

Audit of HPV Information Leaflets for Parents/Students

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1. Background

Human papillomavirus (HPV) vaccine protects girls against developing cervical cancer in adulthood.

In Ireland, a school-based HPV vaccination programme has been in place since 2010. The National Immunisation Advisory Committee of the Royal College of Physicians of Ireland recommends that all girls at age 12-13 years should receive the vaccine. The vaccine used in the HSE school vaccination programme is HPV4 (Gardasil). Two doses, six months apart, are recommended for girls up to 14 years of age. Girls aged 15 and older require three doses to be protected. The HSE vaccination teams visit second level schools twice during the school year. First year girls are given dose one in September/October and dose two in March/April.

At the beginning of the school year, a HPV information pack developed by the National Immunisation Office (NIO) is distributed to parents of all first year girls. This contains an introductory letter and contact details, information leaflet and consent form. Every year, the content of the information leaflet is reviewed by the NIO, taking into account comments and suggestions from parents, school vaccination teams and other relevant stakeholders.

School-based HPV vaccination programmes are also in place in Northern Ireland, England, Wales, Scotland, Australia and New Zealand. Both girls and boys are offered the vaccine in Australia and New Zealand while girls-only programmes are in place in the other five jurisdictions.

In Ireland, HPV vaccine uptake had exceeded the target of 80% since the programme was introduced in 2010. However, this fell to 72% in 2015/16 academic year and it is estimated that only 50% of girls received their first dose in 2016/17 due to unfounded vaccine safety concerns. Uptake has not fallen in the other six countries included in this audit.

In light of this concerning decline in uptake, it is paramount that quality information materials are provided to parents that contain relevant and accurate information about the vaccine and are readable and easy-to-understand. Comparing the Irish leaflet with those distributed in other countries where uptake has remained stable will allow the NIO to identify potential areas for improvement.

2. Standards

Content of leaflet:

No standards were identified that addressed content of the information leaflet. Instead, a list of core information items was agreed based on expert opinion (i.e. following discussion with NIO staff).

Readability of leaflet:

Plain language style guide for documents (HSE Health Promotion Unit; National Adult Literacy Agency (NALA), 2010)

http://www.lenus.ie/hse/bitstream/10147/98048/1/HSE_Style_guide.pdf

Guidance for providers of health and social care services: Communicating in plain English (Health Information and Quality Authority (HIQA), 2015)

<https://www.higa.ie/sites/default/files/2017-02/Guidance-Communicating-in-plain-English-adults.pdf>

Patient Education Materials Assessment Tool for Printable Materials (Agency for Healthcare Research and Quality, 2013)

<https://www.ahrq.gov/sites/default/files/publications/files/pemat-p.pdf>

The audit tool used is contained in Appendix 1.

3. Aim & Objectives

Aim

To review the HPV vaccine information leaflet provided to parents of first year girls in second level schools

Objectives

- To assess the content and readability of the HPV vaccine information leaflet
- To compare the Irish leaflet with those distributed in other countries with school-based programmes
- To make recommendations to inform future HPV vaccine information leaflets

4. Methodology

The HPV vaccine information leaflets for parents/students distributed in Ireland, Northern Ireland, England, Wales, Scotland, Australia and New Zealand were reviewed. There are school-based HPV vaccination programmes in place in all of these countries.

These leaflets were accessed via the websites of the relevant bodies in the seven countries. Links to these information leaflets are contained in Appendix 2.

5. Results

5.1 Content of leaflet

5.1.1 Description of HPV

All leaflets include a description of HPV.

The level of detail provided is broadly similar across the seven countries. All explain that HPV is a common virus, there are several subtypes, it is spread by sexual contact and it can cause cervical cancer.

5.1.2 Description of cervical cancer

A description of cervical cancer is provided in all leaflets except the Australian leaflet.

Leaflets from Ireland, Northern Ireland, England, Wales, Scotland and New Zealand detail the annual number of deaths from cervical cancer in their respective jurisdictions.

Simple anatomical diagrams of the female reproductive system are included in the leaflets from Northern Ireland, England and Scotland.

While the leaflets from Ireland, Northern Ireland, England, Wales and Scotland emphasise cervical cancer prevention, the focus of the publications from Australia and New Zealand is broader (reflecting these countries' gender-neutral vaccination policy).

Australian parents are informed that the vaccine will protect '*...your sons and daughters against a range of cancers and disease caused by HPV*' and that HPV is associated with '*... penile, anal, cervical, vulval, vaginal and throat cancer*' and '*..can cause genital warts*'.

Parents in New Zealand are informed that '*cancers caused by HPV affect both men and women. HPV can cause cancer in various parts of the body, particularly the genital area, throat or mouth*'.

5.1.3 Types of HPV that vaccine protects against

The Irish leaflet explains that the vaccine protects against those HPV types that cause cervical cancer and genital warts, as do the publications in Northern Ireland, England, Wales and Scotland.

In New Zealand, parents are informed that the vaccine protects against nine HPV types, seven of which cause cancer and two that cause genital warts. The Australian leaflet states that boys and girls will be protected against four HPV types known to cause cancers and genital warts.

The leaflet distributed in Northern Ireland is the only one that specifies the types most commonly associated with cancer i.e. HPV 16 and 18.

5.1.4 Benefits of vaccine

All explicitly state that vaccination protects against cervical cancer and genital warts. The leaflets from Australia and New Zealand also refer to protection against other HPV-associated malignancies i.e. cancers of the vulva, vagina, penis, anus, throat, mouth.

5.1.5 What side-effects are listed?

All leaflets listed potential side-effects of the vaccine. The number of side-effects listed differed between the seven countries (Table 1).

The Irish leaflet is the only one to provide an estimate of the risk of side-effects (e.g. 1 in 10 girls will have pain, swelling and redness at the injection site). The others simply differentiate between common and rare side-effects.

The Irish leaflet is also the only one to explicitly state that *'There are no long term effects caused by the HPV vaccine'*. There is no reference to long term sequelae in any of the other publications.

The risk of fainting is mentioned in the leaflets in Ireland, Australia and New Zealand but is not referred to in the publications in the other four countries.

The English and Australian leaflets contain the least information on potential side-effects.

Table 1 Side-effects listed in HPV information leaflets by country

	Country						
	Ireland	N. Ireland	England	Wales	Scotland	Australia	New Zealand
Side-effects	Pain, redness, swelling at injection site, headache (1 in 10); nausea, pain in vaccinated arm, mild fever (1 in 100); itchy rash or hives (1 in 1,000 – 1 in 10,000); occasionally girls faint after an injection; severe allergic reactions are extremely rare; there are no long term side effects caused by the HPV vaccine	Stinging, soreness in the arm; very rarely allergic reaction (rash or itching affecting part or all of the body); even more rarely severe reaction with breathing difficulties and collapse (anaphylactic reaction)	Soreness, swelling, redness in the arm; more serious side-effects are rare	Redness, swelling, tenderness in the arm; feel sick; headache; fever; tiredness; aching muscles; more serious side effects are rare	Soreness, swelling, redness, mild itching at injection site; headache; nausea; fever (high temperature); some have an allergic reaction (rash or itch affecting part or all of the body); very rarely severe reaction causing breathing difficulties and may cause collapse (anaphylactic reaction)	Soreness, swelling, redness at injection site; mild temperature; feeling faint	Sore arm, redness, pain, swelling at injection site; headache; fever (feeling hot); nausea (feeling sick); fainting, dizziness (light-headedness); general discomfort (feeling unwell, aches and pains); serious allergic reaction (anaphylaxis) happens rarely (3 in 1 million)

5.1.6 Vaccine effectiveness

The leaflets in all seven countries include core information on vaccine effectiveness. All state that the vaccine protects against HPV which causes cancer and genital warts.

In Ireland, Northern Ireland, England, Wales and Scotland, parents are informed that the vaccine protects against 70% of cervical cancers. In New Zealand, where HPV9 (Gardasil9) is used, the leaflet states that it protects against 90% of cancers by HPV.

Three countries i.e. Ireland, Australia and New Zealand refer to the impact of population-level HPV vaccination programmes. The Irish leaflet states that *'In Australia, the HPV vaccine has prevented 1 in every 2 cervical cancers'*, the Australian leaflet states that *'Studies have since shown that the vaccine is proving very effective in Australia, with substantial falls in HPV infections, pre-cancers of the cervix and genital warts'* and the leaflet in New Zealand reports that *'Over the past 11 years, the number of HPV infections and diseases have fallen significantly among young people in countries offering HPV immunisation, including New Zealand'*.

5.1.7 Number of vaccine doses required and timing

All leaflets describe the number of doses required and the timing. In Australia, three doses are administered over a six month period. In the other six countries, a two-dose schedule is in place for children aged 14 and under, and all specify that girls aged 15 and older require three rather than two doses to be fully protected.

5.1.8 Who should and who should not receive the vaccine?

All leaflets set out clearly who should be offered the vaccine.

With respect to those who should not be vaccinated, there is variation in the level of detail provided.

The Irish leaflet specifies that a girl should not be vaccinated if she has a history of anaphylaxis to a previous HPV vaccine or is pregnant. It also advises to delay vaccination if the child has a high fever, and to inform the vaccinator of any condition that increases risk of bleeding.

The Welsh leaflet advises that those with a history of anaphylaxis to a previous HPV vaccine should not be vaccinated, and that girls with a bleeding disorder or allergies should inform the vaccinator of same.

In New Zealand, parents are advised to speak with a doctor if their child has had a serious reaction to a vaccine in the past, and that asthma, allergies or a common cold do not prevent children from receiving the vaccine.

The publications in Northern Ireland and Scotland state that girls with asthma, eczema, hay fever or other allergies can still be immunised.

Contraindications/precautions are not mentioned in the English or Australian leaflets.

5.1.9 Need for cervical smears

Cervical screening is still required following HPV immunisation. HPV4 (Gardasil) and HPV9 (Gardasil 9) vaccines protect against those HPV types that cause 70% and 90% of cervical cancers, respectively. The need for cervical smears in adulthood despite HPV vaccination is explained in the leaflets published in all countries except Australia.

5.1.10 Does the leaflet provide links to additional information sources?

All leaflets direct parents/students to additional information resources.

In Ireland, individuals are directed to the websites www.hpv.ie and www.hpra.ie and www.cervicalcheck.ie for further information.

The Welsh leaflet provides the greatest number of additional information resources (Table 2).

In addition to online resources, phone numbers are provided in the leaflets distributed in Northern Ireland, Wales, Scotland, Australia and New Zealand.

Table 2 Addition information resources referred to HPV information leaflets

	Country						
	Ireland	N. Ireland	England	Wales	Scotland	Australia	New Zealand
Info. resources	www.hpv.ie www.hpra.ie www.cervicalcheck.ie	www.helpprotectyourself.info Public Health Agency: www.publichealth.hscni.net ph. 0300 555 014	www.nhs.uk/hpv www.medicines.org.uk/emc/medicine/19033/pil/gardasil www.medicines.org.uk/emc/medicine/19033/spc/gardasil www.cancerscreening.nhs.uk <i>'The nurse or doctor will discuss the HPV vaccination with you at your appointment and will be able to answer any questions you may have'</i>	www.nhsdirect.wales.nhs.uk/immunisations www.screeningservices.org.uk www.wales.gov.uk/immunisation www.publichealthwales.org/routine-immunisation-schedule-wales www.medicines.org.uk/emc NHS Direct Wales ph. 0845 4647 QR code also provided	www.immunisation.scotland.org.uk/hpv www.nhsinform.co.uk/consentunder16 NHS inform helpline ph. 0800 22 44 88 (open every day 8am-10pm & interpreting service available)	www.immunise.health.gov.au <i>'Your state or territory's school immunisation program website'</i> <i>'Visit the TGA website'</i> Immunisation information line ph. 1800 671 811	<i>'Speak to the public health nurse or your doctor or practice nurse'</i> www.health.govt.nz/hpv www.medsafe.govt.nz/consumers/cmi/g/gardasil9.pdf ph. 0800 466 863 (freephone)

5.1.11 Does the leaflet provide a link to Patient Information Leaflet (PIL)?

The Irish leaflet provides a link to the website of the Health Products Regulatory Authority (HPRA) to read the PIL.

Both the English and Welsh leaflets provide links to the PIL. In Wales, parents can also access the PIL by scanning the QR code.

In New Zealand, a link to a Consumer Medicine Information leaflet produced by the manufacturer MSD is provided.

A link to the PIL is not included in the leaflets in Northern Ireland, Scotland or Australia.

5.1.12 Date of publication stated

The date of publication/revision was stated for all leaflets.

5.2 Readability of leaflet

5.2.1 Was leaflet subject to literacy proofing?

The Irish leaflet was approved by the National Adult Literacy Agency (NALA), and it contains the Plain English logo.

This is no reference to literacy proofing on the leaflet/relevant website in Northern Ireland, England, Wales, Scotland, Australia or New Zealand.

5.2.2 Was leaflet translated into different languages?

The Irish leaflet is available in the following nine languages: English, Irish, Arabic, Chinese (simplified), German, French, Portuguese, Polish, Romanian and Russian. The number of languages into which each of the leaflets is translated is outlined in Table 3.

Table 3 Number of translations of HPV information leaflets

	Country						
	Ireland	N. Ireland	England	Wales	Scotland	Australia	New Zealand
No. of languages	10	9	1*	2	4	1*	8
Languages	English, Irish, Arabic, Chinese (simplified), German, French, Portuguese, Polish, Romanian, Russian	English, Irish, Tetum, Slovak, Romanian, Portuguese, Polish, Chinese (simplified), Lithuanian		English, Welsh	English, Urdu, Chinese (traditional), Polish		English, Chinese (simplified & traditional), Cook Islands Maori, Hindi, Maori, Samoan, Tongan

*It is not stated if the leaflets in England and Australia are available in languages other than English.

5.2.3 Abbreviations and acronyms explained

All abbreviations and acronyms are explained in the leaflets from Ireland, Northern Ireland, England, Scotland, Wales and New Zealand (the Scottish publication also includes a glossary of terms used in the leaflet).

However, in the Australian leaflet, parents are advised to ‘... visit the TGA website ...’ if they wish to obtain further information or to report a side-effect. It does not explain that this is the website of the Therapeutic Goods Administration.

5.2.4 Simple language

All publications from the seven countries use simple language.

5.2.5 Personal language

Personal language (i.e. 'I', 'we' and 'you') is used in all leaflets.

5.2.6 Each paragraph limited to one idea

In all leaflets, each paragraph is limited to one idea.

5.2.7 Readable font

Readable font (≥ 11 font size) was used for the leaflets produced in all seven countries.

5.2.8 Contrast between text colour and background colour

In all of the leaflets, the text colour contrasts effectively with the background colour. All mainly use dark text on a light background which most people find easier to read. When using light coloured text on a dark background, it is recommended that bold font is used. This was evident in the leaflets in Northern Ireland, England, Scotland and New Zealand. However, the front cover of the Welsh leaflet contains white writing on a pink background in regular font.

Of note, all publications are in full-colour throughout. The leaflets distributed in Ireland, Northern Ireland, England, Wales and Scotland (where girls-only programmes are in place) predominantly use pink and purple whereas the Australian and New Zealand publications (where both girls and boys are vaccinated) use yellow, green, blue and orange.

5.2.9 Images/graphics/pictures clear and relevant to the text

Images should be used to convey messages rather than to decorate the publication.

The Irish leaflet contains the image of a mobile phone screen reading '*Remember HPV vaccine tomorrow! Had mine yesterday, no probs! Talk to u l8r.*' This underscores that this is a safe vaccine and that many other Irish girls have been immunised. There are also images of a ruler, calculator, post-it and ear phones which indicate that this leaflet is pertinent to students.

All publications, except in England, contain pictures of young people (girls in Ireland, Northern Ireland, Wales and Scotland and boys and girls in Australia and New Zealand). They are wearing school uniforms in the Welsh and Australian leaflets. These are relevant images as they clearly identify the target population and also convey that these are school-based vaccination programmes.

Diagrams of the female reproductive systems are included in the leaflets in Northern Ireland, England and Scotland to aid their description of cervical cancer.

5.2.10 Visual clues (e.g. bubbles, boxes, larger font, bold, highlighting) used to draw attention to key points

The leaflets in all seven countries employ the use of visual clues to emphasise key points. All draw attention to the core message that HPV vaccine protects against cancer. The front cover of the Irish leaflet reads '*The HPV vaccine protects against cervical cancer*' in large bold font.

In the main body of the Irish leaflet, there are five speech and thought bubbles with large bold font informing parents of the following core facts: that it protects against 70% of cervical cancer, the number of vaccine doses that have been distributed in Ireland and worldwide, the impact of the vaccine on the occurrence of cervical cancer in Australia, the absence of long term side effects and that the girl will receive an immunisation passport.

Other publications (Northern Ireland, England, Wales) also highlight that the vaccine protects against 70% of cervical cancers but none focus on the other four facts highlighted in the Irish leaflet.

The Irish leaflet contains more bubbles/boxes than any of the other leaflets with the exception of the Scottish publication.

6. Conclusions

The findings of this audit indicate that the HPV information leaflet provided to parents of girls in first year of second level school in Ireland is of high quality and compares favourably with the leaflets distributed in other countries with school-based vaccination programmes (Northern Ireland, England, Wales, Scotland, Australia and New Zealand).

With respect to its content, it met pre-specified audit criteria and provides core information in all key areas. There is in fact evidence that the Irish leaflet provides more information than other countries with school-based programmes e.g. in relation to potential side-effects, contraindications/precautions, vaccine effectiveness. For additional information resources, parents are directed to three websites which contain extensive information on the vaccine but a telephone number is not provided (in contrast to Northern Ireland, Wales, Scotland, Australia and New Zealand). This would likely result in an increased workload and may be precluded by current resources at the NIO.

With respect to its readability, the Irish leaflet also met all pre-specified audit criteria. It is approved by NALA. It is the only publication that indicates that it has been subject to literacy proofing. NALA's logo is printed on the leaflet. It is available in a total of ten languages which exceeds the number of translations in any of the other six countries.

7. Recommendations

1. Include a QR code in the Irish leaflet to allow individuals to more easily access the PIL
2. Provide numerical value for risk of severe allergic reaction i.e. 1 in 1 million girls (risk estimates are included for other side-effects listed)
3. Consider including a simple diagram of female reproductive system to aid description of cervical cancer
4. Consider advising parents to speak with a health professional if they want more information (i.e. their GP or Local Health Office)

8. Re-audit

A re-audit should be undertaken in two years' time or sooner if there are significant changes to the HPV vaccination programme e.g. extension of vaccination programme to boys.

9. Appendices

Appendix 1 Audit Tool

Audit of HPV Information Leaflets for Parents/Students

Audit Tool

Content

Leaflet contains the following core information:

Description of HPV	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Description of cervical cancer	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Types of HPV that vaccine protects against	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Benefits of vaccine	Yes <input type="checkbox"/>	No <input type="checkbox"/>
What side-effects are listed?	----- ----- -----	
Vaccine effectiveness	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Number of vaccine doses required and timing	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Who should and who should not receive the vaccine	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Need for cervical smears	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does the leaflet provide links to additional information sources?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does leaflet provide link to Patient Information Leaflet?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Date of publication stated	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Readability

Is leaflet subject to literacy proofing?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Is leaflet translated into different languages?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Number of languages	-----	

Abbreviations and acronyms are explained	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Simple language is used	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Personal language (i.e. 'I', 'we' and 'you') is used	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Each paragraph is limited to one idea	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Readable font (at least 11 point) is used	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Text colour contrasts effectively with the background colour	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Images/graphics/pictures clear and relevant to the text	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Visual clues (e.g. bubbles, boxes, larger font, bold, highlighting) used to draw attention to key points	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Appendix 2 Links to HPV information leaflets**Ireland**

<http://www.hse.ie/eng/health/immunisation/pubinfo/schoolprog/HPV/HPV-Vaccine-Information-for-Parent.pdf>

Northern Ireland

<http://www.helpprotectyourself.info/hpv-campaign-northern-ireland>

England

https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/318585/8874_HP_Vaccine_Leaflet_2014_04.pdf

Wales

<http://www.nhsdirect.wales.nhs.uk/pdfs/HPV.pdf>

Scotland

http://www.immunisationscotland.org.uk/uploads/documents/5988-A%20guide%20to%20the%20HPV%20vaccine_1.pdf

Australia

[http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/DE15B222737A43C9CA2580680016A539/\\$File/FS-parents.pdf](http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/DE15B222737A43C9CA2580680016A539/$File/FS-parents.pdf)

[http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/EEAE8932967EB9B3CA2580680014DB85/\\$File/FS-students.pdf](http://www.immunise.health.gov.au/internet/immunise/publishing.nsf/Content/EEAE8932967EB9B3CA2580680014DB85/$File/FS-students.pdf)

New Zealand

https://www.healthed.govt.nz/system/files/resource-files/HE2044_HP_Vaccine_Parent_Consent_Form.pdf