

This patient group direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction (PGD)

For the administration or supply of

Human Papillomavirus Vaccine (HPV)

By registered health care professionals for

Individuals from 12 years of age or from school year 8 in accordance with the national immunisation programme

Throughout the Manx Care and those contracted by the Manx Care where appropriate within practice

PGD NUMBER 03

1. Change History

Version number	Change Details	Date
V01.00	New PHE PGD template	06/04/2016
V02.00	PHE HPV PGD amended to: <ul style="list-style-type: none">• include immunisation of transgender boys and transgender girls as appropriate• provide additional information on capacity to consent with link to the DH 'Reference guide to consent for examination or treatment'• include additional healthcare practitioners (midwives, pharmacists, paramedics, physiotherapists) in Section 3• reference the protocol for ordering storage and handling of vaccines• add additional paragraphs to the off-label section on storage and consent• refer to vaccine incident guidelines• refer to upload of records onto National Health Application Infrastructure Services• include rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	21/03/2018
V03.00	PHE HPV PGD amended to: <ul style="list-style-type: none">• update inclusion criteria to include boys from September 2019• include retention of eligibility until the individuals 25th birthday• update off-label section• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	17/04/2019
V04.00	PHE HPV PGD V03.00 amended to: <ul style="list-style-type: none">• include the nine valent vaccine (Gardasil® 9)• include minor rewording, layout and formatting changes for clarity and consistency with other PHE PGD templates	21/07/2021

2. Medicines practice guideline 2: *Patient group directions*

Refer to the relevant sections of NICE medicines practice guideline 2: *Patient group directions* as stated in the blank template notes. For further information about PGD signatories, see the NHS and Manx Care [PGD website FAQs](#)

3. PGD development

Refer to the [NICE PGD competency framework for people developing PGDs](#)

Job Title & organisation	Name	Signature	Date
Author of the PGD			
Member of the PGD working group			

4. PGD authorisation

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job Title	Name	Signature	Date
Medical Director			
Chief Pharmacist/ Pharmaceutical Adviser			
Senior Paramedic			
Director of Nursing			
GP Adviser			
Senior Microbiologist (if PGD contains antimicrobials)			

5. PGD adoption by the provider

Refer to the [NICE PGD competency framework for people authorising PGDs](#)

Job title and organisation	Signature	Date	Applicable or not applicable to area

6. Training and competency of registered healthcare professionals, employed or contracted by the Manx Care, GP practice or Hospice

Refer to the [NICE PGD competency framework for health professionals using PGDs](#)

	Requirements of registered Healthcare professionals working under the PGD
Qualifications and professional registration	<p>Registered healthcare professionals, working within or contracted by the Manx Care, GP practice or Hospice who are permitted staff groups outlined within the current PGD policy</p> <p>Additionally practitioners:</p> <ul style="list-style-type: none"> • must be familiar with the vaccine product and alert to changes in the Summary of Product Characteristics (SPC), Immunisation Against Infectious Disease ('The Green Book'), and national and local immunisation programmes • must have undertaken training appropriate to this PGD as required by local policy and in line with the National Minimum Standards and Core Curriculum for Immunisation Training • must be competent to undertake immunisation and to discuss issues related to immunisation • must be competent in the handling and storage of vaccines, and management of the 'cold chain' • must be competent in the recognition and management of anaphylaxis <p>Practitioners must ensure they are up to date with relevant issues and clinical skills relating to immunisation and management of anaphylaxis, with evidence of appropriate Continued Professional Development (CPD).</p>
Initial training	<ul style="list-style-type: none"> • Knowledge of current guidelines and the administration of the drug specified in this PGD/BNF and of the inclusion and exclusion criteria • Training which enables the practitioner to make a clinical assessment to establish the need for the medication covered by this PGD • Local training in the use of PGDs
Competency assessment	Staff will be assessed on their knowledge of drugs and clinical assessment as part the competency framework for registered health professionals using PGDs
Ongoing training and competency	The registered health care professionals should make sure they are aware of any changes to the recommendations for this medication; it is the responsibility of the registered health care professionals to keep up to date with continuing professional development. PGD updates will be held every two years

7. Clinical Conditions

<p>Clinical condition or situation to which this PGD applies</p>	<p>Indicated for the active immunisation of individuals from 12 years of age or from school year 8 for the prevention of human papillomavirus infection in accordance with the national immunisation programme and recommendations given in <u>Chapter 18a of Immunisation Against Infectious Disease: ‘The Green Book’</u>.</p>
<p>Inclusion criteria</p>	<p>Individuals who:</p> <ul style="list-style-type: none"> • are aged 12 to 13 years in the birth cohort for school year 8¹ • have been previously eligible for HPV immunisation (that is, boys who attained the birth cohort for school year 8 on or after 1 September 2019¹ and girls who attained eligibility on or after 1 September 2008)^{2,3}
<p>Exclusion criteria⁴</p>	<p>Individuals for whom no valid consent has been received (see <u>DH Reference guide to consent for examination or treatment</u>).</p> <p>Individuals who:</p> <ul style="list-style-type: none"> • are less than 12 years of age and in school year 7 or lower • are less than 9 years of age • are aged 25 years and over, except those who have received a partial course of HPV immunisation⁵ • have had a confirmed anaphylactic reaction to a previous dose of HPV vaccine or to any components of the vaccine • have completed a course of HPV vaccine • are known to be pregnant (Note: routine questioning about last menstrual period and/or pregnancy testing is not required before offering HPV vaccine) • are suffering from acute severe febrile illness (the presence of a minor infection is not a contraindication for immunisation)
<p>Cautions (including any relevant action to be taken)</p>	<ul style="list-style-type: none"> • Syncope (fainting) can occur following, or even before, any vaccination especially in adolescents as a psychogenic response to the needle injection. This can be accompanied by several neurological signs such as transient visual disturbance, paraesthesia and tonic-clonic limb movements during recovery. It is important that procedures are in place to avoid injury from faints • The immunogenicity of the vaccine could be reduced in immunosuppressed subjects. Vaccination should proceed in accordance with the national recommendations. However, re-immunisation may need to be considered. Seek medical advice as appropriate

¹ Individuals in school year 8 who are aged outside the designated birth cohort for the school year may be immunised with their peers

² Transgender girls and transgender boys, in birth cohorts eligible for the girl’s programme from 1 September 2008, may be vaccinated in accordance with this PGD as appropriate.

³ Individuals who enter an eligible cohort for HPV vaccination will retain their eligibility until their 25th birthday.

⁴ Exclusion under this PGD does not necessarily mean the medication is contraindicated, but it would be outside its remit and another form of authorisation will be required.

⁵ It is clinically appropriate to complete the course but vaccination of individuals who have attained 25 years of age will not attract a payment.

Arrangements for referral for medical advice	Patient should be referred to a more experienced clinical practitioner for further assessment
Action to be taken if patient excluded	<ul style="list-style-type: none"> • Patient should be referred to a more experienced clinical practitioner for further assessment • If aged less than 12 years and in a school year below year 8, advise when national routine immunisation is indicated. • If aged less than 9 years HPV vaccination is off-label. Immunisation is not indicated unless in school year 8 or above and a PSD would be required • If aged 25 years and over advise that vaccination against HPV is not provided as a nationally commissioned NHS service. • If a confirmed anaphylactic reaction has been experienced after a previous dose of HPV vaccine or any of its components specialist advice should be sought • Individuals known to be pregnant should complete immunisation after their pregnancy. If high-risk sexual activity continues during pregnancy, and the opportunity for vaccination after pregnancy is uncertain, the benefit of vaccination during pregnancy is likely to outweigh any potential risk. Vaccination during pregnancy is not covered by this PGD so in such instances the individual may need to be referred and/or a PSD may be required • Individuals suffering acute severe febrile illness should postpone immunisation until they have recovered; immunisers should advise when the individual can be vaccinated and ensure another appointment is arranged at the earliest opportunity • Seek appropriate advice from the local Screening and Immunisation Team, local Health Protection Team or the individual's clinician as required • The risk to the individual of not being immunised must be taken into account • Document the reason for exclusion and any action taken in the individual's clinical records • Inform or refer to the GP or a prescriber as appropriate
Action to be taken if patient declines treatment	<ul style="list-style-type: none"> • A verbal explanation should be given to the patient on: the need for the medication and any possible effects or potential risks which may occur as a result of refusing treatment • This information must be documented in the patients' health records • Any patient who declines care must have demonstrated capacity to do so • Where appropriate care should be escalated • Informed consent, from the individual or a person legally able to act on the person's behalf, must be obtained for each administration

8. Details of the medicine

Name, form and strength of medicine	<p>Human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed):</p> <ul style="list-style-type: none"> • Gardasil[®], suspension for injection in a pre-filled syringe or vial <p>Or</p> <p>Human papillomavirus 9-valent vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed):</p> <ul style="list-style-type: none"> • Gardasil[®] 9, suspension for injection in a pre-filled syringe or vial
Legal category	Prescription only medicine (POM)
Black triangle ▼	No
Indicate any <u>off-label use</u> (if relevant)	<ul style="list-style-type: none"> • Administration of a two-dose schedule of Gardasil[®] to individuals aged from 14 years of age to under 15 years of age is off-label but is in accordance with PHE recommendations and Chapter 18a of 'The Green Book' • Administration of a two-dose course with a 0, 6-24 month schedule differs slightly from the schedule at 0, 6 months in the SPC, but is in accordance with official recommendations in Chapter 18a of 'The Green Book' • Completion of a HPV vaccine course using Gardasil[®] or Gardasil[®] 9 when it was not commenced with the same HPV vaccine product is off-label but is in accordance with PHE recommendations and Chapter 18a of 'The Green Book' • The HPV vaccine SPCs state that 'vaccinees should be observed for approximately 15 minutes after vaccine administration'. In line with advice in Chapter 4 of 'The Green Book', recipients of any vaccine should be observed for immediate adverse drug reactions. There is no evidence to support the practice of keeping patients under longer observation • Vaccine should be stored according to the conditions detailed in the Storage section below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to PHE Vaccine Incident Guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use this would constitute off-label administration under this PGD • Where a vaccine is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the vaccine is being offered in accordance with national guidance but that this is outside the product licence
Route/method of administration (continued)	<ul style="list-style-type: none"> • Administer by intramuscular injection. The preferred site is the deltoid region of the upper arm. • When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for all the vaccinations. The vaccines should be given at separate sites, preferably in different limbs. If given in the same limb, they should be given at least 2.5cm apart. The site at which each vaccine was given should be noted in the individual's records.

<p>Route/method of administration (continued)</p>	<ul style="list-style-type: none"> • Individuals with bleeding disorders may be vaccinated intramuscularly if, in the opinion of a doctor familiar with the individual's bleeding risk, vaccines or similar small volume intramuscular injections can be administered with reasonable safety by this route. If the individual receives medication/treatment to reduce bleeding, for example treatment for haemophilia, intramuscular vaccination can be scheduled shortly after such medication/treatment is administered. Individuals on stable anticoagulation therapy, including individuals on warfarin who are up to date with their scheduled INR testing and whose latest INR was below the upper threshold of their therapeutic range, can receive intramuscular vaccination. A fine needle (equal to 23 gauge or finer calibre such as 25 gauge) should be used for the vaccination, followed by firm pressure applied to the site (without rubbing) for at least 2 minutes. If in any doubt, consult with the clinician responsible for prescribing or monitoring the individual's anticoagulant therapy. • The vaccine's normal appearance is a white cloudy liquid which may settle to a clear liquid and white precipitate. Shake well before use. • The vaccine should be visually inspected for particulate matter and discoloration prior to administration. In the event of any foreign particulate matter and/or variation of physical aspect being observed, do not administer the vaccine. • The vaccine's SPC provides further guidance on administration and is available from the electronic Medicines Compendium website: www.medicines.org.uk
<p>Dose and frequency (continued)</p>	<p>Single 0.5ml dose per administration</p> <p>HPV vaccination should be routinely offered in school year 8 (see Additional information)</p> <p>Immunocompetent individuals aged under 15 years at time of first dose</p> <p>Administer a course of two doses with a 6 month to 24 month interval between doses, for instance:</p> <ul style="list-style-type: none"> • first dose of 0.5ml of HPV vaccine, then • second dose at least 6 to 24 months after the first dose <p>If the course is interrupted it should be resumed but not repeated, even if more than 24 months have elapsed since the first dose. Where two doses have been administered less than 6 months apart a third dose should be given at least 3 months after the second dose.</p> <p>For individuals infected with HIV refer to section below for dose schedule.</p>

<p>Dose and frequency (continued)</p>	<p>Individuals aged 15 years to under 25 years at time of first dose and individuals under 25 years of age who are immunosuppressed or known to be HIV-infected (see the ‘Green Book’ Chapter 18a)</p> <p>Administer a course of three doses on a 0, 1 and 4-6 month schedule, for instance:</p> <ul style="list-style-type: none"> • first dose of 0.5ml of HPV vaccine, then • second dose of 0.5ml at least one month after the first dose, then • a third dose of 0.5ml at least three months after the second dose <p>All three doses should ideally be given within a 12-month period. If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses.</p> <p>Whenever possible, immunisations for all individuals on the three dose schedule should follow the recommended 0, 1, 4-6 month schedule. There is no clinical data on whether the interval between doses two and three can be reduced below three months. Where the second dose is given late and there is a high likelihood that the individual will not return for a third dose after three months or if, for practical reasons, it is not possible to schedule a third dose within this time-frame, then a third dose can be given at least one month after the second dose.</p> <p>Vaccination of individuals with unknown or incomplete vaccination status</p> <p>Unimmunised individuals who enter an eligible cohort for HPV vaccination (see Criteria for inclusion) will retain their eligibility until their 25th birthday and should be vaccinated in accordance with the schedules above.</p> <p>For an individual who has started but not completed an HPV immunisation schedule at an eligible age, it is reasonable to complete their vaccination course, with Gardasil[®] or Gardasil[®] 9, in accordance with the schedules above.⁶</p>
<p>Quantity to be administered</p>	<p>As per dose</p>
<p>Maximum or minimum treatment period</p>	<p>A two or three dose course (see Dose and Frequency section above)</p>

⁶ It is clinically appropriate to complete the course but vaccination of individuals who have attained 25 years of age will not attract a payment.

<p>Storage</p>	<ul style="list-style-type: none"> • Store at +2°C to +8°C • Store in original packaging to protect from light • Do not freeze • Gardasil® should be administered as soon as possible after being removed from the cold chain • Data from stability studies demonstrate that the Gardasil® vaccine components are stable for 72 hours when stored at temperatures from +8°C to +42°C and the Gardasil® 9 vaccine components are stable for 72 hours when stored at temperatures from 8°C to 25°C or from 0°C to 2°C. These data are intended to guide healthcare professionals in case of temporary temperature excursion only. This PGD may be used to administer vaccine that has not exceeded these stability data parameters • In the event of an inadvertent or unavoidable deviation of these conditions vaccine that has been stored outside the conditions stated above should be quarantined and risk assessed for suitability of continued off-label use or appropriate disposal, refer to <u>PHE Vaccine Incident Guidance</u>
<p>Adverse effects</p>	<ul style="list-style-type: none"> • Local reactions following vaccination are very common ie pain, swelling or redness at the injection site. • Mild side effects such as headache, nausea, dizziness, pain in extremity, fatigue, fever, injection-site haematoma and injection-site pruritus are reported as common. • Other adverse events have been reported in post-marketing surveillance but the frequency of these is not known. • Hypersensitivity reactions and anaphylaxis can occur but are very rare. • A detailed list of adverse reactions is available in the SPC which is available from the electronic Medicines Compendium website: <u>www.medicines.org.uk</u> <p>Reporting procedure of adverse reactions</p> <ul style="list-style-type: none"> • Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: <u>http://yellowcard.mhra.gov.uk</u> or search for MHRA Yellow Card in the Google Play or Apple App Store • Any adverse reaction to a vaccine should be documented in the individual's record and the individual's GP should be informed
<p>Records to be kept</p>	<p>The administration of any medication given under a PGD must be recorded within the patients' medical records</p> <p>Please see Appendix C for more details.</p>

9. Patient information

Verbal/Written information to be given to patient or carer	<ul style="list-style-type: none">• Verbal information must be given to patients and or carers for all medication being administered under a PGD• Where medication is being supplied under a PGD, written patient information leaflet must also be supplied• A patient information leaflet is available on request• Immunisation promotional material may be provided as appropriate:<ul style="list-style-type: none">○ <u>Immunisations for young people</u>○ <u>Your HPV vaccination guide</u>○ <u>The HPV vaccine: beating cervical cancer – questions and answers</u>○ Available from: <u>www.gov.uk/government/collections/immunisation</u>
Follow-up advice to be given to patient or carer	<ul style="list-style-type: none">• If symptoms do not improve or worsen or you become unwell, seek medical advice immediately• When administration is postponed advise the individual/carer/parent when to return for vaccination• Advise individual/parent/carer when the next dose is due• Advise that individuals should continue to take appropriate precautions to protect themselves from sexually transmitted diseases and unwanted pregnancy• Advise that HPV vaccination is not a replacement for the national cervical screening programme which should be accessed by individuals with a cervix at the appropriate age

10. Appendix A

References

1. British National Formulary (BNF) available online: <https://bnf.nice.org.uk>
2. Nursing and Midwifery (2018) "The code" available online: <https://www.nmc.org.uk>
3. Current Health Care Professions Council standards of practice
4. General Pharmaceutical Council standards
5. The General Optical Council
6. Electronic medicines compendium available online: <https://www.medicines.org.uk>

Human papillomavirus (HPV) vaccine

- Immunisation Against Infectious Disease: The Green Book [Chapter 18a](#), last updated 12 July 2019. <https://www.gov.uk/government/collections/immunisation-against-infectious-disease-the-green-book>
- Summary of Product Characteristic for Gardasil[®], MSD Ltd. Last updated 10 March 2021. <http://www.medicines.org.uk/emc/medicine/19016>
- Summary of Product Characteristic for Gardasil[®]9, MSD Ltd. Last updated 23 April 2021. <https://www.medicines.org.uk/emc/product/7330>
- HPV Vaccination Consent Form, last updated 27 June 2019. <https://www.gov.uk/government/publications/human-papillomavirus-hpv-vaccination-consent-form>

General

- Health Technical Memorandum 07-01: Safe Management of Healthcare Waste. Department of Health 20 March 2013. <https://www.gov.uk/government/publications/guidance-on-the-safe-management-of-healthcare-waste>
- National Minimum Standards and Core Curriculum for Immunisation Training. Published February 2018. <https://www.gov.uk/government/publications/national-minimum-standards-and-core-curriculum-for-immunisation-training-for-registered-healthcare-practitioners>
- NICE Medicines Practice Guideline 2 (MPG2): Patient Group Directions. Published March 2017. <https://www.nice.org.uk/guidance/mpg2>
- NICE MPG2 Patient group directions: competency framework for health professionals using patient group directions. Updated March 2017. <https://www.nice.org.uk/guidance/mpg2/resources>
- PHE Immunisation Collection <https://www.gov.uk/government/collections/immunisation>
- PHE Vaccine Incident Guidance <https://www.gov.uk/government/publications/vaccine-incident-guidance-responding-to-vaccine-errors>

11. Appendix B

Health professionals agreed to practice

- Each registered healthcare professional will hold their own Competency framework which will be signed and agreed by their mentor
- A mentor is defined within the Manx Care policy as any ward/area managers, sisters, senior nurses, GPs, pharmacists or senior paramedics who has completed the PGD training themselves

12. Appendix C

<p>Special considerations/ additional information</p>	<ul style="list-style-type: none"> • Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination. • Minor illnesses without fever or systemic upset are not valid reasons to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered • Ensure there is immediate access to adrenaline (epinephrine) 1 in 1000 injection and access to a telephone at the time of vaccination • Individuals who are not educated in a school year corresponding their birth cohort may be immunised with their eligible peers as assessed as appropriate • For individuals who commenced but did not complete the vaccination course, it is reasonable to complete their HPV vaccination course with Gardasil® or Gardasil® 9. Vaccination of individuals who have attained 25 years of age will not attract a payment • There is no data on fewer than 3 doses of HPV vaccine among HIV-infected or immunocompromised populations. Therefore a 3-dose schedule should be offered to individuals who are known to be HIV-infected, including those on antiretroviral therapy, or who are known to be immunocompromised at the time of immunisation • HPV vaccination is for prophylaxis against future HPV infection. It will not treat pre-existing HPV infection • Gardasil® 9 vaccine will protect against HPV types 6, 11, 16, 18, 31, 33, 45, 52 and 58. Gardasil® vaccine will protect against HPV types 6, 11, 16 and 18 with limited cross protection to other HPV types. Therefore, appropriate precautions against sexually transmitted diseases should continue to be used • For children under the age of 16 years being offered HPV vaccine, those assessed as Gillick competent can self-consent (see DH Reference guide to consent for examination or treatment)
<p>Disposal</p>	<p>Equipment used for immunisation, including used vials, ampoules, or discharged vaccines in a syringe or applicator, should be disposed of safely in a UN-approved puncture-resistant 'sharps' box, according to local authority regulations and guidance in the technical memorandum 07-01: Safe management of healthcare waste (Department of Health, 2013)</p>

Drug interactions	<ul style="list-style-type: none"> • Immunological response may be diminished in those receiving immunosuppressive treatment. Vaccination is recommended even if the antibody response may be limited • May be given at the same time as other vaccines • A trend of lower anti-HPV titres has been observed when Gardasil® is administered concomitantly with dTaP, dT/IPV or dTaP/IPV vaccines, though the clinical significance of this observation is unclear. Gardasil® or Gardasil® 9 may be administered concomitantly with dTaP, dT/IPV or dTaP/IPV with no significant interference with antibody response to any of the components of either vaccine • A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk
Supplies	<ul style="list-style-type: none"> • Centrally purchased vaccines for the national immunisation programme can only be ordered via ImmForm. Vaccines for use for the national immunisation programme are provided free of charge • Protocols for the ordering, storage and handling of vaccines should be followed to prevent vaccine wastage (see the 'Green Book' Chapter 3)
Records <i>(continued)</i>	<p>Record:</p> <ul style="list-style-type: none"> • that valid informed consent was given • name of individual, address, date of birth and GP with whom the individual is registered • name of immuniser • name and brand of vaccine • date of administration • dose, form and route of administration of vaccine • quantity administered • batch number and expiry date • anatomical site of vaccination • advice given, including advice given if excluded or declines immunisation • details of any adverse drug reactions and actions taken • supplied via PGD <ul style="list-style-type: none"> • Records should be signed and dated (or a password-controlled immuniser's record on e-records) • All records should be clear, legible and contemporaneous. • This information should be recorded in the individual's GP record. Where vaccine is administered outside the GP setting appropriate health records should be kept and the individual's GP informed • The local Child Health Information Systems team (Child Health Records Department) must be notified using the appropriate documentation/pathway as required by any local or contractual arrangement • When vaccine is administered to individuals under 19 years of age, notify the local Child Health Information Systems team (Child Health Records Department) using the appropriate documentation/pathway as

Records <i>(continued)</i>	required by any local or contractual arrangement <ul style="list-style-type: none">• Systems should be in place to ensure that the HPV vaccination record is uploaded onto the National Health Application Infrastructure Services (NHAIS) system (also known as Open Exeter) for NHS cervical screening programme call-recall purposes• A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy
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