NHS Grampian | NHS Highland | NHS Orkney | NHS Shetland | NHS Tayside | NHS Eileanan Siar Western Isles

Patient Group Direction For The Administration Of Pneumococcal Polysaccharide Vaccine (PPV) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Lead Author: Adapted from PHS National PGD by the Medicines Management Specialist Nurse NHSG	**Consultation Group**: See relevant page in the PGD	**Approver:** NoS PGD Group **Authorisation:** NHS Grampian
Signature:		**Signature:**
NoS Identifier: NoS/PGD/PPV/MGPG1302	**Review Date:** September 2024 **Expiry Date:** September 2025	**Date Approved:** September 2022

NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles have authorised this Patient Group Direction to help individuals by providing them with more convenient access to an efficient and clearly defined service within the NHS Boards. This Patient Group Direction cannot be used until Appendix 1 and 2 are completed.

Uncontrolled when printed

Version 3

Revision History:

Reference and approval date of PGD that has been adapted and/or superseded	PGD adapted from PHS national template and supersedes NoS/PGD/PPV/MGPG1102, Version 2.3.1	
Date of change	**Summary of Changes**	**Section heading**
July 2022	PGD Review due following an update to the PHS National PGD template. New NoS PGD template used.	Throughout
July 2022	Inclusion criteria expanded to include other patient groups out with the Scottish childhood immunisation programme.	Inclusion criteria
July 2022	Section updated to include dosing information for the other patient groups out with the Scottish childhood immunisation programme.	Frequency of dose/Duration of treatment

NoS Identifier: NoS/PGD/PPV/MGPG1302, Version 3
Keyword(s): PGD Patient Group Direction vaccine immunisation childhood pneumococcal pneumovax PPV

Policy Statement:
It is the responsibility of the individual healthcare professional and their line managers to ensure that they work within the terms laid down in this PGD and to ensure that staff are working to the most up to date PGD. By doing so, the quality of the services offered will be maintained, and the chances of staff making erroneous decisions which may affect individual, staff or visitor safety and comfort will be reduced. Supervisory staff at all levels must ensure that staff using this PGD act within their own level of competence.

The lead author is responsible for the review of this PGD and for ensuring the PGD is updated in line with any changes in clinical practice, relevant guidelines, or new research evidence.

Review date: The review date for a PGD needs to be decided on a case-by-case basis in the interest of safety. The expiry date should not be more than 3 years, unless a change in national policy or update is required.

Document:	Drafted:	July 2022
	Completed:	August 2022
	Approved:	September 2022 (published –September 2022)
	Amended & reauthorised:	

Organisational Authorisations

This PGD is not legally valid until it has had the relevant organisational authorisation.

PGD Developed/Reviewed by;

Medical practitioner	**Name:** Dr Daniel Chandler **Health Board:** NHST **Title:** Consultant in Public Health Medicine **Contact email:** daniel.chandler@nhs.scot **Signature:** ..... **Date Signed:** 08/09/2022
Senior representative of the professional group who will provide care under the direction.	**Name:** Jackie Donachie **Health Board:** NHST **Title:** Vaccination Programme Manager **Contact email:** jacqueline.donachie2@nhs.scot **Signature:** ..... **Date Signed:** 08/09/2022
Lead author	**Name:** Frances Adamson **Health Board:** NHSG **Title :** Medicines Management Specialist Nurse **Contact email:** frances.adamson@nhs.scot **Signature:** ..... **Date Signed:** 07/09/2022
Pharmacist	**Name:** Russell Mackay **Health Board:** NHSO **Title :** Specialist Clinical Pharmacist **Contact email:** russell.mackay@nhs.scot **Signature:** ..... **Date Signed:** 08/09/2022

Approved for use within NoS Boards by;

North of Scotland (NoS) PGD Group Chair	Signature	Date Signed
Lesley Coyle		07/09/2022

Authorised and executively signed for use within NoS Boards by;

NHS Grampian Chief Executive	Signature	Date Signed
Professor Caroline Hiscox		13/09/2022

Management and Monitoring of Patient Group Direction

PGD Consultative Group

The consultative group is legally required to include a medical practitioner, a pharmacist and a representative of the professional group who will provide care under the direction.

Name:	Title:
Frances Adamson	**Lead Author:** Medicines Management Specialist Nurse NHSG
Russell Mackay	**Pharmacist:** Pharmacy Team Leader NHSO
Dr Daniel Chandler	**Medical Practitioner:** Consultant in Public Health Medicine NHST
Jackie Donachie	**Senior Representative:** Vaccination Programme Manager NHST
Fiona Browning	Health Protection Nurse Specialist NHSG
Lynda Davidson	Health Protection Nurse NHSH
Elaine Maguire	Vaccination Programme Team Leader NHSS
Isabell Macinnes	Health Protection Nurse NHSWI

Patient Group Direction For The Administration Of Pneumococcal Polysaccharide Vaccine (PPV) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

Clinical indication to which this PGD applies

Definition of situation/Condition	This Patient Group Direction (PGD) will authorise approved healthcare professionals as detailed in the characteristics of staff authorised to work under this PGD to administer pneumococcal polysaccharide vaccine (PPV) for the active immunisation against invasive disease caused by *Streptococcus pneumoniae* serotypes 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F. This PGD should be used in conjunction with the recommendations in the current British National Formulary (BNF), British National Formulary for Children (BNFC), The Green Book and the individual Summary of Product Characteristics (SmPC).
Inclusion criteria	• Adults aged 65 years and over not previously vaccinated with PPV23 • Individuals aged two years and over included in the clinical risk groups who should receive the PPV23 vaccine as defined in The Green Book Chapter 7 and Chapter 25 • Individuals with asplenia, splenic dysfunction or chronic kidney disease and who require a PPV23 booster (see The Green Book Chapter 25) • Individuals who are recommended vaccination by the local Health Protection Team for the public health management of pneumococcal disease in accordance with UK guidelines for the public health management of clusters of serious pneumococcal disease in closed settings • Revaccination of individuals who have received a haemopoietic stem cell transplant. Prior to the administration of the vaccine, valid consent to receiving treatment under this PGD must be obtained. Consent must be in line with current individual NHS Boards consent policy.
Exclusion criteria	Individuals who: • Are under 2 years of age • Have had an anaphylactic reaction to a previous dose of PPV23 or any component of the vaccine • Have a history of severe (i.e. anaphylactic reaction) to latex where the vaccine is not latex free.

	• Have previously received PPV23 over the age of 2 years, except for individuals with asplenia, splenic dysfunction and chronic kidney disease • Have received pneumococcal conjugate vaccine (PCV13) in the preceding 8 weeks • Are suffering an acute severe febrile illness - immunisation should be postponed until fully recovered. Individuals for whom no valid consent has been received.
Precautions and special warnings	Minor illness without fever or systemic upset is not a valid reason to postpone immunisation. If an individual is acutely unwell, immunisation may be postponed until they have fully recovered. Chapter 25 of The Green Book advises that there are very few individuals who cannot receive PPV23 vaccine. Where there is doubt, rather than withholding vaccination, appropriate advice should be sought from the relevant specialist, or from the local immunisation or health protection team. The presence of a neurological condition is not a contraindication to immunisation but if there is evidence of current neurological deterioration, deferral of vaccination may be considered, to avoid incorrect attribution of any change in the underlying condition. The risk of such deferral should be balanced against the risk of the preventable infection, and vaccination should be promptly given once the diagnosis and/or the expected course of the condition becomes clear. Those requiring splenectomy or commencing immunosuppressive treatment should be vaccinated according to the age-specific advice in The Green Book Chapter 25. Ideally, the vaccines should be given 4-6 weeks before elective splenectomy or initiation of treatment such as chemotherapy or radiotherapy. Where this is not possible, it can be given up to two weeks before treatment. If it is not possible to vaccinate beforehand, splenectomy, chemotherapy or radiotherapy should never be delayed. If it is not practicable to vaccinate two weeks before splenectomy, immunisation should be delayed until at least two weeks after the operation because functional antibody responses may be better from this time. If it is not practicable to vaccinate two weeks before starting chemotherapy or radiotherapy, immunisation should be delayed until at least three months after completion of therapy to maximise vaccine response. Immunisation of these individuals should not be delayed if this is likely to result in a failure to vaccinate.

Action if excluded from treatment	Medical advice must be sought – refer to relevant medical practitioner for advice on the vaccine and circumstances under which it could be given using a patient specific direction. The risk to the individual of not being immunised must be taken into account. Discussion of the risk and benefits of vaccination should take place. Discussions and decisions taken should be documented in clinical records. In case of postponement due to acute severe febrile illness, advise when the individual can be vaccinated at a later date and ensure another appointment is arranged. If aged less than 2 years PPV23 is not indicated, ensure PCV immunisation is up-to-date. If PPV23 has previously been received over the age of 2 years and the individual does not have asplenia, splenic dysfunction or chronic kidney disease and the individual is not recommended vaccination for the public health management of clusters of serious pneumococcal disease in closed settings disease further PPV23 is not indicated. For those individuals who have received PCV in the preceding 8 weeks postpone immunisation until 8 weeks has elapsed. Document the reason for exclusion under the PGD and any action taken in the individual's appropriate clinical records.
Action if treatment is declined	Advise about the protective effects of the vaccine and the risk of infection and disease complications. Ensure they have additional reading material e.g. the Patient Information Leaflet (PIL) available to print here. Document advice given and decision reached. Inform/refer to the relevant medical practitioner if individual/parent/carer declines treatment. Document that the administration of the vaccine was declined, the reason and advice given in appropriate clinical records.

Description of vaccine available under the PGD

Name form and strength of vaccine	23-valent Pneumococcal Polysaccharide Vaccine (PPV). Pneumovax 23® solution for injection 0.5mL pre-filled syringe, with each 0.5mL dose containing 25 micrograms of each of the following 23 pneumococcal polysaccharide serotypes: 1, 2, 3, 4, 5, 6B, 7F, 8, 9N, 9V, 10A, 11A, 12F, 14, 15B, 17F, 18C, 19F, 19A, 20, 22F, 23F, 33F.
Legal status	23-valent Pneumococcal Polysaccharide Vaccine (PPV). Pneumovax 23® is a Prescription-only Medicine (POM).
Is the use out with the SmPC?	No. Vaccine should be stored according to the conditions detailed below. However, in the event of an inadvertent or unavoidable deviation of these conditions refer to NHS Board guidance on storage and handling of vaccines guidance. Where vaccine is assessed in accordance with these guidelines as appropriate for continued use, administration under this PGD is allowed.
Dosage/Maximum total dose	0.5mL
Frequency of dose/Duration of treatment	Single dose for adults and children over the age of 2 years. Those with asplenia, splenic dysfunction or chronic kidney disease should receive a booster dose of PPV23 at five yearly intervals. **Revaccination of individuals who have received a haemopoietic stem cell transplant:** In accordance with the schedule recommended by the Scottish Haematology Society vaccination policy (Post HSC Transplantation): **Management of a pneumococcal disease clusters and outbreaks:** In accordance with advice from local Health Protection Team and informed by Guidelines for the public health management of clusters and outbreaks of pneumococcal disease in closed settings with high-risk individuals
Maximum or minimum treatment period	See Frequency of dose/Duration of treatment section.
Route/Method of administration	Administer by intramuscular or subcutaneous injection. The preferred site is the deltoid region of the upper arm.

	The intramuscular route is routinely used because localised reactions are more common when vaccines are given subcutaneously. However, for individuals with a bleeding disorder, vaccines may alternatively be given by subcutaneous injection to reduce the risk of bleeding. The vaccine's normal appearance is a clear colourless solution. 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. Pneumococcal vaccines can be given at the same time as other vaccines such as DTaP/IPV/Hib/HepB, 4CMenB, MMR, MenACWY, Hib/MenC, Rotavirus and influenza. When administering at the same time as other vaccines care should be taken to ensure that the appropriate route of injection is used for each of the vaccinations. The vaccines should be given when possible in different limbs to allow monitoring of local reactions to PPV23 vaccine. If given in the same limb they should be given at different sites at least 2.5cm apart (American Academy of Paediatrics 2003). The site at which each vaccine was administered should be noted in the individual's records.
Quantity to be administered	0.5mL
Storage requirements	Vaccine will be stored in a temperature controlled refrigerator between +2°C and +8°C. Refrigerators should have maximum and minimum temperatures recorded daily. Store in original packaging in order to protect from light. Do not freeze. Individual NHS Board guidance on the storage, handling and cold chain in relation to vaccines must be observed. Likewise, individual NHS Board guidance in relation to waste management and the disposal of all spent, partially spent or unused vaccines must also be observed. 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.

Additional Information	Pneumococcal vaccines may be given to pregnant women when the need for protection is required without delay. There is no evidence of risk from vaccinating pregnant women or those who are breast-feeding with inactivated viral or bacterial vaccines or toxoids.
Follow-up (if applicable)	Following immunisation patients should remain under observation in line with individual NHS Board policy. Individuals should not leave if they are feeling unwell without speaking to the healthcare professional who administered the vaccine first. If necessary a doctor or the individuals GP should be contacted for advice.
Advice (Verbal)	• Advise individual/parent/carer what to expect and of the possible side effects and their management. • Individuals at especially increased risk of serious pneumococcal infection (such as asplenics and those who have received immunosuppressive therapy for any reason), should be advised regarding the possible need for early antimicrobial treatment in the event of severe, sudden febrile illness. • The individual should be advised to seek medical advice in the event of a severe adverse reaction. • Individuals/carers should be advised to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme. When administration is postponed advise the individual/parent/carer when to return for vaccination. If appropriate, advise when subsequent doses are due and if any follow up is required.
Advice (Written)	The PIL contained in the medicine(s) should be made available to the individual/parent/carer. Where this is unavailable, or unsuitable, sufficient information should be given in a language that they can understand. Supply immunisation promotional material as appropriate. More information regarding this vaccine can be found at: https://www.nhsinform.scot/healthy-living/immunisation
Identifying and managing possible adverse reactions	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 most commonly seen reactions are minor local injection site reactions such as hardening of the skin, oedema, pain and redness. A small painless nodule may form at the injection site lasting one to three days and, less commonly, a low-grade fever may occur. More severe systemic reactions are infrequent. In general, local and systemic reactions are more common in people with higher concentrations of antibodies to pneumococcal polysaccharides. As with all vaccines there is a very small possibility of anaphylaxis and facilities for its management must be available. **This list is not exhaustive. Please also refer to current BNF/BNFC and manufacturers SmPC for details of all potential adverse reactions.** **BNF/BNFC**: BNF British National Formulary - NICE BNF for Children British National Formulary - NICE **SmPC/PIL/Risk Minimisation Material:** Home - electronic medicines compendium (emc) MHRA Products | Home RMM Directory - (emc) If an adverse reaction does occur give immediate treatment and inform relevant medical practitioner as soon as possible. Document in accordance with locally agreed procedures in the individual's record. Report any suspected adverse reactions using the Yellow Card System. Yellow Card Scheme - MHRA

Facilities and supplies required	The following are to be available at sites where the vaccine is to be administered: • Pharmaceutical refrigerator (or a validated cool box for storing vaccine if mobile unit) • An acceptable level of privacy to respect individual's right to confidentiality and safety • Basic airway resuscitation equipment (e.g. bag valve mask) • Immediate access to Epinephrine (Adrenaline) 1 in 1000 injection • Access to a working telephone • Another competent adult, who can summon urgent emergency support if required should ideally be present • Access to medical support (this may be via the telephone) • Approved equipment for the disposal of used materials • Clean and tidy work areas, including access to hand washing facilities or alcohol hand gel • A copy of this PGD in print or electronically

Characteristics of staff authorised to administer vaccine under PGD

Professional qualifications	The following classes of registered healthcare practitioners are permitted to administer vaccines as identified and included in individual Board immunisation delivery plans: • Nurses and midwives currently registered with the Nursing and Midwifery Council (NMC) • Pharmacists currently registered with the General Pharmaceutical Council (GPhC) • Chiropodists/podiatrists, dieticians, occupational therapists, orthoptists, orthotists/prosthetists, paramedics, physiotherapists, radiographers and speech and language therapists currently registered with the Health and Care Professions Council (HCPC) • Dental hygienists and dental therapists registered with the General Dental Council • Optometrists registered with the General Optical Council.
Specialist competencies	**Approved by the organisation as:** • Competent to assess the individual's/parent's/carer's capacity to understand the nature and purpose of vaccination in order to give or refuse consent • Familiar with the vaccine product and alert to changes in the product information.

	• Competent to undertake administration of the vaccine and discuss issues related to vaccination • Competent in the recognition and management of anaphylaxis or under the supervision of persons able to respond appropriately to immediate adverse reactions • Competent in the handling and storage of vaccines, and management of the "cold chain" • Competent to work under this PGD and authorised by name as an approved person to work under the terms of the PGD.

Ongoing training and competency	**All professionals working under this PGD must:**
	• Have undertaken NoS PGD module training on TURAS Learn
	• Have attended basic life support training either face to face or online and updated in-line with individual Board requirements
	• Have undertaken immunisation training
	• Have undertaken NHS e-anaphylaxis training or equivalent which covers all aspects of the identification and management of anaphylaxis updated in-line with individual Board requirements
	• Maintain their skills, knowledge and their own professional level of competence in this area according to their individual Code of Professional Conduct. **Note:** All practitioners operating under the PGD are responsible for ensuring they remain up to date with the use of the vaccine. If any training needs are identified these should be discussed with those responsible for authorisation to act under the PGD.
	• Have knowledge and familiarity of the following;
	  ○ Current edition of the Green Book
	  ○ SmPC for the vaccine to be administered in accordance with this PGD
	  ○ Relevant policy relating to vaccine storage and immunisation procedures for use within their Health Board
	  ○ Relevant Scottish Government Health Directorate advice including the relevant CMO letter(s).

Responsibilities of professional manager(s)	**Professional manager(s) will be responsible for;** Ensuring that the current PGD is available to all staff providing care under this direction. Ensuring that staff have received adequate training in all areas relevant to this PGD and meet the requirements above.

	Maintain up to date record of all staff authorised to administer the vaccine specified in this direction.

Documentation

Authorisation of administration	Qualified registered healthcare professionals working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles listed and approved in legislation as able to operate under PGD can be authorised to administer the vaccine specified in this PGD in accordance with local delivery plans and by agreement at individual Board level as per the following: Nurses, midwives and health visitors can be authorised by their line manager. Pharmacists working within NHS Grampian, Highland, Orkney, Shetland, Tayside and Western Isles can be authorised to administer the medicine(s) specified in this PGD when they have completed local Board requirements for service registration. The following list of healthcare professionals can be authorised by their Line Manager, Head of Service or Vaccine Coordinator: Chiropodists, dental hygienists, dental therapists, dieticians, occupational therapists, optometrists, orthoptists, orthotist/prosthetists, paramedics, physiotherapists, podiatrists, radiographers and speech and language therapists. All authorised staff are required to read the PGD and sign the Agreement to Administer Medicines Under PGD (Appendix 1). A Certificate of Authorisation (Appendix 2) signed by the authorising professional/manager should be supplied. This should be held in the individual health professional's records, or as agreed within the individual Health Board.
Record of administration	An electronic or paper record must be completed to allow audit of practice. An electronic/Hospital Electronic Prescribing and Medicines Administration (HEPMA) record of the screening and subsequent administration, or not of the medicine(s) specified in this PGD should be made in accordance with individual Health Board electronic/HEPMA recording processes. If a paper record is used for recording the screening of individuals and the subsequent administration, or not of the medicine(s) specified in this PGD, it should include as a minimum:

	• Date and time of vaccine administration • Individuals name, address and CHI • GP with whom the individual is registered • Exclusion criteria, record why the vaccine was not administered (if applicable) • Record that valid consent to treatment under this PGD was obtained • The name, brand, dose, form, batch number, expiry date, route/and anatomical site of the vaccination administered • Advice given, including advice given if excluded or declined vaccination under this PGD • Signature and name in capital letters of the healthcare professional who administered the vaccine, and who undertook the assessment of the individual's clinical suitability for the vaccine • Record of any adverse effects and the actions taken (advise individuals' GP/relevant medical practitioner). Depending on the clinical setting where administration is undertaken, the information should be recorded manually or electronically on the individual service specific system, as appropriate. • Individual's GP records if appropriate • HEPMA • Individual service specific systems. Local policy should be followed with respect to sharing information with the individual's General Practitioner. All records should be clear, legible and contemporaneous and in an easily retrievable format.
Audit	All records of the vaccine specified in this PGD will be filed with the normal records of medicines in each practice/service. A designated person within each practice/service where the PGD will be used will be responsible for annual audit to ensure a system of recording medicines administered under a PGD.
References	Electronic Medicines Compendium http://www.medicines.org.uk Pneumovax® 23 solution for injection in pre-filled syringe – Date of revision of text 29/01/21, accessed 19/07/2022. British National Formulary for Children and the British National Formulary accessed 19/07/2022. Department of Health (2006): Immunisation against Infectious Disease [Green Book]

	Pneumococcal: the green book, chapter 25 - GOV.UK (www.gov.uk) American Academy of Pediatrics (2003) Active immunisation. In: Pickering LK (ed.) Red Book: 2003 Report of the Committee on Infectious Diseases, 26th edition. Elk Grove Village, IL: American Academy of Pediatrics, p 33.

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 1

Healthcare Professional Agreement to Administer Vaccine Under Patient Group Direction

I: _____ (Insert name)

Working within: _____ e.g. Area, Practice

Agree to administer the vaccine contained within the following Patient Group Direction:

Patient Group Direction For The Administration Of Pneumococcal Polysaccharide Vaccine (PPV) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles

I have completed the appropriate training to my professional standards enabling me to administer the vaccine under the above direction. I agree not to act beyond my professional competence, nor out with the recommendations of the direction.

Signed: _____

Print Name: _____

Date: _____

Profession: _____

Professional Registration number/PIN _____

NHS Grampian NHS Highland NHS Orkney NHS Shetland NHS Tayside NHS Eileanan Siar Western Isles

Appendix 2

Healthcare Professionals Authorisation to Administer Vaccine Under Patient Group Direction

The Lead manager/Professional of each clinical area is responsible for maintaining records of all clinical areas where this PGD is in use, and to whom it has been disseminated.
The Senior Nurse/Professional who approves a healthcare professional to administer the vaccine under this PGD is responsible for ensuring that they are competent, qualified and trained to do so, and for maintaining an up-to-date record of such approved persons.
The Healthcare Professional that is approved to administer the vaccine under this PGD is responsible for ensuring that they understand and are qualified, trained and competent to undertake the duties required. The approved person is also responsible for ensuring that administration is carried out within the terms of the direction, and according to their individual code of professional practice and conduct.
Patient Group Direction For The Administration Of Pneumococcal Polysaccharide Vaccine (PPV) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles
Local clinical area(s) where the listed healthcare professionals will operate under this PGD:

Name of Healthcare Professional	Signature	Date	Name of Manager	Signature	Date

Patient Group Direction For The Administration Of Pneumococcal Polysaccharide Vaccine (PPV) By Approved Healthcare Professionals Working Within NHS Grampian, Highland, Orkney, Shetland, Tayside And Western Isles					
Name of Healthcare Professional	**Signature**	**Date**	**Name of Manager**	**Signature**	**Date**