



The seasonal influenza immunisation programme

*Consultation: a review of the procurement of
seasonal flu vaccine*

DH INFORMATION READER BOX

Policy	Estates HR / Workforce Commissioning Management IM & T Planning / Finance Clinical Social Care / Partnership Working
Document Purpose	Consultation/Discussion
Gateway Reference	16071
Title	A Review of the Procurement of Seasonal Flu Vaccine 2011
Author	Immunisation Branch
Publication Date	25 May 2011
Target Audience	PCT CEs, NHS Trust CEs, SHA CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, PCT Chairs, GPs, Chief Pharmacists, PCT pharmaceutical advisers, PCT Directors of Public Health, Immunisation & Flu Co-ordinators, Lead nurses at PCTs, GP practice nurses,
Circulation List	Local Authority CEs, PCT PEC Chairs, NHS Trust Board Chairs, Directors of Finance, All pharmacists, Chairs of Infection Control committees, Consultants in Communicable Disease Control, Monitor, British Medical Association, Royal College of General Practitioners, Royal Pharmaceutical Society, Pharmaceutical Services Negotiating Committee, National Pharmacy Association, Company Chemists Association.
Description	The Government is considering the introduction of central procurement of seasonal vaccine. The consultation seeks views on these proposals.
Cross Ref	N/A
Superseded Docs	N/A
Action Required	N/A
Timing	Consultation deadline: 17 August 2011
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First published 25 May 2011

Published to DH website, in electronic PDF format only.

<http://consultations.dh.gov.uk/>

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Executive summary

1. The Public Health White Paper *Healthy lives, healthy people* set out the government's long-term vision for the future of public health in England. The plans outlined will transform public health and for the first time create a 'wellness' service: 'Public Health England' (PHE), to meet today's health challenges.
2. PHE is a dedicated new public health service that will take the place of the complex structures that exist today. It will be a professional and efficient service with a clear mission to achieve improvements in public health outcomes; provide effective protection from public health threats; and deliver best value and best results.
3. Some public health elements of primary care services will be funded from the public health budget, but commissioned by the new NHS Commissioning Board (NHSCB). Given the existing contractual arrangements in primary care commissioning for some immunisation programmes, the consultation on funding and commissioning routes for public health, which accompanied *Healthy lives, healthy people*, proposed that in future funds would be transferred from the public health budget to the NHSCB to allow them to commission some programmes. This would include the childhood, seasonal flu and pneumococcal (for older people) vaccination programmes. The NHSCB would be responsible for commissioning a service for the whole population. For programmes where GPs are not preferred providers, such as the flu vaccination, or where individual GPs opt out or are decommissioned from providing a service, the NHSCB would be able to commission services from alternative providers as appropriate (for example, community pharmacies) as well as GPs. We will publish our response to the consultation following careful analysis of comments on our proposals.
4. Although it is proposed that many aspects of public health will be devolved to local decision making, consideration of the existing system of local procurement of flu vaccine suggests that it does not provide the best approach within the NHS. In particular, the localised vaccine shortages experienced in the winter of 2010/11 suggest that a more robust procurement arrangement may be required.
5. The government is therefore considering the introduction of central procurement of seasonal flu vaccine. Any change to the current procurement system needs to be considered against the following criteria:
 - does it make the vaccine supply system more robust?
 - could it improve vaccine uptake?
 - what would be the implications for value for money of the vaccination programme?
6. This document sets out proposals for a new approach to seasonal flu vaccine procurement and seeks views on these proposals in light of the above criteria.

Introduction

7. The Public Health White Paper *Healthy lives, healthy people* set out the government's long-term vision for the future of public health in England. The plans outlined will transform public health and for the first time create a 'wellness' service: 'Public Health England' (PHE), to meet today's health challenges.
8. PHE is a new dedicated public health service that will take the place of the complex health structures that exist today. It will be a professional and efficient service with a clear mission to achieve improvements in public health outcomes: provide effective protection from public health threats; and deliver best value and best results.
9. Some public health elements of primary care services will be funded by PHE but commissioned by the NHS Commissioning Board (NHSCB) (in exercise of its own functions). Given the existing contractual arrangements in the GP contract for provision of some immunisation programmes, we propose that in future funds would be transferred from the public health budget to the NHSCB to allow them to commission those programmes. This would include the childhood and seasonal flu vaccination programmes. The NHSCB would be responsible for commissioning a service for the whole population. For programmes where GPs are not preferred providers, such as flu vaccinations, or where individual GPs opt out or are decommissioned from providing a service, the NHSCB would be able to commission services from alternative providers as appropriate (for example community pharmacies) as well as GPs.
10. Although many aspects of public health will be devolved to local decision making, consideration of the existing system of local procurement of flu vaccine suggests that this approach may not provide the best approach to ensuring the effective delivery of the seasonal flu vaccination programme. For these reasons, the government has initiated a review of the current arrangements for procurement of flu vaccine.
11. The universal vaccination programmes currently delivered by the National Health Service (NHS) in England include the routine childhood immunisation programme and the seasonal flu vaccination programme. Procurement of vaccine for these programmes is delivered in different ways:
 - **vaccines for the routine childhood programme** are procured centrally by the Department of Health (DH), and distributed directly to GPs. Most GPs are paid for provision of the service through arrangements laid down in the GP contract and related statement of financial entitlement. GPs have preferred provider status for delivering childhood immunisations.
 - **vaccines for the seasonal flu vaccination programme** are ordered directly by GPs or other contractors (hereafter referred to as GPs) from the manufacturers or suppliers. GPs are paid for provision of the service through arrangements set out in the GP contract and agreed locally. GPs do not have preferred provider status for delivering the seasonal flu vaccination programme. PCTs are free to contract with alternative providers, for example some PCTs are commissioning community pharmacists to support the seasonal flu vaccination programme.

12. Vaccine supply problems caused by manufacturing difficulties in 2005 led to the *Review of the arrangements for the seasonal influenza programme in England*¹, an independent review of the arrangements for the seasonal flu programme in England. The review concluded that a central negotiation of the cost of flu vaccine between DH and vaccine manufacturers could be implemented. This centrally negotiated discounted price would have been used as the reimbursable price applied to GP claims, which would in turn have reduced the overall cost of the programme by an estimated £20-30m. The 2005 flu review recommendations were not taken forward. Since then there have been continuous developments in the use of online ordering of other vaccines, including the pandemic flu vaccine and making it available for use at short notice in January 2011, with sophisticated systems now in place for vaccine ordering and tracking.
13. This consultation on seasonal flu vaccine procurement focuses on securing the best value service for the NHS, whilst also seeking to ensure a robust supply of vaccine and improve vaccine uptake. GPs are best placed to know how much vaccine is required for their eligible populations, and DH is not proposing to change this. Any procurement system will still rely heavily on GPs to provide accurate and timely information on the needs of their populations so that the correct amount of vaccine can be ordered. No changes are proposed to the arrangements for seasonal flu vaccine supplies purchased for private use.
14. This consultation seeks views on the future arrangements for procurement of seasonal flu vaccines.

Background

The seasonal influenza immunisation programme

15. Effective and safe vaccines remain the cornerstone of influenza prophylaxis in most countries. Influenza immunisation has been recommended in the UK since the late 1960s, with the aim of directly protecting those in clinical risk groups at a higher risk of serious morbidity and mortality. In 2000, the policy was extended to include all people aged 65 years or over. A list of the current groups eligible for seasonal flu vaccination is set out below (table 1). A more detailed list of the eligible groups is set out in the Chief Medical Officer's (CMO) letter of 25 May 2011, available here: www.dh.gov.uk/en/Publichealth/Immunisation/Officialimmunisationletters/index.htm#jumpTo1

Table 1. Patient groups that should be vaccinated in the 2011 flu season

Patient groups to be vaccinated
People aged 65 years and over
All those aged six months or over in a clinical risk group
All pregnant women
People living in long-stay residential care homes or other long-stay care facilities where there is a risk of high morbidity and mortality
Those who are in receipt of a carer's allowance, or those who are the main carer, or the carer of an elderly or disabled person whose welfare may be at risk if the carer falls ill.
Frontline health and social care workers

16. DH has commissioned the Health Protection Agency (HPA) to conduct a comprehensive study of the effectiveness and cost-effectiveness of the current seasonal flu vaccination programme, and of possible extensions to it. This study is due to be completed in 2011. Any changes to recommendations arising from this study would not be implemented before the 2012 flu vaccination programme.

Current arrangements for procurement of vaccines

17. The seasonal flu vaccination programme is delivered primarily by GPs, although some PCTs also commission community pharmacists and community nurses to implement the programme. The majority of patients receiving flu vaccine are immunised during the period from September to November but the campaign may continue until February (this is particularly relevant with the introduction of pregnant women as an eligible group, as women become pregnant, and therefore eligible for the vaccine, throughout the flu season).
18. It is the responsibility of GPs to purchase sufficient vaccine for the needs of their eligible populations. The current arrangement for the purchase and supply of seasonal flu vaccine is a private one between GPs, vaccine manufacturers and their distributors. The arrangements place the responsibility, financial and administrative burdens on GPs.

19. This is in contrast to the central purchase of childhood vaccines, where DH procures vaccine from the manufacturers and has a central contract for distributing the vaccines free of charge to the NHS. Through careful stock management and forecasting, the appropriate quantities of vaccines can be ordered and levels maintained throughout the financial year. Where equivalent products are available, contracts are awarded to more than one manufacturer in order to reduce the risk associated with having a sole supplier. The central procurement process results in securing vaccine at favourable prices due to the size of the procurement.
20. However, the routine childhood immunisation programme is a continuous programme throughout the year with relatively few seasonal spikes. This means that it is easier to forecast the stock requirements and deal with surpluses or shortages of a particular vaccine. By contrast, the seasonal flu programme runs over a short period with large quantities of vaccines being distributed and implemented across the country within a space of only a few months. It is, therefore, likely to be more difficult than for the childhood programme to accommodate any surpluses or shortages through central procurement. The main benefit of central procurement would therefore be the savings that could be achieved for the NHS, estimated to be £40m a year.

Current seasonal flu vaccine procurement timetable

21. The key stages of the current procurement process are:

- 21.1. Annually, usually between December and January (but as early as August and as late as March), GP practices order vaccine for the forthcoming flu season. The rationale underpinning how much vaccine is ordered may vary; it may be based on previous years' ordering, expected or previous uptake, or an analysis of their target population size. The practice negotiates directly with their flu vaccine suppliers to obtain stocks of vaccine.
- 21.2. Staged delivery dates for batches of the vaccine between September and November are agreed between the GP practice and the supplier.
- 21.3. The CMO writes to the NHS in the spring setting out the seasonal flu immunisation programme for the coming winter. Practices then identify those patients on their practice list that fall into the eligible groups specified in the letter. Where necessary, GPs may need to amend the number of vaccines ordered.
- 21.4. If a GP overestimates the amount of stock they need, some suppliers have arrangements for unused stock to be returned by GPs with variable levels of reimbursement. Returns usually take place from December onwards.
- 21.5. Any additional stocks of vaccine needed by GPs may be fulfilled by suppliers later in the season if available.

Payments to GPs

22. The contractual arrangements under the General Medical Services (GMS) Influenza and Pneumococcal Directly Enhanced Service (DES) agreement², set out that PCTs' plans must include payment arrangements with the contractors, and these are set locally.

23. GPs currently receive:

- an item of service (IoS) payment for administering the vaccine
- an administration fee for procuring the vaccine
- reimbursement for the cost of the vaccine
- payments under the Quality and Outcomes Framework (QOF)³ to reward practices achieving certain levels of uptake in specified at risk groups

24. In total these payments amount to approximately £17 per dose of seasonal flu vaccine administered.

Improving seasonal flu vaccine procurement

25. During the 2010/11 flu season the NHS experienced localised shortages of seasonal flu vaccine. Where possible, PCTs managed the shortages by redistributing stock between GP practices. However, DH intervened to release monovalent vaccine from the pandemic stockpile to help alleviate local shortages, while efforts were also made to source and import supplies of trivalent vaccine.

26. This was not a unique experience. Since 2005, there have been two years when there were shortages of seasonal flu vaccine, although there has also been one year when practices returned considerable quantities of surplus vaccines to suppliers.

27. The government wishes to reduce the risk of similar shortfalls in stock for future years. It believes that central procurement would assist with this by allowing greater flexibility in deployment of stock and the possibility of building in a small strategic reserve, over and above GP requirements.

A central procurement process for seasonal flu vaccine

28. Under a central procurement process, DH would hold a contract or contracts to supply flu vaccine to GPs in England. A central tendering exercise would be carried out by DH to purchase all the flu vaccine required for the NHS in England. This could match the system used for the childhood vaccination programme.
29. DH would estimate the amount of vaccine needed for the next flu season based on data provided by GPs and other vaccination providers giving accurate data on their vaccine requirements. As now, GPs would need to identify their eligible populations and planned uptake rates. This could be audited using samples of GPs by comparing their orders against the central data on GPs' eligible populations.
30. DH would need to place separate contracts under EU procurement regulations with several manufacturers to ensure vaccines were available in sufficient quantities.
31. GPs would place orders for seasonal flu vaccine through ImmForm, the online ordering system already used by all GPs to order their childhood vaccines. This would make use of an existing, cost effective and straightforward ordering process. GPs could estimate their vaccine stock requirements as they do at present and, where possible, would retain some degree of choice over which flu vaccine they received, subject to the number of contracts placed with manufacturers.
32. This system would allow for automatic alerts to be triggered if GPs used more vaccine than they had initially requested. This strategic management could enable an early warning mechanism to spot possible local shortages and would enable DH to make rapid arrangements with manufacturers to purchase any additional available stock to maintain vaccine supply.
33. DH would explore the options available to allow for changes in orders late in the season. GPs would maintain control over vaccine ordering but would not need to procure vaccine, reducing their administrative burden and the administration fees paid in recognition of this work.
34. We will consider the best way of distributing the vaccine – either centrally or direct from manufacturers.

Impact of central procurement on delivery of the seasonal flu vaccination programme

35. The NHS must always seek to achieve the best results at the best value. As well as considering the need to enhance the robustness of the supply of vaccine, the potential impact of central procurement on efforts to improve vaccine uptake and value for money need to be considered.

Impact on vaccine uptake

36. Uptake of the seasonal flu vaccine for those aged 65 and over has stalled in recent years, and uptake for those in the clinical risk groups is only rising very slowly (Fig 1). People in at risk groups are more than 15 times more likely to die from flu than healthy people, so it is important that as many patients as possible in risk groups are vaccinated. The World Health Organization (WHO) has set a target that 75% of people aged 65 and over should be vaccinated against seasonal flu annually. This is matched by an EU target that 75% of all people aged under 65 in at risk groups, including pregnant women, should be vaccinated annually.

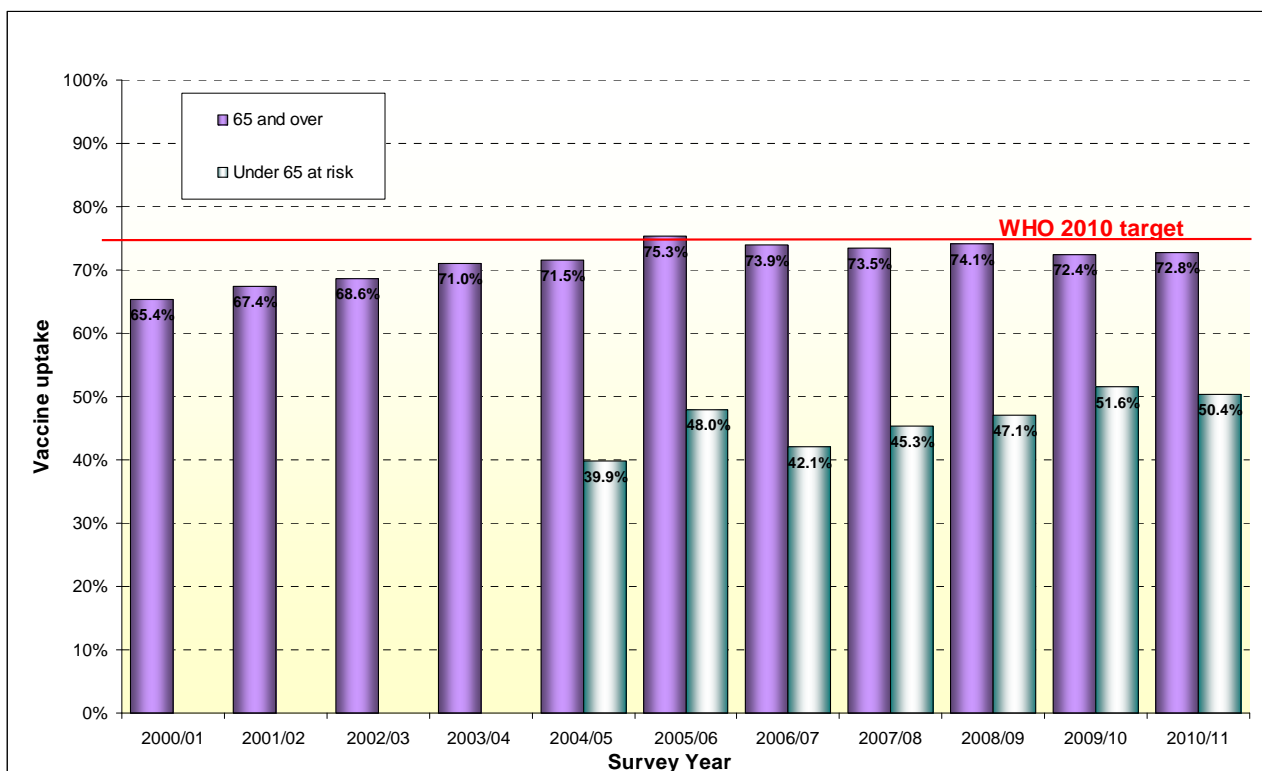


Figure 1: Seasonal influenza vaccine percentage uptake by year for England

37. Under current arrangements GPs incur a financial risk in seeking to improve vaccine uptake rates, as they have to purchase additional vaccine at the start of the season which may then not be used. Although some manufacturers offer a sale or return facility, this is generally limited in scope. Under central procurement GPs would no longer incur this risk.

Value for money

38. The total cost of the seasonal flu vaccination programme is approximately £180 million each year. The government believes that there may be scope to reduce these costs through the introduction of central procurement of seasonal flu vaccine.

39. Under central procurement, vaccine administration costs and QOF payments would be unchanged. However, the cost of the administration fee currently paid to GPs in recognition of work to procure the vaccine would be saved. This currently costs up to about £20m each year. Bulk procurement of vaccine would also be expected to achieve savings on the cost of the vaccine itself, estimated at a further £20-25m. This is in line with the findings of the 2007 flu review, which predicted savings of £20-30m using a centrally negotiated price.

40. Estimates of the national cost of the seasonal flu payment system under the current arrangements and using central procurement are set out below.

Table 2 Approximate cost of flu vaccine procurement

	Current system	Central procurement
Item of Service payment	£77 million	£77 million
Quality Outcomes Framework payment	£20 million	£20 million
Administration fee for procurement	£21 million	n/a (approx £5 million central costs)
Cost of vaccine	Approx £62 million (average £6.21 per dose reimbursement from PCTs)	Approx £40 million (based on an assumed average price of £4 per dose)
Cost to the Exchequer	£180 million	£142 million

41. There would be some increase in central costs to run the procurement, estimated at £5m, but this is substantially less than the potential saving.

Consultation questions

The government recognises that a change of this nature would have implications – both beneficial and potentially adverse - for the delivery of the vaccination programme. The government is keen to make sure that the decision about whether or not to proceed is informed by the expertise of relevant organisations and individuals. It would therefore welcome views on the following questions:

1	Do you agree that central procurement of seasonal flu vaccine would help improve the robustness of vaccine supply?
2	What benefits or disadvantages would central procurement of vaccine have for efforts to improve vaccine uptake?
3a	Are there any considerations in relation to the value for money of the seasonal flu vaccination programme other than those set out in the Impact Assessment, that should be taken into account?
3b	Would central procurement have an additional impact on GP finances in relation to any profits arising from directly procuring vaccine at a lower price than the NHS reimbursement? (See paragraph 59 of the Impact Assessment).
4	Are there any other points the government should consider?

How to respond

Consultation on the specific questions as set out above closes **on 17 August 2011**. You can contribute to the consultation by providing written comments to:

By website: <http://consultations.dh.gov.uk/>

By email: fluconsultation@dh.gsi.gov.uk

By post: Flu Consultation
Immunisation Branch
Department of Health
Room 504 Wellington House
133-155 Waterloo Road
London SE1 8UG

The consultation process

Criteria for consultation

This consultation follows the 'Government Code of Practice', in particular we aim to:

- formally consult at a stage where there is scope to influence the policy outcome;
- consult for at least 12 weeks with consideration given to longer timescales where feasible and sensible;
- be clear about the consultation's process in the consultation documents, what is being proposed, the scope to influence and the expected costs and benefits of the proposals;
- ensure the consultation exercise is designed to be accessible to, and clearly targeted at, those people it is intended to reach;
- keep the burden of consultation to a minimum to ensure consultations are effective and to obtain consultees' 'buy-in' to the process;
- analyse responses carefully and give clear feedback to participants following the consultation;
- ensure officials running consultations are guided in how to run an effective consultation; and
- exercise and share what they learn from the experience.

The full text of the code of practice is on the Better Regulation website at:

www.bis.gov.uk/policies/better-regulation/consultation-guidance

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Co-ordinator
Department of Health
3E48, Quarry House
Leeds
LS2 7UE
e-mail consultations.co-ordinator@dh.gsi.gov.uk

Please do not send consultation responses to this address.

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the Department of Health's Information Charter at:

www.dh.gov.uk/en/FreedomOfInformation/DH_088010

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and, in most circumstances; this will mean that your personal data will not be disclosed to third parties.

Summary of the consultation response

A summary of the response to this consultation will be made available before or alongside any further action, and will be placed on the Consultations website at

www.dh.gov.uk/en/Consultations/Responsestoconsultations/index.htm

References

¹ Review of the arrangements for the seasonal influenza programme in England – report of an independent panel - March 2007

http://webarchive.nationalarchives.gov.uk/+www.dh.gov.uk/en/Publichealth/Flu/Flugeneralinformation/DH_072767

² The Primary Medical Services (Directed Enhanced Services)(England) Directions 2006

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_4133121

³ Statement of financial entitlement

www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_097632