June 2012

GPC

General Practitioners Committee

Focus on vaccines and immunisations

Guidance for GPs

BMA

Focus on vaccines and immunisations
Updated June 2012

Introduction

Since April 2004, under the new GMS contract, vaccines and immunisations have been paid for through various mechanisms dependent on which services a practice wishes to provide. Payment may be through the:

- global sum
- directed enhanced services
- quality and outcomes framework
- private income for some travel immunisations

The regulations regarding the NHS provision of immunisations can be traced back to the original 'Red Book'[1] regulations of the 1960's. Under the Red Book, most vaccines and immunisations were paid on an item-of-service basis and additionally the main childhood immunisations had a target-based remuneration. The regulations were written to cover the immunisations available at that time and consequently do not reflect today's clinical practice. In 2004 the new GMS contract [2]took those regulations and carried them into the new contract as an additional service. Consequently everything in the Red Book was transferred unchanged and included in the global sum rather than the previous item of service system. The fact that these regulations had become out of date because of changes in the vaccines themselves and continued to contain inappropriate references, such as smallpox, did not prevent their being carried over into the new contract. The newly published amendments to the Additional Services section of the NHS Regulations 2004 (see extract in Appendix 1) now reflect current practice and attempts to clarify the previous regulations to make them fully up to date, and are not intended to introduce any new work.

Occupational vaccination

The new wording of the regulations makes it clearer that certain at-risk groups have been included, e.g. rabies immunisation for laboratory workers, and typhoid immunisation for hospital doctors who might come in to contact with the disease. This has always been the case (as set out in the Red Book), but it is now more clearly set out in the new regulations.

Although only the vaccine itself is remunerated via the global sum, there is no funding within the global sum to provide the occupational health aspects of case finding, risk assessing and documenting. If there are any attempts to transfer occupational health commitments to practices, then we expect there to be appropriate remuneration for these services. Please note our comments in Appendix 1 where we feel this applies.

Note that hepatitis B is not covered in the new regulations because it is not included in 'Additional Services', so this will be covered in separate guidance *Focus on hepatitis B immunisations* to be published in summer 2012. There is currently BMA guidance available on *Hepatitis B immunisation for employees at risk*[3]*(2005)*, which will be updated and included in the *Focus on hepatitis B immunisations* guidance.

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[1] 'Red Book' - *Statement of fees and allowances payable to general medical practitioners in England and Wales* is unavailable online.
[2] http://webarchive.nationalarchives.gov.uk/+/www.dh.gov.uk/en/Healthcare/Primarycare/Primarycarecontracting/GMS/DH_4125639
[3] http://www.bma.org.uk/health_promotion_ethics/vaccination_immunisation/HepBimmunisationforemployeesatrisk.jsp

The global sum

The global sum pays for essential and additional services to patients on your list. Regulation 15 of the NHS Contract Regulations defines essential services[4], and paragraph 5 provides an obligation to provide ongoing treatment and care for all registered patients and temporary residents taking account of their specific needs. This may include immunisation against disease where it is in the patient's interest.

Within the global sum there is payment for two additional services:

Vaccines and immunisations - all necessary vaccines and immunisations as set out in Annex BA of the Statement of Financial Entitlements (SFE)[5], published on 30 April 2012 (this excludes the influenza and pneumococcal immunisation DES and certain travel vaccines that can be charged for privately). The full list of vaccines and immunisations is attached at Appendix 1 and Appendix 2 (for travel) and the Regulations at Appendix 3.

Childhood vaccines and immunisations – providing all necessary childhood vaccines and immunisations as set out in section 8 of the SFE, *Childhood Immunisations Scheme.* The full list is attached at Appendix 1 and the Regulations at Appendix 3.

Childhood vaccinations have changed significantly over the years. There are gains and losses; many single vaccines have been combined although the funding for each component remains in the global sum (e.g. diphtheria, pertussis, tetanus, polio and Hib); whilst on the other hand new vaccines have been introduced with either no additional global sum funding (e.g. Men C at 3 and 4 months) or as new payments outside of the global sum (e.g. PCV and booster Hib/Men C). However, on balance a similar amount of funding is available under the new regulations as under the old.

Should a practice for whatever reason feel unable to provide these additional services a percentage of the global sum will be extracted from the practice's global sum. For vaccines and immunisations this will be a 2% reduction and for childhood immunisations and pre-school boosters there will be a 1% reduction (SFE, Part 1 (2.5)[6]).

Directed enhanced services

There are several directed enhanced services (DESs) that GPs can provide in relation to vaccines and immunisations. The **influenza and pneumococcal immunisation DES** is for those patients at risk of infection. For influenza immunisation this includes:

- those aged 65 or over at the end of the financial year
- those patients suffering from:
  - chronic respiratory disease (including asthma and COPD)
  - chronic heart disease
  - chronic renal disease
  - chronic liver disease
  - chronic neurological disease
  - diabetes mellitus
  - immuno-suppression due to disease or treatment
- those living in long-stay residential or nursing homes
- carers.

[4] Regulation 15 of the NHS Regulations 2004 http://www.legislation.gov.uk/uksi/2004/291/regulation/15/made
[5] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_134302.pdf
[6] http://www.dh.gov.uk/en/Healthcare/Primarycare/PMC/contractingroutes/DH_4133079

The list above does not include all at-risk groups as advised by the Department of Health (such as pregnant women, who were added in 2011). For information about the at-risk groups and the recommendations by the Department of Health, see the letter from the Chief Medical Officer (England)[7] published in May 2011.

When the new GMS contract was negotiated, the pricing of the influenza DES was clarified in the "Blue book" (*The new General Medical Services (GMS) contract 2003*). This included uplifts for the following few years until 2006/7. Since 2006, the pricing of this DES has been frozen. The payment for the influenza DES is now negotiated locally and should be in line with contract uplifts, but LESs have been set up in most places which cover those at-risk groups included in the DES and others (e.g. pregnant women). There is a template specification for the influenza DES, *Influenza immunisation for those in the 65 and over and other at-risk groups*, available on the BMA website.

For **pneumococcal immunisation** the at-risk group includes those aged 65 or over. In 2011 there was a review by the Joint Committee on Vaccination and Immunisation (JCVI) of the evidence on the impact of the pneumococcal vaccination programme and on the clinical effectiveness of pneumococcal polysaccharide vaccine (PPV), which showed some uncertainty about the effectiveness of PPV. However, new analysis also showed that the programme remains cost effective, despite the limited effectiveness of the vaccine, and may be more cost effective than implementing a risk group-based programme. For these reasons, the JCVI advised that the existing routine programme for those aged 65 years and older should continue, although be kept under review. For further information about this review and decision, see the letter from Professor David Salisbury published in July 2011[8]

Although the influenza and pneumococcal immunisations are annual campaigns, the influenza scheme is time specific whilst pneumococcal can be given throughout the year. Practices do not have preferred provider status for this DES, but in reality, practices are the only realistic way of targeting the at-risk populations.

Practices providing the childhood vaccination and immunisation additional service have preferred provider status for the **childhood immunisation DES** which incorporates the 70% and 90% target payments that existed under the Red Book. Since the introduction of the new GMS contract in 2004, very few practices have opted out from providing childhood immunisations through additional services.

Quality and Outcomes Framework (QOF)

Whether a practice is commissioned for the influenza and pneumococcal DES or not, a practice may acquire Quality and Outcomes Framework (QOF) points for vaccinating patients within specific disease groups. The following indicators reward doctors for vaccinating patients against flu: CHD12, STROKE10, DM18 and COPD8.

The influenza DES has an item of service payment per vaccination that is provided whether the target is met or not. The QOF indicator targets can go as high as 90%. Any practice that completes the influenza DES successfully will also automatically qualify for QOF points. If a practice does not take on the influenza DES but still vaccinates patients in disease groups they can earn QOF points.

The latest QOF guidance can be found on the BMA website QOF pages.

[7] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_128175.pdf
[8] http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_128537.pdf

Travel immunisations

The situation with regard to travel immunisations was not straightforward as what can and cannot be charged for was also not altered from the old 'Red Book' to the new GMS contract. Under the Red Book a limited number of travel immunisations were provided on the NHS. In 2004 the new GMS contract took those regulations too, and carried them into the new contract as an additional service. Consequently everything in the Red Book was transferred unchanged and included in the global sum rather than the previous item of service system. This caused a lot of confusion as the change in availability of immunisations and the nature of foreign travel made the regulations difficult to interpret.

This has now become clearer with the publication of Annex BA of the SFE. An example is Hepatitis A (referred to by its old name of "Infectious Hepatitis" in the Red Book). This was previously paid under item of service for one dose as that was all that was available before the active vaccine was introduced in 1993, although it was always intended to cover courses of treatment this was not clear in the Red Book, and the new regulations now clearly states that "a *course* of immunisation should be offered".

The following travel immunisations are not prescribable as part of NHS services and are not remunerated by the NHS as part of additional services:

- Yellow Fever
- Japanese B encephalitis
- Tick borne encephalitis
- Rabies

The following travel immunisations that can be given as *either* NHS or as a private service:

- Hepatitis B (single agent) any dose
- Meningitis ACWY (quadrivalent meningococcal meningitis vaccine; A, C, Y and W135)

The regulations do not impose any circumstances or conditions as to when these immunisations should be given on the NHS or as a private service. In some areas local policy has been agreed with the LMC that seeks to exclude NHS provision, and practices should consider any such local policies. Most practices provide hepatitis B as part of a combined A+B vaccination rather than as a single agent, and this has been the focus of local attention. Ultimately the decision still resides with the practice. We would remind practices that there is no funding within GMS for hepatitis B for travel.

The list of travel immunisations available on the NHS is available in Appendix 2. Practices may choose to opt-out of providing the additional vaccines and immunisations service, but will as a result have their global sum abated by 2%. Practices opting out of the additional service will not be able to charge their registered patients for travel vaccines which are available on the NHS.

Schedule 5 of the NHS Regulations (see Appendix 4) lists all those services for which practices may choose to charge patients. This includes all vaccines requested for travel that are not paid for by the NHS. It also permits charging for prescribing or supplying malaria chemoprophylaxis and for other drugs and kits to be used for illnesses arising when abroad.

Detailed information about travel immunisations is available in *Focus on travel immunisations*.

APPENDIX 1 – Vaccines and immunisations for persons not travelling abroad

Based on Annex BA of the SFE[5] with comments from the GPC.

Disease	At-risk groups who should be vaccinated and number of doses
Anthrax	Persons at an identifiable risk of contracting anthrax should receive **four doses** of the vaccine (plus an annual reinforcing dose). This would mainly be those who come into contact with imported animal products. Also see note about occupational health on page 1 of this guide[9].
Diphtheria, Tetanus and Polio	a) Children under age of 6 years should be offered immunisation in accordance with Section 8 of the Childhood Immunisations Scheme[5] b) Those aged 6 years or over who have not had the full course of immunisation, or whose immunisation history is unknown should be offered either: i) **a primary course of three doses plus two reinforcing doses** at suitable time intervals; or ii) **as many doses as required to ensure that a full five dose schedule has been administered**, which ever is clinically appropriate[10].
Hepatitis A	Persons in residential care or those residing in an educational establishment who are exposed to a high risk of infection and for whom vaccination is recommended by the local Director of Public Health. **A course of immunisation** (the number of doses required will be dependent upon the chosen vaccine and should be sufficient to provide satisfactory long-term protection against the disease). This is an example where changes of the vaccine available (from single dose immunoglobulin to hepatitis A vaccine) mean that there are changes to the practice of administration requiring more than one dose.
Measles, Mumps and Rubella (MMR)	a) Children under 6 years should be offered MMR immunisation in accordance with the Childhood Immunisations Scheme (SFE[5], section 8). b) Children under 6 years should be offered a **second dose** as a follow up to the dose given under the Childhood Immunisations Scheme c) Children from age 6 to 15 years who have not previously received two doses or whose immunisation history is incomplete or unknown should be offered **one or two doses** (which ever is clinically appropriate) d) Women who may become, but are not pregnant and are sero-negative should be offered **one or two doses** (which ever is clinically appropriate) e) Male staff working in ante-natal clinics who are sero-negative should be offered **one or two doses** (which ever is clinically appropriate). Also see note on occupational health[9] and 'whenever clinically appropriate'[10].

[9] The new wording of the regulations makes it clearer that certain at-risk groups have been included. However, there is no funding within the global sum to provide the occupational health aspects of case finding, risk assessing and documenting. This is explained in more detail on page 1 of this guidance.

[10] The regulations use the words 'whichever clinically appropriate' to ensure that immunisation schedules for patients are completed, with primary and booster immunisations.

Meningococcal Group C	(a) Children under 6 years should be offered meningococcal immunisation and pneumococcal and Hib/MenC booster vaccine in accordance with the Childhood Immunisations Scheme (section 8 and 8A of the SFE)[5]. (b) Persons aged between 6 and not yet 25 years who have not been previously been immunised with conjugate meningococcal C vaccine, or whose immunisation history is incomplete or unknown, are to be offered **one dose** of conjugate meningococcal C vaccine.
Rabies	**Three doses** of the Rabies vaccine are to be offered to: a) laboratory workers handling rabies virus b) bat-handlers c) persons who regularly handle imported animals, such as those • at animal quarantine stations • at zoos • at animal research centres and acclimatisation centres • at ports where contact with imported animals occurs and this may include certain HM Revenue and Custom offices • persons carrying agents of imported animals • who are veterinary or technical staff in animal health d) animal control and wildlife workers who regularly travel in rabies enzootic areas e) health workers who are a risk of direct exposure to body fluids or tissue from a patient with confirmed or probable rabies. Reinforcing doses are to be provided at recommended intervals to those at continuing risk (according to the 'Green Book'[11]). Also see note regarding occupational health[9]
Typhoid	**A course of** typhoid vaccine is to be offered to a) hospital doctors, nurses and other staff likely to come into contact with cases of typhoid b) laboratory staff likely to handle material contaminated with typhoid organisms. The number of doses (including reinforcing doses) required will be dependent on the chosen vaccine and is to be offered so as to provide satisfactory protection against the disease. Also see note regarding occupational health[9]

Paratyphoid[12]	No vaccine currently exists for the immunisation of paratyphoid.
Smallpox[13]	The smallpox vaccine exists but is not currently available to Contractors.

[11] http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_079917
[12] No vaccine is currently available for paratyphoid. Should a vaccine become available a review would be considered and consultation would be required in accordance with section 87 of the National Health Service Act 2006.
[13] Routine vaccination of smallpox is not appropriate and no vaccine is available for use in general practice. Should it become appropriate to vaccinate, a review and consultation would be required (section 87 of the NHS 2006).

Appendix 2 - Vaccines and immunisations for persons travelling abroad

Contractors who offer and provide immunisations for travel must have regard to the guidance set out in the 'Green Book'[11] and the information provided by NaTHNaC[14].

Disease	Groups or persons affected who should be vaccinated
Cholera	**A course** of immunisation should be offered to persons travelling (a) to an area, as defined by NaTHNaC, where they may risk exposure to infections as a consequence of being in that area or (b) to a country where it is a condition of entry to that country that persons have been immunised. The appropriate course of immunisation is dependent on age and will consist of an initial course and a subsequent reinforcing course of immunisation. If more than two years have elapsed since the last course of immunisation, a new course of immunisation should be commenced.
Hepatitis A	**A course** of immunisation should be offered to persons travelling to areas, as defined by NaTHNaC, where the degree of exposure to infections is believed to be 'high'[15]. Persons who may be at a higher risk of infection include those who (a) intend to reside in an area for at least three months and may be exposed to hepatitis A during that period; or (a) if exposed to hepatitis A, may be less resistant to infection because of a pre-existing disease or condition or who are at risk of developing medical complications from exposure. The number of doses (either **two or three**) of the vaccine required will be dependent upon the chosen vaccine and should be sufficient to provide satisfactory long-term protection against the disease.
Poliomyelitis	a) **A course** of immunisation (using an age appropriate combined vaccine) should be offered to persons travelling (i) to an area, as defined by NaTHNaC, where they may risk exposure to infection as a consequence of being in that area; or (ii) to a country where it is a condition of entry to that country that persons have been immunised. (b) Children under the age of 6 years are to be offered immunisation in accordance with the Childhood Immunisations Scheme (Section 8)[Error! Bookmark not defined.]. (c) Persons aged 6 years and over who have not had the full course of immunisation or whose immunisation history is incomplete or unknown are to be offered, either (i) a **primary course of three doses plus two reinforcing doses** at suitable time intervals; or (ii) **as many doses as required** to ensure that a full five dose schedule has been administered, which ever is clinically appropriate[10].
Typhoid	**A course** of typhoid vaccine should be offered to persons travelling: (a) to an area, as defined by NaTHNaC, where they may risk exposure to infection as a consequence of being in that area; or (b) to a country where it is a condition of entry to that country that persons have been immunised. The number of doses (including reinforcing doses) required will be dependent on the chosen vaccine and is to be offered so as to provide satisfactory protection against the disease.

[14] National Travel Health Network and Centre (NaTHNaC) www.nathnac.org

[15] The NaTHNaC website only refers to risk which is assumed be 'significant'. The definition in the regulations is 'high', as 'significant' does not have any meaning in law and cannot be in the regulations. Since the risk can never be zero the wording in the regulations has to remain 'high'.

APPENDIX 3 – Extract from Additional Services section of NHS Regulations

The National Health Service (General Medical Services Contracts) Regulations 2004

SCHEDULE 2, Regulation 16 (Amended 30 April 2012)[16]

ADDITIONAL SERVICES

Vaccines and Immunisations

4. - (1) This paragraph applies to a contractor whose contract includes the provision of vaccines and immunisations but does not apply in the case of the provision of –

(a) childhood immunisations; and
(b) the combined Haemophilus influenza type B and Meningitis C booster vaccine.

(2) A contractor must comply with the requirements in sub-paragraph (3) and (4).

(3) The contractor must -

(a) offer to provide to patients, all vaccines and immunisations (other than those mentioned in sub-paragraph (1)(a) and (b)) of the type and in the circumstances which are set out in the GMS Statement of Financial Entitlements;

(b) taking into account the individual circumstances of the patient, consider whether immunisation ought to be administered by the contractor or other health professional or a prescription form ought to be provided for the purpose of the patient self-administering immunisation;

(c) provide appropriate information and advice to patients about such vaccines and immunisation;

(d) record in the patient's record, any refusal of the offer referred to in paragraph (a);

(e) where the offer is accepted and immunisation is to be administered by the contractor or other health professional, include in the patient's record -

(i) the patient's consent to immunisation or the name of the person who gave consent to immunisation and that person's relationship to the patient;

(ii) the batch numbers, expiry date and title of the vaccine;

(iii) the date of administration;

(iv) in the case where two vaccines are administrated by injection, in close succession, the route of the administration and the injection site of each vaccine;

(v) any contraindications to the vaccine; and

(vi) any adverse reactions to the vaccine; and

(f) where the offer is accepted and the immunisation is not to be administered by the contractor or other health professional, issue a prescription form for the purpose of self-administration by the patient.

(4) The contractor must ensure that all staff involved in the administration of immunisations are trained in the recognition and initial treatment of anaphylaxis.

[16] The National Health Service (Primary Medical Services) (Miscellaneous Amendments) Regulations 2012 , Schedule 2: http://www.legislation.gov.uk/uksi/2012/970/regulation/5/made

(5) In this paragraph “patient’s record” means the record which is kept in accordance with paragraph 73 of Schedule 6.

Childhood vaccines and immunisations

5. - (1) A contractor whose contract includes the provision of childhood vaccines and immunisations shall comply with the requirements in sub-paragraphs (2) and (3).

(2) The contractor shall -

(a) offer to provide to children, all vaccines and immunisations of the type and in the circumstances which are set out in the GMS Statement of Financial Entitlements,

(b) provide appropriate information and advice to patients and, where appropriate, their parents, about such vaccines and immunisations;

(c) record in the patient's record kept in accordance with paragraph 73 of Schedule 6 any refusal of the offer referred to in paragraph (a);

(d) where the offer is accepted, administer the immunisations and include in the patient's record kept in accordance with paragraph 73 of Schedule 6 -

(i) the name of the person who gave consent to the immunisation and his relationship to the patient;

(ii) the batch numbers, expiry date and title of the vaccine;

(iii) the date of administration;

(iv) in a case where two vaccines are administered in close succession, the route of administration and the injection site of each vaccine;

(v) any contraindications to the vaccine or immunisation; and

(vi) any adverse reactions to the vaccine or immunisation.

(3) The contractor shall ensure that all staff involved in administering vaccines are trained in the recognition and initial treatment of anaphylaxis.

APPENDIX 4 – Extract from Fees and Charges section of the NHS regulations[17]

The National Health Service (General Medical Services Contracts) Regulations 2004

SCHEDULE 5, Regulation 24

FEES AND CHARGES

1. The contractor may demand or accept a fee or other remuneration -

(a) from any statutory body for services rendered for the purposes of that body's statutory functions;

(b) from any body, employer or school for a routine medical examination of persons for whose welfare the body, employer or school is responsible, or an examination of such persons for the purpose of advising the body, employer or school of any administrative action they might take;

(c) for treatment which is not primary medical services or otherwise required to be provided under the contract and which is given -

(i) pursuant to the provisions of section 65 of the Act (accommodation and services for private patients), or

(ii) in a registered nursing home which is not providing services under that Act,

if, in either case, the person administering the treatment is serving on the staff of a hospital providing services under the Act as a specialist providing treatment of the kind the patient requires and if, within 7 days of giving the treatment, the contractor or the person providing the treatment supplies the Primary Care Trust, on a form provided by it for the purpose, with such information about the treatment as it may require;

(d) under section 158 of the Road Traffic Act 1988 (payment for emergency treatment of traffic casualties);

(e) when it treats a patient under regulation 24(3), in which case it shall be entitled to demand and accept a reasonable fee (recoverable in certain circumstances under regulation 24(4)) for any treatment given, if it gives the patient a receipt;

(f) for attending and examining (but not otherwise treating) a patient -

(i) at his request at a police station in connection with possible criminal proceedings against him,

(ii) at the request of a commercial, educational or not-for-profit organisation for the purpose of creating a medical report or certificate,

(iii) for the purpose of creating a medical report required in connection with an actual or potential claim for compensation by the patient;

(g) for treatment consisting of an immunisation for which no remuneration is payable by the Primary Care Trust and which is requested in connection with travel abroad;

(h) for prescribing or providing drugs, medicines or appliances (including a collection of such drugs, medicines or appliances in the form of a travel kit) which a patient requires to have in his possession solely in anticipation of the onset of an ailment or occurrence of an injury while he is outside the United Kingdom but for which he is not requiring treatment when the medicine is prescribed;

[17] http://www.legislation.gov.uk/uksi/2004/291/schedule/5/made

(i) for a medical examination -

(i) to enable a decision to be made whether or not it is inadvisable on medical grounds for a person to wear a seat belt, or

(ii) for the purpose of creating a report -

(aa) relating to a road traffic accident or criminal assault, or

(bb) that offers an opinion as to whether a patient is fit to travel;

(j) for testing the sight of a person to whom none of paragraphs (a), (b) or (c) of section 38(1) of the Act (arrangements for general ophthalmic services) applies (including by reason of regulations under section 38(6) of that Act);

(k) where it is a contractor which is authorised or required by a Primary Care Trust under regulation 20 of the Pharmaceutical Regulations or paragraphs 47 or 49 of Schedule 6 to provide drugs, medicines or appliances to a patient and provides for that patient, otherwise than by way of pharmaceutical services or dispensing services, any Scheduled drug;

(l) for prescribing or providing drugs or medicines for malaria chemoprophylaxis.