einstein Cross. It was a tiny, fuzzy collection of five blobs of starlight looking a little like a Gaelic brooch.

When I looked away from the eyepiece I was looking at a landscape of fields and trees lit only by starlight. When I looked back in the eyepiece I was looking at a universe that was a third its present age. Back then there were big fierce stars and little else. There was no rock, no heavy elements, and no life.

Things like that change your perspective. Certainly, if I ever have dentures, I'm not going to have a "Not So Good" pair.

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