

GPNI Vaccines update

Shingles (Herpes Zoster) & HPV

September 2023

Human Papilloma Virus (HPV)

September 2023



Human Papilloma Virus (HPV)

Is a double stranded DNA virus



(HPV) Associated Cancers

HPV-related cancer site	No attributable to HPV	Relative contribution of HPV 16/18		Relative contribution of HPV 6/11/16/18/31/33/45/52/58	
		Percent (%)	Number	Percent (%)	Number
Cervix uteri	530 000	70.8	370 000	89.5	470 000
Anus	35 000	87.0	30 000	95.9	33 000
Vulva	8 500	72.6	6 200	87.1	7 400
Vagina	12 000	63.7	7 400	85.3	9 900
Penis	13 000	70.2	9 100	84.6	11 000
Head and neck	38 000	84.9	32 000	89.7	34 000
Total HPV-related sites in women	570 000	71.4	410 000	89.6	510 000
Total HPV-related sites in men	60 000	82.3	50 000	90.4	55 000
Larynx	630 000	72.4	460 000	89.7	570 000



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Transmission and incubation

- The virus infects surface tissues, including the skin and the lining of the upper respiratory and anogenital tracts.
- Spread of HPV is via direct contact with an infected area of skin or mucosa.
- Genital HPVs are transmitted by sexual contact with an infected individual, primarily through sexual intercourse.
- Anogenital warts usually develop between one and three months after infection.
- Persistent infection can lead to early pre-cancerous changes.

HPV vaccination in N. Ireland

- The national HPV vaccination programme began in 2008 in the UK, initially vaccinating girls aged 12-13 years with the Cervarix vaccine.
- In 2012, the Gardasil vaccine has been used, with protection against HPV types 6, 11, 16 and 18.
- Gardasil 9 (introduced to the programme in 2022) contains antigens from nine HPV viruses - 6, 11, 16, 18, 31, 33, 45, 52 and 58.
- Since 2016, vaccination has been offered opportunistically to MSM up to 45 years through sexual health clinics.
- The adolescent vaccination programme was extended in September 2019 to include boys (JCVI recommended).

HPV vaccination changes

From 1st September 2023

Those eligible adolescents and adults up until the age of 25 , will require **1 dose of HPV vaccine instead of 2 doses**, to complete the course.

The same applies to anyone receiving the vaccine through the MSM HPV vaccination programme but does not apply to individuals who are known to be living with HIV including those on antiretroviral therapy, or are known to be immunocompromised at the time of vaccination.

Why has the dosage changed?

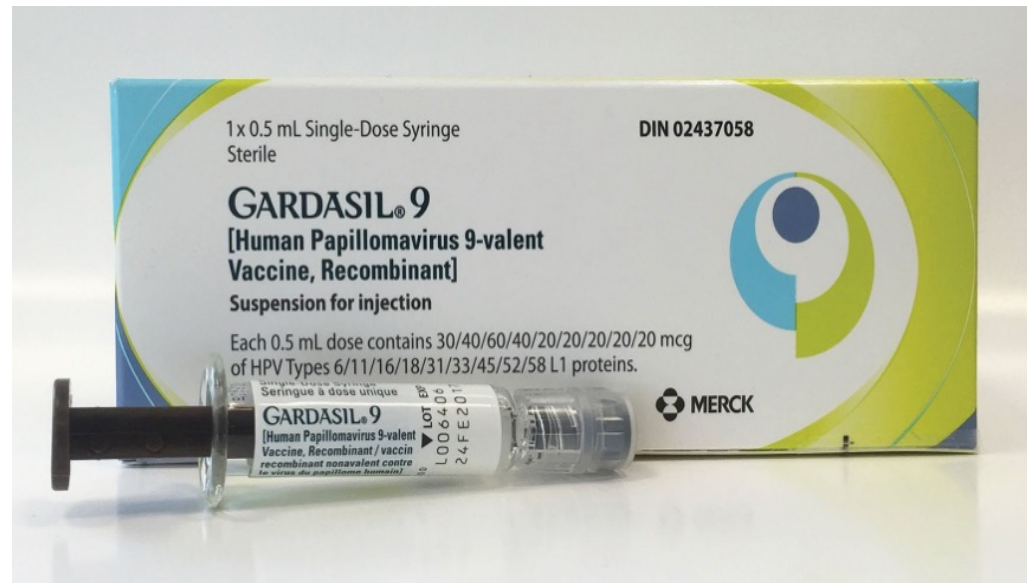
The Joint Committee on Vaccination and Immunisation (JCVI) has reviewed the scientific evidence about the doses of the HPV vaccine. They agree that there's very strong evidence that most people only need 1 dose of the HPV vaccine to provide full protection

This means that most people who've already received 1 dose are now fully vaccinated. They don't require any further doses of the HPV vaccine.

Vaccine Effectiveness

- The vaccines have been shown to be highly (99%) effective at preventing HPV infection, caused by the strains included in the vaccine.
- All the vaccines reduce the incidence of high grade precancerous cervical and anal changes, including carcinoma in situ.
- Modelling work carried out by the University of Warwick estimates that by 2058 in the UK, the HPV vaccine currently being used may have prevented up to 64,138 HPV-related cervical cancers and 49,649 other HPV-related cancers. The introduction of Gardasil 9 will increase this.

HPV VACCINE



Gardasil 9 has been the available vaccine since September 2022

Recommended HPV Vaccine

- In 2022, the vaccine supplied for the adolescent HPV and HPV-MSM programme changed from Gardasil to Gardasil®9
- Like Gardasil, Gardasil®9 vaccine is prepared using recombinant DNA technology (similar to hepatitis B vaccine). There is no live virus present and the vaccines do not contain any antibiotics or preservatives.
- Both vaccines contain an aluminium adjuvant (read a full definition of this term).

Gardasil®9

- Gardasil®9 contains antigens from nine HPV viruses - 6, 11, 16, 18, 31, 33, 45, 52 and 58.
- Like Gardasil, Gardasil®9 , protects against
 - 16 and 18** - 2 high risk HPV types that can lead to cancer
 - 6 and 11** - 2 HPV types that cause approx. 90% of all anogenital warts in males and females
- Gardasil®9 also offers protection against 5 additional types of HPV (31, 33, 45, 52, 58), although less common than types 16 and 18 , are also considered high risk.

Gardasil®9 vaccine safety

- The safety of the HPV vaccines has been established through rigorous testing in clinical trials, followed by the use of millions of doses across the world.
- Gardasil®9 has been used extensively in other countries since it was first licensed in 2015 and its safety is well established. The Medicines and Healthcare products Regulatory Agency (MHRA) and the Joint Committee on Vaccination and Immunisation (JCVI) keep the safety of vaccines under review
- Some people may experience mild side-effects, generally of short duration, far outweighed by the expected benefits of the vaccine.

Vaccine safety reviews

- **JCVI** carried out a routine review of HPV vaccine safety in 2015 and concluded it had ***no concerns about the vaccine safety***.
- Extensive reviews of HPV vaccine safety have also been undertaken by independent health bodies & authorities worldwide.
- ***ALL conclude the evidence does not support a link between HPV vaccine and development of a range of chronic illnesses:***
 - MHRA
 - World Health Organization's Global Advisory Committee on Vaccine Safety
 - European Medicines Agency
 - US Centre for Disease Control and Prevention
 - Health Canada

Gardasil 9 Vaccine Schedule

One dose schedule

Immunocompetent individuals who are not known to be HIV positive

- In the routine adolescent programme**
- MSM programme before the age of 25**

Gardasil®9

- 0.5ml of HPV vaccine



Gardasil 9 Vaccine Schedule

Two dose schedule

Immunocompetent individuals who are not known to be HIV positive who are:

- Over the age of 25 in the MSM programme**

Gardasil®9

- first dose of 0.5ml of HPV vaccine
- second dose of 0.5ml six to 24 months after the first dose



Gardasil 9 Vaccine Schedule

Three dose schedule

Immunosuppressed or known to be HIV positive and aged under 25 years

Gardasil®9

Administer three doses on a 0, 1 and 4-6 month schedule, for instance:

- first dose of 0.5ml of HPV vaccine
- second dose of 0.5ml at least one month after the first dose
- third dose of 0.5ml at least three months after the second dose

Gardasil 9 vaccine schedule cont.

- Vaccination is now covered by the national HPV vaccination programme for eligible cohorts, up to the age of 25 years.
- Prior infection with one HPV type does not diminish the efficacy of the vaccine against other HPV types included in the vaccine.

Contraindications and precautions to Gardasil 9

Gardasil®9 should not be administered to those who have had a

- Confirmed anaphylactic reaction to a previous dose of the vaccine.
- Confirmed anaphylactic reaction to any component of the vaccine.

Immunisation should be deferred in

- Cases of fever or acute illness
- Pregnancy

Note: yeast allergy is not a contraindication to the HPV vaccine. Even though Gardasil is grown in yeast cells, the vaccine product does not contain any yeast.

Possible adverse reactions

Most common adverse reactions after HPV vaccination are usually mild to moderate in intensity and include:

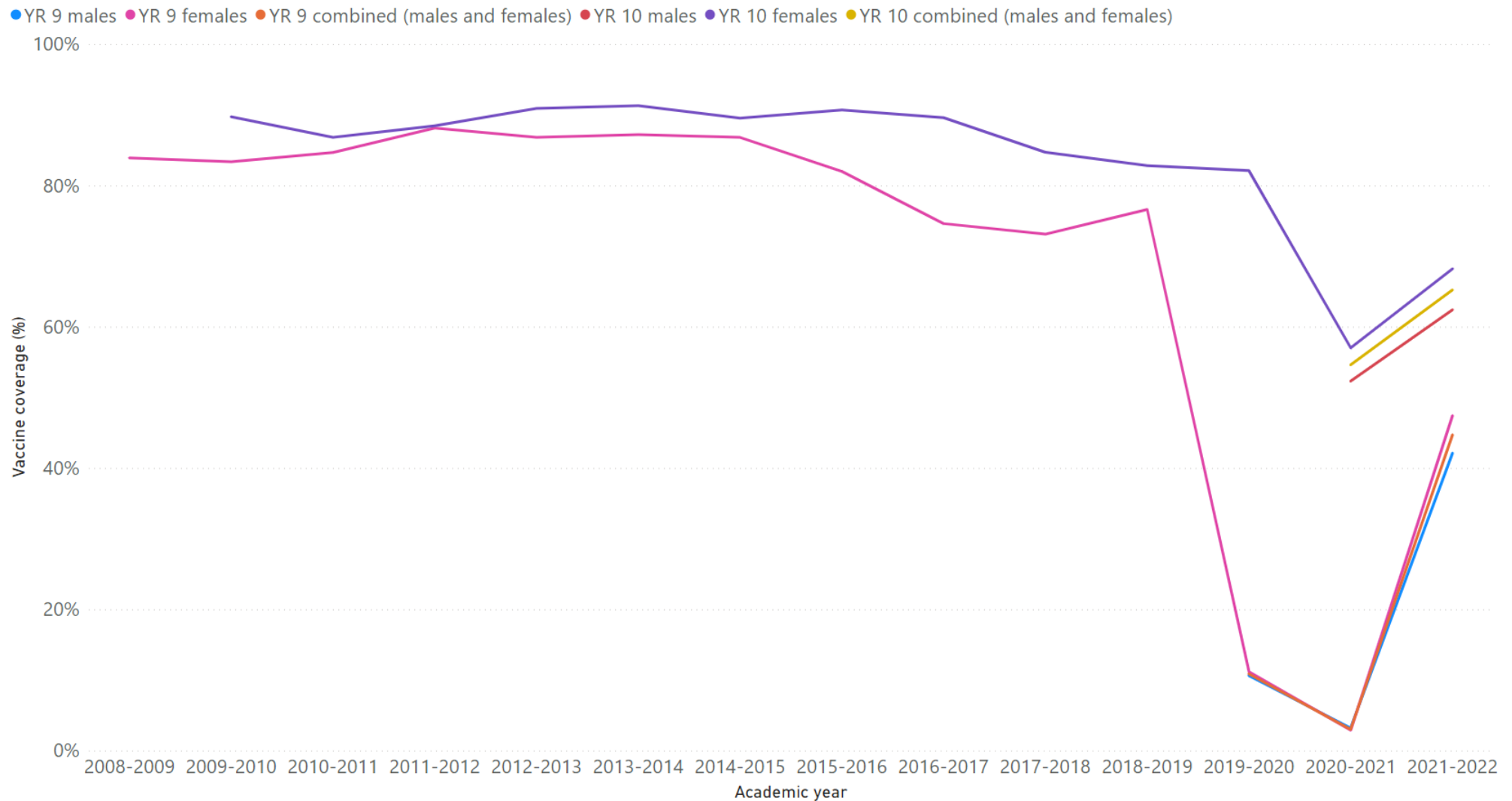
- Injection site reactions, such as pain, redness or swelling
- Systemic reactions, such as headache, fatigue, muscle aches, low grade fever
- Anaphylaxis is possible but extremely rare

Pregnancy and breastfeeding

- If someone becomes pregnant after starting a course of HPV vaccine they should continue the pregnancy and complete the course after delivery.
- Inactivated vaccines are not a risk in pregnancy however as a precaution HPV vaccine is not recommended in pregnancy
- Routine questioning about pregnancy or LMP is not required before offering vaccine.



HPV vaccine coverage, year 9 and 10 males, females and combined completing full course, 2008-2022*, Northern Ireland



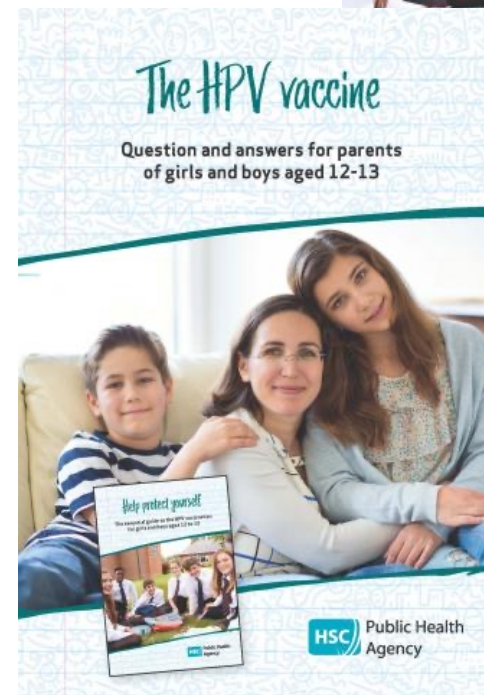
Resources

Health professionals

- Green Book chapter 18a
- PGD
- Factsheet for healthcare professionals (PHA website)

Parents and young people

- Leaflets
- Record card
- Online resources (PHA website and NI direct)



HPV Operational planning

- HPV Vaccine is being delivered by school nursing teams through each trust with:
 - 2 offers in year 9
 - 2 offer in year 10
- If the vaccination has been missed at the 4th offer, a letter will be sent to the parent and GP practice via school nursing teams.
- Last offer of HPV will be through Primary Care settings.

Shingles (Herpes Zoster)

September 2023



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Shingles (Herpes Zoster)

- is an infection of the nerve & the skin around it
- is caused by reactivation of a latent varicella zoster virus infection



Why vaccinate older adults and those immunosuppressed against shingles?

- Increased risk of developing shingles
- Increased risk of developing a more severe form of the disease including PHN and increased hospital admissions

Epidemiology of shingles

- An estimated 50,000 cases of shingles occur in people aged over 70 years each year in England & Wales
- Of these, 14,000 develop Post Herpetic Neuralgia
- 1,400 cases of shingles result in hospitalisation
- 1 in 1,000 cases of shingles are estimated to result in death
- **In Northern Ireland this corresponds to 900-1000 cases of shingles in people in their 70s and 250 cases of PHN each year**

National programme for adults aged 60-79

The JCVI recommended that:

- Shingrix should replace Zostavax® in the routine programme
- should be offered at 60 years of age.

For this immunocompetent cohort:

- the eligible age for immunocompetent individuals will change from 70 to 60 years of age for the routine cohort, in a phased implementation over a 10 year period
- This will be completed in 2 stages during that period

National programme for adults aged 60-79 years (2)

- ***During Stage 1 (1st September 2023 to 31st August 2028) Shingrix® will be offered to those who are aged 70 and 65 years of age on 1 September 2023 (and each year up to 2028).***
- ***During Stage 2 (1 September 2028 to 31 August 2033) Shingrix® will be offered to those aged 65 and 60 years of age on 1 September 2028 (and each year up to 2033).***
- From 1 September 2033 and thereafter, Shingrix® will be offered routinely at age 60 years
- *Those who have been previously eligible (i.e. in stages 1 and 2) will remain eligible until their 80th birthday. Where an individual has turned 80 years of age following their first dose of Shingrix, a second dose should be provided before the individual's 81st birthday to complete the course*

**IMMUNOCOMPETENT PATIENTS: TIMELINE FOR THE PHASED
IMPLEMENTATION OF THE CHANGE TO ELIGIBLE AGE**

		Those turning age (years) in each new programme year												
	Programme year	60	61	62	63	64	65	66	67	68	69	70	71-79	
Stage 1 of catch up (offer to those turning 65 and 70 years)	01 Sept 2023 – 31 Aug 2024												Those previously eligible for the Zostavax® programme remain eligible for Zostavax® until stocks deplete, after which time they become eligible for Shingrix®	
	01 Sept 2024 – 31 Aug 2025													
	01 Sept 2025 – 31 Aug 2026													
	01 Sept 2026 – 31 Aug 2027													
	01 Sept 2027 -31 Aug 2028													
Stage 2 of catch up (offer to those turning 60 and 65 years)	01 Sept 2028 – 31 Aug 2029													
	01 Sept 2029 – 31 Aug 2030													
	01 Sept 2030 -31 Aug 2031													
	01 Sept 2031 – 31 Aug 2032													
	01 Sept 2032 – 31 Aug 2033													
Routine offer at 60 years	01 Sept 2033 Onwards													

Key

	Newly eligible for Shingrix on/after birthday
	Completed / remain eligible until 80 th birthday
	Not currently eligible



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Severely Immunosuppressed individuals aged 50 years and over

From September 2021,

- Shingrix® made available to immuno-suppressed individuals aged 70 to 79 years, who are contraindicated to receive Zostavax®, as part of the NHS shingles vaccination programme.

From 1 September 2023

- eligibility will be expanded to all severely immunosuppressed individuals aged 50 years and over (with no upper age limit) who should be offered two doses of Shingrix.

Severely Immunosuppressed individuals aged 50 years and over (2)

- Severely Immunosuppressed individuals represent the highest priority for vaccination given their risk of severe disease, and therefore the programme aims to catch up all eligible individuals aged 50 years and over in the first year of programme implementation.
- Individuals who should be offered Shingrix® amongst this cohort are summarised:

Box: Definition of severe immunosuppression
p7 Chapter 28a Green Book

National Shingles Vaccination Programme

From 1st September 2023

Eligible Cohorts:

- 1. Those aged 65 and 70 years old on 1st September 2023**
(i.e. those born between- 02/09/1957 to 01/09/1958 and 02/9/1952 to 01/09/1953)
- 2. Those aged 50 years and above who are severely immunosuppressed**
- 3. Those aged 71 to 79 years of age who have not previously received a Shingles vaccine**

National Shingles Vaccination Programme cont.

- The 2023/24 vaccination programme continues until 31 August 2024
- GPs should continue to ensure patients who meet the eligibility criteria for the 2023/24 programme, irrespective of their age now, are offered the vaccine, particularly those who will become ineligible due to being aged 80 or older on 1 September 2024.

National Shingles Vaccination Programme cont.

- From Autumn 2023 GP's should offer Shingrix vaccine to eligible patients **aged 65 or 70 years of age on 1 September 2023 and those over the age of 50 and are severely immunosuppressed.**
- A limited quantity of Zostavax vaccine will still be available until January 2024 (or central stocks deplete)
- Zostavax should only be offered to those aged 71-79 who are previously eligible while supply remains, unless contraindicated e.g. immunosuppressed.
- After this date they should be offered Shingrix if remain eligible.

Shingles vaccine

- Shingrix® is recommended for the prevention of shingles and shingles-related PHN



Shingrix

- Shingrix® is a recombinant vaccine and contains varicella zoster virus glycoprotein E antigen produced by recombinant DNA technology, adjuvanted with AS01B.
- Shingrix® is available as a white powder for reconstitution with diluent and is injected as a suspension. After reconstitution, the suspension is an opalescent colourless to pale brownish liquid.
- Shingrix® is available in a pack size of 1 vial of powder plus 1 vial of suspension or in a pack size of 10 vials of powder plus 10 vials of suspension. The reconstituted vaccine should be inspected visually for any foreign particulate matter and/or variation of appearance. If either is observed, the vaccine should not be administered.
- After reconstitution, the vaccine should be used promptly; if this is not possible, the vaccine should be stored in a refrigerator (2°C – 8°C). If not used within 6 hours it should be discarded.

Efficacy

Shingrix:

- Clinical trials of 15,411 participants: Vaccine efficacy in the 7,695 immunocompetent adults ≥ 50 years and 6,950 ≥ 70 years, administered with two doses of Shingrix® 2 months apart was estimated at 97.2% and 91.2% respectively
- US study of adults ≥ 65 years, two dose vaccine effectiveness against postherpetic neuralgia was 76.0%

In immunocompetent adults ≥ 70 , Shingrix® immunity remained high throughout 7 years following vaccination

Shingrix®

Administration:

- Adults should receive two doses of 0.5ml of Shingrix® a minimum of 2 months apart
- Shingrix® should be given by intramuscular injection
- Subcutaneous administration is not recommended
- Shingrix® should be given with caution to individuals with thrombocytopenia or any coagulation disorder since bleeding may occur following intramuscular administration.

Shingrix Schedule- Northern Ireland

Immunocompetent cohort:

- Administer 2 doses, 6-12 months apart

Immunosuppressed cohort:

- Administer 2 doses, 2-6 months apart

Co-administration- Shingrix®

- Shingrix® can be given concomitantly with **inactivated influenza vaccine**
- Interim data from the US on co-administration of Shingrix® with **adjuvanted influenza vaccine** is reassuring, therefore these 2 vaccines can be given together if required
- As **COVID vaccines** are considered inactivated, Shingrix® vaccine can be co-administered to individuals in an eligible cohort
- Where more than one vaccine is offered, patients should be informed about the likely timing of potential adverse events relating to each vaccine

Contraindications- Shingrix®

- Shingrix® should not be administered to an individual with a confirmed anaphylactic reaction to any component of the vaccine.

Precautions

Delay if:

- Acutely unwell
- Individuals with shingles / PHN



Inadvertent administration- Shingrix®

Inadvertent vaccination in individuals under 18 years of age

- Shingrix® is licensed for use in individuals over 18 years of age
- Most children aged >10 are likely to be immune to varicella and therefore inadvertent vaccination is highly unlikely to result in serious adverse reactions
- Vaccination of varicella naïve children also unlikely to result in serious adverse reactions and should count as a valid dose of varicella vaccine

Inadvertent vaccination with Shingrix® during pregnancy

- No known risk associated with giving inactivated, recombinant viral or bacterial vaccines or toxoids during pregnancy or whilst breast-feeding.
- If indicated, Shingrix® can be considered in pregnancy after full discussion of the risks and benefits of vaccination with the recipient

Possible adverse reactions- Shingrix®

Most frequently reported side effects were:

- Pain at injection site
- Myalgia
- Fatigue



Common Queries

- What if an individual does not have a previous history of chickenpox; should they still be offered the vaccine?

Yes these people **should** be vaccinated

- What if an individual presents with a previous hx of shingles; should they still be offered the vaccine?

Yes these people **should** be vaccinated **however** wait until fully recovered from active shingles infection

Orders

- Movianto via online web portal
- Deliveries usually within 2 working days
- Guidance on vaccine handling and storage in GP practices
- Vaccine wastage

VMS

- All shingles vaccines must be recorded in VMS from 1st Sept 2023
- Clinical assessments for shingles vaccines are not recorded in VMS
- VMS recall dashboard
- **Shingrix vaccines not recorded within VMS will not be displayed on practice recall dashboards**

Shingrix recall report

To help support recall of patients for their second Shingrix dose, VMS now includes a report which shows:

All patients within the practice who have been recorded as having received their first dose of Shingrix, but not yet their second dose

Log in to VMS, select practice

 Vaccine Management

 Department of Health
NI Health Service
Improving the Health of the People

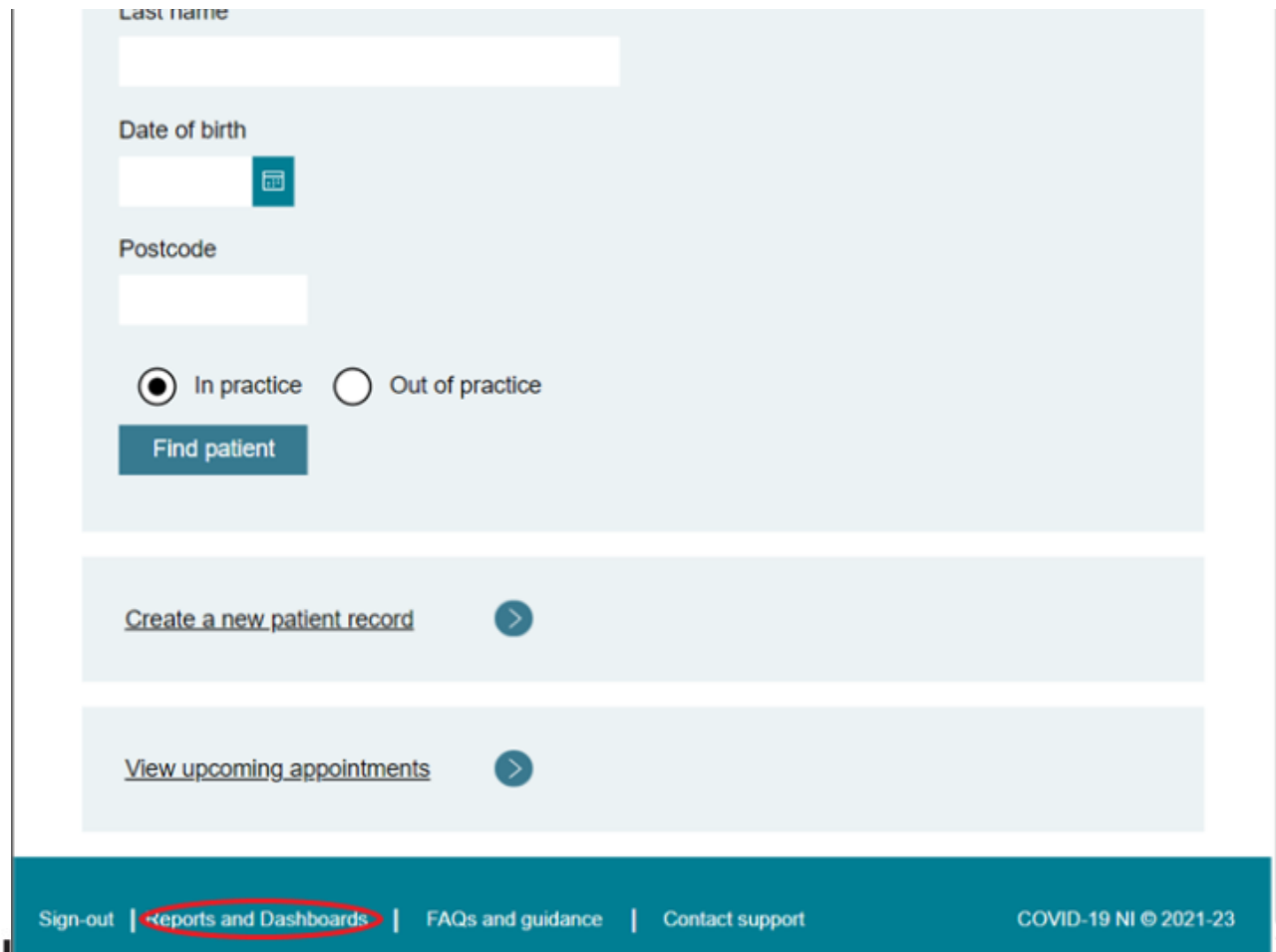
Where are you working today?

Location Name	Filter locations
	GP 
<u>Vision Test Practice-Z00900</u>	GP

[Sign-out](#) | [FAQs and guidance](#) | [Contact support](#)

COVID-19 NI © 2021-23

Scroll to end, click Reports & Dashboards



The screenshot displays a patient search interface. It includes input fields for 'Last name', 'Date of birth' (with a calendar icon), and 'Postcode'. Below these are radio buttons for 'In practice' (selected) and 'Out of practice'. A 'Find patient' button is positioned below the radio buttons. Further down, there are two links: 'Create a new patient record' and 'View upcoming appointments', each accompanied by a right-pointing arrow. The footer is a dark teal bar containing the text 'Sign-out | Reports and Dashboards | FAQs and guidance | Contact support' and 'COVID-19 NI © 2021-23'. The 'Reports and Dashboards' link is circled in red.

Last name
[Input field]

Date of birth
[Input field] [Calendar icon]

Postcode
[Input field]

☒ In practice ☐ Out of practice

Find patient

[Create a new patient record](#) >

[View upcoming appointments](#) >

Sign-out | **Reports and Dashboards** | FAQs and guidance | Contact support COVID-19 NI © 2021-23



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Click GP practice dashboard link

Reports and Dashboards

All vaccinations report

Download the latest report showing all vaccinations for all patients registered in your practice, independent of which location the vaccination was administered in.

 all_vaccinations_report_Z00900_2023-08-10T23:24:41.1738009Z.csv

GP practice dashboard

View reports based on VMS records for your patients.

[GP practice dashboard](#)

Data quality dashboard

View potential data quality issues with vaccinations recorded by your practice

[Data quality dashboard](#)

Flu report

Download the latest report showing flu vaccinations for all patients registered in your practice from 21/22 onwards, independent of which location the vaccination was administered in.

Shingrix Dose 1 report

GP Practice Dashboard

Date Of Shingrix First Dose		HCN	Date Of Shingrix First Dose	First Name	Last Name	Date Of Birth
6/13/2023	6/13/2023	3628596203	13/06/2023	James	VMSTESTONE	14/07/1986

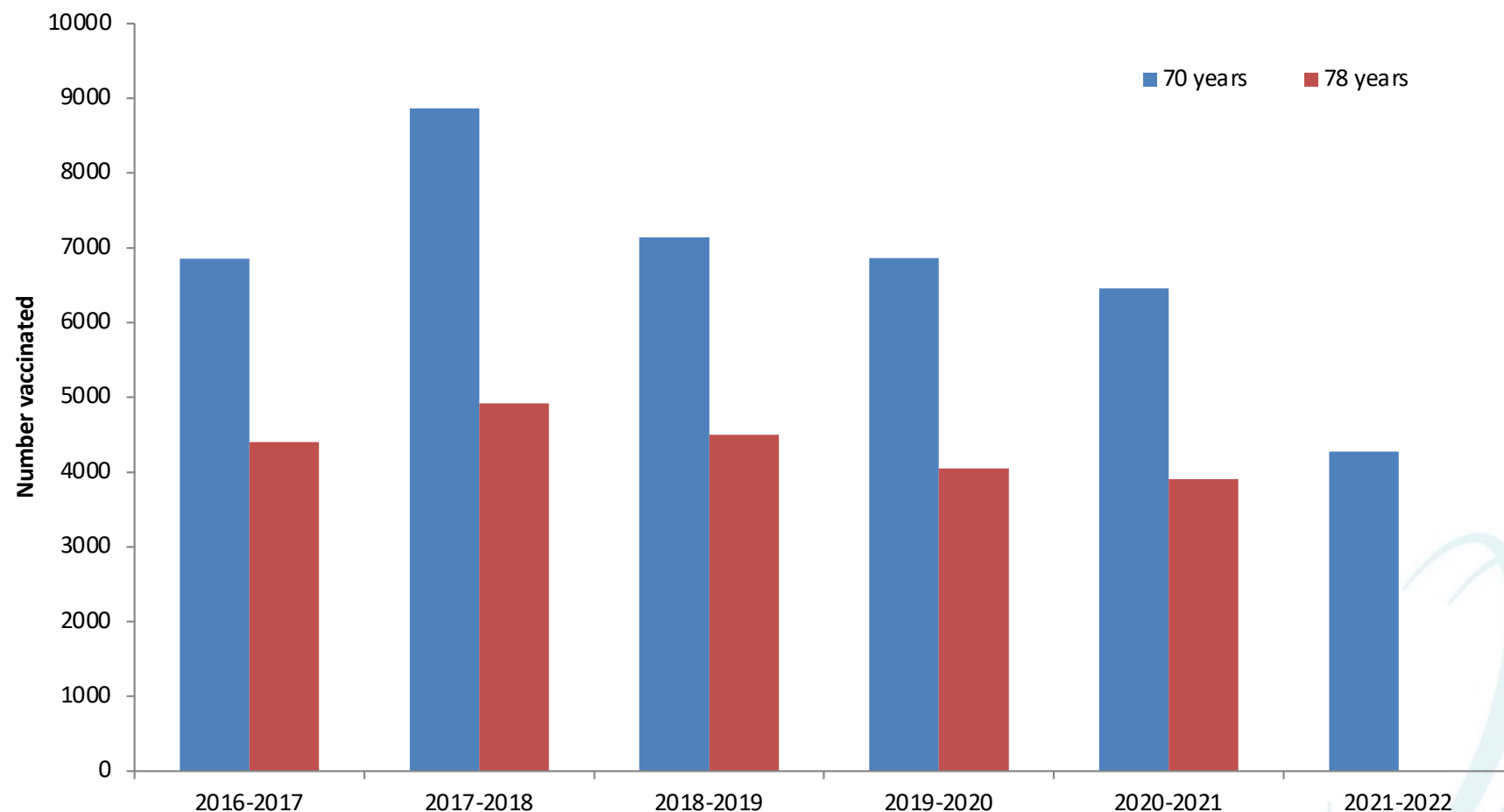
This report shows all living patients registered in your practice who are recorded in VMS as having received a Shingrix first dose vaccination and are not yet recorded as having received a second dose of Shingrix.

You can use the filter to the right to only show vaccinations within a range of dates.

You can download the list of patients by holding the mouse pointer over the table above and clicking the three dots (...) that appear bottom or top right and then selecting 'Export data'.

[Return to homepage](#)

No. patients aged 70 & 78 years, receiving shingles NI 2016-2022

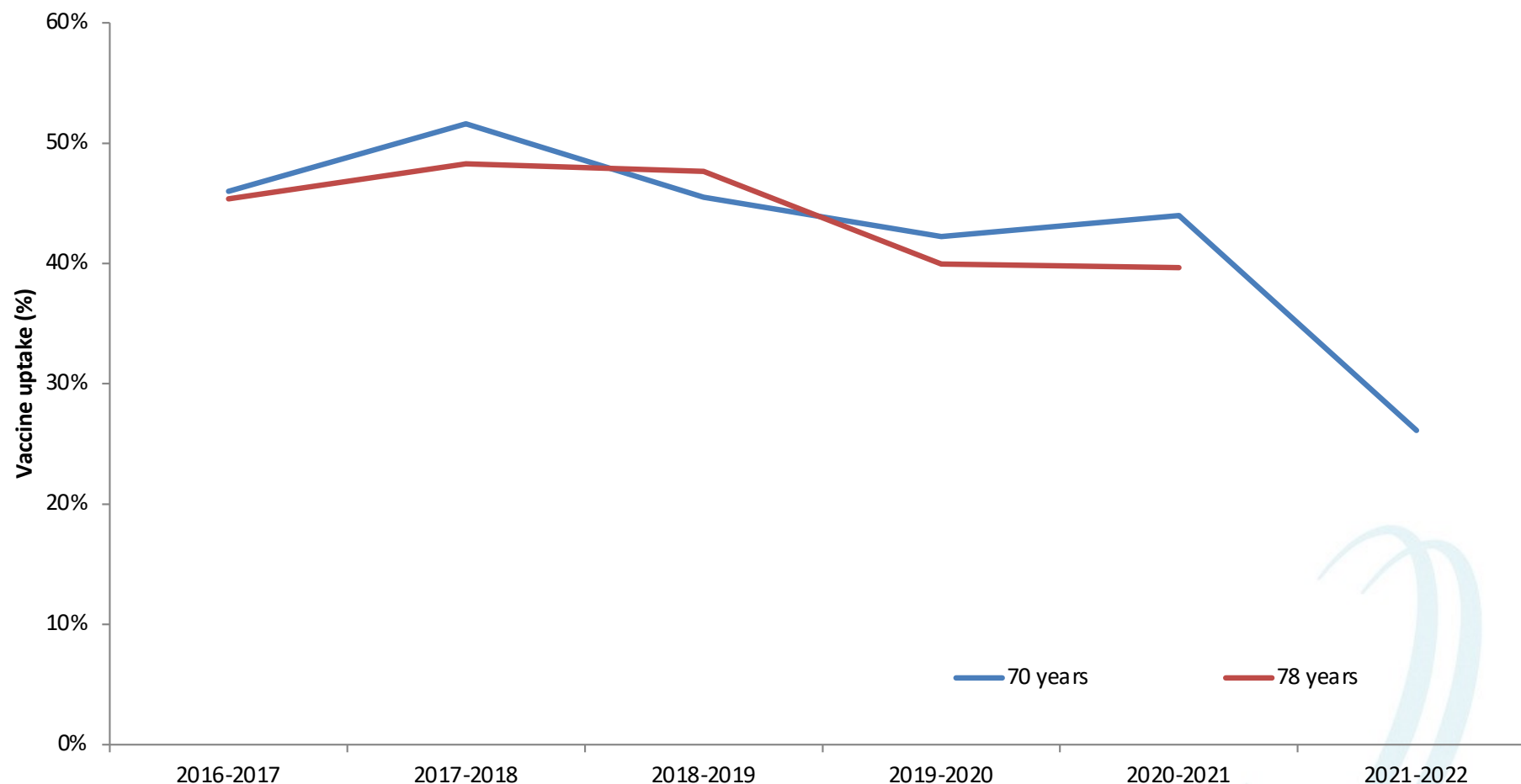


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Please note: The number of patients receiving shingles vaccine and the uptake (%) should be interpreted with caution in 2021-2022. All shingles vaccines are recorded under a generic shingles vaccination code on GP systems, therefore it is not possible to distinguish between Zostavax, Shingrix dose 1 and Shingrix dose 2. Shingles not proactively offered to 78 year olds in 2021-22.

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Shingles Vaccine Uptake in patients aged 70 & 78 years, NI 2016-2022



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