

Risk and Uncertainty

The Precautionary Principle:
Immunisation safety: risks, benefits and precautions.

Prof. David Salisbury CB
Director of Immunisation, Department of Health.

The **precautionary principle** or precautionary approach states that if an action or policy has a suspected risk of causing harm to the [public](#) or to the [environment](#), in the absence of [scientific consensus](#) that the action or policy is harmful, the [burden of proof](#) that it is *not* harmful falls on those taking the action.

This principle allows policy makers to make discretionary decisions in situations where there is the possibility of harm from taking a particular course or making a certain decision when extensive scientific knowledge on the matter is lacking. The principle implies that there is a social responsibility to protect the public from exposure to harm, when scientific investigation has found a plausible risk. These protections can be relaxed only if further scientific findings emerge that provide sound evidence that no harm will result. (Wikipedia 2012)

The precautionary principle enables rapid response in the face of a possible danger to human, animal or plant health, or to protect the environment. In particular, where scientific data do not permit a complete evaluation of the risk, recourse to this principle may, for example, be used to stop distribution or order withdrawal from the market of products likely to be hazardous. (Communication from the Commission on the precautionary principle/* COM/2000/0001 final */)

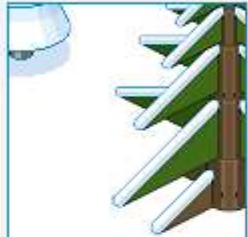
Measles-mumps-rubella-varicella combination vaccine and the risk of febrile seizures.

[Klein NP](#), [Fireman B](#), [Yih WK](#), [Lewis E](#), [Kulldorff M](#), [Ray P](#), [Baxter R](#), [Hambidge S](#), [Nordin J](#), [Naleway A](#), [Belongia EA](#), [Lieu T](#), [Baqqs J](#), [Weintraub E](#); [Vaccine Safety Datalink](#).

Kaiser Permanente Vaccine Study Center, Oakland, CA 94612, USA. nicola.klein@kp.org

RESULTS: MMRV vaccine recipients (83,107) were compared with recipients of MMR + varicella vaccines (376,354). Seizure and fever significantly clustered 7 to 10 days after vaccination with all measles-containing vaccines but not after varicella vaccination alone. Seizure risk during days 7 to 10 was higher after MMRV than after MMR + varicella vaccination (relative risk: 1.98 [95% confidence interval: 1.43-2.73]). Supplementary analyses yielded similar results. The excess risk for febrile seizures 7 to 10 days after MMRV compared with separate MMR + varicella vaccination was 4.3 per 10,000 doses (95% confidence interval: 2.6-5.6).

CONCLUSIONS: Among 12- to 23-month-olds who received their first dose of measles-containing vaccine, fever and seizure were elevated 7 to 10 days after vaccination. Vaccination with MMRV results in 1 additional febrile seizure for every 2300 doses given instead of separate MMR + varicella vaccines. Providers who recommend MMRV should communicate to parents that it increases the risk of fever and seizure over that already associated with measles-containing vaccines.



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Did swine flu vaccine give boy's sleeping sickness that causes him to lose control of his body?

By LYDIA WARREN

Last updated at 12:04 AM on 2nd April 2011

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He used to love nothing more than a giggle with his friends.

But now five-year-old Joshua Hadfield is afraid to laugh because, since developing a rare sleeping disorder, it causes him to lose control of his body and nod off for hours.

His mother Caroline believes he has contracted narcolepsy with cataplexy after having a swine flu vaccination. It is the first case of its kind to be made public.



But the UK's Medicines and Healthcare Products Regulatory Agency, which is aiding research into the vaccination, insisted: 'The benefits of vaccination outweigh any risk of a possible side effect.'

GLOBAL UPDATE

A Surge of Sleepiness in China Appears to Have Been Caused by Flu



STR/AGENCE FRANCE-PRESSE/GETTY IMAGES

By DONALD G. McNEIL Jr.

Published: August 22, 2011

Cases of narcolepsy — a condition that causes sufferers to fall asleep without warning — tripled in China after the 2009 [swine flu](#) pandemic, according to a study released Monday. But the surge appeared to be an annual late spring event caused by [the flu](#) itself, not by China's swine flu vaccination campaign.

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Narcolepsy in Finland after adjuvanted H1N1 influenza vaccine

On 1 February 2011, the National Institute for Health and Welfare of Finland issued a preliminary statement following an investigation into the cases of narcolepsy in Finland¹. A systematic retrospective registry-based review was conducted of all new narcolepsy cases diagnosed during 2006-2010. Cases from 2009-2010, who were born in 1990 or later, were reviewed using newly developed Brighton collaboration criteria for the disease. *During 2009-2010 they found that the risk of narcolepsy among people aged 4-19 years old who had received pandemic influenza vaccine was nine times higher than that among those who had not been vaccinated.* This corresponds to a risk of about 1 case of narcolepsy per 12,000 vaccinated in this age group. No increased risk has been seen in younger or older age groups.

Narcolepsy in Sweden after adjuvanted H1N1 influenza vaccine

The Swedish Medical Products Agency issued a preliminary report on 28 March 2011 following an investigation on pandemic influenza vaccination using data drawn from regional vaccination registries of four Swedish counties². Covering a population of 5.3 million, the risk of narcolepsy was compared in vaccinated and unvaccinated individuals from October 2009 to December 2010. *The Agency reported that the relative risk of narcolepsy was four times higher in vaccinated children and adolescents (born from 1990) compared to unvaccinated individuals.* The relative risk estimate translates into an absolute risk of about 3 cases of narcolepsy in 100,000 vaccinated adolescents/children. The incidence rates for narcolepsy in adults irrespective of vaccination status were similar to historical national registry- based rates during the years before the pandemic period (i.e. about 1/100,000).

[Am J Epidemiol.](#) 1984 Jun;119(6):841-79.

An epidemiologic and clinical evaluation of Guillain-Barré syndrome reported in association with the administration of swine influenza vaccines.

[Langmuir AD](#), [Bregman DJ](#), [Kurland LT](#), [Nathanson N](#), [Victor M](#).

Abstract

As a result of a court order, computerized summaries of approximately 1,300 cases reported as Guillain-Barré syndrome by state health departments to the Centers for Disease Control during the intensive national surveillance instituted following the swine influenza vaccination program in 1976-1977 became available for further study. Although the data were not uniformly adequate to confirm the diagnosis of Guillain-Barré syndrome, they were sufficient to enable classification according to extent of motor involvement. Vaccinated cases with "extensive" paresis or paralysis occurred in a characteristic epidemiologic pattern closely approximated by a lognormal curve, suggesting a causal relationship between the disease and the vaccine. Cases with "limited" motor involvement showed no such pattern, suggesting that this group included a substantial proportion of cases which were unrelated to the vaccine. The effect attributed to the vaccine lasted for at least six weeks and possibly for eight weeks but not longer. *The relative risk of acquiring "extensive" disease over a six-week period following vaccination ranged from 3.96 to 7.75* depending on the particular baseline estimate of expected normal or endemic incidence that was chosen. Correspondingly, the number of cases that could be attributed to the vaccine over the six-week period ranged from 211 to 246, or very slightly higher over an eight-week period if the lowest baseline estimate was used. *The total rate of Guillain-Barré syndrome cases attributed to prior use of the vaccine was 4.9 to 5.9 per million vaccinees.*

Bol Asoc Med P.R. 2010 Apr-Jun;102(2):39-41.

Guillain-Barre syndrome after influenza vaccine administration: two adult cases.

Bedard Marrero V, Osorio Figueroa RL, Vázquez Torres O.

Department of Medicine, Ponce School of Medicine, Ponce, Puerto Rico. vbedard_76@hotmail.com

Abstract

We describe two adult cases of neurologic complications occurring after the administration of the influenza vaccine. The first case described is a 68 year-old man who experienced paresthesias of the upper and lower extremities two weeks after vaccination, and the second case was a 64 year-old female who exhibited paraplegia eighteen days after vaccination. Diagnosis of acute idiopathic demyelinating polyradiculopathy (Guillain-Barré syndrome) was made for both patients, and intravenous gammaglobulin therapy was given with marked improvement of the first case, but poor response on the second case. Although the efficacy of influenza vaccination has been widely accepted, such neurologic complications might occur in the elderly and adult population. Even if Guillain-Barré syndrome was a true side effect of vaccination, the risk is substantially lower than is the risk for complications following influenza. The rare occurrence of neurological complications after influenza vaccine should not discourage against the vaccination.



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Swine flu jab link to killer nerve disease: Leaked letter reveals concern of neurologists over 25 deaths in America

By JO MACFARLANE

Created 9:29 PM on 15th August 2009

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A warning that the new swine flu jab is linked to a deadly nerve disease has been sent by the Government to senior neurologists in a confidential letter.

The letter from the Health Protection Agency, the official body that oversees public health, has been leaked to The Mail on Sunday, leading to demands to know why the information has not been given to the public before the vaccination of millions of people, including children, begins.

It tells the neurologists that they must be alert for an increase in a brain disorder called Guillain-Barre Syndrome (GBS), which could be triggered by the vaccine.



Investigation of the temporal association of Guillain-Barre syndrome with influenza vaccine and influenzalike illness using the United Kingdom General Practice Research Database.

Stowe J, Andrews N, Wise L, Miller E.

Immunisation Department, Health Protection Agency Centre for Infections, London, UK. julia.stowe@hpa.org.uk

Abstract

In 1976, the national swine influenza vaccination program in the United States was suspended because of an increased risk of Guillain-Barré syndrome. Subsequent studies of seasonal influenza vaccine have given conflicting results. The authors used the self-controlled case series method to investigate the relation of Guillain-Barré syndrome with influenza vaccine and influenzalike illness using cases recorded in the General Practice Research Database from 1990 to 2005 in the United Kingdom. The relative incidence of Guillain-Barré syndrome within 90 days of vaccination was 0.76 (95% confidence interval: 0.41, 1.40). In contrast, the relative incidence of Guillain-Barré syndrome within 90 days of an influenzalike illness was 7.35 (95% confidence interval: 4.36, 12.38), with the greatest relative incidence (16.64, 95% confidence interval: 9.37, 29.54) within 30 days. The relative incidence was similar (0.89, 95% confidence interval: 0.42, 1.89) when the analysis was restricted to a subset of validated cases. The authors found no evidence of an increased risk of Guillain-Barré syndrome after seasonal influenza vaccine. The finding of a greatly increased risk after influenzalike illness is consistent with anecdotal reports of a preceding respiratory illness in Guillain-Barré syndrome and has important implications for the risk/benefit assessment that would be carried out should pandemic vaccines be deployed in the future.

Vaccine. 2011 Oct 19;29(45):7878-82. Epub 2011 Aug 27.

Guillain-Barré syndrome and H1N1 (2009) pandemic influenza vaccination using an AS03 adjuvanted vaccine in the United Kingdom: self-controlled case series.

Andrews N, Stowe J, Al-Shahi Salman R, Miller E.

Statistics Modelling and Economics Department, Health Protection Services, Health Protection Agency, Colindale, London NW9 5EQ, United Kingdom. nick.andrews@hpa.org.uk

Abstract

In 1976 a swine influenza vaccine was associated with an increased risk of Guillain-Barré syndrome (GBS). Although subsequent studies did not find an increased risk of GBS following seasonal influenza vaccine, there was concern that the monovalent H1N1 vaccines developed against the swine influenza pandemic of 2009 might increase the risk of GBS. In the UK a split-virion AS03 oil-in-water adjuvanted vaccine (Pandemrix™) was predominantly used. To determine whether the risk of GBS increased after Pandemrix administration, we sought GBS cases during the period of vaccine use from neurologists and a patient support group, and following the vaccination period from hospital episode statistics (HES) in England. We obtained cases' vaccination histories and illness onset dates from general practitioners. We determined the relative incidence of GBS in the 6 weeks after vaccination using the self-controlled case series method on the cases identified in HES. We included 327 GBS cases, of whom 37 received pandemic vaccine in the study period, nine of whom developed GBS within 6 weeks of vaccination (relative incidence 1.05 [95% confidence interval (CI) 0.37 to 2.24]). We found no evidence of an increased risk of GBS in the 6 weeks following pandemic influenza vaccination.

*Weekly***November 05, 1999 / 48(43);996-8**

Recommendations Regarding the Use of Vaccines That Contain Thimerosal as a Preservative

The risk, if any, to infants from exposure to thimerosal is believed to be slight. The demonstrated risks for not vaccinating children far outweigh the theoretical risk for exposure to thimerosal-containing vaccines during the first 6 months of life.



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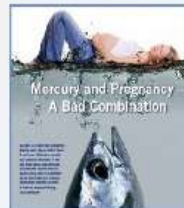
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News and Updates

FEBRUARY 22, 2012 Scott Laster, a SafeMinds' Board Member debated vaccine safety on Public Affairs on Peach, a Sunday morning production of CBS Atlanta News. [Click here to watch.](#)

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EVIDENCE OF HARM

MERCURY IN VACCINES
AND THE AUTISM EPIDEMIC:
A MEDICAL CONTROVERSY



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—**NEWSDAY**

DAVID KIRBY

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MMR jab 'may cause autism'

From Page One

world authority on the detection of viruses, revealed his findings to a US Congress hearing on Thursday. He said further research was immediately needed to establish whether the MMR jab might be responsible for the children's brain damage.

The professor was in Washington with British researcher Andrew Wakefield, who caused uproar two years ago by suggesting the possibility of a link between MMR and autism in children should be thoroughly investigated. Dr Wakefield sent bowel samples to the professor for independent analysis.

Professor O'Leary said his discovery provided 'compelling evidence' of an association between infection by the measles virus and autism in the children, many of whose par-

THE DAMNING EVIDENCE

Full report: Pages 8, 9

ents said they developed the condition after they had been injected with MMR. 'Measles virus is present in the gut of these children,' he said. 'It shouldn't be there. There needs to be a full investigation of this with proper funding.'

Dr Wakefield, who works at the Royal Free Hospital in London, claims to have identified a new disease, autistic enterocolitis, characterised by unusual inflammation of the gut, in nearly 150 children who became autistic after first developing normally. Doctors are investigating the theory that it is the interaction of the measles and the mumps viruses in the same inoc-

ulation that causes the gut damage and consequent autism.

Dr Wakefield's claims have been consistently attacked by the medical establishment, and he has been banned by his employers from speaking to the Press. Last night, vaccine makers insisted there was 'no evidence' to link the vaccine and autism.

The Department of Health said Professor O'Leary's study was 'uninterpretable' and there was no reason for parents to be concerned. A spokesman said: 'It does not prove anything and there remains no evidence to suggest there is any link between MMR and autism. It would be a disaster if children were to die of vaccine-preventable disease over unfounded vaccine safety scares.'

The Mail
ON SUNDAY

**MEASLES
JAB: NEW
LINK TO
BRAIN
DAMAGE**

"It's a moral issue for me," he announced at the 1998 press conference, where he called for a boycott of the triple MMR in favour of breaking it up into single measles, mumps and rubella shots, to be given at yearly intervals. "I can't support the continued use of these three vaccines, given in combination," he said, "until this issue has been resolved."



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Single MMR jabs soar

by BEEZY MARSH, Daily Mail

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Fears over the safety of the MMR vaccine have boosted demand for single jabs to record levels, official figures reveal.

Parents' desperation to find an alternative to the triple-vaccine has led to a huge rise in the number of single measles jabs imported into Britain.

Last year 103,000 doses were brought in, compared to just under 85,000 in 2002 and only 11,800 in 2001.



© PA

Jab fears: parents increasingly prefer single MMR jabs

Welcome to the support group for vaccine-damaged children



JABS INFORMATION ON SINGLE DOSE VACCINES

JABS is not primarily a provider of vaccine information but a support group of parents who feel their children have suffered a reaction or have been severely damaged by a vaccine. However, we are pleased to provide the following information which you may find helpful in your decision.

First, no childhood vaccine is compulsory in the UK so you have control over if, when and how you proceed with vaccinations for your child.

JABS believes that the MMR vaccine should be suspended and parents should have a right under the NHS system to request the single component vaccines. Parents need to be aware when considering single dose vaccines that Merck and Co (USA, the manufacturers of Mumpsax (Jeryl Lynn strain) announced that it will no longer manufacture single mumps vaccines (as of 21st January 2010).

Parents also need to be aware that single dose vaccines also carry a risk of side effects so please ensure you have accurate information on the side effects and also accurate information about the diseases.

The Telegraph

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MMR: Give parents the right to single vaccinations to halt measles rise

As cases of measles rise, give parents the right to single vaccinations not MMR says Cassandra Jardine.

By Cassandra Jardine

1:59PM GMT 01 Dec 2008

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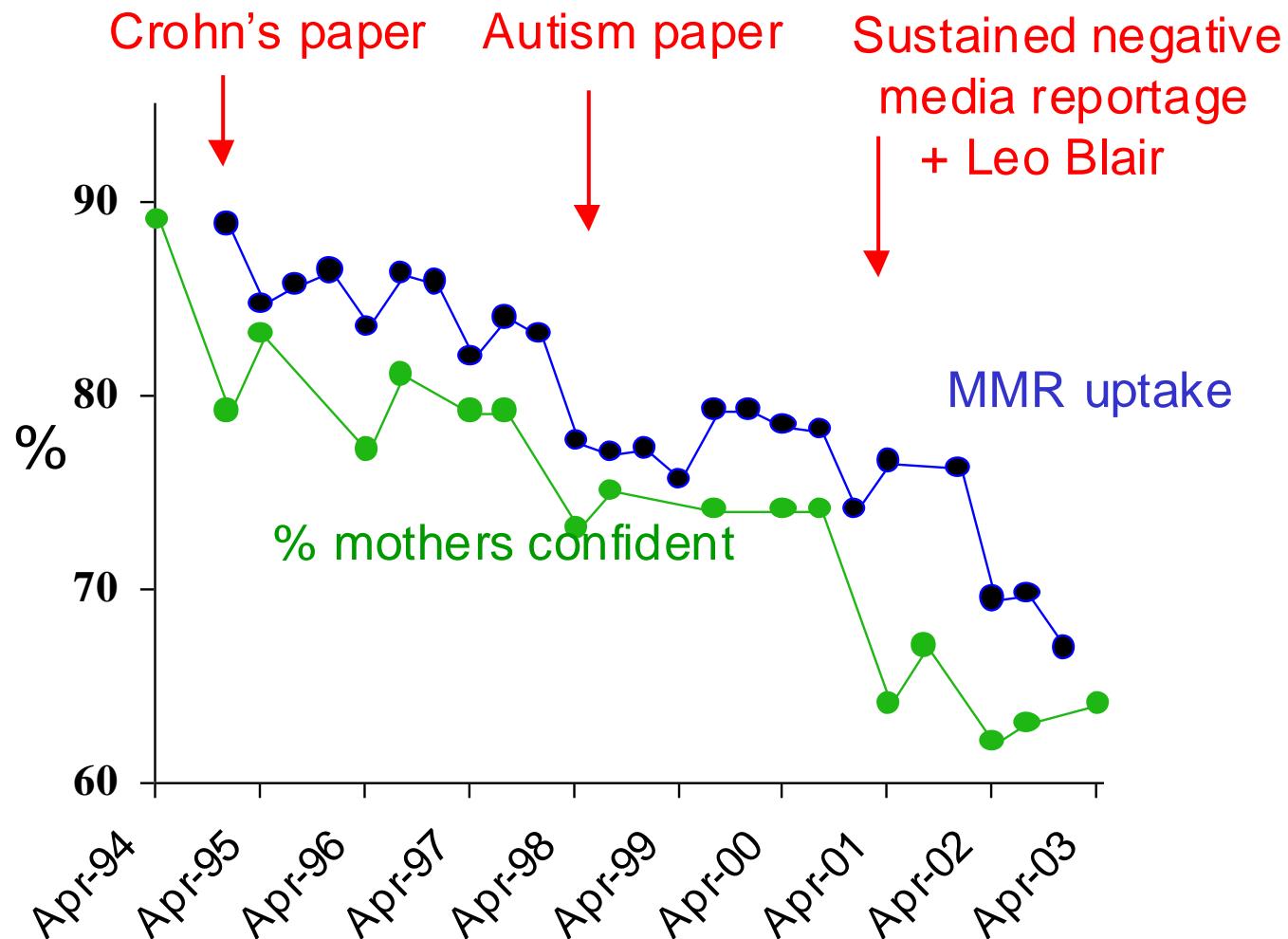
News Society

Error warning over separate MMR jabs

James Meikle, health correspondent
The Guardian, Monday 10 February 2003 08.32 GMT
[Article history](#)

Hundreds of children may have been given ineffective vaccines against measles, mumps or rubella by private clinics offering single-shot alternatives to the combined MMR immunisation.

MMR uptake at 16 months and proportion of mothers believing in complete or almost complete safety of MMR vaccine



'Health in the News: Risk, reporting and media influence'.

- ▶ **All (public health experts and policy makers) subscribed to a view that the media could exert a powerful influence over human behaviour and public policy.**
- ▶ **News media neglected issues that were important to public health, while giving undue prominence to 'scare' stories.**
- ▶ **The news media did not always report numerical data in ways that conveyed risks accurately.**
- ▶ **There is evidence that some kinds of media coverage of some health issues make an impact on public behaviour. Arguably, this is a case (reporting of MMR and autism stories) of media coverage affecting public behaviour in ways that may increase rather than reduce health risks.**

Harrobin, Coote & Allen. www.kingsfund.org.uk

On 28 September 2009, a 14-year-old girl died shortly after receiving an HPV vaccination at her school in Coventry, UK.



SEPT 09

Page last updated at 14:01 GMT, Tuesday, 29 September 2009 15:01 UK

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Cancer jab alert after girl dies

Health chiefs have launched a "full and urgent" investigation into the death of a 14-year-old girl after she was given a cervical cancer vaccine at school.

Natalie Morton died in hospital on Monday after receiving the Cervarix jab at the Blue Coat Church of England School in Coventry.

Headteacher Dr Julie Roberts paid tribute to her as a "happy easy-going child who worked hard".

Post-mortem tests into the exact cause are expected to be held on Tuesday.

"Staff and students are shocked and deeply saddened at what's happened," said Dr Roberts.

"As a Christian school we look to God in these times of trouble, and

Dr Caron Grainger, joint director of public health for NHS Coventry and Coventry City Council, said their sympathies were with the girl's family and friends.

She said: "The incident happened shortly after the girl had received her HPV vaccine in the school. No link can be made between the death and the vaccine until all the facts are known and a post-mortem takes place.



Natalie Morton died in hospital following a cervical cancer jab at school

"We are conducting an urgent and full investigation into the events surrounding this tragedy."

A small number of girls at the school had also reported mild symptoms such as dizziness and nausea but were not admitted to hospital.

The injection - part of a national immunisation programme - protects against the human papilloma virus (HPV), a sexually transmitted disease linked to most cervical cancers.

A routine programme of vaccinating 12 and 13-year-old girls started in September 2008 across the UK using the Cervarix vaccine made by GlaxoSmithKline. A catch-up campaign is now under way for older girls.

It is thought about a million girls have already safely received the jab.

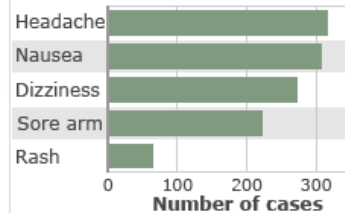
Dr David Elliman, a consultant in community paediatrics at Great Ormond Street Hospital, told the BBC it was important to investigate "very quickly" to allay people's fears about the safety of the jab.

Adverse reactions to Cervarix

1.4million
vaccinations

4657
adverse reactions

Some key reactions



Source: MRHA

Total number of reactions reported between April 2008 and 23 September 2009

[► Q and A: Cervical cancer](#)

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Actions taken following girl's death.

- By the end of the day of the child's death, we had post codes and addresses of all places where that batch had been distributed. We knew that the adverse event profile of the batch was no different to other batches.
- We issued an immediate public health alert for overnight transmission to Public Health providers and primary care providers saying that the vaccine batch should be quarantined but the programme was NOT suspended. Vaccine from different batches was issued immediately to those requesting it.
- Routine vaccinations were to continue in schools and primary care.
- DH Press Office issued statements that acknowledged that the death had occurred but the cause of death had not been determined.
- DH did not provide a Minister or Medical expert (Chief Medical Officer or Director of Immunisation) in response to media requests – until the cause of death was known.

Understanding risk – numeracy.

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23 February 2012 Last updated at 02:41 472  Share 

'Third of UK postcodes' have slow broadband speeds

A third of homes in the UK have broadband speeds well below the national average, according to research from price comparison site uSwitch.



"There is an ominous and widening gap between scientists' assessment of various risks and the popular perception of those risks, a gap that threatens to lead to unfounded and crippling anxieties".

John Allen Paulos,

Professor of Mathematics, Temple University, Philadelphia.

From 'Innumeracy'.

The Precautionary Principle: Immunisation safety: risks, benefits and precautions.

- It is hard to think of examples when the precautionary principle has been applied in vaccinology in advance of confirmed evidence of risk.
- The application of the precautionary principle in vaccinology, as defined – withdrawal of an intervention without complete evaluation of the risk, has the potential to leave far more individuals at the risk of harm than may benefit.
- Public pressure is not a reason to invoke the precautionary principle.