Study claiming Tamiflu saved lives was “flawed”

Zosia Kmietowicz [BMJ]
A study that found that neuraminidase inhibitors reduced the risk of death among adults treated in hospital during the 2009-10 H1N1 flu pandemic was based on a flawed analysis, a statistician has claimed.

Mark Jones, a senior research fellow in the School of Population Health at the University of Queensland in Brisbane, told the BMJ that “a crude analysis of the data shows an increased risk of mortality associated with neuraminidase inhibitor treatment,” suggesting that the finding of a reduced risk of death was incorrect.

He has called for the authors of the meta-analysis to release their data for independent analysis. Jones is working on a study to answer the same research question.

For the study, researchers analysed data on 29 234 patients who were admitted to hospital with suspected or confirmed H1N1 flu from January 2009 to March 2011 and treated with a neuraminidase inhibitor, mainly oseltamivir (Tamiflu).

The study was funded by Roche, the manufacturer of oseltamivir, and published this week in Lancet Respiratory Medicine.1

The researchers reported that, in a comparison with placebo, neuraminidase inhibitors reduced the risk of death by 19% in adults treated in hospital for flu (adjusted odds ratio 0.81 (95% confidence interval 0.70 to 0.93); P=0.002). Their data also provided evidence that treatment within two days of the onset of symptoms halved the risk of death in adults in comparison with later treatment (adjusted odds ratio 0.48 (0.41 to 0.56); P<0.0001). They found no reduced mortality risk in children treated with neuraminidase inhibitors.

However, when Jones looked at the data in the paper he found that slightly more patients treated with neuraminidase inhibitors died (1825 of 18 803 (9.7%)) than those who were not treated (959 of 10 431 (9.2%)).

He concluded, “The crude relative risk is 1.06 (95% confidence interval 0.98 to 1.14), suggesting a non-significant increased risk of mortality due to neuraminidase inhibitor treatment.”

He added, “The complex analysis does not take into account time-dependent bias. The analysis that is reported to include NAI [neuraminidase inhibitor] treatment as a time-dependent exposure is incorrect, because the result is impossible, and the survival curves indicate a standard Cox regression has been fitted.”

Jones is working with Cochrane researchers on their analysis of full clinical trial data held by Roche on oseltamivir and by GlaxoSmithKline on its drug, zanamivir (Relenza), which is expected to be published in the next few weeks.

The authors of the Lancet Respiratory Medicine study claimed that their findings vindicated the spending of billions of pounds on stockpiling oseltamivir and other neuraminidase inhibitors during the H1N1 pandemic.

Jonathan Nguyen-Van-Tam, from the University of Nottingham and an author of the meta-analysis, said that that treatment guidelines should support early treatment with neuraminidase inhibitors for influenza-like illness.

Evidence does not support guidelines on saturated fat, researchers say

Jacqui Wise LONDON
Current guidelines that promote high consumption of polyunsaturated fatty acids and low consumption of total saturated fats to reduce the risk of cardiovascular disease are based on inadequate evidence, a new analysis concludes.1

Nutritional guidelines generally encourage eating a relatively low amount of saturated fats such as butter in favour of polyunsaturated fat such as olive oil and sunflower oil. However, guidance about the optimum amounts and types of fatty acids varies from country to country.

The systematic review and meta-analysis, published in the Annals of Internal Medicine, included studies involving more than 600 000 people in 18 countries. The researchers found no association between total saturated fatty acid consumption and coronary risk when they analysed 32 observational studies of fatty acids in dietary intake and 17 observational studies of fatty acid biomarkers. However, total intake of trans fats, found in some processed foods, was associated with coronary disease risk.

The researchers, led by Rajiv Chowdhury from the University of Cambridge, also found that higher intake of polyunsaturated fats did not offer any protection against heart disease. They found some evidence that circulating levels of two main types of long chain omega 3 polyunsaturated fatty acids and arachidonic acid are each associated with lower coronary risk. However, their meta-analysis of 27 randomised trials involving more than 100 000 participants indicated that taking supplements with these nutrients did not significantly reduce the risk of poor coronary outcomes.

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IN BRIEF

Public helps to decode genetic data: Members of the public helped to speed up research at Cancer Research UK by analysing in one month DNA data that would have taken a scientist six months, by playing the smartphone game Play to Cure: Genes in Space.1 Since the game was launched in February there have been 1.5 million classifications (the analysis of the DNA of one chromosome) by players from across the world. Scientists hope the data will help them discover genetic faults that cause cancer.

Children are attracted to colourful packaging, survey finds: Bright, colourful, or interesting packaging is twice as likely as celebrities to influence children (60% versus 20%) when they think about buying a product, a YouGov survey of 550 children commissioned by Cancer Research UK has found. The respondents, who were aged 8 to 15 years, perceived brightly coloured Pall Mall (59%) and Mayfair (63%) cigarette packs as less likely to be harmful than a standardised pack (89%).

Scottish GPs vote for restrictions on e-cigarettes: GPs in Scotland have called for controls to be placed on the use, sale, and display of electronic cigarettes. Their annual conference passed a motion calling on the NHS to introduce restrictions, as a recent YouGov poll showed that children (40% versus 20%) perceived brightly coloured products, such as celebrities to influence children (60% versus 20%) when they think about buying a product, a YouGov survey of 550 children commissioned by Cancer Research UK has found. The respondents, who were aged 8 to 15 years, perceived brightly coloured Pall Mall (59%) and Mayfair (63%) cigarette packs as less likely to be harmful than a standardised pack (89%).

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Nearly 4000 NHS staff laid off in England now rehired: The latest estimate of the number of managers and administrative staff rehired by the NHS in England after losing their jobs because of the changes to the health service has risen to 3950, up from 3234 in December 2013.2 A reported 19126 staff lost their jobs during the reorganisation at a cost to the NHS of £600m to £700m in redundancy payments.

Cases of tuberculosis fall in China: The prevalence of tuberculosis in China fell by more than half between 1990 and 2010 from 170 to 59 cases per 100 000 people, a study in the Lancet has reported.3 The success has been attributed to the roll out of the directly observed, short course (DOTS) strategy, from half the population in the 1990s to the entire country after 2000.

Statins may have fewer side effects than is claimed, analysis finds

Jacqui Wise LONDON

Only a few types of side effect reported from use of statins are genuinely due to the drug itself, as almost all side effects were reported just as often with a placebo, a systematic review of randomised controlled trials has concluded.1 The findings are important, as the NHS in England is considering wider prescribing of statins. Draft guidance from the National Institute for Health and Care Excellence has recommended lowering the risk threshold for starting treatment with statins to prevent cardiovascular disease.2 Researchers from the National Heart and Lung Institute in London carried out a meta-analysis of 29 randomised controlled trials involving 83 880 patients. Overall, the study found serious adverse events among 14.6% of patients receiving statins and 14.9% given a placebo in the primary prevention trials and in 9.9% of those on statins and 11.2% of those on placebo in the secondary prevention trials.

The authors said that evaluation of the efficacy of statins was always based on evidence from randomised controlled trials of the drugs against placebo but that the evaluation of side effects was not. Adverse events listed for statins come from many sources, including observational studies. Many side effects such as myopathy, fatigue, muscle aches, and rhabdomyolysis have been commonly attributed to statins, but the researchers found that these were no more common among patients taking statins than among those taking a placebo. The withdrawal rate from trials was also similar for statins and placebo, at around 12-15%.

Ben Goldacre, one of the authors of the study, said that since their paper was written more research had shown that published research papers often under-reported the side effects of drugs. He said in his Bad Science blog (http://bit.ly/1gf68So) that he would have liked to add a paragraph to the paper: “It is also likely that side effects data [are] collected but not reported in the academic paper: a recent study by IQWig, the German government’s cost effectiveness agency, found complete information for 87% of adverse event outcomes in the standard lengthy regulatory document for industry trials (the clinical study report) but for only 26% of adverse event outcomes in the journal publication.”

Goldacre and colleagues’ study, published in the European Journal of Preventive Cardiology, found that only the risk of developing new onset diabetes mellitus was significantly higher in patients taking statins than in those taking a placebo. Across primary and secondary prevention trials, the rate of developing diabetes was 3% with statins and 2.4% with placebo.

In 14 primary prevention trials that involved 46 262 participants, treatment with statins was associated with an increase in the absolute risk of diabetes of 0.5% (95% confidence interval 0.1% to 1%; P=0.012) and with a reduced risk of death by a similar amount (−0.5% (−0.9 to −0.2%); P=0.003).

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GP pay rise of 0.28% is a “kick in the teeth”

Zosia Kmietowicz BMJ

The government has rejected a recommended pay award of 1% for all NHS staff in England for 2014-15,1 saying that only those staff who were not entitled to an incremental pay rise related to length of service would get the rise. However, about 400 very senior managers in the NHS will get nothing.

The BMA has described the decision—which effectively gives GPs a pay rise of 0.28%—as a “kick in the teeth.”

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Nagpaul said that many doctors were considering leaving general practice or retiring; job satisfaction was at its lowest level since 2001. He added, “Not investing in general practice will make it even harder to retain and recruit more GPs. This is at total odds with the government’s stated aim of expanding the GP workforce to recognise the expanding role and workload in general practice that shows no signs of abating. “It will inevitably result in yet another pay cut. To add insult to injury, this decision comes on the back of several years of effective pay cuts. GPs will justifiably feel they are being unfairly treated as well as devalued. This settlement will also be a blow to patient services, as it will effectively reduce resources for GP practices and frontline services.”

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Cite this as: BMJ 2014;348:g2206
**Young women most at risk are least likely to be offered vaccine**

**Jacqui Wise**  **LONDON**

Young women most at risk of developing cervical cancer are the least likely to have been offered the human papillomavirus (HPV) vaccine or to have completed the course, according to a survey of women attending sexual health services in England. In the journal *Sexually Transmitted Infections* the researchers said that higher risk individuals need to be better targeted to boost uptake of the vaccine, which is below the 80% level needed to make a significant difference to cervical cancer rates.¹

In 2008 an HPV vaccination programme was introduced in the United Kingdom for girls aged 12 to 13 in the UK, with an accelerated catch-up programme for 14 to 18 year olds.²

Researchers surveyed 2247 women aged 13 to 19 attending sexual health clinics in 19 hospitals and 13 community services across England in 2011. The survey respondents had higher than average rates for this age group of risk factors for cervical cancer, including smoking, first sex under the age of 16, and previous sexually transmitted infections.

The survey found that 74% of respondents had been offered the vaccination, mostly in schools. But the proportion was lower in London (66%); among those who were not white (64 to 69%); 17 to 19 year olds (67%); smokers (69%); and those with a previous sexually transmitted infection (63%). Among women not in education, employment, or training the rate was only 49%.

Two thirds of those offered the vaccination took it up, but completion rates were significantly lower among those in the higher risk groups.

Cite this as: BMJ 2014;348:g2190

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**GSK is to employ doctors to speak about its drugs**

**Zosia Kmietowicz**  **BMJ**

The UK based pharmaceutical giant GlaxoSmithKline has said that it plans to employ doctors to educate their peers, rather than pay key opinion leaders to speak about its products at conferences and other events.

GSK announced last December that it was changing its marketing practices to end undue influence on prescribers.¹

In an interview with the news agency Bloomberg, Deirdre Connelly, head of GSK’s US pharmaceuticals business, said that employing doctors to speak as in-house representatives of the company would provide more transparency.²

She said, “We’ll continue to disseminate this very important information on drug benefits and risks, but we’re just not going to do that by hiring external speakers. We want to ensure that no one even perceives us to be doing anything wrong.”

A spokesperson for GSK said, “This doesn’t mean we will simply be bringing KOLs [key opinion leaders] in-house but does mean having more in-house doctors and scientists who can engage with their peers in a transparent way that makes it clear they are GSK employees.”

Cite this as: BMJ 2014;348:g2241

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**HIV tests should be offered irrespective of age**

**Jacqui Wise**  **LONDON**

Healthcare professionals are often reluctant to offer HIV tests to elderly people, with the result that HIV is diagnosed late in many of these patients, an editorial argues.

Eva Bunting and colleagues from the Royal Sussex County Hospital wrote in *Age and Ageing* that it was imperative that geriatricians consider HIV infection within their differential diagnosis and recommend testing when appropriate.¹

As a result of improvements in antiretroviral treatment, an increasing proportion of people infected with HIV are living to an older age. In 2011 a fifth of adults being treated for HIV (22% or 16 550) in the United Kingdom were aged over 50, whereas in 2002 the proportion was one in nine (12% or 3640).

Historically, the medical care of patients with HIV has been largely within genitourinary medicine or infectious disease clinics. But, with an ageing HIV cohort, the editorial said, elderly care physicians will be increasingly involved. Management of older patients with HIV needs consideration of complex drug interactions and comorbidities. The article calls for greater discussion and collaboration among pharmacists, HIV physicians, and doctors from other specialties.

Coauthor Martin Fisher, a consultant physician in HIV and genitourinary medicine, said, “Even when HIV testing is introduced as a routine test there is a reluctance of healthcare professionals to offer HIV tests to older persons. This is despite a year on year increase in the number of older individuals being diagnosed for the first time with HIV. Geriatricians need to enhance their diagnostic consideration of undiagnosed HIV infection and offer HIV testing to persons with clinical indicator diseases, irrespective of age.”

Cite this as: BMJ 2014;348:g2113
Surgeon wins fight over how much he has to tell patients about his record

Clare Dyer BMJ

A cardiac surgeon at the centre of the world’s worst recorded outbreak of prosthetic valve endocarditis need not tell his future patients of his history when he returns to full practice, a High Court judge has ruled.

But Mr Justice Lewis held that Nottingham University Hospitals NHS Trust was not in breach of contract in not getting John Lu back in the operating theatre sooner.

Lu, who became a consultant surgeon at Trent Cardiac Centre in 2007, was colonised with antibiotic resistant *Staphylococcus epidermidis*, which was present in the unit before he arrived.

Eleven patients he operated on between December 2008 and July 2009 developed prosthetic valve endocarditis, of whom five died and another five underwent further surgery. Lu decided to stop doing heart valve replacements and in October 2009 agreed to discontinue surgery altogether during investigations.

Lu, whose clinical skills were not in question, is still employed by the trust. For the past four and a half years he has been on full pay while doing no surgery, although he has done other work.

He has been free of the infection since April 2010, and in August 2012 the trust board decided that he could return to surgery under a phased re-entry programme. But various investigations and some disagreements between Lu and the trust about the terms of his re-entry delayed the process, and he sued the trust for breach of contract.

One issue was what patients should be told about Lu’s part in the outbreak. The chief executive, the medical director, and Lu’s case manager at the trust wanted him to reveal the history of the outbreak when seeking consent from patients to valve surgery.

The judge said that there would be a breach of contract if the trust required Lu to tell patients anything more than the information the individual surgeon considered necessary to obtain the patient’s consent to surgery.

Cite this as: BMJ 2014;348:g2160

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Report clarifies who is responsible for commissioning obesity services in England

Jacqui Wise LONDON

A joint report has set out who should be responsible for commissioning obesity services in England, so as to reduce variation in access to weight management services and bariatric surgery.¹

NHS England and Public Health England set up a working group in response to feedback from local stakeholders that in some areas of the country no organisations were commissioning multidisciplinary team interventions known as tier 3 services.²

A tier 3 obesity service is usually for people with a body mass index >35 with comorbidities or people with a BMI ≥40 with or without comorbidities who have not responded to previous interventions. The weight management programme is delivered by a multidisciplinary team typically made up of a consultant or GP with a special interest, specialist nurse, specialist diettian, psychologist or psychiatrist, and physiotherapist or physical activity specialist.

The working group’s report says that provision of tier 3 services was variable and completely absent in some areas. Without tier 3 services patients can’t usually access bariatric surgery (tier 4), but until now it has not been clear who has primary commissioning responsibility for them.

Families believed that the counselling and support they received at the time their child’s heart condition was diagnosed through the antenatal scan was inadequate and lacked compassion and empathy. “We felt like a piece of meat on a conveyer belt. It didn’t seem like they were talking about our little girl, they were talking about a thing. They kept calling her the fetus,” recalled one parent.

Families felt pressured to have a termination, including a Muslim mother who had religious objections to abortion, and if they refused they thought they were being treated with “contempt,” said Cantrill. Parents complained that they were not fully informed of treatment options and that there seemed to be no care plan for their child. Some said they were not aware that their child’s condition was being managed by care or an operation that was palliative and not curative.

The parent of one child said they had waited three years for surgery only to be told that their daughter’s condition was inoperable and she was not on the waiting list. Parents reported distress caused by what they perceived as the reluctance of Leeds doctors to refer their child to other heart units.

“Some families believe that as a result of requesting a transfer to another hospital they have been accused of harming their children and in some cases they have been referred to social services,” Cantrill said.

Cite this as: BMJ 2014;348:g2147

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Leeds paediatric cardiac care was safe but not caring, report says

Clare Dyer BMJ

The families of 16 children born with serious heart defects did not receive the compassion and support they deserved from Leeds General Infirmary, a review commissioned by NHS England has found.³

In stories described by NHS England deputy medical director Mike Bewick as “harrowing,” parents said they felt pressured to have terminations, were treated coldly and without empathy, and in some cases were not told that their children’s treatment was merely palliative.

But children’s cardiac surgery services, which were suspended briefly in March 2013 after concerns were raised about mortality figures, are safe, a second strand of the review has concluded. An independent examination of 35 deaths between 2009 and 2013 determined that the unit’s medical and surgical care of patients was “in line with standard practice.”

The original mortality figures were incomplete and further analysis showed the unit was safe, although, along with two other units in England, close to the “alert” threshold.³ Families had also complained to the Care Quality Commission and NHS commissioner about the standard of care, so NHS England launched the two strand review.

The 16 families came forward to tell their stories after the family experience reviewer, Pat Cantrill, contacted parent support groups. Six of the children had died, and the families of six had chosen to have their care transferred to a different cardiac unit.

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Smoking in most deprived parts of England is double that in wealthiest areas

Jacqui Wise  LONDON

A new analysis from the Office for National Statistics confirms the strong association between the prevalence of smoking and levels of deprivation in England. Men and women living in the most deprived areas of England were more than twice as likely to smoke as those living in the wealthiest areas, the analysis found.¹

The analysis divided areas of the country into quintiles according to level of deprivation. In the most deprived fifth of areas 32.9% of men and 26.1% of women currently smoke, whereas in the least deprived fifth the respective figures are 14.3% and 10.2% (figure).

The data show that in the most deprived areas smoking among men aged over 18 rises with age to peak at 37.2% at 35–44 years and then declines to its lowest level (13.5%) at age 75 and over. Among women smoking in the most deprived areas drops sharply at 25–34 years but then rises to a high of 31.3% at ages 45–54 before dropping to its lowest level (11.8%) at age 75 and over.

Cite this as: BMJ 2014;348:g2184

Seriously ill patients in UK will have access to unlicensed drugs

Nigel Hawkes  LONDON

Patients in the United Kingdom are to be given access to some drugs before they have been formally licensed, in an effort to speed up access.

The early access scheme, which was first proposed in 2006 and has been under active discussion for the past two years,¹ will apply to life threatening and seriously debilitating conditions.

The first step is for the Medicines and Healthcare Products Regulatory Agency to designate a new drug as a “promising innovative medicine” (PIM) on the basis of early trial data and as long as the agency is satisfied the drug meets an unmet need. Drugs with PIM designation may, once enough data on quality, safety, and efficacy are gathered, be submitted for the second step: approval for use in the early access scheme.

The purpose is to leapfrog the licensing process, which can take a year or more. But the scheme is intended to process only a small number of drugs each year, reckoned to be between five and 12. Typically the drugs will be in or have been in phase II trials. Because the drugs will be unlicensed they will be used on a named patient basis, as unlicensed drugs already are, with legal obligations falling on the prescriber. Patients will need to be well informed and to give active consent.

The scheme’s purpose is twofold: to give patients who have conditions for which there is no effective treatment the earliest possible access to new drugs; and to encourage drug companies to see the UK as a good place to launch new drugs.

The idea was first proposed by David Cooksey in his review of the funding of UK health research, published in December 2006. A plan was produced by November 2009 but languished until revived two years later. The scheme will not be unique—a similar scheme in France has operated for 15 years.

Jeremy Hunt, the health secretary for England, said, “Making Britain the best place in the world for science, research, and development is a central part of our long term economic plan. This groundbreaking scheme will provide cutting edge medicines earlier to give hope to patients and their families and save lives. And as part of our strategy for life sciences it will create more jobs and opportunities for people, helping secure a better future for our country.”

Harpal Kumar, chief executive of the charity Cancer Research UK, backed the scheme. “Time is of the essence for many cancer patients, particularly those with more advanced disease,” he said. “It can mean the difference between life and death. Therefore this scheme, which has at its heart the potential to bring promising new medicines to patients faster, is to be warmly welcomed.

“The scheme should also make it more attractive for life sciences companies to conduct their development activities in the UK.”

The scheme will be introduced in April.
Jennifer Dixon
Not shy about public health

What was your early ambition?
To play Cleopatra. But I was always the shyest girl at school, and I ran a mile from acting or public speaking of any kind.

Who has been your biggest inspiration?
The Russian writer, Varlam Shalamov, for his endurance and fortitude in the Kolyma Gulag camp for 16 years, while remaining human and providing exquisite testimony. Thankfully, none of us has been tested in this way, and remembering him after 90 hour weeks as a junior hospital doctor put a few things into perspective.

What was the worst mistake in your career?
Believing that I was a scientist at heart. It took time to realise (at about age 30) that I could offer more as a “synthesiser” (seeing patterns across a lot of information) than as a “dissector” (pushing the boundaries in any one furrow).

Bevan or Lansley? Who has been the best and the worst health secretary in your lifetime?
I couldn’t possibly say. But politicians ultimately shape the NHS far less than a much bigger set of forces, so it doesn’t matter much in the long run despite what the papers say.

What is your best career move?
“Leaving clinical medicine to develop my skills in policy analysis through public health. I still remember the incredulity on the face of the professor of paediatric cardiology in my last clinical job when I told him I was leaving for public health: “You mean you’re interested in drains and nit control?” But that was 1989, and things have changed . . . a bit.

To whom would you most like to apologise?
I apologise too much, to too many people.

If you were given £1m what would you spend it on?
Kids Company or the Family Nurse Partnership—that is, reducing early life anxiety for babies and children.

What single unheralded change has made the most difference in your field in your lifetime?
The fact that because of technology the public is now in the same “information space” as politicians, who face a challenge as a result.

Do you believe in doctor assisted suicide?
Probably.

What book should every doctor read?
Modern Man in Search of a Soul by C G Jung. And all of Ecclesiastes—life is brief and we are dust in a flash, so enjoy and don’t work too hard.

What poem, song, or passage of prose would you like mourners at your funeral to hear?
Loveliest of Trees by George Butterworth, sung by Roderick Williams (no mourning, please).

What is your guiltiest pleasure?
Kitsch (it’s a love-hate thing) and eBay.

If you could be invisible for a day what would you do?
Lie under a grand piano on which Martha Argerich was playing Prokofiev’s 8th piano sonata.

What television programmes do you enjoy?
You must be joking; life is too short for television.

What do you do for fun?
Paint—plein air when I can and in my studio most of the time. I have an easel in the kitchen, which I enjoy using.

What was your best career move?
Leaving clinical medicine to develop my skills in policy analysis through public health—a much better fit. I still remember the incredulity on the face of the professor of paediatric cardiology in my last clinical job when I told him I was leaving for public health: “You mean you’re interested in drains and nit control?” But that was 1989, and things have changed . . . a bit.

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What is your most treasured possession?
I don’t seem to have one.

What personal ambition do you still have?
Still? To conquer the Russian genitive and paint a few pictures I am happy with.

Summarise your personality in three words.
Driven, (still) shy, intuitive, somewhat contrary. (OK, that’s six, but following rules is not my thing.)

Where does alcohol fit into your life?
We like each other but are distant friends.

What is your pet hate?
Self regard and tinned tomatoes.

What would be on the menu for your last supper?
Grilled buttered lobster with samphire, and a bottle of 2013 Cloudy Bay sauvignon blanc.

Do you have any regrets about becoming a doctor and health policy expert?
No, but the opportunity cost has been very high.

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