

IMMUNISATION NEWSLETTER



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Welcome...

Dear Colleague,

This newsletter follows the Scottish Government announcement, on 26 October 2007, that it has been agreed to introduce a new vaccine in Scotland against human papilloma virus (HPV). This decision follows advice from the Joint Committee on Vaccination and Immunisation (JCVI), the independent expert body that provides advice on vaccines, that there is sufficient evidence on the protective effect of HPV vaccines against cervical cancer to proceed with an immunisation programme in the UK.

Commencing in September 2008, this programme is intended to protect girls by routinely immunising them at around 12-13 years of age, with the aim of preventing them from developing cervical cancer later in life.

Human papilloma viruses cause 99% of cervical cancers. The available vaccines provide protection against the two most common cancer-causing types. It is estimated that immunisation would reduce the number of cases of cervical cancer by up to 70%.

It is recommended that the vaccine should be delivered mainly through a schools-based programme. Three doses of vaccine will be required. There will also be a one-off immunisation catch-up campaign for older girls. Girls aged under 18 at the start of the

routine programme in September 2008 will also be offered HPV immunisation. The catch-up will take place over a two to three year period and details of the phasing and timing of this are currently being considered.

The Scottish Government is working closely with Health Protection Scotland, which has the responsibility for co-ordinating the implementation of immunisation programmes in Scotland, to prepare for the introduction of this new immunisation programme. The input and support of NHS boards will be critical both at a national and a local level and boards are invited to begin considering the local implementation issues.

The Scottish Cervical Screening Programme remains an essential element of the cervical cancer prevention service and will continue for all eligible women after the HPV vaccine is introduced.

We look forward to working in partnership with you to deliver this important programme, and will continue to update you with progress towards the start of the programme in September 2008.

Yours sincerely,



Martin Donaghy
Medical Director, HPS

Background - Human Papilloma Virus and Cervical Cancer

Human papilloma viruses (HPV) are recognised as the major cause of cervical cancer. Studies have also linked HPVs to other genital and non-genital cancers.

There are over 100 different types of the virus and, of those, about 20 'high-risk' types are known to cause cervical cancer. HPV infects the skin and certain other mucosal surfaces in the body. The virus is spread by skin-to-skin contact, including sexual contact and several types infect the genital area. Genital HPV infections are very common. It is estimated that 80% of sexually active women will acquire HPV at some point in their life. Most

of these infections clear with no adverse clinical effects. However, in some cases the virus persists and some of these persistent infections go on to cause 'pre-cancerous lesions', which if untreated, may progress to cervical cancer.

The Scottish Cervical Screening Programme offers a cervical smear test every three years to all women between the ages of 20 and 60. Cervical smears can identify pre-cancerous cell changes in women who

otherwise have no symptoms. At this stage, any abnormalities can be easily treated, and treatment is usually very effective.

However, cervical cancer still claims around 100 lives in Scotland every year.

Two HPV vaccines have been licensed for use in the UK - Gardasil® (Sanofi Pasteur) and Cervarix™ (GSK). Both products protect against the two main cancer causing types of the virus (types 16 and 18) which are associated with 70% of all cervical cancers. Gardasil also protects against two other types of HPV (types 6 and 11) which cause most cases of genital warts.

Both vaccines would require a 3-dose schedule over a 6-month period.

JCVI Advice

On 20 June 2007, the JCVI recommended that, subject to an independent peer review of the cost benefit analysis, HPV vaccines should be introduced routinely for adolescent females aged around 12-13 years.

The Cabinet Secretary for Health and Wellbeing, Nicola Sturgeon welcomed this recommendation for Scotland and said that the Scottish Government is committed to providing this vaccine free of charge to adolescent females around 12-13 years of age by Autumn 2008.

Further JCVI advice on 26 October 2007 recommended that it would be beneficial to also offer catch up immunisation to older girls under the age of 18 (in September 2008). The Scottish Government has stated its intention to follow this recommendation.



The Scottish Cervical Screening Programme

Scotland has a highly successful Cervical Screening Programme. Since the 1980s when the programme began routinely inviting all eligible women for screening, deaths from cervical cancer have fallen by over 45%.

It will be essential that the screening programme continues even for vaccinated women as the vaccines will only protect against 70% of cervical cancers. Immunisation does not protect those who are already infected with the vaccine virus types. Women will still be invited for routine screening and should be encouraged to attend.

Development and Delivery of the HPV Immunisation Programme

HPV immunisation will be incorporated into the routine childhood immunisation programme, as an adolescent immunisation for females. It is recommended that the programme be mainly delivered through schools, as this is considered to be the most effective way to deliver a 3-dose immunisation programme over a short timescale for this target age group. However, GPs may also have a role in delivering some immunisations.

Planning the Campaign Nationally

Responsibility for co-ordinating routine childhood and adult immunisation programmes rests with Health Protection Scotland (HPS). The Scottish Government continues to set policy and agree strategy. A steering group and working groups have been established by HPS, with representation from the Scottish Government, NHS Health Scotland (NHS/HS), NHS boards, National Services Scotland and education authorities and school health services to identify and progress the streams of work required to roll out the incorporation of an HPV vaccine into the routine childhood immunisation programme.

Dr Allan Gunning, Chief Operating Officer for NHS Ayrshire and Arran will chair the Steering Group.

This will be a complex programme to deliver. The working groups will cover the following areas:

Surveillance

This will include preliminary research, surveillance of HPV infection, cervical cancer and vaccine uptake as well as any possible adverse events that may be associated with the immunisation programme.

Data Management

This will include issues regarding population registers, call/recall systems and vaccine uptake monitoring and analysis.

Communications

A major communications programme will be required to inform the general public, parents and young people, health professionals and the education sector. Communications materials will be developed and tested. Training needs for immunisers and school health staff will be considered.

Service Delivery

This will include the requirements for school/community nurses, storage facilities for the vaccine, the timing of the immunisation schedule during the school year and the role of primary care.

In addition some research programmes have already been established.

- Defining the burden of HPV associated cancers and other disease in Scotland.
- Defining the prevalence of HPV infection in young people in Scotland.
- An attitudinal survey of parents, young people and health professionals.

The Scottish Government will work closely with the Department of Health and the other devolved administrations on this programme.

Planning the Campaign Locally

Planning the introduction of the new programme locally will involve:

1. Assessing the number of adolescent females eligible for immunisation ;
2. Assessing the local infrastructure to ensure there are adequate resources and service capacity;
3. Beginning to address local implementation issues working with the local NHS board immunisation co-ordinator and the local education authorities and school health services.

Staff in NHS boards will be key to developments at a national level through membership of the steering and working groups. Further guidance on the roles and responsibilities of NHS boards will be issued by the Scottish Government Health Directorate.

Communication with the NHS

Primary care, NHS boards and the education sector will be engaged in the development of the programme locally and nationally through involvement in and membership of the programme steering group, working groups and other relevant planning groups. The Scottish Government will issue letters to the Service and future issues of this newsletter will include updates on the HPV programme.



Questions and Answers to Explain the New Human Papilloma Virus Immunisation Programme for Cervical Cancer Prevention

The new Immunisation Programme is intended to protect girls in Scotland against developing cervical cancer later in life.

The immunisation programme will protect against the two types of the human papilloma virus (HPV) known to be associated with most cases of cervical cancer.



HPV Infection and Cervical Cancer

What is HPV?

HPV stands for human papilloma virus, of which there are many (over 100) different types. Some of these types can be prevented by vaccination, and some, as yet, cannot.

How does HPV cause cervical cancer?

Around 30 types of HPV can infect the genital area. Usually genital HPV infection clears with no adverse clinical effects but infection can persist and some persistent infections cause 'pre-cancerous lesions', which if untreated, may progress to cervical cancer.

What types of HPV cause cervical cancer?

Two 'high risk' types of HPV, known as types 16 and 18, are responsible for about 70% of all cervical cancers. These two types are now vaccine preventable. Some other types of HPV can also cause cervical cancer.

Does HPV infection cause other diseases?

Yes, some HPV types can cause warts, including genital warts. HPV has also been associated with other genital and non-genital cancers.

Is HPV common?

Yes, it is a very common viral infection in both men and women. Around 80% of sexually active women will acquire HPV infection at some point in their life.

What is cervical cancer and how common is it?

Cervical cancer is cancer of the neck of the womb (the cervix). Cervical cancer is the second most common cancer in women worldwide. At current rates, 1 in 124 women will develop cervical cancer in their lifetime.

How many women get cervical cancer each year?

Around 300 new cases of cervical cancer are diagnosed in Scotland every year.

How can cervical cancer be detected?

The Scottish Cervical Screening Programme offers a cervical smear test every three years to all women between the ages of 20

and 60. Cervical smears can identify pre-cancerous cell changes in women who otherwise have no symptoms; at this stage, any abnormalities can be easily treated, and treatment is usually very effective. Since the 1980s when the programme began routinely inviting all eligible women for screening, deaths from cervical cancer have dropped by over 45%.

How common are cervical abnormalities?

Cervical abnormalities are quite common. In 2006-2007, over 400,000 cervical smears were screened by the Scottish Cervical Screening Programme - around 1 in 30 of these, just over 14,000, had some degree of abnormality, a small percentage of which might, if untreated, have led to cervical cancer.

At what age do women get cervical cancer?

The rate of cervical cancer increases when women reach their late 30s, with a further peak in women in their 70s and 80s.

How many women die of cervical cancer?

Although deaths from cervical cancer have decreased, mainly because of the screening programme, there are still around 100 deaths from cervical cancer every year in Scotland.

How is genital HPV infection spread?

The HPV infection lives on the skin and certain other mucosal surfaces in the body. Several types infect the genital area and are spread by skin to skin contact, including sexual contact. Rarely, the infection can also be passed vertically from mother to child during childbirth.

Do you have to be sexually active to get HPV infection?

No. Although the risk is higher in those who have sexual intercourse, anyone who has any form of intimate sexual contact is at risk of picking up this common infection. Immunisation is therefore targeted at an age group at which the majority are not yet sexually active.

Can HPV infection be treated?

There is no specific treatment that directly gets rid of HPV infection. Treatments for cervical cancer and pre-cancer (and other diseases caused by HPV such as warts) mainly involve removing damaged tissue. Therefore immunisation to prevent cancer is a welcome development.

Is it possible to test young women for HPV infection?

Tests for HPV infection exist but currently these are used for research purposes and are not normally available on the NHS.

HPV Vaccines

What vaccines are available for HPV?

Two HPV vaccines have been licensed for use in the UK - Gardasil®, (Sanofi Pasteur) and Cervarix™, (GSK). Both products protect against the two main cancer causing types of the virus (types 16 and 18). Gardasil also protects against the two main types of HPV that cause genital warts (types 6 and 11). Gardasil is licensed for females aged 9 to 26 years; Cervarix for females aged 10 to 25 years.

What impact will the HPV vaccine have on cervical cancer?

Immunisation against HPV (types 16 and 18) protects against around 70% of cervical cancers. However, it is important to remember that the vaccine does not offer protection against all cervical cancers so women should still attend for cervical screening.

How safe is HPV vaccine?

The licensing authorities have examined evidence on the safety of both HPV vaccines. The evidence showed that they had excellent safety profiles on the basis of clinical trials. The vaccines

have been licensed by several authorities worldwide and have undergone a thorough examination of their safety. HPV immunisation is already underway in the United States, Australia and several countries within the European Union. As with all vaccines, its safety will continue to be monitored after it has been introduced into the national immunisation programme.

How effective is HPV vaccine?

Both vaccines have been shown to be highly effective in individuals who have not already been exposed to the target HPV types. So far, clinical trials for both products have demonstrated near 100% protection against the high-grade pre-cancerous changes caused by these viruses.

Are there any instances where vaccination would not be given i.e. contraindications?

Licensing authorities have assessed data on the safety of the vaccines. There are no specific contraindications for use of either other than those that apply to administering most vaccines e.g. hypersensitivity to the active substances. The administration of both products should be postponed in subjects suffering from an acute severe febrile illness and in women who are known to be pregnant. With regard to the latter, in the clinical trials for both products, vaccine was administered inadvertently to almost 2000 pregnant women with no evidence of any increase in the rate of adverse outcomes in those who received the vaccines compared to those who did not. However as a precaution neither product should be offered to pregnant women.



Is one of the vaccines 'better' than the other?

Both vaccines have been shown to be very effective against the cancer causing HPV types (16 and 18). One of the vaccines, Gardasil also protects against two other common but low risk HPV types (6 and 11), which cause most cases of genital warts.

Who will be offered the vaccine?

The vaccine will be routinely offered to girls around 12-13 years of age. This will mean targeting girls who are pupils in their second year of secondary school. In Scotland, we estimate that the routine programme will target around 30,000 girls each year. The JCVI also recommended a one-off catch-up immunisation for older girls aged under the age of 18 to protect them and enhance the overall level of protection in the population in general. In Scotland we have defined those eligible for the catch-up campaign as those aged over 13 years and under 18 years at the start of the programme in September 2008. This recommendation was made on the basis of the cost-effectiveness of immunisation in this age-group. Further work is being taken forward to define when the catch-up programme will commence and over what timescale it will run.

Where will the immunisation programme be delivered?

The JCVI advice is for a school-based immunisation programme as most evidence shows this to be the most cost-effective approach to immunisation in adolescent age groups. In addition, studies

have shown that both young people and parents generally find this setting more acceptable. However, the mode of delivery is being discussed further and it maybe that GPs will have some role to play. The Scottish Government has accepted this advice and the routine immunisation of girls and the catch-up campaign will mainly be delivered through schools.

How many doses of vaccine are needed?

Individuals receiving the vaccine should have three doses, over a six-month period for it to be most effective. This is the same for both of the licensed vaccines.

What happens if someone misses a dose or gets it late?

The general advice if any course of immunisation is interrupted is to resume and complete the course as soon as possible. There is no need to re-start a course of immunisation. All vaccines should be administered according to the recommended schedule. The schedule will have been designed in order to make sure that an individual gets the best protection possible from the immunisation course. Most other vaccines in the routine immunisation program require several doses to provide long-term protection.

How long does protection last for?

Follow-up evidence from clinical trials of both vaccines show that they still offer good levels of protection for women at least five years post-immunisation, which is as long as we have information for. It is expected that protection will be long-lasting but this is not yet known and is the subject of continuing scientific study.

Does it protect those who are already infected with HPV?

The vaccine will not protect against existing HPV infection (i.e. HPV infection already present before immunisation). Hence the rationale for immunising girls at an age before most are exposed to the virus.

Are there side effects from HPV vaccine?

As with other vaccines, side effects such as a sore arm and a mild temperature can occur. Early reports of potential adverse events that were reported in the USA were investigated and found not to have been caused by the vaccines.

What about women older than the recommended groups?

JCVI advice is that it would not be cost effective to run a national vaccination programme for women over aged 18-25. This is mainly because a relatively high proportion are already infected with the virus and would therefore benefit less from vaccination. Whether vaccination should be offered to an individual or whether they would be best protected by cervical screening would be a matter for clinical judgement depending on individual circumstances and this issue is being considered further.

Immunisation Policy

Who advises the government on immunisation policy?

The Scottish Government takes advice from the UK Joint Committee for Vaccination and Immunisation (JCVI), which is an independent committee of medical and scientific experts who make recommendations to government on all vaccination issues.

What has JCVI recommended?

After a detailed review of evidence on the cost effectiveness of HPV immunisation, the JCVI has recommended:

- Confirmation of the decision announced in June i.e. a routine immunisation programme for girls aged around 12 - 13 years
- A time limited catch-up vaccination of girls aged 13-17 years is cost effective
- A catch-up vaccination of women aged 18-25 years would not be cost effective but HPV vaccination could be beneficial to women in that category who were at risk of newly acquired HPV infection and mechanisms should be explored for ways of meeting such requests

Has the Scottish Government accepted this advice?

Yes. The Scottish Government has announced its commitment to provide routine HPV immunisation to girls around 12-13 years of age, from September 2008 and for a catch-up campaign for older girls (aged under 18 in September 2008) to be carried out over the following two to three year period.

Will the Scottish immunisation programme and the English/Welsh programme be the same?

The immunisation programme in Scotland is the same as England and Wales. All countries are planning routine immunisation for girls aged around 12 to 13 years with a catch-up for older girls aged under 18. The phasing and timing of the catch-up campaign in Scotland has not yet been announced.



Why immunise girls at such a young age?

It is sensible and important to immunise individuals before they are likely to become exposed to the HPV virus. The vaccine is effective in preventing rather than treating infection.

Have the views of parents been taken into account?

There has been research into parental attitudes (in England), which has shown that parents would prefer this vaccine to be offered after primary school. Further research is currently underway to establish what parents, young people and other stakeholders in Scotland think about the new vaccine and its introduction and what type of information they require to support them. The findings of this study are expected to be available by the end of 2007 and will be used to guide further communications about the programme.

Why aren't we immunising boys?

The priority is to directly protect girls against their future risk of cervical cancer. Protecting boys was discussed by JCVI who did not consider it to be cost-effective in preventing cervical cancer. Studies show that a female-only vaccination programme that has a high uptake rate (over 70%) should have an indirect protective effect on males as well because of herd immunity.

What is happening in other countries?

Expert advisory groups - equivalent to the UK's JCVI - in a number of other countries, including the USA, Australia and several

countries in Europe have now recommended HPV vaccine be routinely offered to girls of a similar age.

Introduction of the HPV Immunisation Programme

When will the programme be introduced?

It is intended that HPV vaccines will be introduced into the routine immunisation schedule for girls around 12-13 years of age in September 2008. This will mean targeting girls who are pupils in their second year of secondary school. The catch-up campaign will take place over two to three years. The exact phasing and timing of this is being considered. The Scottish Government, Health Protection Scotland (HPS), NHS Health Scotland and local NHS boards are taking this work forward. HPS is co-ordinating the streams of work for planning and rolling out the project

Why not start immunisation this year?

A great deal of practical and logistical planning is required before a national immunisation programme can be introduced. Appropriate supplies of vaccine will need to be ordered and this will take until next year.

How will the immunisation programme be introduced?

The introduction of a comprehensive nationwide HPV immunisation programme will be a considerable undertaking for Scotland and many practical issues need to be considered. We have begun work with partners and other stakeholders to plan for the introduction of the vaccine. NHS boards will liaise with schools, primary care, school health services, pharmacists and other local players to produce plans to ensure that the immunisation of girls can begin in September 2008.

The Scottish Cervical Screening Programme

What is cervical screening?

Cervical screening is a method of preventing cancer by early detection and treatment of abnormal changes in a woman's cervix which, if left untreated, may develop into invasive cervical cancer. The aim of the Scottish Cervical Screening Programme is to reduce the number of women who develop invasive cervical cancer and the number of women who die from it. The first stage in cervical cancer screening is a smear test. In Scotland, it is normal practice to offer a smear test every three years to all women between the ages of 20 and 60.

Will the cervical screening programme now be stopped?

Absolutely not. To continue to reduce the new cases of and deaths from cervical cancer, a combination of screening and immunisation will be required for the foreseeable future. This dual prevention strategy should see a further fall in new cases and deaths from cervical cancer in the longer term.

Should women attend for cervical screening if they have been immunised?

Yes. It is vital that women continue to attend for cervical smears as they do now. The vaccine can prevent up to 70% of cervical cancer. However, that means that some cases of cervical cancer will not be prevented by the vaccine, but could be picked up through screening.

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Notes for contributors: Short comments or articles would be welcomed and can be sent to the Editorial team noted above using the above email address.

Submissions will be considered for inclusion in the next available edition of this quarterly newsletter.