Title: Consultation: A Review of the Procurement of Seasonal Flu Vaccine 2011 Lead department or agency: **Department of Health** Other departments or agencies:	**Impact Assessment (IA)** **IA No:** 3056 **Date:** 05/05/2011 **Stage:** Consultation **Source of intervention:** Domestic **Type of measure:** Other

Summary: Intervention and Options

What is the problem under consideration? Why is government intervention necessary?

Assessment of the existing system of local procurement of flu vaccine suggests that it does not provide the most effective or efficient approach. Savings can be achieved through a more centralised purchasing scheme, so that resources can be reinvested elsewhere. The current arrangements for procuring seasonal flu vaccine leave GPs and public at risk: either of GPs being left with a large surplus and potentially leaving them out of pocket; or alternately experiencing a shortfall in supply and therefore being unable to vaccinate everyone in their area who is eligible for the programme. Therefore a different approach to supply of vaccine may both better safeguard public and GPs in delivering vaccinations. In addition, the localised vaccine shortages experienced in the winter of 2010/2012.

What are the policy objectives and the intended effects?

The policy objective is to determine whether to change current arrangements for procuring seasonal flu vaccine for the NHS in England, in which GPs order vaccine directly from manufacturers or suppliers for their eligible patients, to a system of centralised procurement. Central procurement would help prevent vaccine shortages by allowing greater flexibility in deployment of stock and the possibility of building in a small strategic reserve, over and above GP requirements.The total cost of the seasonal flu vaccination programme is approximately £180 million each year. There may be scope to reduce these costs through the introduction of central procurement of seasonal flu vaccine. The consultation questions are in Annex 4.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

1. Do Nothing
2. Introduce a central procurement process for seasonal influenza vaccines

Preferred option: Option 2 - Introduce an 'in-house' procurement process for seasonal influenza vaccines

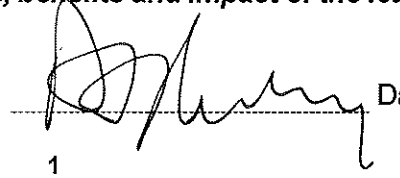
Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 6/2014

What is the basis for this review? Please select. **If applicable, set sunset clause date:** Month/Year

Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review? Yes

SELECT SIGNATORY Sign-off For consultation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible SELECT SIGNATORY:  Date: 24 May 2011

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Summary: Analysis and Evidence

Policy Option 1

Description:

Do nothing.

Price Base Year	PV Base Year	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
	2011		Low: **Optional**	High: **Optional**	Best Estimate: 0

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	Optional		Optional	**0**
High	Optional		Optional	**0**
Best Estimate				**0**

Description and scale of key monetised costs by 'main affected groups'

The current annual cost of the seasonal flu vaccination programme is estimated to be approximately £180m. This will be unaffected by the do nothing option, therefore additional costs are 0.
Please see paragraphs 8-21 of the evidence section.

Other key non-monetised costs by 'main affected groups'

Please see paragraphs 8-21 of the evidence section.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	Optional		Optional	**0**
High	Optional		Optional	**0**
Best Estimate				**0**

Description and scale of key monetised benefits by 'main affected groups'

The benefits of the seasonal flu vaccination programme will be unaffected by the do nothing option, therefore additional benefits are 0.
Please see paragraphs 8-21 of the evidence section.

Other key non-monetised benefits by 'main affected groups'

Please see paragraphs 8-21 of the evidence section.

Key assumptions/sensitivities/risks **Discount rate (%)** NA

Please see paragraphs 8-21 of the evidence section.

Direct impact on business (Equivalent Annual) £m):			**In scope of OIOO?**	**Measure qualifies as**
Costs:	**Benefits:**	**Net:**	No	NA

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			Existing policy		
Which organisation(s) will enforce the policy?			N/A		
What is the annual change in enforcement cost (£m)?			N/A		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			No		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** N/A	**Benefits:** N/A	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	
Small firms Small Firms Impact Test guidance	No	
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	
Human rights Human Rights Impact Test guidance	No	
Justice system Justice Impact Test guidance	No	
Rural proofing Rural Proofing Impact Test guidance	No	
Sustainable development Sustainable Development Impact Test guidance	No	

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Summary: Analysis and Evidence

Policy Option 2

Description:

DH tender for a direct contract for flu vaccine - distribution by manufacturers or specialised cold chain

Price Base Year	PV Base Year **2011**	Time Period Years **10**	Net Benefit (Present Value (PV)) (£m)		
			Low: **£299m**	High: **£340m**	Best Estimate: £320m

COSTS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Cost** (Present Value)
Low	£0		£81m	
High	£0		£85m	
Best Estimate	£0		£83m	**£686m**

Description and scale of key monetised costs by 'main affected groups'

Costs include: i) costs to the Department of Health (administration, wastage, overordering risk); ii) costs to GPs (in terms of loss in profit from no longer being reimbursed above the price paid for the vaccine); and iii) costs to the manufacturers (in terms of loss of revenue, if the Department were able to secure a higher discount in vaccine purchasing price as a larger purchaser). This is a public sector focussed IA.

Other key non-monetised costs by 'main affected groups'

Key non-monetised costs include i) unknown outcome of the negotiations with GPC ii) possible reduced choice for GPs in choosing the vaccine to use in their practice; iii) possible negative impact on vaccine coverage as a result of changed financial incentives to vaccinate for the GP.

BENEFITS (£m)	**Total Transition** (Constant Price)	Years	**Average Annual** (excl. Transition) (Constant Price)	**Total Benefit** (Present Value)
Low	£0		£117m	
High	£0		£126m	
Best Estimate	£0		£122m	**£1,006m**

Description and scale of key monetised benefits by 'main affected groups'

Benefits include: i) benefits to the Department of Health (reduced vaccine price reimbursement, reduced cost of paying personal administration fees, possible bulk purchasing discount above that secured by GPs); ii) benefits to GPs (from no longer holding the financial risk for wastage and over-ordering); iii) reduced local administration costs (from no longer having to administer payments to GPs for procuring vaccine).

Other key non-monetised benefits by 'main affected groups'

There may be some benefits from a centralised system associated with the availability of data to make future decisions. A centralised system of ordering would allow DH to monitor vaccine supplied locally and nationally, and wastage levels more effectively. Reduction in the incentives to return stock before the end of the flu season could lead to better availability of vaccine for patients who attend late for vaccination. Benefits to manufacturers in terms of reduced admin costs from fewer negot

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

See "Other key non-monetised costs by 'main affected groups'".

DH funds (including GP impacts) include an opportunity cost of funds of 2.4 (see Annex 2)

Direct impact on business (Equivalent Annual) £m):			**In scope of OIOO?**	**Measure qualifies as**
Costs:	**Benefits:**	**Net:**	No	NA

Enforcement, Implementation and Wider Impacts

What is the geographic coverage of the policy/option?			England		
From what date will the policy be implemented?			Depends on outcome		
Which organisation(s) will enforce the policy?			N/A		
What is the annual change in enforcement cost (£m)?			N/a		
Does enforcement comply with Hampton principles?			Yes		
Does implementation go beyond minimum EU requirements?			N/A		
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)			**Traded:** N/A	**Non-traded:** N/A	
Does the proposal have an impact on competition?			No		
What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable?			**Costs:** N/A	**Benefits:** N/A	
Distribution of annual cost (%) by organisation size (excl. Transition) (Constant Price)	**Micro**	**< 20**	**Small**	**Medium**	**Large**
Are any of these organisations exempt?	No	No	No	No	No

Specific Impact Tests: Checklist

Set out in the table below where information on any SITs undertaken as part of the analysis of the policy options can be found in the evidence base. For guidance on how to complete each test, double-click on the link for the guidance provided by the relevant department.

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

Does your policy option/proposal have an impact on…?	**Impact**	**Page ref within IA**
Statutory equality duties[1] Statutory Equality Duties Impact Test guidance	No	17
Economic impacts		
Competition Competition Assessment Impact Test guidance	No	18
Small firms Small Firms Impact Test guidance	No	18
Environmental impacts		
Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance	No	18
Wider environmental issues Wider Environmental Issues Impact Test guidance	No	18
Social impacts		
Health and well-being Health and Well-being Impact Test guidance	No	18
Human rights Human Rights Impact Test guidance	No	18
Justice system Justice Impact Test guidance	No	18
Rural proofing Rural Proofing Impact Test guidance	No	18
Sustainable development Sustainable Development Impact Test guidance	No	18

[1] Public bodies including Whitehall departments are required to consider the impact of their policies and measures on race, disability and gender. It is intended to extend this consideration requirement under the Equality Act 2010 to cover age, sexual orientation, religion or belief and gender reassignment from April 2011 (to Great Britain only). The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

References

Include the links to relevant legislation and publications, such as public impact assessments of earlier stages (e.g. Consultation, Final, Enactment) and those of the matching IN or OUTs measures.

No.	Legislation or publication
1	
2	
3	
4	

+ Add another row

Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

Annual profile of monetised costs and benefits* - (£m) constant prices

	Y_0	Y_1	Y_2	Y_3	Y_4	Y_5	Y_6	Y_7	Y_8	Y_9
Transition costs										
Annual recurring cost										
Total annual costs										
Transition benefits										
Annual recurring benefits										
Total annual benefits										

* For non-monetised benefits please see summary pages and main evidence base section

Microsoft Office
Excel Worksheet

Evidence Base (for summary sheets)

There is discretion for departments and regulators as to how to set out the evidence base. However, it is desirable that the following points are covered:

- Problem under consideration;
- Rationale for intervention;
- Policy objective;
- Description of options considered (including do nothing);
- Costs and benefits of each option (including administrative burden);
- Risks and assumptions;
- Direct costs and benefits to business calculations (following OIOO methodology);
- Wider impacts;
- Summary and preferred option with description of implementation plan.

Inserting text for this section:

Evidence Base (for summary sheets)

A: Problem under consideration

1. The vaccination programmes delivered by the National Health Service (NHS) in England include the routine childhood immunisation programme and the pneumococcal and seasonal influenza vaccination programme. Vaccines for the routine childhood programme are centrally procured by the Department of Health (DH) and distributed directly to GPs (or in the case of the human papillomavirus vaccine to Primary Care Trusts) who order vaccine via ImmForm, a central, online vaccine ordering system. Vaccine is then delivered by a commercial cold chain distributer. At present, adult vaccines are not procured or distributed in this way. However, this approach was used for the 2009/10 H1N1 pandemic influenza vaccine. This consultation asks whether seasonal flu vaccines should be procured centrally, and if so how. Any change to the current procurement system would aim to:

   - provide better value for money for the NHS;
   - aim to maintain and possibly improve vaccination uptake by patients;
   - help assure continuity and consistency of vaccine supplies, ensuring sufficient supplies are available for target groups; and
   - reduce the administrative burden at local level by centralising and simplifying the system.

2. This is not the first time that procurement of seasonal flu vaccines has been examined. Vaccine supply problems in 2005 led to the "Review of the Arrangements for the Seasonal Influenza Programme in England" (the Flu Review)[3], an independent review of the arrangements for the seasonal influenza programme in England. The review recommended changes to the procurement and supply of seasonal vaccines through a reduction in the list price, which would in turn have reduced the overall cost of the programme by an estimated £20-30m. However, this was not taken forward as it relied on changes to the Pharmaceutical Price Regulation Scheme (PPRS), which would have had much wider implications.

[3] 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

Evidence / background

3. Influenza is usually a self-limiting infection in healthy people, but can be associated with substantial morbidity and mortality[4]. Influenza viruses can cause disease among persons in any age group but school age children are efficient transmitters of influenza viruses and typically are those in whom rates of infection are highest[5,6]. However, severe morbidity and mortality are usually highest among older people, children under six months of age, and persons of any age who have medical conditions that place them at increased risk of complications from influenza ([1,4,7]).

4. A modelling study estimating the burden of influenza in England and Wales suggested that annually there might be between 779,000 and 1,164,000 GP consultations, between 19,000 and 31,200 hospital admissions and between 18,500 and 24,800 deaths attributable to influenza infections, although the confidence intervals around these figures were wide [8]. Annual influenza vaccination is the most effective method for preventing influenza virus infection and its complications. Influenza viruses undergo frequent changes. Immunity resulting from infection by one strain of influenza may not protect fully against infection from new strains. Influenza outbreaks occur every year. New influenza vaccines must be designed annually to match the circulating viruses which are expected to be the predominant circulating strains in the coming year.

5. Efficacious 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 (including those with chronic respiratory disease, chronic heart disease, chronic kidney disease, chronic neurological disease, diabetes and that are immunosuppressed[9]). In 2000, the policy was extended to include all people aged 65 years or over. The annual influenza vaccination campaign in England achieves uptake levels of around 73% of those aged 65 years and over, which is among the highest in Europe[10].

6. Whilst there have been calls for further studies to allow better quantification of the benefits of influenza vaccination[11,12], it is clear that influenza vaccination programmes can have a significant public health impact. Studies have shown that influenza vaccines can offer approximately 70–90% protection against clinical disease in young healthy adults, provided there is a good match between the influenza strains used to make the vaccine and the strains of virus that subsequently circulate, although people become less responsive to the vaccine in older ages[13]. Influenza vaccination has also been shown to be effective in people aged under 65 years in clinical risk groups and in those aged 65 years and older from a study of data collected from combined clinical and virological community surveillance in England and Wales[14]. In addition, large observational studies from the United States have provided evidence that in

[4] Nicholson KG, Wood JM, Zambon M. Influenza. Lancet 2003;362(9397):1733–45.
[5] Stephenson I and Zambon M. The epidemiology of influenza. 2002:52:241-247.
[6] Glezen WP, Greenberg SB, Atmar RL, Piedra PA, Couch RB. Impact of respiratory virus infections on persons with chronic underlying conditions. JAMA 2000;283:499–505.
[7] Barker WH, Mullooly JP. Impact of epidemic type A influenza in a defined adult population. Am J Epidemiol 1980;112:798–811
[8] Pitman RJ *et al.* Assessing the burden of influenza and other respiratory infections in England and Wales.J. Infect. 2007:54:530-538.
[9] Green Book Chapter 19 - Influenza
[10] Blank PR, Schwenkglenks M, Szucs TD. (2008) Influenza vaccination coverage rates in five European countries during season 2006/7 and trends over six consecutive seasons. *BMC Public Health* 2008;8:272
[11] Simonsen L, Taylor RJ, Viboud C, Miller MA, Jackson LA. (2007) Mortality benefits of influenza vaccination in elderly people: an ongoing controversy. *Lancet Infect Dis* 2007;7:658-66.
[12] Jefferson T et al. Vaccines for preventing influenza in the elderly (review). Cochrane Database of Systematic Reviews. 2010
[13] Goodwin K et al. Antibody response to influenza vaccination in the elderly: a quantitative review. 2006:24:1159-1169.
[14] Fleming DM et al. Estimating influenza vaccine effectiveness using routinely collected laboratory data. J. Epidemiol. Community Health. 2009.

the over 65s the vaccine reduces hospital admissions for pneumonia and influenza by 27%[15] and all cause mortality by 48%[16]. Smaller UK studies have shown similar results[17,18].

7. To quantify better the effect of influenza vaccination in the UK, DH has commissioned the HPA to conduct a comprehensive study of the impact and cost-effectiveness of the UK's seasonal influenza programme and possible extensions to it. This study is expected to complete in 2011.

Existing arrangements for the procurement of seasonal flu vaccine

8. The seasonal influenza vaccination programme is delivered primarily by GPs. Contractual arrangements under the Influenza and Pneumococcal Immunisation Scheme Directed Enhanced Service (DES)[19] and the GMS Statement of Financial Entitlements provide for remuneration and incentive payments to GPs delivering the vaccine to specified 'at-risk' groups. The majority of patients receiving influenza vaccine are immunised during the period from September to November but the programme is not usually completed until January.

9. The current arrangement for the purchase and the supply of seasonal influenza vaccine is a private arrangement between GPs and vaccine manufacturers. GPs order stocks of influenza vaccine direct from the supplier. This requires little direct input (budgetary or otherwise) from the centre, though it does present an administrative burden to both GPs and PCTs. This is in contrast to the central purchase of childhood vaccines, described earlier.

10. Each year the DH writes to all healthcare providers, including GPs, setting out the arrangements for flu vaccination for the coming season[20]. The letter includes the composition of the vaccine, which manufacturers will supply vaccine and to whom the vaccine should be offered on the NHS.

Key elements of the existing system

11. In December to January each year, GP Practices order vaccine for the forthcoming flu season based on previous years' uptake figures and estimates of the number of their patients likely to be in the target population. The practice contracts directly with the flu vaccine suppliers and wholesalers to obtain stocks of vaccine.

12. Staged delivery dates for batches of the vaccine between September and November are agreed.

13. Following receipt of DH's Professional Letter on seasonal flu vaccination, usually issued in the spring, GPs identify those patients on their practice list that fall within the groups that have been identified to be offered the seasonal flu vaccination.

14. If a GP has overestimated the amount of stock they need, some suppliers and wholesalers have arrangements for unused stock to be returned by GPs. Seasonal flu vaccine is licensed to cover one flu season as the composition of flu vaccine can change annually.

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[15] Barker WH. Excess pneumonia and influenza associated hospitalization during influenza epidemics in the United States, 1970–78. Am J Public Health 1986;76:761–5

[16] Nichol KL, Nordin JD, Nelson DB, Mullooly JP, Hak E. Effectiveness of 3 influenza vaccine in the community-dwelling elderly. *N Engl J Med* 2007;357:1373-81.

[17] Ahmed A et al. (1995) Reduction in mortality associated with influenza vaccine during 1989-90 epidemic. Lancet. 346, 591-595.

[18] Ahmed A et al. (1997) Effectiveness of influenza vaccine in reducing hospital admissions during the 1989-90 epidemic. Epidemiol. Infect. 118, 27-33.

[19] The Primary Medical Services (Directed Enhanced Services)(England) Directions 2006 – paragraph 9 http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsLegislation/DH_4133121

[20] The influenza immunisation programme 2010/11 – Professional Letter: Annex 1 http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Professionalletters/Chiefmedicalofficerletters/DH_116507

GP remuneration for providing flu vaccinations (existing system)

15. As set out above, GPs themselves currently order stocks of flu vaccine direct from the suppliers. GPs are then reimbursed on administered stock by their PCT for the list price of the vaccine less a discount ranging from 3.17% to 11.18% depending on the total basic price of vaccinations given in a month[21]. Since GPs usually purchase vaccine at a discounted price (estimated to be between 30 and 40% below list price[22]) they retain the resulting surplus.

16. GPs claim a Personal Administration (PA) Fee from the PCT for each vaccination given of between £1.87 and £2.11 per dose[23]. The PA fee is paid in recognition of the work required to procure vaccine but is not based on any estimate of the cost of that work.

17. An Item of Service Charge is paid by the PCT (locally agreed but often around £7.64 per dose) for each vaccination given by GP practices.

18. In some cases, Local Enhanced Service (LES) agreements are also negotiated to meet a local need or to provide for vaccination of target groups which are not covered by the Influenza and Pneumococcal DES agreement[24].

19. In addition, Quality and Outcomes Framework payments[25]; reward practices for the percentage (above a threshold) of patients with the following conditions who receive seasonal flu immunisation:

    - Chronic Heart Disease (≥40 – 90%)
    - Transient ischemic attack, or stroke (≥40 – 85%)
    - Diabetes (≥40 – 85%)
    - Chronic Obstructive Pulmonary Disease (≥40 – 85%)

Arguments for retaining or changing the existing system

20. There are some clear arguments for retaining the current system of influenza vaccine procurement. It is arguable that uptake of the influenza vaccine has remained reasonably high over the last few years, just below the WHO 2010 target of 75% uptake in people aged 65 years and over[26]. However, the uptake of the flu vaccine for those aged 65 and over has remained steady over recent years, and uptake for those aged under 65 is somewhat lower and rising only very slowly (see Figure 2 in the consultation document). The current system where GPs take a financial risk for ordering additional vaccine in order to fulfil an uncertain increase in uptake may act as a barrier to increasing uptake rates.

21. The current system is difficult to performance manage and the monitoring of vaccine wastage is almost impossible. Payment mechanisms are complex, partly as a result of payments attached to local procurement and it is difficult to calculate the national cost of the programme and whether it provides value for money. Efficiencies achieved by altering the way vaccine is procured may deliver savings to the NHS, increasing value for money whilst also reducing the administrative burden on frontline NHS organisations and risks to GPs.

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[21] Statement of Financial Entitlement - paragraph 17.3 and Annex G Part 1
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_097632

[22] 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

[23] Statement of Financial Entitlement - paragraph 17.3 and Annex G Part 2
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_097632

[24] The influenza immunisation programme 2010/11 – Professional Letter: Annex 1
http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Professionalletters/Chiefmedicalofficerletters/DH_116507

[25] Statement of Financial Entitlement – paragraph 4.1 and Annex D
http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_097632

[26] http://apps.who.int/gb/ebwha/pdf_files/WHA58/A58_12Add1-en.pdf

B: Options under consideration

22. There are several elements of the existing system that could be changed, including management of the tender exercise, type of contract, ordering control and distribution of vaccine. These are captured by two options for alternative ordering and delivery mechanisms which DH considers will best deliver the objectives.

Option 1: Do nothing and maintain the existing system

23. This case is as described above. Its costs and benefits are taken as the base case for option 2, which reflects potential changes.

Option 2: DH tender for a direct contract for flu vaccine - distribution by manufacturers or specialised cold chain distributor

24. DH would put out to tender to a number of vaccine suppliers a direct contract to supply seasonal influenza vaccine. The vaccine would be paid for centrally by DH. This would be a split agreement award with either a small number of manufacturers or all manufacturers, according to the tendering process and results.

25. The vaccine would be ordered by GPs via ImmForm and distributed by manufacturers or specialised cold chain distributors. In the current mechanism, manufacturers organise delivery, which may continue under the new scheme. If this were not part of the central contract, there would be separate costs for organising cold chain delivery, however, a greater discount on the price per vaccine would be expected.

26. Given the nature of the viruses, influenza vaccines are only used for a single season. It is therefore important that DH should contract to purchase a correct quantity of vaccine to avoid eroding savings through wasted surplus.

27. This contract may require DH to buy from a limited pool of manufacturers, thereby limiting the choice of vaccines a GP can order to those manufacturers that have been contracted centrally, when contrasted to the current system where GPs can choose any manufacturer.

C: Economic case

28. This section presents an economic appraisal of the proposed option. It first sets out the quantified costs and benefits, and then considers possible impacts, which are not quantified but could have a material impact on the case. Together, these evaluate the overall impact on society, which allows recommendations and conclusions to be made about the preferred Option.

Quantified costs and savings associated with Option 2

29. This section sets out the quantified costs, transfers and savings of Option 2 relative to the 'do nothing' option (Option 1) to three parties: i) the Department of Health (DH); ii) General Practitioners (GPs); and iii) vaccine manufacturers. In general, these are costs, transfers and savings that will clearly occur as a result of the proposed changes[27], be material to the case, and be estimable in terms of magnitude. Where a cost or saving is both a clear impact of the proposed changes and material to the case, but is not estimable, a range of plausible sensitivities are considered. All costs are rounded to the nearest million.

[27] For example, rather than costs and savings which may be coincidental and not as a result of the proposed changes set out in this IA.

30. We consider the costs and cost savings associated with each of the following areas for each Option:
    - Personal Administration fees
    - Administration effort and contract management within DH
    - Additional distribution costs
    - GP vaccine price reimbursement
    - Additional wastage by GPs
    - Potential risk of additional costs as a result of ordering by DH
    - Bulk purchase discounts relative to direct GP purchasing
    - Local level administration effort

31. By comparing the costs and benefits (savings), the net present value (NPV)[28] of each option can be calculated. This provides a basis for a numerical comparative assessment of each of the different options; the option with the highest NPV should have the greatest overall benefit.[29] Costs are presented rounded to the nearest million.

Costs and cost savings of Option 2 relative to Option 1

Personal Administration fees

32. GPs will no longer have to undertake the work of procuring vaccines. The Personal Administration (PA) fee, under Option 2, is no longer applicable. On average, GPs currently receive £2.00 per dose administered, paid in recognition of work required to procure vaccine. With procurement shifted away from GPs to within DH, this GP cost is avoided. There will be a cost saving to Government:

Cost saving = 10m x £2.00 = £20m per annum

Administration effort and contract management within DH

33. The cost savings in the previous section will be countered, to some extent, by the additional administrative cost to DH associated with the tender transaction. This additional administrative burden is estimated to be two full time equivalent (FTE staff) with salaries of £50,000 per annum each plus 30% overheads.

Further, there will be central administration effort associated with managing the contract and ensuring that deliveries are properly coordinated. Based on what is needed to manage and coordinate the childhood immunisation programme, this cost is estimated to be around £2m per annum. This includes, for example, staff time of CMU, BSA and NHS Supply Chain.

Total cost = £50,000 x 2 x 1.3 + £2m = approx £2m per annum

Additional distribution costs

34. The existing system has agreements involving the distribution undertaken by the manufacturers with the costs built into the sale price. Distribution may be through either the manufacturer or a specialised cold chain distribution firm.

35. Using specialised cold chain distributors will involve additional cost of external distribution firm(s) and additional storage charges associated with that method of distribution. Due to these

[28] The net present value is a measure of the net benefit of an option, considering all of the likely benefits and subtracting all of the likely costs. Costs and benefits in future years are discounted at an appropriate rate to give their value from the perspective of the decision point.

[29] In general, the option with the highest NPV should be selected. However, there may be unquantifiable or unintended costs and savings associated with a particular option which may have a material impact on the case, and therefore should be considered alongside the NPV calculation.

complexities the exact cost is unclear. An estimate of £3m is used to illustrate the distribution costs.

36. Where distribution is through a manufacturer, costs related to distribution may be passed onto the NHS through increases in the price of the vaccine. The net effect on costs and benefits will be the same.

37. Distribution using specialised firms may involve several distributors since the product is seasonal and several million doses need to be delivered in a short period of time (identified in the introduction as the influenza immunisation season), this is recognised as a potential risk.

GP vaccine price reimbursement

38. Under the existing system, GPs are reimbursed by PCTs for the list price of the vaccines less a discount ranging from 3.17% to 11.18%. This percentage deduction is thought to be an under-estimate of the discount GPs actually get – which could be between 30 to 40% below list price[30]. GPs retain the resulting surplus. Under Option 2, this surplus will no longer be paid to GPs but will be retained by Government; this therefore represents a transfer from GPs to the Government.

39. The total profit currently made by GPs is estimated as the total number of doses multiplied by the average reimbursement per dose less the average GP-arranged transaction price. For these purposes, the average reimbursement per dose is assumed to equal the median list price, £6.37, minus 3.17% discount, i.e. £6.21. The average GP-arranged transaction price is assumed to equal the median list price minus a 35% discount, i.e. £4.17. Therefore:

Lost profits for GPs = 10m x (£6.21 - £4.17) = approx £20m per annum

The equivalent cost saving is made by DH in reduced costs of the payment.

Additional wastage by GPs

40. The new proposal involves no financial risk to GPs, since DH is responsible for purchase of vaccine; this means that the financial risk shifts to DH. This suggests that under the proposed system, there is likely to be no financial incentive on GPs to limit wastage.

41. Potential increases in wastage are difficult to estimate, particularly as the baseline level of wastage is unknown. To provide some indicative cost estimate, we assume that wastage under the current system is 5% and will increase to 10% under the proposed system.

42. GPs will therefore make a savings from no longer holding the risk of wastage. On the basis of 5% wastage under the current system at a estimated GP purchase price per dose of £4.17:

Savings to GPs = 5% x 10m x £4.17 = approx £2m per annum

43. However, there will now be a cost to DH in holding this risk. On the basis of 10% wastage under the proposed system at the estimated central price per dose of £3.85, where DH achieves a 40% discount on the list price:

Total cost to DH = 10% x £3.85 x 10m = approx £4m per annum

Potential risk of additional costs as a result of ordering by DH

[30] 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

44. There are two potential risks to DH of bringing the ordering of flu vaccine in-house. Firstly, there is the risk of ordering too much vaccine, creating a surplus. Under the proposals to bring flu vaccine procurement in-house, this risk transfers from GPs to DH.

45. Note that Option 2, the direct contract, has the least flexibility with regard to using historical data on ordering patterns to project future volume requirements. Since seasonal influenza vaccines last only a single season and product is unable to be held as stock for the following season in the same way as other vaccination programmes, wastage due to over- or under-estimation represents a genuine risk. However, uptake is relatively constant in the target groups and JCVI has never historically reduced the target groups, only added to them.

46. Since this risk is currently faced by GPs at a local level, it is difficult to predict the likely probability and scale of under- or over-ordering centrally. To provide some indicative cost estimates, we assume that there is a 25% probability of over-ordering by 10%. Furthermore, we assume that these assumptions hold under the current system; the only change is in the ability of DH to manage this risk, as compared to GPs. The total cost of over-ordering to DH is shown below:

    Cost of over-ordering = 25% x 10% x 10m x £4.17 = approx £1m per annum

47. If a GP has overestimated the amount of stock they need, some suppliers and wholesalers have arrangements for unused stock to be returned by GPs with variable levels of reimbursement. Specifics of contracts with GPs are commercially sensitive, so we assume that GPs are reimbursed 70% of the price that they paid under the current system. If GPs were no longer asked to hold this risk, they would therefore save:

    GP saving = 25% x 10% x £10m x [£4.17 x 70%] = approx £1m per annum.

    Bulk purchase discounts relative to direct GP purchasing

48. DH might be able to achieve lower prices with manufacturers than GPs are currently able to, due to buying several million doses rather than several hundred per GP (the effect of contract tender competition between manufacturers and economies of scale in supply might have the effect of driving down the price). In addition, DH will have control over which vaccines are purchased and be able to purchase the cheapest vaccine(s) rather than the ones reflecting the personal preferences of a GP.

49. GPs currently receive, on average, a discount of around 30-40% on list price; we assume that the DH will achieve at least this discount. For the lower estimate of savings, we assume that the DH achieves a discount of 35%. For the upper estimate, we assume that the DH would be able to achieve a discount on list price of 40%. On that basis, the average amount paid to manufacturers per dose under a direct contract is estimated to be £4.17-£3.85, in comparison with the estimated £4.17 currently paid by GPs. Assuming 10m doses purchased per annum:

    Saving to DH (lower estimate) = £0
    Saving to DH (upper estimate) = 10m x (£4.17-£3.85) = approx £3m per annum

    For the upper estimate, we assume that this saving mainly reflects the manufacturer achieving greater economies of scale, rather than losing profits. In this instance, the loss to manufacturers will be close to zero, since they will recoup any losses from reductions in price by reducing costs. However, when summarising the costs and benefits, we do also consider the case where the saving to DH reflects lost profits to manufacturers.

50. Note that the cost saving of this bulk purchase is likely to be higher than for a framework agreement since the volume risk and inflexibility of ordering, in terms of the consequences of

buying the correct quantity of vaccine, is borne by DH rather than by manufacturers.[31] This estimate is based on historic volume discounts arranged for other vaccines – in terms of direct contracts. The discount may also be influenced by the distribution decisions taken.

Local level administration effort

51. There is currently an administration burden on local level authorities (currently PCTs) associated with the payment of PA fees – this is no longer applicable under Option 2. Assuming 0.25 FTEs per PCT (ie ¼ of one person's time), this currently represents 38 FTEs in total across the 152 PCTs. (The time needed is assumed to be unaffected by the current NHS reforms.) For administering PA fees, an average salary of £25,000 per annum plus 30% overheads is assumed. Therefore:

Saving = 38 x £25,000 x 1.3 = approx £1m per annum

Summary of the quantified impacts

52. Table 1, below, summarises the costs and savings associated with Option 2, to the DH (and government), GPs and manufacturers of the vaccine. This suggests that the overall net impact is a cost saving of £14m in the first year. The net impact is positive since the cost of administrative effort and contract management within DH, additional wastage by GPs and the risk of under-ordering by DH are outweighed by the cost savings bought about by reducing the administration efforts of GPs in negotiating contracts (i.e. Personal Administration Fees), local level administration effort and reduced cost of purchasing the vaccine.

Table 1 – Summary of annual costs of Option 2 (relative to Option 1 – Do Nothing)
(figures rounded to nearest £1m)

	Costs for year one								
	DH			GPs	Manufacturers			Total		
Personal Administration Fees	-£20m							-£20m		
Administration Effort and contract management in DH	£2m							£2m		
Additional Distribution Costs	£3m							£3m		
GP vaccine price reimbursement	-£20m			£20m				£m		
Additional Wastage by GPs	£4m			-£2m				£2m		
Risk of over-ordering	£1m			-£1m				£m		
Bulk Purchase Discounts relative to direct GP purchasing	£0m	to	-£3m		£0m	to	£3m	£0m	to	£0m
Local level administration effort	-£1m							-£1m		
Total Savings	£42m	to	£45m	£3m				£44m	to	£48m
Total Cost	£10m			£20m	£0m	to	£3m	£31m	to	£34m
Net Benefit	£31m	to	£35m	-£18m	£m	to	-£3m	£14m	to	£14m

53. The impacts of this option will continue for a number of years. Net benefits on DH, GPs and manufacturers have been taken from the first year of implementation (see table 1) and projected

[31] Manufacturers will be able to charge lower prices as they are able to produce for a guaranteed purchase volume, rather than carrying the risk of having unsold stock.

over the next 10 years. All impacts have been scaled with an index for the population over 65, the largest 'at risk' group vaccinated. The increase in the number of people in the 'at risk' groups will lead to more vaccinations being purchased; therefore, costs and savings are expected to increase. Table 2 shows the impact on each of the three groups over 10 years.

Table 2 – Impact on DH, GPs and Manufacturers over 10 years

Population growth index		DH		GP	Manufacturer		TOTAL	
		Min	Max		Min	Max	Min	Max
	TOTAL COSTS	£344m	£380m	-£194m	£0m	-£35m	£151m	£151m
1.00	2012/13	£31m	£35m	-£18m	£0m	-£3m	£14m	£14m
1.03	2013/14	£32m	£36m	-£18m	£0m	-£3m	£14m	£14m
1.05	2014/15	£33m	£36m	-£19m	£0m	-£3m	£14m	£14m
1.07	2015/16	£34m	£37m	-£19m	£0m	-£3m	£15m	£15m
1.09	2016/17	£34m	£38m	-£19m	£0m	-£4m	£15m	£15m
1.11	2017/18	£35m	£38m	-£20m	£0m	-£4m	£15m	£15m
1.13	2018/19	£35m	£39m	-£20m	£0m	-£4m	£15m	£15m
1.15	2019/20	£36m	£40m	-£20m	£0m	-£4m	£16m	£16m
1.17	2020/21	£37m	£40m	-£21m	£0m	-£4m	£16m	£16m
1.19	2021/22	£37m	£41m	-£21m	£0m	-£4m	£16m	£16m

54. Impact Assessment guidance suggests that each £25,000 saved by the NHS can be used to produce health gains valued by the public at £60,000. In short, the health opportunity cost of £1 of public funding is currently estimated to be £2.40 (see Annex B for further details). Table 3 includes this health opportunity cost[32], applied to both DH and GP costs and benefits. Future costs are also discounted at 3.5%, according to Green Book[33] principles.

Table 3 – Summary of total costs of Option 2, including health opportunity costs (relative to Option 1)

	DH		GP	Manufacturer		TOTAL	
	Min	Max		Min	Max	Min	Max
Net Impact	£285m	£314m	-£160m	£0m	-£29m	£125m	£125m
Net Impact with health opportunity costs	£684m	£754m	-£384m	£0m	-£29m	£299m	£340m

55. The overall quantified impact of implementing option 2 is estimated to be a net present saving of £299m to £340m over 10 years, after discounting and incorporating the health opportunity cost.

Non-quantified possible costs, risks and savings of Option 2

56. These are possible costs, risks and savings that are either unquantifiable due to uncertainty or a lack of robustness about the likely effect, or are immaterial to the overall economic case. Where a possible cost of changing the current system has not been quantified but could have a material impact on the case, it should be identified as a risk and considered when making overall recommendations.

Reduced choice for GPs

57. The reduced vaccine choice for GPs is regarded as being unquantifiable. The direct contract does not generally offer the choice of vaccine and obliges the GP to commit to order and buy a particular product, whereas the framework agreement might reduce choice should the vaccine not be included within the framework choice. This may be considered damaging to localised

[32] This is our central case, and is summarised at in the pages at the beginning of the Impact Assessment
[33] HM Treasury, *The Green Book*, 2003: TSO

decision making, but there should be no associated disbenefit to patients (vaccine choice is a GP, not a patient, choice – hence it is reasonable to assume there would be no detriment to patient choice). The seasonal flu vaccines are licensed for use across a range of population age groups and are considered equivalent.

Negotiations with GPC

58. GPs would no longer be required to undertake the work of procuring vaccines and would no longer be paid for this work. In total this would reduce GPs' income by about £20m; amongst approximately 36,000 GPs in England[34], on average this would be about £555 each.

59. In addition, GPs would lose the profit they make from the discrepancy between the small deduction applied and the larger discount they are believed to receive on the price of vaccine. In total this would reduce GPs' income by about £20m; amongst approximately 36,000 GPs in England, on average this would be about £555 each. Some part of these cost savings may be available for renegotiation within the GP contract, for example for improved incentive schemes aimed at increasing uptake of vaccination by patients. This would be discussed with the GPC once proposals were worked up by DH officials.

Central controls

60. There may be some benefits from a centralised system associated with the availability of data to make future decisions. A centralised system of ordering would allow DH to monitor vaccine purchase and wastage levels more effectively and would allow DH to facilitate a future change in policy.

Incentives to vaccinate and vaccine coverage

61. The incentive to vaccinate and the associated health consequences are assumed not to change. It is conceivable that, with the withdrawal of the PA fee, paid on a per unit basis, and the removal of associated surplus on vaccine purchases, there may be a reduced incentive to vaccinate. However, under Option 2, there would be less work needed to obtain vaccine and no incentive to be conservative during the ordering transaction, which may improve GP effort in some cases. As a result, the overall effect on incentives to vaccinate is somewhat ambiguous.

62. Further, the relationship between GP financial payments and vaccine uptake is not well established. Limited empirical evidence implies that payment structures have only marginal effect on vaccine uptake. Many other features determine coverage, particularly patient factors. Therefore, it is assumed there is no change in coverage or uptake and this underlies the assumption that there are no health consequences of a proposed change to the procurement system.

D: Wider impacts

Statutory equality duties

63. An Equality Impact Assessment has been conducted as part of the development of the review covering issues including; human rights, race, disability, age and gender, etc. This assessment is also available as a separate document and will be published separately alongside the Impact Assessment. The Equality Impact Assessment is also available in Annex 3 to this document.

Economic impacts

[34] Information Centre, *General Practice Trends*, March 2011: http://www.ic.nhs.uk/webfiles/publications/TSC/General_Practice_Trends_in_the_UK.pdf

64. A change to central procurement of seasonal flu vaccine will have no negative impact on competition or small firms.

Environmental impacts and sustainable development

65. The potential impact of a change to central procurement of seasonal flu vaccine on the environment, including on greenhouse gas emissions has been considered. The main impact is on human resources and so has little greenhouse gas effects. None of the areas of slight potential impact, such as linear accelerator bunkers, seem to have a significant or clearly one-way effect on greenhouse gas emissions and so have not been valued.

Social impacts

66. No significant adverse impact has been found in relation to rural issues or the justice system.

Human rights issues are covered within the separate Equality Impact Assessment

The consultation proposal is expected to have a positive impact on health and well-being, no impact on broader social, economic and environmental living conditions (such as housing, transport, education etc), and no adverse impact on individuals' ability to improve their own health and wellbeing.

E: Conclusions

67. While the results of this Impact Assessment indicate that there are substantial savings to be made from centralising procurement of seasonal flu vaccines, these savings need to be weighed up against some of the non-quantified costs and risks, in particular the possible impact of negotiations with the GPC and a perceived reduction in vaccine choice for GPs. However, it is not felt that either of these costs or risks will be sufficient to prevent centralisation from being attractive and in the public interest. ***The preferred option is option 2.***

Annex 1: Post Implementation Review (PIR) Plan

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), it could be to review existing policy or there could be a political commitment to review];

Policy review.

Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]

To check that the policy outcome matches the objective: to create a more robust supply chain and increase efficiency.

Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]

We will review the outcome of the procurement process, the associated costs of the vaccination programme under the new system and carry out stakeholder engagement with vaccine suppliers and GP practices.

Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]

The current estimated cost of the seasonal flu vaccination programme is approximately £180m a year. 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 influenza vaccine is a private one between GPs, vaccine manufacturers and their distributors. The arrangements place the responsibility and financial and administrative burdens on GPs.

Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]

Robustness of vaccine supply system

Increased efficiency

Vaccine uptake increasing or staying on the same trajectory.

Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]

Stakeholder engagement with vaccine suppliers and GP practices as above.

Vaccine uptake data collection from GP practices via ImmForm.

Reasons for not planning a PIR: [If there is no plan to do a PIR please provide reasons here]

N/A.

Annex 2: Opportunity cost of exchequer funding

Department of Health Impact Assessment Guidance says that funding of marginal projects out of the DH budget should be assessed for its opportunity cost.

The opportunity cost of DH funding is determined by the next best use of that funding. NICE assesses this to be the purchase of additional QALYs at £25,000 each.[1] Hence, the opportunity cost of £25,000 of DH funding, its shadow price, is one QALY.

It is assumed that other public sector spending authorities have the same shadow price attaching to their programmes as does DH – that is that the marginal benefit arising from an additional spend of £25,000 is of equal social value irrespective of the authority responsible for its deployment.[2] Were it otherwise, the Government would have reallocated to secure additional value.

The QALYs foregone to fund a policy can then be monetised using an estimate of the average willingness to pay for a QALY of the general public; this is currently £60,000 per QALY.

Thus for all public spending required for an option, whether from the DH budget, from local authorities or from other Government Departments, the opportunity cost is calculated first by working out how many extra QALYs could have been purchased with that sum (currently at £25,000 per QALY), and then how much those QALYs are valued by the recipients (currently at £60,000 per QALY). In short, the opportunity cost of a £1 of public funding is currently estimated to be £2.40.

[1] "NICE should explain its reasons when it decides that an intervention with an ICER [incremental cost effectiveness ratio] below £20,000 per QALY gained is not cost effective; and when an intervention with an ICER of more than £20,000 to £30,000 per QALY gained is cost effective." See http://www.nice.org.uk/aboutnice/howwework/socialvaluejudgements/socialvaluejudgements.jsp
For empirical work that suggests that the NHS can purchase QALYs for £25,000 or less, depending upon the specialty, see Martin S, Rice N, Smith PC. The link between health care spending and health outcomes for the new English Primary Care Trusts, CHE Research Paper 42; 2008. Centre for Health Economics, University of York. www.york.ac.uk/inst/che/pdf/rp42.pdf

[2] Note that the **social** value of spending may exceed or fall short of the value to the beneficiaries of that spending. See for example the discussion in Section IVh relating to the UK citizen's valuation of spending that benefits overseas citizens.

Annex 3: Equality analysis

Title: "Consultation: A Review of the Procurement of Seasonal Flu Vaccine 2011"
Relevant line in DH Business Plan 2011-2015**:**

Introduction

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', to meet today's health challenges.

This dedicated new public health service – Public Health England – will take the place of the complex structures that exist today. Public Health England 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.

Some public health elements of primary care services will be funded by Public Health England but commissioned by the NHS Commissioning Board (in exercise of its own functions). Given the existing contractual arrangements in the GP contract for provision of some immunisation programmes, we propose that Public Health England transfers funds from the public health budget to the NHS Commissioning Board to allow them to commission those programmes. This will include the childhood and seasonal flu vaccination programmes. The NHS Commissioning Board will be responsible for commissioning a service for the whole population. For programmes where GPs are not preferred providers, such as flu, or where individual GPs opt out or are decommissioned from providing a service, the NHS Commissioning Board will be able to commission services from alternative providers as appropriate (for example community pharmacies) as well as GPs.

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 influenza vaccine.

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 influenza 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.

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 influenza programme in England. The Review concluded that a central negotiation of the cost of influenza 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.

The current review of the seasonal flu vaccination programme 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 the Department 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.

This consultation seeks views on the future arrangements for procurement of seasonal flu vaccines. It does not prejudge the issue, and makes it clear that the responses to the consultation will be taken into account before any decisions are taken on how flu vaccines are procured in the future.

What are the intended outcomes of this work?

This consultation gives interested parties the opportunity to make their views known about future arrangements for the procurement of seasonal flu vaccine. One of the options under consideration is a system of central procurement.

The consultation document makes it clear that the eventual solution must secure the best value service for the NHS, whilst also seeking to ensure a robust supply of vaccine and improve vaccine uptake.

The current arrangements for procuring seasonal flu vaccine leave GPs and public at risk: either of GPs being left with a large surplus and potentially leaving them out of pocket; or alternately experiencing a shortfall in supply and therefore being unable to vaccinate everyone in their area who is eligible for the programme. Therefore a different approach to supply of vaccine would both better safeguard public and GPs in delivering vaccinations.

In addition, the localised vaccine shortages experienced in the winter of 2010/2011 suggest that a new procurement arrangement may help to mitigate this in future.

The outcome of the consultation will therefore be a set of informed comments, which will enable the Department to make an informed decision on the best way forward.

Who will be affected?

GP practice staff, SHA Flu Leads, PCT Flu Coordinators, SHA and PCT Directors of Finance (if still in existence when any revised arrangements are introduced), vaccine manufacturers.

Evidence *The Government's commitment to transparency requires public bodies to be open about the information on which they base their decisions and the results. You must understand your responsibilities under the transparency agenda before completing this section of the*

assessment. For more information, see the current DH Transparency Plan.

What evidence have you considered? *List the main sources of data, research and other sources of evidence (including full references) reviewed to determine impact on each equality group (protected characteristic). This can include national research, surveys, reports, research interviews, focus groups, pilot activity evaluations etc. If there are gaps in evidence, state what you will do to close them in the Action Plan on the last page of this template.*

Departmental report

- 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

Research

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- Pitman RJ et al. Assessing the burden of influenza and other respiratory infections in England and Wales.J. Infect. 2007:54:530-538.
- Blank PR, Schwenkglenks M, Szucs TD. (2008) Influenza vaccination coverage rates in five European countries during season 2006/7 and trends over six consecutive seasons. BMC Public Health 2008;8:272

Disability
There is no evidence to suggest that a change in procurement of seasonal flu vaccine will have a negative impact on the grounds of disability. The review of procurement of seasonal flu vaccine is intended to ensure that eligible people in this group receive the flu vaccine.

Sex
There is no evidence to suggest that a change in procurement of seasonal flu vaccine will have an impact, either positively or negatively, on the grounds of sex or gender.

Race
There is no evidence to suggest that a change in procurement of seasonal flu vaccine will have an impact, either positively or negatively, on the grounds of race.

Age
There is no evidence to suggest that a change in procurement of seasonal flu vaccine will have a negative impact on the grounds of age. The review of procurement of seasonal flu vaccine is intended to ensure that eligible people in this group receive the flu vaccine.

Gender reassignment (including transgender)
There is no evidence to suggest that a change in procurement of seasonal flu vaccine will have an impact, either positively or negatively, on the grounds of gender reassignment (including transgender).

Sexual orientation
There is no evidence to suggest that a change in procurement of seasonal flu vaccine will have an impact, either positively or negatively, on the grounds of sexual orientation.

Religion or belief
There is no evidence to suggest that a change in procurement of seasonal flu vaccine will have an impact, either positively or negatively, on the grounds of religion or belief.

Pregnancy and maternity
There is no evidence to suggest that a change in procurement of seasonal flu vaccine will have a negative impact on the grounds of pregnancy and maternity. The review of procurement of seasonal flu vaccine is intended to ensure that eligible people in this group receive the flu vaccine.

Carers
There is no evidence to suggest that a change in procurement of seasonal flu vaccine will have a negative impact on the grounds of disability. The review of procurement of seasonal flu vaccine is intended to ensure that eligible people in this group receive the flu vaccine.

Other identified groups
There is no evidence to suggest that a change in procurement of seasonal flu vaccine will have a negative impact on the grounds of being in an alternatively identified group.
The review of procurement of seasonal flu vaccine is intended to ensure that eligible people in this group receive the flu vaccine.

Engagement and involvement

Was this work subject to the requirements of the cross-government Code of Practice on Consultation? (Y/~~N~~) Yes it will be.

How have you engaged stakeholders in gathering evidence or testing the evidence available?

The purpose of undertaking the consultation is to actively engage stakeholders. The Department will actively seek feedback from key stakeholders during the consultation period.

How have you engaged stakeholders in testing the policy or programme proposals?

We are publishing the consultation document in order to test the proposal with stakeholders.

For each engagement activity, please state who was involved, how and when they were engaged, and the key outputs:

We expect the consultation exercise to be of particular interest to vaccine manufacturers, GPs, PCTs and possibly SHAs but are looking for a wider range of comment from other stakeholders.

Summary of Analysis *Considering the evidence and engagement activity you listed above, please summarise the impact of your work. Consider whether the evidence shows potential for differential impact, if so state whether adverse or positive and for which groups. How you will mitigate any negative impacts. How you will include certain protected groups in services or expand their participation in public life.*
It should be emphasised that it is premature to consider whether a different way of procuring seasonal flu vaccine will have a significant impact on equalities. This is because account will need to be taken of the responses to the consultation.

The preliminary view of the impact of one option (central procurement) is positive, as it should reduce the likelihood of vaccine shortages for any of those in the eligible groups.
Now consider and detail below how the proposals impact on elimination of discrimination, harassment and victimisation, advance the equality of opportunity and promote good relations between groups.

Eliminate discrimination, harassment and victimisation *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*
N/A.

Advance equality of opportunity *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*
N/A.

Promote good relations between groups *Where there is evidence, address each protected characteristic (age, disability, gender, gender reassignment, pregnancy and maternity, race, religion or belief, sexual orientation).*
N/A.

What is the overall impact? *Consider whether there are different levels of access experienced, needs or experiences, whether there are barriers to engagement, are there regional variations and what is the combined impact?*
N/A.

Addressing the impact on equalities *Please give an outline of what broad action you or any other bodies are taking to address any inequalities identified through the evidence.*
N/A.

Action planning for improvement

Please give an outline of the key actions based on any gaps, challenges and opportunities you have identified. Actions to improve the policy/programmes need to be summarised (An action plan template is appended for specific action planning). Include here any general action to address specific equality issues and data gaps that need to be addressed through consultation or further research.

N/A.

Please give an outline of your next steps based on the challenges and opportunities you have identified. *Include here any or all of the following, based on your assessment*

- *Plans already under way or in development to address the **challenges** and **priorities** identified.*
- *Arrangements for continued engagement of stakeholders.*
- *Arrangements for continued monitoring and evaluating the policy for its impact on different groups as the policy is implemented (or pilot activity progresses)*
- *Arrangements for embedding findings of the assessment within the wider system, OGDs, other agencies, local service providers and regulatory bodies*
- *Arrangements for publishing the assessment and ensuring relevant colleagues are informed of the results*
- *Arrangements for making information accessible to staff, patients, service users and the public*
- *Arrangements to make sure the assessment contributes to reviews of DH strategic equality objectives.*

The consultation will be launched on 25 May 2011 and will run until 17 August 2011.

The responses to the consultation will be analysed and taken into account in developing new arrangements for the procurement of seasonal flu vaccine.

For the record

Name of person who carried out this assessment:

Madeleine Pym

Date assessment completed:

3 May 2011

Name of responsible Director/Director General:

David Salisbury

Date assessment was signed:

Annex 4: 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:

	Question
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 para 59 of the Impact Assessment].**
4	Are there any other points the Government should consider?

Annexes

Annex 1 should be used to set out the Post Implementation Review Plan as detailed below. Further annexes may be added where the Specific Impact Tests yield information relevant to an overall understanding of policy options.

Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. If the policy is subject to a sunset clause, the review should be carried out sufficiently early that any renewal or amendment to legislation can be enacted before the expiry date. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

Basis of the review: [The basis of the review could be statutory (forming part of the legislation), i.e. a sunset clause or a duty to review , or there could be a political commitment to review (PIR)];

Review objective: [Is it intended as a proportionate check that regulation is operating as expected to tackle the problem of concern?; or as a wider exploration of the policy approach taken?; or as a link from policy objective to outcome?]

Review approach and rationale: [e.g. describe here the review approach (in-depth evaluation, scope review of monitoring data, scan of stakeholder views, etc.) and the rationale that made choosing such an approach]

Baseline: [The current (baseline) position against which the change introduced by the legislation can be measured]

Success criteria: [Criteria showing achievement of the policy objectives as set out in the final impact assessment; criteria for modifying or replacing the policy if it does not achieve its objectives]

Monitoring information arrangements: [Provide further details of the planned/existing arrangements in place that will allow a systematic collection systematic collection of monitoring information for future policy review]

Reasons for not planning a review: [If there is no plan to do a PIR please provide reasons here]