



Royal College
of Nursing

Nurse-led immunisation of school-aged children

Guidance for nurses





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This publication is due for review in July 2016. To provide feedback on its contents or on your experience of using the publication, please email publications.feedback@rcn.org.uk

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Introduction

Part of the *Healthy child programme* (DH, 2009; www.dh.gov.uk) and the Government strategy *Getting it right for children, young people and families* (DH, 2012), immunisation is a safe and highly effective method of preventing disease. Nurses working with school-aged children are best placed to provide good quality, evidence-based information and advice on immunisations.

NICE guidance (NICE, 2009) on reducing differences in the uptake of immunisation supports implementation of the vaccination courses recommended by the Joint Committee on Vaccination and Immunisation and indicated in the *Green book* (Public Health England, 2013; see www.gov.uk). It also supports the pursuit of timely vaccination according to the recommended immunisation schedule guidance provided in Chapter 11 of the *Green book* (see www.gov.uk).

This publication provides signposts that enable you to access appropriate websites and resources where you can obtain the latest information on immunisation.

Environments

Nurse-led immunisation for school-aged children may be undertaken via NHS-directed school immunisation teams or by nurses employed by educational establishments working alongside a local general practice.

Successful immunisation depends on the:

- production of a safe and effective vaccine
- maintenance of the cold chain during vaccine transportation and storage
- injection into the correct anatomical site and an appropriate recipient
- correct injection technique.

The nurse/s will work in partnership with an identified link person from the location at which the vaccination is to be administered. Together you will assess and plan the environment in which the immunisation session will be carried out. In doing this you should consider:

- access to a telephone
- access to hand washing facilities
- privacy
- first aid and emergency support
- local health and safety policy.

You should also look at the management of:

- adverse reactions
- adverse incident handling
- needlestick injury issues
- safe disposal of sharps and clinical waste
- updating patient records.

Governance

Nurses providing immunisations are professionally accountable and need to keep up-to-date with fast changing legislation, policy and practice. Nurses must follow the professional standards and guidelines as set out in the NMC Code (2008a) and the *Administration of medicines standards* (NMC, 2008b).

All health care professionals advising on immunisation or administering vaccines must have received specific training in immunisation, including the recognition and treatment of anaphylaxis. They should maintain and update their professional knowledge and skills through appropriate training. More information can be found in the Health Protection Agency's *National minimum standards for immunisation training* (HPA, 2005), available online at www.hpa.org.uk

Clinical governance is an umbrella term for everything that helps to maintain and improve high standards of patient care. This includes clinical audit, which is a way of reviewing health care delivery and allowing clinical staff to review their practice continually. The RCN's detailed online guidance and resources on clinical governance can be found at www.rcn.org.uk

Local practice protocols and training govern the supply and administration of vaccines, maintenance of the cold chain, clinical competency, consent, risk assessment procedures, disposal of waste, documentation and record keeping. An example of good practice is provided at the close of this document.

Patient group directions

Patient group directions (PGDs) are written agreements for the supply and administration of medicines to groups of patients who may not be individually known before they present for treatment.

The RCN believes that PGDs are helpful to nurses and support the advancement of quality patient care. A separate PGD must be used for every different vaccine given. PGDs

are a statutory instrument and are legally binding. PGDs also have to be signed by a doctor and pharmacist, and meet specific criteria.

Nurses employed by educational establishments will require a patient-specific direction (PSD) from the associated medical officer to administer routine or travel vaccinations. The RCN's detailed online guidance on PGDs can be found at www.rcn.org.uk

An example of a local PGD protocol document is on [page 23](#).

Consent

When vaccination involves children and young people under the age of 16 years, nurses and midwives must be aware of the local protocols and legislation that affect their care or treatment. Consent requirements relating to people under 16 years of age is very complex, so local, legal or professional organisation advice may need to be sought where there maybe differences of opinion.

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 to make up his or her own decisions; when deciding whether a child is mature enough to make decisions people often refer to whether a child is 'Gillick competent' or whether they meet the 'Fraser guidelines'. The website of the National Society for the Prevention of Cruelty to Children (NSPCC) provides detailed information on Gillick competency and the Fraser guidelines (available at www.nspcc.org.uk).

Children aged 16 or 17 years of age are presumed to be able to consent for themselves, although it is considered good practice to involve their parents. In exceptional circumstances it may be necessary to seek an order from the court.

In Scotland, a young person reaches the age of capacity at 16 years of age. Parents or those with parental responsibility may override the refusal of a child of any age up to 18 years. One important difference under Scottish law is that a parent's consent cannot override a refusal of consent by a

competent young person aged 16 as they have the same right to consent or refuse treatment as adults.

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

Before a patient can make their decision, they need to have a clear explanation of the vaccination procedure and be given an opportunity to ask you questions about the:

- need for vaccination
- vaccine and number of doses required
- risks associated with the disease they are being immunised against
- risks and side-effects associated with the vaccine.

The following resources provide further information and guidance in this area:

- RCN online advice – available at www.rcn.org.uk
- Nursing and Midwifery Council advice on consent – available at www.nmc-uk.org
- Care Quality Commission guidance about compliance; specifically *Outcome 2: consent to care and treatment consent to care and treatment and Regulation 18 of the Health and Social Care Act (2008)* – available at www.cqc.org.uk
- Public Health England: *Consent, the green book*, Chapter 2 – available at www.gov.uk
- Department of Health (2001) *Seeking consent: working with children* – available at www.webarchive.nationalarchives.gov.uk
- British Medical Association *Children and young people toolkit* – available at www.bma.org.uk
- General Medical Council *Consent guidance: involving children and young people in making decisions* – available at www.gmc-uk.org
- General Medical Council *0-18 years: guidance for all doctors* – available at www.gmc-uk.org.

Recording

You should record details of all vaccinations in accordance with national and local guidelines, including:

- date administered
- vaccine manufacturer
- lot batch number and vaccine expiry date
- dose administered
- route/site
- signed by the nurse and name printed.

For further information see the Nursing and Midwifery Council (2010) *Guidelines for records and record keeping*, available at www.nmc-org.uk

References

- British Medical Association (2010) *Children and young people tool kit*, London: BMA. Available at www.bma.org.uk
- Care Quality Commission (2010) *Guidance about compliance: summary of regulations, outcomes and judgement framework*, London: CQC. Available at www.cqc.org.uk
- Public Health England (2013) *Immunisation against infectious disease: the greenbook*. Available at www.gov.uk
- Department of Health (2012) *Getting it right for children, young people and families. Maximising the contribution of the school nursing team: vision and call to action*, London: DH. Available at www.gov.uk
- Department of Health (2009) *Healthy child programme from 5 to 19 years old*, London: DH. Available at www.webarchive.nationalarchives.gov.uk
- Department of Health (2001) *Seeking consent, working with children*, London: DH. Available at www.webarchive.nationalarchives.gov.uk
- General Medical Council *Consent guidance: involving children and young people in making decisions*. Available at www.gmc-uk.org
- General Medical Council (2007) *0-18 years: guidance for all doctors*, London: GMC. Available at www.gmc-uk.org
- Health Protection Agency (2005) *National minimum standards for immunisation training*, London: HPA. Available at www.hpa.org.uk
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- Nursing and Midwifery Council (2013) *Consent*, London: NMC. (Online resource) (Modified 10 May 2013). Available at www.nmc-uk.org
- Nursing and Midwifery Council (2010) *Guidelines for records and record keeping*, London: NMC. Available at www.nmc-uk.org
- Nursing and Midwifery Council (2008a) *The code: standards of conduct, performance and ethics for nurses and midwives*, London: NMC. Available at www.nmc-uk.org
- Nursing and Midwifery Council (2008b) *Standards for medicines management*, London: NMC. Available at www.nmc-uk.org
- RCN online guidance www.rcn.org.uk/support/rcn_direct_online_advice/a-z2/patient_group_directions_pgds/pgds
- RCN online advice www.rcn.org.uk/support/rcn_direct_online_advice/a-z2/consent
- You will need your membership number to access these RCN online advice guides.

Local practice protocol: good practice example

Sheffield Children's NHS Foundation Trust

Protocol for school nursing combined HPV and TDP vaccination programme

Author and contact person	Date approved by CGC	Implementation date	Version number	Issue date	Review date
(school nurse advanced practitioners)		Sept 2012	2	Sept 2012	Sept 2013

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- 1. Statement of intent**
- 2. Protocol**
- 3. Appendices**
 - A. Risk assessment tool
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1. Statement of intent

Separate HPV and TDP school nursing protocols were last reviewed and ratified by SPCT clinical governance group in July 2010. In September 2011 practice is changing to combine the giving of both vaccines at Year 8 in secondary school. This protocol is a combination of both previous documents to ensure safe practice within the school nursing service, to provide a clear framework that will support professional practice, and to ensure young people and their families receive an immunisation service of a consistent standard.

Requirement	Action
Who should be aware of the protocol and where to access it?	Community director, service managers, professional leads, child health department.
Who should understand the protocol?	Professional leads, all staff in school nursing service. Staff in child health department.
Who should have a good working knowledge of the policy?	School nursing staff, vaccination team and relevant child health staff.
Whether the protocol should be included in the general trust induction programme and/or departmental specific induction programme.	School nursing/child health specific.
Where is the protocol available?	Trust intranet. Clinical governance department.
Copy to be sent to HR with a request for inclusion in induction documents.	No
Copy to:	IT for Intranet site.
Process for monitoring the effectiveness of this document.	Audit and data collection.
Patient version.	No
Groups/persons consulted.	School nurses. Child health department.
Training.	Nurses need specific training for vaccinations and annual updates. All school nursing staff and relevant child health staff need understanding of this protocol.

2. Protocol

1. All school nursing staff will receive training in the general principles and practice of immunisation, in accordance with the National Standards for Immunisation and the implementation of this protocol. Additional training will be provided on an annual basis. Nurses will be accountable for their own practice in accordance with the Nursing and Midwifery Council's (NMC) *The code of professional conduct*.
2. Administration of the HPV and TDP vaccines are under patient group directions (PGD). These must only be given by nurses who have been trained and authorised to do so under the NHS Sheffield Cervarix®, Gardasil® and Revaxis PGDs (Gardasil® replaces Cervarix® from 1/9/12. Courses started with Cervarix® should be completed with Cervarix®). Refer to appropriate PGDs.
3. Whilst undertaking this procedure all staff must adhere to standard universal precautions, as in the Sheffield Children's Hospital Foundation Trust Control of Infection Policy (CP546).
4. Towards the end of the summer term the school nurse vaccination co-ordinator, in partnership with administration support, will obtain class lists for Year 8 children for the next academic year, book all immunisation sessions directly with the schools, and will then inform all school nurse advanced practitioners for cascading to their teams. An assessment of surroundings for vaccination checklist will be completed for each venue (see [appendix F](#)). A separate, generic, risk assessment for school nurse vaccination in community settings has been completed (see [appendix A](#)).
5. The Child Health Department will send an information booklet with the consent form and details of the immunisation dates directly to the child's home address. This will provide the written parental consent in order for the course of immunisations to be undertaken, or the refusal for the immunisations to be undertaken, for each child.
6. A freepost envelope is included in the pack sent to the child's home address for the return of the consent form to the Child Health Department. The consent forms will then be checked by clerical staff to ensure that all sections have been completed. Consent will be recorded on TPP SystemOne and the child's individual complete immunisation status will be printed and attached to the child's consent form.
7. If the consent form is incomplete, the clerks will contact parents and/or send a further consent form for completion.
8. If consent forms are not returned, a second pack will be sent out approximately 10 days after the initial consent letter.
9. The Child Health Department will check any changes to the list of children with the school at least 1-2 weeks before the session. The Child Health Department will then produce a list of all children requiring immunisation.
10. At least one week before the session, the school nursing vaccination co-ordinator or delegated nurse will collect consents from the Child Health Department to check through them for any contra-indications and liaise with parents, other health professionals and/or the area immunisation co-ordinator where necessary. Consent forms, together with school lists, will be kept securely in the nurses immunisation office. Mop-up sessions require admin/nurse to check TPP SystemOne and/or General Practitioner for vaccination having been given. This must be documented on TPP/consent form.
11. Consent forms returned on the day of the session will be processed at the immunisation session and added to TPP SystemOne and the data tool contemporaneously.
12. Nurses will undertake the immunisation. Responsibility for having all necessary equipment at a session lies with the co-ordinating nurse for the session. Responsibility for checking the consent form, discussing consent with the child and verifying identity of the child lies with the individual nurse administering the vaccine.

13. A child who has consent but, for whatever reason, misses their vaccination will be able to commence, or continue, the course during 'mop-up' sessions, arranged as required with individual schools or as home visits by the school nurse vaccination co-ordinator. In exceptional circumstances, vaccinations may be carried out by the practice nurse at the child's GP practice.
14. During the immunisation session itself, if a child indicates that they do not wish to receive the immunisation and providing the nurse has taken reasonable action to reassure the child, then the child's wishes must be respected. The co-ordinating nurse for the session will then inform the parent/carer and discuss a way forward to vaccination.
15. If a child indicates that they wish to be immunised, no communication has been received from parent/carer, and they are able to understand the implications, the child should be informed that they are entitled to receive the immunisation (Gillick principle). Only written refusal from the parent overrides the child being able to consent (instruction from Sheffield Vaccination and Immunisation Committee 2011). The nurse or co-ordinator should, if possible, discuss this with the parent. After trying to contact the parent/carer one of the following actions should be taken:
 - a) if the parent cannot be contacted, the child – if Fraser competent – can self consent
 - b) if the parent agrees, the nurse will accept and document the verbal consent, alongside the child's consent
 - c) if the parent gives verbal consent but the child, for whatever reason, is deemed not to be Fraser competent at that time and child consent is not going to be used, then the conversation with the parent must be witnessed by another nurse and documented on the consent form before the vaccination is given.

(See Sheffield Children's (NHS) Foundation Trust Consent Policy (CP80) and *Immunisation against infectious diseases – the green book* (2006) Chapter 2 – consent and Checklist for self consent – [appendix C](#) of this document.)
16. All single vaccinations are given in the left arm. If a child indicates that they wish to be immunised in a particular arm (for example, right arm if left-handed) this must be respected and recorded on the consent form. Where the two separate vaccines are being given at the same time, HPV will be given in the left arm and TDP in the right. If for some reason it is necessary to vaccinate in one arm only, then the injection sites must be 2.5cms apart.
17. Vaccines must be stored and transported in accordance with the NHS Sheffield Vaccine Transport and Storage Policy (July 2010). This can be found on the NHS Sheffield intranet site. The process for transporting and monitoring temperature of the vaccine for school clinics can be found in [appendix D](#).
18. Any wasted vaccine must be reported to the school nurse vaccination co-ordinator – this is recorded and reported to the Department of Health.
19. The nurses vaccinating at the session are responsible for ensuring that the batch numbers of the vaccines are recorded on individual consent forms and signing the consent form to confirm the vaccine has been given.
20. A nurse and one colleague, with an adrenaline box, will remain on the school site for a minimum of 30 minutes after the completion of the session, in order to be available to respond immediately to any resulting medical emergency. Where school sessions are conducted in the afternoon, half an hour will be left between the last vaccination and the end of the school day. Home visits do not require nurses to stay on site a set length of time.
21. Nurses or assistants will dispose of clinical waste in accordance with Sheffield Children's (NHS) Foundation Trust Waste Management Policy and Procedure (CP732), see [appendix B](#).
22. Within 24 hours of completing the immunisation session, clerical staff and nurses will be responsible for uploading data to the TPP SystemOne and vaccination data tool systems, regarding the children who have been immunised.

23. The Child Health Department will be responsible for ensuring that all GPs (general practitioners) are notified that their patients have received immunisation in the school-based programme.
24. Specialist advice will be available from the Sheffield immunisation co-ordinator (at the Health Protection Unit) or hospital paediatrician where this is appropriate.
25. The Child Health Department and SN immunisation co-ordinator will be responsible for returning the city-wide collated information to the Department of Health and the Sheffield immunisation co-ordinator.
26. Immunisation information will be held on the TPP SystemOne and vaccination tool databases.
27. This protocol will be reviewed in September 2013, or before if necessary, by the School Nursing Service and Child Health Department.
28. This protocol will be part of the Clinical Audit Programme.
29. All instructions in this protocol should be followed and reasons for any deviation must be documented.

Appendix A – Risk assessment

Directorate	Community				
Department	School nursing (SN)				
Source of risk (eg, incident form)	Community vaccination sessions in various settings – mostly local authority school premises				
Risk assessment of	Clinical environment and general tasks				
Type of risk	Health and safety		Patient safety		Security
Location	School and various other community settings				

Risk assessor		Department Manager	
Signed		Signed	
Date of assessment		Review date	
Contact phone no.			

Indicate below whether this risk is department only or for inclusion on directorate or trust risk register?					
Internal department risk assessment?			Yes		No
Escalate to risk register?	No	Yes	Strategic		Directorate

Current revision	Summary of changes

Description of risk being assessed

School nurses vaccinate large numbers of children and young people (CYP) in various community settings – mostly school premises. Safe practice requires risk assessment of environment, moving and handling, sharps use/disposal, infection control and vaccine storage/transportation.

Summary of current control measures

- Adherence local protocol for SN combined HPV/TDP vaccination programme
- Check list for school vaccination session completed for each venue
- All nurse trained and signed up to PGDs for Cervarix® and Revaxis vaccines
- Hand hygiene, record keeping, vaccine storage and transportation audits carried out as per trust policy

Overall risk grading

Consequence (C)		Likelihood (L)		Risk (C x L)	
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Date of assessment		Review date	
Contact phone no.			

Consequence			Likelihood		
1	Negligible	Minimal injury, none or minor treatment/adverse health outcome/some disruption to service/small financial loss/potential for public concern.	1	Rare	This will probably never happen/recur (not expected to occur for years).
2	Low	Minor injury/<3 days off work/adverse health outcome/short term disruption to service/financial loss or claim < £10,000/local media coverage short term.	2	Unlikely	Do not expect it to happen/recur but it is possible it may do so (expected to occur annually).
3	Medium	Medium injury/4-14 days off work/adverse health outcome/moderate service disruption/financial loss or claim £10,000-£100,00/local media coverage long term.	3	Possible	Might happen or recur occasionally (expected to occur monthly).
4	Very high	Major injury or disability/closure of a service financial loss or claim £100,000-£1 million/possible litigation/national media coverage short term.	4	Likely	Will probably happen/recur but it is not a persisting issue (expected to occur weekly).
5	Extreme	Death(s)/multiple permanent injury or health effects/extended service disruption or closure/financial loss or claim >£1 million/national media coverage long term.	5	Almost certain	Will undoubtedly happen/recur possibly frequently (expected to occur daily).
Extreme 15 -25		High 8 – 12	Moderate 4 – 6		Low 1 -3
Extreme risk: immediate action required		High risk: action planned immediately, commenced within one month.	Moderate risk: action planned within one month, commenced within three months.		Low risk: action planned within three months, reviewed within one year.

Activity and task	Hazards and risks identified	People at risk	Controls in place	Consequence	Likelihood	Risk rating	Recommended additional controls	Post risk rating
				1-5	1-5	1-25		
				C x L = R				
1. Violence and aggression/abuse to staff	Children and young people (CYP) may be abusive. Verbal aggression on phone from parents.	Staff CYP Parents SCHFT	Staff trained in conflict resolution and have knowledge of trust incident reporting policies. School staff present at all sessions.	1	2	2	None	2
2. Safe environment	CYP being vaccinated in settings without parents. Local authority (LA) premises not clinical, room space and furniture provided by school.	Staff CYP Parents SCHFT	Staff wear ID badges. School staff present at sessions. Consent taken as per school nurse (SN) protocol. SN checklist for suitability of room/area used for each school as per protocol for vaccinating. Copy of blank checklist can be found in the protocol.	1	2	2	None	2
3. Moving and handling	Post-vaccination fainting. Anaphylactic collapse. Vaccinating equipment transportation.	Staff CYP Parents SCHFT	CYP sit for vaccination. Space allocated for recovering 'fainters' within room. Staff do not move CYP if collapsed – usually only minor and very short time. Vaccination equipment divided between two suitcases on wheels for ease of movement. Training for anaphylaxis and moving and handling annually.	2	3	6		6
4. Sharps	Use of sharps at vaccination station. Risk of needlestick either during procedure or following due to incorrect disposal. See trust sharps risk assessment.	Staff CYP Parents SCHFT	Each vaccination station set up with sharps disposal container for individual staff use – not shared. Protocol for disposal of sharps adhered to.	3	1	2	Possibility in future of 'Sharp Smart' bins being used. Investigated at time of change on main SCFT site, concluded they were too heavy and bulky for school sessions.	3
5. COSHH	Infection control between CYP and staff. Invasive procedure. Skin-to-skin contact.	Staff CYP Parents SCHFT	Staff trained in hand hygiene procedures. Hand washing facilities available at each venue. Hand sanitising gel at each vaccination station. Hand wash audit 3/12.	1	2	2	Possible future attendance of immunisation manager at COSHH training.	2

Activity and task	Hazards and risks identified	People at risk	Controls in place	Consequence	Likelihood	Risk rating	Recommended additional controls	Post risk rating
				1-5	1-5	1-25		
				C x L = R				
6. Latex	Staff may have or develop sensitivity to latex. Latex sensitive patients. Extreme reaction can result in anaphylaxis. Hospital is not latex free.	Staff CYP Parents SCHFT	General use non sterile gloves (if/when used) are not latex. Good quality low protein powder free gloves supplied where latex is used. Latex sensitive patients identified at consent. Staff with suspected or known allergy to latex referred to occupational health. Adrenalin for use in anaphylaxis at every session.	3	1	3	See latex policy for more guidance.	3
7. Waste, segregation, transportation and disposal	Waste is segregated for later disposal. Short term storage at vaccination venue. Infection control. Access to waste by CYP. Disposal.	Staff CYP SCHFT	Orange boxes (clinical) used on each vaccination station and black bags used for domestic waste. Transportation and disposal as per SN protocol.	1	2	2	None	2
8. Dermatitis	Staff may develop skin problems on hands as continually washing hands and applying alcohol gel. Staff may have or develop sensitivity to certain products.	Staff SCHFT	ICT teach correct hand washing and care. Staff to follow guidelines. Staff with skin problems should be referred to occupational health.	2	1	2	None	2

You will have inevitably used some subjectivity in completing the risk assessment based on your knowledge, experience and judgement. You should record the rationale behind your decision making throughout this assessment. You should also provide supporting evidence for your rationale if the rating is high or extreme.

Rationale – the school nursing service vaccinates approximately 6,000 young people each year against human papilloma virus and diphtheria, tetanus and polio. Half the cohort have vaccinations x 4 and the other half x1 = approximately 15,000 injections. As an invasive procedure, using sharps in a non-clinical environment, a risk assessment is necessary.

Appendix B – Procedure for disposal of clinical waste

1. All nurses or assistants will dispose of clinical waste in accordance with Sheffield Children's (NHS) Foundation Trust Waste Management Policy and Procedure (CP732).
2. The co-ordinating nurse for the school session will check at the beginning of the session that all sharps bins are correctly assembled, signed and dated. Correct colour-coded sharps bins must be used. The position of the sharps bins, at the session, must be risk assessed, and the temporary closure mechanism used appropriately.
3. All needles, syringes, ampoules, and any other sharps should be disposed into the sharps bins. All swabs and cotton wool should be disposed into 'soft infectious waste' boxes. Sharps bins should not exceed three-quarters full capacity.
4. Other waste such as couch roll, empty syringe packets (in other words, non-clinical waste) should be disposed into black bags and can be discarded along with household waste, as long as this waste is not contaminated with blood or body fluids.
5. At the end of the session the co-ordinating nurse will check that the sharps bins are signed and dated by the nurses who have used and locked them, and that they are securely sealed. The 'disposed of by' sections must also be signed and dated by the person designated for transporting and disposal.
6. All sharps bins will then be placed in a clear plastic bag for transportation to the disposal site. Transportation must only occur in a locked car boot, not inside the car (you cannot transport in foot wells or on seats, for example).
7. Soft infectious waste boxes will be collected together at the end of the session and put in an orange plastic bag for transportation to disposal site along with the sharps bins.
8. The co-ordinating nurse for the session will designate a health care assistant or nurse to transport the clinical waste to the disposal site.
9. On arrival at the disposal site the designated nurse or health care assistant will remove the sharps bins from the clear plastic bags and place into the designated disposal bin. The orange plastic bag will be placed in the designated disposal bin – in other words, yellow bin/ yellow lid for sharps bins and yellow bin/orange lid for the soft infectious waste boxes. The clear bag can then be placed in the domestic waste.

All staff should be aware of the SCFT waste management policy.

Appendix C – Checklist for self consent

- No evidence of written refusal from parent/carer.
- Parental consent sought.
- Young person presented for vaccination with no coercion.
- Young person read and understood literature relating to vaccination.
- Nurse discussed vaccination and implications with young person.
- Young person asked – do your parents know there is a vaccination session today?
- Young person asked – are your parents aware that you are giving self consent?
- Fraser competence established.
- Child consent documentation completed.

Appendix D – Cold chain process for transporting and monitoring vaccine for school clinics

- Responsibility for vaccine up to the point of removal from child health refrigerator for a school clinic is the responsibility of the child health department.
- There is no formal training for removal and transporting vaccine but anyone transporting vaccine will be expected to have completed the National minimum standards for immunisation training, and be working under the Sheffield Children's NHS Foundation Trust Patient Group Directions (HPV, Tetanus, Diphtheria and Polio vaccine).
- Specialised cool bags with digital thermometers and a monitoring sheet are to be used when transporting vaccine from the refrigerator in the child health department.
- Vaccines must be kept in the original packaging.
- The correct amount of vaccine needed for the session is to be packed into a cool bag, containing two frozen ice packs, immediately before departure from child health, and the temperature of the cool bag recorded on a monitoring sheet. Care should be taken to keep frozen ice packs out of direct contact with the vaccine as this can cause the vaccine to freeze.
- Cool bag to be carried in the boot of the health worker's car.
- At the session, one designated nurse should be responsible for overseeing the amount of vaccine out on 'stations' and removing vaccine, as needed, from the cool bag. Vaccines must be stored in the cool bag until needed for use.
- That same nurse to be responsible for reading the temperature of the cool bag every hour during the session and recording on a monitoring sheet. Recorded temperatures should be between 2°C - 8°C, aim for 5°C giving a safety margin of +/- 3°C (Health Protection Agency, 2008). Unexplained fluctuation of temperature outside of 2°C - 8°C must be recorded, reported to the nurse co-ordinating the session and appropriate action taken. Contact:
 1. Team leader, Child Health Department.
 2. NHS Sheffield Medicines Management Team
 3. The vaccine manufacturer.
- Purchase of new or calibration of used thermometers should be done annually to ensure they are working correctly.
- Vaccines should not be left unattended at outlying clinics/schools.
- If correct procedures are followed and the monitoring sheet shows the cold chain is unbroken, any unused vaccine may be returned to the child health fridge and marked 'USE NEXT'. This vaccine must be used at the next session; if not used on second time out at a session it cannot be returned to the fridge. It must be discarded.
- Ice packs to be returned to the child health freezer.

Appendix E – Assessment of surroundings for immunisation session in an individual setting

School	School contact name for planning:
Date of session:	Contact number:
Start time:	
First aider available on the day	School staff co-ordinator on the day
Name:	Name:
Can be found:	
Number of children on year group roll:	Number of immunising staff:
	(roughly 70 injections per member of staff each session)
Room available is:	School nurse co-ordinator
	Name:
Resources:	Immunising staff:
Table each for immunising staff =	Name:
Two chairs for each immunising nurse =	Name:
Large tables and seating for two clerical staff at the entrance to the room	Name:
	Name:
Space for drug cool boxes and resources case	Name:
Screening or private space: Yes No	Name:
Holding place for class of 30 prior to immunisation is:	Name:
	Name:
Holding place for class of 30 for five minutes post-immunisation is:	Crowd co-ordinator, band 2
	Name:
Nearest hand washing and toileting facilities are:	
Is the room or space big enough?	Is there appropriate lighting?
Yes No	Yes No
Signature of school nurse	Signature of co-ordinator
Date:	Date:

Appendix F – References

1. NMC *The code of professional conduct* (2008)
2. *Immunisation against infectious diseases* (2006) – plus new chapter for HPV 2008
3. The Children’s Act (2004)
4. Fraser competence (Gillick principle) 1985
5. *National standard for immunisation training*, Health Protection Agency (2005)
6. Sheffield Children’s NHS Foundation Trust Waste Management Policy and Procedure (CP732)
7. Care Quality Commission outcome 2: Consent to care and treatment
8. Regulation 18 of the Health and Social Care Act (2008) (Regulated Activities) Regulations 2009
9. Sheffield Children’s NHS Foundation Trust Medicines Management Policy
10. Sheffield Children’s NHS Foundation Trust Hand Hygiene Policy (CP547)

Patient group direction: good practice example

Patient group direction (PGD) for

GARDASIL®v
Human Papilloma virus vaccine [Types 6, 11, 16, 18]
 (recombinant, adsorbed)

You must be authorised by name, under the current version of this PGD before you attempt to work according to it.

Clinical area(s) in which PGD may be used	Community settings (school nursing)
Circumstances in which PGD may be used	Implementation as per vaccination schedule

1. Clinical condition

Indication	<p>Gardasil® is a vaccine for use from the age of 9 years for the prevention of:</p> <ul style="list-style-type: none"> • premalignant genital lesions (cervical, vaginal and vulval) and cervical cancer causally related to certain oncogenic human papillomavirus (HPV) types • genital warts (condyloma acuminata) causally related to specific HPV types. <p>Gardasil® will only protect against diseases that are caused by HPV types 6, 11, 16 and 18 and to a limited extent against diseases caused by certain related HPV types.</p>
Criteria for inclusion	<p>Females aged 11-19 as a primary course With informed consent (see appendix 2)</p>
Exclusion criteria	<ul style="list-style-type: none"> • Acute severe febrile illness. • Hypersensitivity to the vaccine or to any of the excipients. • Pregnancy: routine questioning about last menstrual period and/or pregnancy testing is required before offering HPV vaccine. • Anaphylaxis to previous dose of Gardasil® vaccine. • Consent not given.
Cautions/need for further advice	<ul style="list-style-type: none"> • Acute/febrile illness, advise when to return/follow up, arrange further appointment. • Thrombocytopenia or any coagulation disorder – give by deep subcutaneous injection to reduce risk of bleeding. • If giving other vaccines, give separately, ideally in separate limb or if this is not possible then at least 2.5cm apart. • Individuals with immunosuppression or with HIV infection (regardless of CD4 counts) should be considered for HPV vaccines in accordance with Department of Health recommendations. • Further advice can be sought from the trust's immunisation medical advisor.

Action if patient declines or is excluded	<p>For example if acute infection present; also refer to pregnancy section – rearrange date for administration of vaccine.</p> <p>Document reason in notes, refer to doctor, advise about transmission and discuss preventative measures that can be taken to prevent genital human papillomavirus infection.</p> <p>Refer to the HPV and TdP vaccination protocol. CAEC registration ID no. 1495.</p>
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Patient group direction (PGD) for:

GARDASIL®
Human papilloma virus vaccine [Types 6, 11, 16, 18]
(recombinant, adsorbed)
Vaccination is not a substitute for routine cervical screening

2. Drug details

Name, form and strength of medicine	GARDASIL® Human papilloma virus vaccine [Types 6, 11, 16, 18] (recombinant, adsorbed)
Legal classification	POM – Prescription only medicine
Dose	0.5 mL dose supplied in a pre-filled syringe should be used for each injection in accordance with the recommended schedule.
Route/method	The vaccine should be administered by intramuscular injection. The preferred site is the deltoid area of the upper arm or in the higher anterolateral area of the thigh. For individuals who have a bleeding disorder - see cautions section.
Prior to administration	Check correct vaccine and expiry date. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine. Prior to agitation, Gardasil® may appear as a clear liquid with a white precipitate. Shake well to obtain a white, cloudy suspension. Attach the needle by twisting in a clockwise direction until the needle fits securely on the syringe. Discard the product if particulates are present or if it appears discoloured. Any unused product or waste material should be disposed of in accordance with the Waste Management Policy and Procedure (CP732).
Frequency/duration of treatment	<i>Primary vaccination series</i> Three separate 0.5ml doses administered at 0, 2, 6 months. <i>Alternative vaccination schedule</i> The second dose should be administered at least one month after the first dose and the third dose should be administered at least three months after the second dose. All three doses should be given within a one year period. It is recommended that subjects who receive a first dose of Gardasil® complete the three-dose vaccination course with Gardasil®. If the course is interrupted, it should be resumed but not repeated, ideally allowing the appropriate interval between the remaining doses.
Quantity to supply/administer	Single dose 0.5ml

<p>Side effects</p> <p>Reporting procedures for adverse reactions</p>	<p>Gardasil®</p> <p>Very common Headache and at the injection site, erythema, pain and swelling.</p> <p>Common Haematoma and pruritus at the injection site, pain in the extremity, nausea and pyrexia.</p> <p>Rarely Urticaria.</p> <p>Very rarely Bronchospasm has been reported. Idiopathic thrombocytopenic purpura, lymphadenopathy, dizziness, syncope, Guillain-Barre syndrome and hypersensitivity reactions including, anaphylactic/anaphylactoid reactions have also been reported.</p> <p>See Gardasil® summary of product characteristics (SPC) for further information For advice on faints and panic attacks in association with vaccines see the <i>Green book</i> chapter 18a Human Papilloma virus.</p> <p>Patients should inform their doctor. Any adverse reactions should be reported to the MHRA (Medicines and Healthcare Products Regulatory Agency) through the yellow card system. Information about adverse event reporting can be found at www.yellowcard.gov.uk.</p> <p>Adverse events should also be reported to Sanofi Pasteur MSD by calling 01628 785291.</p> <p>Any serious adverse reaction to the vaccine should be documented in the patient's medical records. The nurse should inform their line manager. The GP should also be informed.</p> <p>Due to the relatively limited experience of HPV vaccine in pregnant women, cases of inadvertent administration during pregnancy should be reported to the HPA website www.hpa.org.uk or by phone to 01788 540 298 or 0208 327 7471, and to Sanofi Pasteur MSD on 01628 785291.</p> <p>Immediate access to adrenaline (epinephrine) 1 in 1000 injection.</p> <p>Note: Resuscitation Council guideline update – Jan 2008. See updated Chapter 8 in the <i>Green book</i> at www.dh.gov.uk/greenbook and www.resus.org.uk/siteindx.htm</p>
<p>Use in pregnancy/lactation</p>	<p>If a girl volunteers the information that she is or may be pregnant further advice should be sought and vaccination delayed.</p>
<p>Follow up</p>	<ul style="list-style-type: none"> • Issue Gardasil® patient information leaflet. • Give advice regarding normal reaction to the injection (for example, sore arm). • Issue Gardasil® patient information leaflet. • Give advice regarding normal reaction to the injection (for example, sore arm). • Inform patient when subsequent doses are due when applicable. • Advise vaccination is not a substitute for routine cervical screening.
<p>Advice to patient/carer</p>	<ul style="list-style-type: none"> • Impaired immune responsiveness including HIV – advise patient/carer that response may be inadequate.

Patient group direction (PGD) for:

GARDASIL®
Human Papillomavirus Vaccine [Types 6, 11, 16, 18]
(Recombinant, adsorbed)

3. Characteristics of staff

Professional qualifications	Staff authorised to administer vaccines under this direction Registered nurse with valid registration with the NMC.
Specialist competencies or qualifications	<ul style="list-style-type: none"> • Adequate training in all aspects of immunisation as detailed in appendix 1. • Responsibility for maintaining and updating professional knowledge as appropriate. • Access to most recent edition of “Immunisation against Infectious Disease” and any updates; also access to latest issue of the BNF and CMO updates. • Competence to recognise and treat anaphylaxis. • Immediate access to adrenaline 1:1000 injection syringes and needles. <p>Immediate access to a communication link whereby assistance could be summoned.</p>
Continued education and training	All school nursing staff will receive training in the general principles and practice of immunisation, in accordance with the <i>National Standards for Immunisation</i> and the implementation of this PGD. Additional training will be provided on an annual basis. Nurses will be accountable for their own practice in accordance with the Nursing and Midwifery Council’s (NMC) <i>The code of professional conduct</i> .

4. Audit trail

Records/audit trail, including documentation to be completed	<p>Each treatment is recorded on the patient consent form, consent forms securely held in immunisation nurses office. Immunisation data recorded on SystemOne and HPV data tool.</p>
References/resources and comments Policies or guidelines National Local	<p>Summary of product characteristics for GARDASIL® human papilloma virus vaccine [Types 6, 11, 16, 18] (recombinant, adsorbed)</p> <p>Immunisation against infectious disease (the <i>Green book</i>) Human Papilloma virus (updated November 2008) Check local guidelines</p> <p>References:</p> <ol style="list-style-type: none"> 1. Department of Health (1998) <i>Review of prescribing, supply and administration of medicines: a report on the supply and administration of medicines under group protocol</i>, London: DH. 2. Department of Health (2006) <i>Immunisation against infectious disease (the Green book)</i> www.dh.gov.uk/greenbook 3. NHS Executive (2000) HSC 2000/026: <i>Patient group directions</i> [England only], London: TSO. 4. NPC Patient Group Directions guide and framework of competencies, December 2009 www.npc.nhs.uk/non_medical/resources/patient_group_directions.pdf 5. <i>Prescription only medicines (human use)</i> amendment order 2000, the <i>Medicine (pharmacy and general sale – exemption)</i> amendment order 2000 and the <i>Medicines (sale and supply) (miscellaneous provisions) amendment (No. 2) regulation 2000</i>. <i>Statutory instruments Nos. 1917, 1918, 1919</i>, London: TSO. 6. NMC standards (2008) - <i>The code: standards for conduct, performance and ethics for nurses and midwives</i>, London: NMC. 7. NMC standards (2010) <i>Standards for medicines management</i>, London: NMC. 8. NMC guidance (2009) <i>Record keeping: guidance for nurses and midwives</i>, London: NMC. 9. NMC documents can be accessed at www.nmc-uk.org

Patient group direction (PGD) for

GARDASIL®v
Human Papilloma virus vaccine [Types 6, 11, 16, 18]
(recombinant, adsorbed)

5. Authorisation

This PGD must be agreed to and signed by all health professionals involved in its use. The NHS trust should hold the original signed copy. The PGD must be easily accessible in the clinical setting.

Patient group direction developed by	Name:
	Position:
	Signature:
	Date:
Lead doctor	Name:
	Position:
	Signature:
	Date:
Lead nurse/allied health professional	Name:
	Position:
	Signature:
	Date:
Lead pharmacist	Name:
	Position:
	Signature:
	Date:
Clinical governance lead	Name:
	Position:
	Signature:
	Date:
Organisational authorisation (medical director)	Name:
	Position:
	Signature:
	Date:

Appendix 1: Competence in immunisation

Aim

To ensure safe practice in the administration of immunisations by nurses. Before undertaking immunisation, the nurse should ensure that they have achieved competence in the following areas of practice. This may be achieved either by a formal programme of study or by self-directed learning within the practice setting, as per the requirements of *The code: standards for conduct, performance and ethics for nurses and midwives* (NMC, 2008).

- You must have the knowledge and skills for safe and effective practice when working without direct supervision.
- You must recognise and work within the limits of your competence.
- You must keep your knowledge and skills up to date throughout your working life.
- You must take part in appropriate learning and practice activities that maintain and develop your competence and performance.

All nurses are advised to consult the full text of the NMC's code.

1. Immunity – active and passive.
2. Storage, distribution and disposal of vaccines, including cold chain.
3. Understanding of the principles of valid consent and implied consent.
4. Indications and contraindications of specific vaccines.
5. Adverse reactions.
6. Reporting of adverse reactions and reporting requirements of 'Black triangle' drugs.
7. Anaphylaxis and resuscitation.
8. Disposal of sharps and clinical waste.
9. Needlestick injury.
10. Understanding of the principles of immunisation under patient group directions
11. Record keeping requirements.
12. Reconstitution of vaccines, skin preparation, site of immunisation and injection technique.

All nurses need to ensure that they know the policies of their local organisation that relate to immunisation; for instance, what action to take if a needle stick injury occurs. Health Protection Agency (HPA) immunisation training resources for health care professionals are available at www.hpa.org.uk

All nurses involved in immunisation have a professional responsibility to reinforce and update their knowledge and skills in this area, with particular reference to recent and current changes in practice. See also: The Vaccine Administration Taskforce (2001) *UK guidance on best practice in vaccine administration*, London: Shire Hall Communications.

Appendix 2: Valid consent

Before undertaking immunisation the nurse must be aware of the different forms of consent and the importance of obtaining valid consent prior to immunisation. As far as the law is concerned there is no specific requirement that consent for treatment should be given in any particular way. Consent can be expressed by word of mouth or in writing. It can also be implied, for example, the patient rolling up his sleeve for a blood pressure (reference: Dimond B (1995) *Legal aspects of nursing* (second edition), London: Prentice Hall, p.98).

Consent is discussed in more detail in *Immunisation against infectious disease (the green book)*: Chapter 2 – consent, and *The code: standards of conduct, performance and ethics for nurses and midwives* (NMC, 2008).

Please refer to Sheffield Children's NHS Foundation Trust Consent Policy (January 2012), which can be found on the Sheffield Children's Hospital intranet under *Corporate policies CP80 – consent policy*.

Please refer also to Sheffield Children's NHS Foundation Trust school nursing vaccination protocol C 1495.

Further information

Government and NHS resources

NHS Choices

www.nhs.uk

Health Protection Agency (part of Public Health England)

www.hpa.org.uk

Department of Health England

www.gov.uk/government/organisations/department-of-health

Public Health England

www.gov.uk/government/organisations/public-health-england

NHS England

www.england.nhs.uk

Northern Ireland

Department of Health, Social Services and Public Safety

www.dhsspsni.gov.uk

Public Health Agency

www.publichealth.hscni.net

Scotland

Health Protection Scotland

www.hps.scot.nhs.uk

Immunisation best practice guidelines 2013

www.nhs.gov.uk/nhsdocuments/2013/09/immunisation-best-practice-guidelines-2013

www.hps.scot.nhs.uk/immvax/scottishvaccineupdate.aspx

Wales

NHS Wales

www.wales.nhs.uk

Welsh Assembly Government

www.wales.gov.uk/topics/health/?lang=en

Public Health Wales

www.wales.nhs.uk/immunisation



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