

Revealed: The serious health concerns about the cervical cancer jab

By Isla Whitcroft

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The pink leaflets are ready, the posters are poised to go up and the advertising slots have been booked both on kids and primetime TV and radio.

Tomorrow marks the start of a new academic year. It is also the launch date of a campaign which heralds the introduction of the biggest mass vaccination programme for more than a decade.

By the end of September, there will hardly be a Year Eight girl (aged 12-13) in the country who doesn't know that, barring an opt-out, she is shortly to receive three injections of the drug Cervarix, which will offer her 70 per cent protection against cervical cancer.



Christina Vernon, 50 and her daughter Sophie, 12 think that the cervical cancer injection is a positive thing

Later in the year, another 300,000 girls aged 17 and 18 will be vaccinated before they leave school. By 2012, most girls over the age of 12 should have received the vaccine.

Made by pharmaceutical giant GlaxoSmith-Kline, Cervarix works by creating an immunity against the two strains of the human papillomavirus (HPV), numbers 16 and 18, responsible for 70 per cent of all cervical cancers.

For the Government, the programme - reputed to have cost tens of millions of pounds - has been seen as little short of a community medicine triumph.

'This vaccine could save the lives of 400 women a year,' pronounced public health minister Dawn Primarolo earlier this year, shortly after it was announced that GlaxoSmithKline had won the contract to supply the drug over its rival Merck, who make the more expensive vaccine, Gardasil.

'It is an exciting opportunity to immunise young girls against the future risk of cancer, the impact of which will be felt by women and their families for generations to come,' she said.

And, on the face of it, who could argue? Cervical cancer is a dreadful disease.

The HPV (said to be carried by one in ten girls under 16) is sexually transmitted and once it enters the cervix causes cell mutation which, if undetected, will lead to cancer.

Once the cells are past the pre-cancerous stage, treatment is notoriously drastic. 'Women who are caught early and end up having just a hysterectomy are the lucky ones,' says consultant gynaecologist Thomas Ind from the Royal Marsden Hospital and St Thomas'.

'It is not uncommon to see a woman in her early 30s who has lost her bowel, vagina, bladder and colon to the disease.'

Quickly introduced

In that context, perhaps it is laudable that the vaccine programme has been introduced in the UK so quickly (the drug was approved by the European Union only in September 2007 and has yet to receive full approval by the American FDA).

Indeed, there has been some criticism that the Government had not acted as quickly as European countries such as France, Italy and Germany who began their programmes a year earlier.

But look more closely and it is not hard to see why many British experts are uneasy about the rush to vaccinate all our young girls.

Cervical cancer may be a nasty disease, but it is also, thanks to our world-class screening programme - where all women from 25 to 64 are eligible for a free cervical screening test every three to five years - very rare in the UK.

Around 3,000 cases are diagnosed each year and about 940 women die. While this is 940 too many, it equates to less than three deaths per 100,000 of population and does not even begin to compare with the carnage caused by breast or lung cancer.

We have one of the highest rates of teenage sexual activity in the developed world. We should be experiencing an epidemic of cervical cancer,' says Thomas Ind.

'The fact that we are not is down to our screening programme. I fear that introducing another preventative method will dilute both money and attention away from this.'

Indeed, one of the main worries about the mass vaccination is that girls will then feel 'safe' against cervical cancer and ignore the screening programme.

That would be nothing short of disastrous, because the jab gives protection only against HPV 16 and 18 which are implicated in around 70 per cent of cervical cancers.

Smear tests still needed

There is still a 30 per cent chance that another strain could cause cancer, making it vital that women go for regular smears.

Cervarix is also very new - large-scale trials go back only six years - and there is no way of knowing just how long protection will last.

The worst case scenario is that the Government could be paying a fortune for a vaccination that may protect young girls for only the next six or so years. So just as they hit the peak years for sexual activity they are totally unprotected.

Furthermore, with the possibility that women will stop going for smears because they think they're protected, the vaccination programme could end up being counter-productive and costing more lives than it saves.

But according to Dr David Elliman, a consultant community paediatrician who works for Haringey NHS Trust and Great Ormond Street Hospital and sits on the cervical cancer screening board, this is an unlikely scenario.

'The girls receiving the jab are many years away from the age of screening,' he explains. 'In addition, in all the literature it is made extremely clear that the vaccination is not a substitute.'

'For all its merits, our screening process doesn't prevent cancer, it simply picks it up at an early stage. The vaccination is the only thing that actually prevents HPV 16 and 18 from causing cancer.'

However, some people feel the programme is a case of taking a sledgehammer to crack a nut. 'Six million women carry the HPV virus at any one time,' says Chris Woollams, founder of the charity CancerActive and a former biochemist.

Protection

'In the majority of cases the immune system renders it harmless. Only 3,000 women get cervical cancer each year and less than 1,000 actually die.'

'Looking at those figures, you have to ask whether the most sensible response is to put a drug that has little long-term safety and efficacy data behind it into the immune system of all our young girls and women?'

'The best protection against contracting HPV and therefore cervical cancer is to use a condom. It gives you 100 per cent protection. For a fraction of the money you could run a very effective sex education campaign.'

The Government refuses to release the cost of the vaccination programme, claiming commercial confidentiality. But given that, privately, Gardasil costs around £160 per injection, it will not be cheap.

In July, the British Medical Journal calculated that by using Cervarix - cheaper than Gardasil because it protects only against strains 16 and 18 and not 6 and 11, the strains responsible for genital warts - the Government will save up to £18million in the first year alone.

Either way, huge sums are involved and there has been criticism that drug companies funded charities and doctors to lobby the Government in the battle to ensure the programme went ahead.

In America, where the vaccination programme using Gardasil has been in place since June 2006, some experts are now expressing unease about the scheme.

Twenty seemingly healthy girls died within a few days of being injected with the vaccine which has a similar generic make-up to Cervarix.

These deaths have been dismissed as coincidence by Merck who make the American jab, although both Cervarix and Gardasil list fainting, dizzying and sore arms as side-effects.

Here in the UK, the awareness group JABS is reporting an upsurge in calls from parents who are worried about possible side-effects.

Last month, an article in the New England Journal Of Medicine claimed that serious questions regarding the overall effectiveness of the vaccine remained unanswered.

It pointed out that studies into the vaccine were carried out on girls aged 15 to 24 so there is no way of knowing how the drug will affect pre-pubescent girls, how long it will last and whether there was the potential for interference with the body's natural defence against other HPV strains.

So parents are being faced with an agonising decision. Do they say no to the vaccine and risk their child contracting a dreadful disease.

Or do they put their trust in a drug for which evidence of safety and efficacy is probably insufficient and at worst may do harm?

YES

Christina Vernon, 50, is an office manager from Northampton. She has three children Carrie, 26, Matthew, 23, and Sophie, 12, who will be having the jab.

She says... I WAS diagnosed with pre-cancerous cells at 33, after a routine smear.

I had always been very careful to keep up with my smear tests and there had never been a problem before. So when the doctor told me I needed investigating it was quite a shock.

I knew people who had had breast cancer but I was the only person I knew who had been in this situation, so I felt very alone.

Between 1990 and 1995, I had four operations to have abnormal cells lasered away, but they kept returning. My children were very young and it was a worrying time.

But I was relatively lucky because although the abnormal cells kept coming back they were only graded as a low risk.

Even so, the laser treatment had unpleasant side-effects - painful, heavy periods and abnormal bleeding for several months afterwards which badly affected my quality of life.

The last treatment was done under local anaesthetic and was extremely painful.

I had also become aware of just how awful cervical cancer can be if it becomes aggressive and how the treatment can involve extensive surgery.

Each time I went back for my test results I was in a panic about what the doctor would say.

I am delighted that Sophie has the opportunity to have the jab. She is aware of my medical history, so, naturally, she is keen to be protected. I just wish it had been available for my older daughter, Carrie, because I wouldn't want either of my daughters to go through what I did.

Cervical cancer tends to affect young women with young families and if just one life can be saved by the vaccine it will have been worthwhile.

I definitely don't subscribe to the argument that the vaccination will give young girls the green light to behave in a sexually irresponsible way. Girls who act like that are going to do it anyway, irrespective of an injection.

NO

Marylin Smith, 55, a shop assistant from Harrow, Middlesex, has two children Daniel, 15, and Gaby, 11. Gaby is due for the jab in September 2009 but will opt out.

She says: Since Gaby suffered a bad reaction to a tetanus jab as a baby I have become much more questioning about the idea of vaccination.

I am not against it, but if I am going to agree to something being injected into my daughter I want to make sure it is safe, effective and has no side-effects.

Cervarix answers none of my questions satisfactorily. So until there is more long-term data I feel there are better ways of protecting my daughter against cervical cancer.



Marilyn Smith, 55, is determined not to expose her daughter Gaby, 11, to the cervical cancer vaccine

We already have a good open relationship and I will be rigorous in educating her about the perils of unsafe sex - not just in regard to cervical cancer but also about genital warts, other sexually transmitted diseases and, of course, unwanted pregnancy.

Using a condom gives 100 per cent protection against cervical cancer, the vaccination can only offer 70 per cent at best.

I am not particularly impressed by the fact that this vaccine will be given at school by an anonymous medical team.

It should be a matter between the parent, the child and their GP, who knows the child and is aware of her medical history and can watch and record any adverse side-effects.

I am fully expecting that both Gaby and I will be put under considerable pressure for her to have the jab and I know in America those who opted out have been made to feel as if they were bad parents, which is outrageous.

I don't think the vaccine will encourage promiscuity, there will always be girls who sleep around, but I do think it will make girls more blasé about their sexual health, less likely to use a condom and less likely to go for screening.

But my main concern is that we have no idea of the long-term effects of this vaccine - whether it works, for how long and whether it can harm the immune system.

I am not going to expose my daughter to that level of risk and she doesn't want it either.

What you need to know

What causes cervical cancer?

Most cervical cancer is caused by the human papillomavirus (HPV). HPVs are sexually transmitted and invade the cervix, although 90 per cent of infections are cleared by the immune system within two years.

If it remains, the virus begins to cause cell mutation which will lead, if untreated, to cancerous lesions and eventually cancer. Most cases occur in women aged 25 to 34.

How does the vaccination work?

Both Gardasil and Cervarix work by mimicking the structure of the live HPV strains 16 and 18 and stimulating an immune reaction in the body which will enable it to fight the real infection at a later date.

The vaccine does not contain live strains of HPV and tests so far show it cannot cause the disease. There is no significant data on how long the vaccination will be effective.

Who will receive the vaccination?

This year, all girls aged 12 to 13 will be offered the injection at school. Any 17 to 18-year-olds will receive the injection as a 'catch-up' before they leave school.

Why are we vaccinating so early?

For the vaccination to work, it has to be administered before the girl has been infected by HPV. Given that around one in ten girls under the age of 16 already have the virus, it was thought best to vaccinate girls before they were likely to have had sexual activity.

Can my daughter opt out?

Every parent will be asked to sign a consent form before the jab is given. If your daughter wishes to have the jab and you don't, the final decision is legally yours for a Year Eight girl, but not for a girl over 16.

• **HELPLINES:** www.nhs.uk/hpv or 0845 602 3303; www.jabs.org.uk

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Here's what readers have had to say so far. Why not add your thoughts below?

I'm glad other people have noted Mariyin's mistake in saying condoms are 100% protective against HPV because they are not. Being taught about safe sex is extremely important but one day many girls are going to grow up and want a family of their own and when this is the case they can never be sure whether their partner has HPV or not and therefore put themselves at risk if they haven't had the vaccine.

- Halley, London, 02/9/2008 15:16

I live in Germany where the vaccine has been available for approx 1 year now. Although I am now 34 years of age, I also decided to have the vaccine as I have encountered many problems over the years with abnormal cells. I am happily married but decided to go ahead anyway on the advice of my doctor.

What amazes me most is that the free cervical screening is now only available from the age of 25. I was shocked when a younger colleague of mine who recently moved here from England told me of this. The screening used to be from the age when you commence sexual activity and we received reminders in the post when the due date was approaching (3-5 years)

I had already had two operations to remove cells by the age of 23 and then had regular screening every 6mths to a year. Maybe my problems would have progressed into something far more serious had I not had the tests when I did.

- Aly, Munich, Germany, 02/9/2008 15:16

I'm a 22yr old female, and here in Australia we've experienced a similar campaign lead by the Government to immunise ever Australian female between 12 -26 years of age.

Quite frankly, I object to any form of vaccination, let alone one that has only had less than 6 years of testing.. Oh, and its also Cervarix here as well.. The posters scare you into thinking you may well die of having sex, but they don't say the number of deaths caused directly/indirectly via this immunisation.

If the posters and media pressure isn't enough.. Our local GP is sponsored by Cervarix it seems.. No matter what my current ailment, as soon as they check my medical history and see i havent had the shot (rather, 3 shots infact) they start pitching it to me like a used car salesman..

We have the choice to say no, and If you want to choose to say no, then that should be accepted with no repercussions.. and besides.. Drug companies make 2 things.. Drugs and \$\$\$... not morals..

- A girl, Sydney, Australia, 02/9/2008 15:01

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