Position Statement on Human Papilloma Virus Vaccine

Introduction

Cervical cancer is the second most common cancer after breast cancer affecting women aged 15-44 in the European Union. Each year there are around 33,000 cases of cervical cancer in the EU, and 15,000 deaths[1] HPV is responsible for nearly 3,000 cases of cervical cancer in the UK every year. Persistent infection with HPV types 16 and 18 is the most important causal factor for the development of cervical pre-cancerous and cancerous lesions.[2]

The introduction of a national cervical screening programme in the UK has made a major contribution to the fall in the incidence and death rate from cervical cancer, however there are particular groups of women, including some ethnic minorities and young women, who are under represented at screening programmes.[3]

The Joint Committee on Vaccination and Immunisation recommends routine immunisation for all 12 to 13 year old girls, to protect them against their future risk of cervical cancer. It is their job to assess the scientific data and cost benefit analysis, audit the programme and follow emerging research.

Cervarix is the vaccine to be offered to school girls from September 2008. This vaccine protects against the main two viruses (16 and 18) which cause over 70% cervical cancers. It is essential that there are sufficient antibodies in place before a girl is exposed to human papilloma viruses, and for this reason most health authorities across Europe, advise offering it just before individual girls in a population start to become sexually active. In the UK, the school year group 8 (aged 12-13) has been chosen.[2]

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This briefing is to clarify the public health approach to Human Papilloma Virus (HPV) vaccine, and to act as supplementary professional guidance for nurses who deliver it. Unite/CPHVA supports the introduction of HPV vaccine into the childhood immunisation schedule for girls to help protect them from viruses which lead to cervical cancer.

How nurses should implement the HPV immunisation

The NMC standards of conduct, performance and ethics (the Code)[4] puts a duty on nurses to keep their skills and knowledge up to date, take part in appropriate learning and work within their limits of competence.

Therefore, prior to undertaking immunisations for HPV the nurse will need to:

- Read the relevant chapter, 18a, in the Green book[3] (this can be accessed from the department of health website).
- Read the government guidance[5] which was sent out to all school nurses (it can be accessed at www.immunisation.nhs.uk/hpv).
- Read the patient group direction (PGD) from your employer, if working in schools or in clinic sessions.
- Be competent in resuscitation of children and young adults.
- Be competent to administer immunisations according to the manufacturers' instructions.

Preparation

If doing a school based programme it is important to visit all schools which may have 12 year old girls, including special schools, pupil referral units and private schools.

Information about the immunisation must be given to the girl and her parent/carer prior to her attendance for the injection. When working in schools, the nurse should ascertain that the families did receive the intended information. Language and communication difficulties need to be taken into account. Nurses must explain to the pupils that although this is an anti-cancer immunisation, this does not mean that if their parents refuse consent that they are likely to die from cancer. The word 'cancer' may be frightening to young girls, and will need some explanation.

The room where the session is to take place must be well ventilated, adequately lit, clean and tidy.

There must be an area available for confidential discussion.

Nurses must be able to sit comfortably, and change position easily, to prevent back pain and repetitive strain injury.

A risk assessment must be carried out to make sure that emergency services could have easy access. A nearby landline or mobile phone is essential.

Consent of people under 16

Before administering any immunisation, you must have consent.

The Nursing and Midwifery Council[6] states that 'if the person is under the age of 16 (a minor), nurses and midwives must be aware of local protocols and legislation that affect their care or treatment.

Children under the age of 16 are generally considered to lack the capacity to consent or to refuse treatment. The right to do so remains with the parents, or those with parental responsibility, unless the child is considered to have significant understanding and intelligence to make up his or her own mind about it.' This is often referred to as 'Gillick' or 'Fraser' competency[7], and it is up to the practitioner dealing with the child to determine whether this particular girl fully understands how she could catch HPV, the fact that most infections are asymptomatic and self limiting, the fact that the virus causes cervical cancer in some women, that if diagnosed early, that this cancer can be cured, but women can die from it, and that the immunisation being offered is new and has been proved to protect against the commonest 73% of HPV infections[1].

Children of 16 or 17 are presumed to be able to consent for themselves, although it is considered good practice to involve the parents. Parents or those with parental responsibility may override the refusal of a child of any age up to 18 years[6]. Nurses must however be careful not to assault the child, which is why it is important that all those who administer injections are trained to work with children and young people and are able to judge when the girl needs support to enable her to stay still during the injection procedure, and when despite explanations and encouragement, she has decided to refuse to have the immunisation at this time. In this case the girl is entitled to dignity and confidentiality just as every other patient, and her decision must be respected and recorded in writing. She should be given further information about how she can access it at a later date if she chooses. Under no circumstances should she be under the impression that her refusal might lead to a substantially increased risk of developing cervical cancer.

Child minders, teachers and other adults caring for the child cannot give consent to immunisations.

The Age of Legal Capacity (Scotland) Act 8 (1991) sets out the current position on the legal capacity of children, including giving or withholding consent to treatment. The law is broadly similar to that in England and Wales. However, one important difference is that parents consent cannot override a refusal of consent by a competent child. In Scotland a child under the age of 16 has the legal capacity to consent to his or her own treatment where, according to the Act…"in the opinion of the qualified medical practitioner attending to him/her, he/she is capable of understanding the nature and possible consequences of the procedure or treatment."

The environment of care

The aim must be for a quality service to each girl. This will include answering any questions, checking understanding, checking the documentation, delivering the injection, and explaining follow up, including giving any leaflet from the manufacturer and any written correspondence home. This experience may affect the way this girl views immunisations for the rest of her life.

Nurses who are stressed by noise, too many pupils in the room, or who feel unable to take a break from their work station, are likely to become irritable and make mistakes. All practitioners must maintain their competency at all times, and if necessary the session must be suspended or abandoned.

Keep clear and accurate contemporaneous records

The nurse must record data as required by local protocol, immediately after administering the injection, including any discussions or assessments s/he has made. The consent forms must be kept confidential at all times.

All adverse reactions must be reported to the Commission on Human Medicines (CHM) using the Yellow Card reporting scheme[3].

Audit

According to local protocol, nurses must either do their own audit or contribute to their employers' audit, on wastage, uptake levels and uptake in relation to health inequalities.

It will be a very good idea to audit all the time and expense needed to carry out this task, including liaison, ordering, preparation and clearing up, clerical activity, travelling and parking, time spent immunising, and number of immunisations given.

How Primary Care Trusts (PCTs), Health boards and Community Health Boards should implement the HPV immunisation programme Infrastructure[2]

The Department of Health (England) lays out responsibilities for Primary Care Trusts:

- Maintain clear communication with parents, girls and schools, including leaflets in several languages.
- Ensure robust arrangements are in place to obtain consent for immunisation and for informing GPs when their patients have been vaccinated.
- Make arrangements for girls who miss a scheduled immunisation, and for those who attend schools in neighbouring areas.
- Training and staffing levels are appropriate.

Keep vaccine wastage to a minimum by having good clerical supervision of ordering and storage, and arrange for disposal of sharps.

Workforce planning

There must be sufficient qualified staff to carry out these immunisations, supported by clerical staff and the child health department. Plans must be in place to skill up new or temporary staff, who will also need to be checked by the Criminal Records Bureau. As this is an on-going programme, extra money must be set aside each year to cover it.

Unite does not support the use of healthcare assistants to deliver immunisations at school

A Patient Group Direction must be supplied, drawn up and signed by a doctor and pharmacist.

Legally, patient group directions can only be used by registered healthcare professionals. Non-registered staff cannot administer medicines using a PGD, and cannot train to prescribe medicines. The administration of drugs via a PGD may not be delegated[9].

There is a further consideration here; any school nursing team which allows healthcare assistants to deliver immunisations is in danger of jeopardising the entire immunisation programme. Parents send their children to school and trust the school to look after them. The school allows the school nurses in to deliver immunisations because they are trusted to deliver a quality service. Health staff have no right of access and are there as guests. If the parents discovered that the immunisations were being administered by non qualified staff, there could be complaints. Healthcare assistants are invaluable in many areas of nursing, but they are not trained in issues such as safeguarding, confidentiality, anaphylaxis, sex and relationships and the law pertaining to children.

Ethics

There has been much written about this vaccine, but the fact is that it is now available, and so one question is: if there is an available and safe vaccine to prevent HPV infection, is it ethical not to offer it to vulnerable populations (girls) at an appropriate time (before they become sexually active)?

What about poor girls from countries without well financed health care systems? Shouldn't they be equally entitled to it? If so, then who should pay?[11]

Why isn't it being offered to boys? Boys can of course spread the viruses, but they can also suffer from genital warts (against which the bivalent vaccine offers no protection) and anogenital cancers.[5] There is a legitimate argument that by immunising girls, heterosexual boys will be less likely to become exposed to some viruses, but that is no protection for homosexual males, who would benefit from the quadrivalent vaccine.

What should a nurse do if he or she either knows, or has good reason to think, that this girl is sexually active, or at risk of becoming sexually active, but her parent has refused consent? Is this a child protection matter? If so, then obviously local protocols must be followed, but meanwhile, should she be vaccinated, for her own protection? Ideally, the parent should be contacted to see whether he or she can be persuaded to give consent, but if this is not possible, Unite/CPHVA advice would be that if the nurse assesses the girl to be Fraser competent[7] then she should have all the information explained to her so that she can come to a decision, and that if she decides to receive the immunisation, then the nurse should give it.

How much effort should staff put into following up poor attendees? High uptake of immunisation in lower socio economic groups is important, for they are at greatest risk of developing cervical cancer[10]. We know that poor school attendance can be for a variety of reasons (bullying, young carer responsibilities, parental disputes, truanting, poor parenting etc). There is the additional problem of school exclusion; the girl may be excluded from school on the day of the immunisation. If considering this in terms of health inequalities, then it is obvious that practitioners must make great effort to include those girls who have, for whatever reason, become excluded from the mainstream. It is not ethical to only offer this immunisation to those who have no problems.

Should school nurses do anything about schools which refuse to allow immunisations to take place on their premises? School governors can decide not to accept the offer to give children immunisations on school premises, and it is not the school nurse's concern to have an opinion on the moral or business case for that decision. The local health authority must simply make alternative arrangements for these girls.

What else practitioners need to know

This issue needs to be taken on board as part of the whole public health ethos of the school, along with excellent sex and relationship education, self esteem work, citizenship involving informed choice, and young people growing up to gradually take responsibility for ensuring their own health and that of others, and understanding the role of immunisation in the wider scheme of keeping populations healthy. This will pay dividends when they have to take responsibility for allowing their own offspring to be immunised. The prevention of cervical cancer can be used as an opening for parents to talk to their children about sexuality.

In addition to cervical cancer, HPV is causally associated with other less common cancers, which include cancer of the vagina, vulva, penis and anus. The use of condoms reduces, but does not eliminate the risk of sexual transmission. Non–sexual routes of HPV transmission include vertical transmission from mother to new born baby[3].

Two HPV vaccines have been licensed in Europe: the quadrivalent vaccine GardasilTM (manufactured by Sanofi Pasteur) and the bivalent vaccine CervarixTM (manufactured by GlaxoSmithKline). Both CervarixTM and GardasilTM protect against HPV types 16 and 18 which cause over 70% cervical cancers. Additionally, GardasilTM protects against HPV types 6 and 11 which cause most cases of genital warts. Both have good safety records with six years' data so far.[1]

Follow up and research will be needed for several decades, in order to evaluate the effectiveness and cost effectiveness of this vaccine. These girls will continue to need cervical screening tests, as the immunisation only protects against the two most common varieties of HPV which account for 70% cancers. This is an individual immunisation, unlike others where 'herd immunity' is desirable to prevent outbreaks.

This is an expensive programme. Each dose costs £80 plus VAT, as well as the costs of leaflets, letters, staffing etc. The Department of Health (England) has given £8.9 million to PCTs this year to be shared out on a per capita basis by the number of girls in the cohort. It is not clear whether further money will be made available next year.

Girls who have been sexually abused, may have already been exposed to the virus.

The Department of Health (England) has advertised the campaign through multi-media outlets, including having banners on MSN (www.msn.com), and in Habbo hotel (www.habbo.com) and Lola's Land (www.lolasland.com), which are social networking sites used by this age group.

What we don't know

- We do not know how long immunity from vaccination lasts, so there may be a need for booster doses.
- The effectiveness of vaccinating men is not known, and studies are on going.

Recommendations:

1. Provide sufficient qualified staff including clerical
2. Remember police checks for staff working with children
3. Good governance/ Patient group directions
4. Logistics, who/where/how/mobile phone
5. Duty of care to staff and pupils
6. Follow up non attendees if vulnerable
7. Remember special schools EBD units, pupil referral units, and children home educated.

References

[1] European Centre for disease prevention and control, Jan 2008; Guidance for the introduction of HPV vaccines in EU countries, Stockholm, Sweden.

[2] Department of Health, May 2008, Introduction of Human Papillomavirus into the National Immunisation programme, letter from the Chief Medical Officer, the Chief Nursing Officer and the Chief Pharmaceutical Officer http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Professionalletters/Chiefmedicalofficerletters/DH_084542

[3] Department of Health, May 2008; The Green book (2006) TSO, chapter18a, amended 2008, http://www.dh.gov.uk/en/Publichealth/Healthprotection/Immunisation/Greenbook/DH_4097254

[4] Nursing and Midwifery Council, April 2008, The Code: Standards of conduct, performance and ethics for nurses and midwives. www.nmc-uk.org accessed 05/11/08

[5] Department of Health, 2008; The human papillomavirus vaccine: information for health professionals and head teachers on the new HPV vaccine for 12 – 13 year old girls, TSO London, England.

[6] Nursing and Midwifery Council, July 2008 Advice sheet, www.nmc-uk.org accessed 05/11/08

[7] Walters, H. October 2008, Gillick competency or Fraser guidelines; an overview. NSPCC http://www.nspcc.org.uk/inform/resourcesforprofessionals/informationbriefings/gillick_wda61289.htmlAccessed 07/11/08

[8] Office of public sector information;1991, Age of Legal Capacity Scotland Act http://www.opsi.gov.uk/acts/acts1991/ukpga_19910050_en_1

[9] Department of Health, July 2006, Medicines Matters: A guide to mechanisms for the prescribing, supply and administration of medicines, TSO London, England

[10] Franco E. Commentary: health inequity could increase in poor countries if universal HPV vaccine is not adopted, British Medical Journal 25/08/07 volume 335

[11] Raffle A., Challenges of implementing human papillomavirus (HPV) vaccination policy, British Medical Journal 25/08/07, volume 335

FURTHER SOURCES OF INFORMATION

www.tellher.com

HPV and cervical cancer: What you and your pupils need to know, a teaching and learning resource pack from the Royal Society of Health hpvinfo@rsph.org

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