Review of the arrangements for the

Seasonal Influenza Programme

in England

Report of an independent panel

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Executive summary

On 22 November 2005, the Secretary of State for Health announced in the House of Commons that a review of the arrangements currently in place for the seasonal influenza vaccination programme in England would be carried out. This was prompted by reports of alleged delays and shortages in seasonal influenza vaccine supply during October and November 2005. The purpose of this review is to examine the supply and distribution of influenza vaccine for the annual seasonal influenza immunisation programme and make recommendations to the Department of Health (DH) to improve existing systems without incurring additional costs while maintaining the cooperation of general practitioners.

An independent panel was appointed by the DH to undertake the review. The panel sought evidence from a broad range of stakeholders across the DH, the NHS, professional representative bodies, vaccine manufacturers and organisations representing patients.

Influenza is an acute viral infection and, in most years, occurs predominantly during a six to eight week period during the winter. The very young, the elderly and people with underlying diseases such as heart or chest disease are particularly at risk of serious illness from influenza. Without interventions such as annual influenza immunisation, the elderly and those of all ages in disease-based risk groups suffer significant morbidity and mortality even in a non-epidemic year. An estimated 12,000, mainly elderly people, die each year from seasonal influenza in England and Wales.

Influenza virus strains active in the community change annually and the population at risk must be immunised annually with the recommended strains for that year. The process involved in identifying the active strains, and developing and manufacturing an effective vaccine presents considerable challenges to ensure that the seasonal timetable is met and that sufficient vaccine is available to meet demand.

The seasonal influenza campaign in the UK has made considerable progress in increasing coverage for people aged 65 and over, set against the WHO 2010 target of 75%. The UK has already achieved this target and amongst European countries is one of the highest achievers.

Seasonal influenza vaccination is delivered by a campaign organised primarily through general medical (GP) practices. Contractual arrangements provide a framework, which provides remuneration and incentive payments. The purchase and supply of seasonal influenza vaccine is a private arrangement between general practices and vaccine manufacturers, and the negotiated discount arrangements contribute to

practice income. The majority of patients receiving influenza vaccine are immunised during the period from September to November, but the campaign is not completed until January.

We have reviewed the procurement of vaccine by general practices and the practice programme for influenza vaccination, and identified factors influencing attainment levels.

The key question raised in November 2005 concerned the provision of seasonal influenza vaccine in England. Shortages of influenza vaccine and delays in supply were being reported in October and November 2005. At the time, indicators of uptake pointed to coverage of risk groups then no higher than in previous years, despite a reported supply of influenza vaccine to front-line services 27% greater than was used in the previous year. These reported shortages occurred at a time when there was heightened media interest in Government action to address the risks of avian and pandemic influenza, and public confidence in the seasonal influenza programme was eroded as a consequence.

In a number of previous years there had been shortages or delays due to a variety of factors including lower than expected yields of the selected strains. This has highlighted that one of the key challenges in the production of influenza vaccine is the variable yield from the culture of different influenza virus strains.

We have reviewed data from a number of sources to enable us to assess the supply and demand for seasonal influenza vaccine during the autumn of 2005. The data available are of mixed quality. In some instances the data available were incomplete and it has, therefore, been difficult to establish a precise audit of events. These deficiencies need to be borne in mind when interpreting the findings.

The available data suggest that sufficient vaccine was eventually available for at-risk and target groups, even though there were delays in the supply of vaccine to practices and a consequent delayed start to the influenza campaign. Although only 1.9% of influenza vaccinations were supplied in September 2005, there was a rapid catch-up in October (49.5%) and November (34.4%) to match or exceed usual attainment levels by the end of November 2005. This suggested to us that although the majority of practices were able to manage patient demand and ensure vaccine was given, any local variation in supply could have been misconstrued as indicative of a more general shortage.

In taking a balanced view, we concluded that the concerns reported in October and November 2005 could not be attributed to a single cause, but identified a number of contributory factors, which may have led to the problems experienced. We identified a number of latent conditions that contributed to weaknesses in the programme which were compounded by a number of active factors. These active factors included heightened media awareness of the risks of avian and pandemic influenza, and reported shortages of vaccine.

We believe this led to a rapid destabilisation of confidence in the seasonal influenza programme and fuelled further public and professional perception that there were shortages of available influenza vaccine. These events increased demand by patients on GP practices, which could not in some cases be matched by immediately available supplies. This resulted in the need to reschedule clinics, thereby further increasing concerns that there was a shortage of vaccine despite an adequate supply of vaccine being available to meet the needs of the programme overall.

We have undertaken a detailed review of these contributory factors and have made a range of recommendations to strengthen the management of the programme. These include a review of the procurement and management of DH contingency stock as there was considerable wastage during 2005.

We were specifically asked to examine the current seasonal influenza vaccine supply system and to evaluate alternative systems, including those currently

used in other UK territories. We considered four different models of procurement and delivery, including a potential new model which was developed to take account of comments from stakeholders consulted during the review. We undertook an option appraisal based upon 20 criteria relating to the feasibility of the option, acceptability to stakeholders, performance management, access, and resilience of the provider to be able to cope with changes in demand.

We have recommended that further detailed consideration be given to developing an alternative model for the procurement and delivery of the seasonal influenza immunisation programme. This model proposes the central negotiation of the cost of influenza vaccine between the DH and vaccine manufacturers. GP practices would continue to procure vaccine, but the centrally negotiated discounted price would be used as the reimbursable price applied to GP claims. This discount on the current NHS price is likely to be quite significant. There is no desire to erode GP income and it is, therefore, proposed that these savings be used to fund a graduated incentive scheme to improve performance and increase access to the benefits of immunisation. This could be used exclusively for the seasonal influenza programme, or more widely to include other immunisation programmes.

We recognise that the models are not mutually exclusive and that there are a number of common features. Furthermore, the models are not rigidly demarcated and elements of each option could be combined to create further options or a new mixed model. In particular, it would be possible to modify the proposed model to incorporate central procurement and distribution.

The NHS reform programme encourages the diversification of the healthcare workforce with greater skill mixing, expansion of the skills of health professionals, and innovation and flexibility in the range of clinical practice. The programme of reform in primary care has established new contractual frameworks providing opportunities, flexibilities and incentives for new ways of working. Examples include: the new flexibilities in the contractual framework for community pharmacy enabling the delivery of a wider range of clinical services; and the expansion of nurse and pharmacist prescribing. The NHS is also committed to expanding access and equity in healthcare, underpinned by a programme of plurality and choice.

The seasonal influenza programme should be maintained and further developed in line with these policies. New flexibilities in service provision may help manage and enhance the capacity of a GP-based supply system and contribute to increasing population coverage and the additional pressures that would arise in the event of an epidemic. In particular, we have highlighted the need to review the potential contribution of community pharmacy and healthcare assistants.

We have made a number of detailed recommendations intended to strengthen the programme delivery and build on what the DH has already achieved. This includes strategy, programme governance, performance management, communication, and contingency planning. We have highlighted the need to further develop the role of influenza coordinators, strengthening roles and accountabilities and improving communication. We have assumed that the recommended changes would apply irrespective of the model adopted.

The effective delivery of the seasonal influenza programme involves a broad range of stakeholders within government, the NHS and the commercial sector. These interdependencies are further complicated by the biological nature of the vaccine, the viral strain identification, vaccine manufacture, distribution and administration to the at-risk and target population. Delivery is also influenced by the range of contractual relationships with general practitioners, procurement policy and the commercial arrangements between GPs and vaccine manufacturers.

The management of the seasonal influenza programme, and successful delivery of programme objectives, is vulnerable to a broad range of risks, compounded by complex governance arrangements and contractual relationships.

We believe that the recommendations that we have made to strengthen the management of the programme, coupled with the opportunity to implement changes in the procurement and delivery of influenza vaccine, will improve the resilience of the programme to meet the objectives of this important public health programme and provide improved and equitable access to its benefits.

We believe the DH should maintain its close working relationship with vaccine supply manufacturers so that the industry can continue to respond appropriately to changes in health policy and strategy. However, we are aware that there are constraints on manufacturing capacity within vaccine manufacturers and that current demand for influenza vaccine is approaching the limits of current production capacity. Events in recent years have highlighted this volatility and the impact of delays in vaccine manufacture.

The challenges of manufacturing a biological product, such as influenza vaccine, mean that irrespective of the other measures to strengthen the seasonal influenza programme outlined in this report, there will continue to be a critical dependence on the processes related to the identification of viral strains and the manufacture of vaccine which may continue to compromise the effective delivery of this programme.

Part A

Background

Section 1

Introduction

1.1 The Secretary of State for Health has asked for a review of the supply and distribution of influenza vaccines for the annual seasonal influenza immunisation programme. In this report, we review the problems that were reported in November 2005 and provide an analysis of factors which may have contributed to these events. We then set out in full our recommendations to improve programme delivery, which are found throughout the report.

1.2 On 22 November 2005, the Secretary of State for Health announced in the House of Commons that a review of the arrangements currently in place for the seasonal influenza vaccination programme in England would be carried out.

In previous years, the GP-led arrangement that I have described has, on the whole, worked well. In view of what has happened this year, however, I am reviewing the arrangements currently in place for the seasonal flu vaccination programme and will consider this matter urgently.
Hansard: 22 November 2005: Column 1372

1.3 The announcement of a review by the Secretary of State for Health was prompted by media reports of alleged delays and shortages and claims that the vaccine was being given to people outside the recommended risk groups.

1.4 The purpose of this review was to examine the seasonal influenza immunisation programme in the context of those claims and to make recommendations to the Department of Health (DH) which would build on existing achievements and improve systems in cooperation with general practitioners without incurring additional costs.

1.5 It is our hope that the package of measures included in this report will make it possible to build on the progress already achieved in reaching the WHO 2010 target of 75% coverage of the at-risk and target population.

Terms of Reference

1.6 A commissioning paper, issued by the DH set out a series of questions to determine how the seasonal influenza immunisation programme could be improved, and defined Terms of Reference for the review.

> **1.6.1** The seasonal influenza programme review team will operate as independent advisors to the DH.
>
> **1.6.2** The review will receive, consider and interpret evidence on the reported vaccine supply shortage in November 2005.

1.6.3 The review will assess current service arrangements, service specifications and purchasing arrangements by primary medical care contract type.

1.6.4 The review will submit its recommendations to the DH, which will consider and approve the review's findings for publication.

1.6.5 The members of the review will act in accordance with the probity arrangements of the Joint Committee on Vaccination and Immunisation (JCVI), including those related to the declaration of interests.

The review team

1.7 The members of the review panel appointed by the DH were:

Dr Ian Spencer
Former Director of Clinical Governance Northumberland, Tyne and Wear Strategic Health Authority (Now North East Strategic Health Authority)

Dr James Kennedy
General Practitioner, The Cedar Brook Practice, Hayes, Middlesex Primary Care Advisor to the Healthcare Commission and Chair of the Prescribing Committee of the RCGP

Structure of the report

1.8 The report is divided into four sections (plus six appendices). Part A comprises this introduction, a summary of the influenza programme, a summary of roles across the NHS and the DH and associated levels of responsibility, and information flows and data quality.

1.9 In Part B we consider the problems reported in October and November 2005. We analyse data and comment on the quality of data available.

1.10 In Part C we provide our review of the programme and develop a series of options for further improving the seasonal influenza programme including the systems that may potentially mitigate fluctuations in supply.

1.11 Part D contains a summary of our recommendations.

The consultation exercise

1.12 The review team received an initial written briefing from the DH. This reference document provided the basis of detailed discussion to enable us to determine the structure of the independent review and the scope of stakeholders that needed to be consulted. We requested supplementary documentation based upon the initial review of the information provided and requested further documentation throughout to clarify the information highlighted by stakeholders and an interim analysis of emerging findings.

1.13 We sought submissions from a wide range of stakeholders within the DH, the NHS (including Strategic Health Authorities (SHAs) and Primary Care Trusts (PCTs)), NHS implementing agencies, the Purchasing and Supply Agency (PASA), NHS Employers, and the BMA General Practitioners Committee (GPC), vaccine manufacturers, and patient and carer groups. We attempted to obtain views from a wide range of organisations representing health professionals and manufacturers.

1.14 A broad range of stakeholders was invited to submit their evidence to the review (Appendix 1), and we undertook interviews with respondents in six sessions. These were held on 26 May, 9, 15 and 30 June, 12 and 14 July 2006.

1.15 Supplementary documentary evidence was provided by a number of those interviewed.

1.16 Written comments were invited through SHA leads for Primary Care Contracting, Pharmacy and Prescribing, and Clinical Governance, who cascaded the request to PCTs. Thirty-eight e-mail responses

were obtained in response to this call for evidence, including nine SHAs, 27 PCTs, and two hospital trusts. Whilst it was not practical in the time available for field work to seek comments from individual general practices, responses from PCTs included information direct from their general practices. However we acknowledge that the experiences reported may not be representative of general practices as a whole. We list the persons and organisations that commented in Appendix 1.

1.17 We received additional evidence that was submitted via e-mail or telephone conversations from a number of individuals. These included the Working in Partnership Programme (WiPP), a pharmaceutical industry representative, a practice manager, and other clinicians and professionals not affiliated to any organisation or who wish to remain anonymous.

1.18 We met on a number of occasions to review the evidence, to agree the key findings, and to frame recommendations in light of the views expressed by those consulted.

1.19 Our report has been shared with the DH, to ensure factual accuracy. In addition, some technical sections have been reviewed by the stakeholder that provided the information to ensure accuracy.

Acknowledgements

1.20 We would like to thank all of those who found time to meet with the review team or who shared their opinion, observations and evidence via e-mail or telephone. We greatly appreciated the openness and candour of those who submitted their evidence and the willingness of so many people to give generously of their time, energy and expertise.

1.21 We were privileged to have the benefit to take evidence directly from a number of national and international experts in the field and this enormously helped our understanding of the epidemiology of influenza, influenza vaccine development and manufacture, and the logistics of the seasonal influenza immunisation programme.

1.22 We are aware that all of those we met have very demanding commitments and we are grateful for the courtesy they afforded us in responding to our enquiries and challenging timescales.

1.23 We met a wide range of stakeholders from primary care (including the representative body the BMA GPC) who were able to provide observations on the frontline delivery and management of the seasonal influenza immunisation programme. This experience was complemented by evidence from the DH who outlined the context of primary care contracting and the health reform programme and clarified the policy environment. The views of the BMA's GPC and from NHS Employers provided a detailed understanding of the framework for contractual negotiations and how this might support further development of the seasonal influenza programme.

1.24 Vaccine manufacturers assisted us greatly in understanding the production, sales and distribution mechanisms for seasonal influenza vaccines.

1.25 We would also like to thank all those individuals and organisations that submitted written observations and regret that the constraints on the time available for fieldwork prevented us meeting with more of them to hear directly of their experience.

1.26 We would like to offer personal acknowledgement to a number of DH officials for their continued expert support and advice during the review and in particular Zoltan Bozoky and Jeff Porter.

1.27 We would also like to thank Julie Pettman for providing administrative and organisational support.

Section 2

A summary of the influenza programme in its context

2.1 Influenza is an acute viral infection characterised by the sudden onset of fever, chills, headache, muscle pains, severe prostration and usually cough, with or without a sore throat or other respiratory symptoms. The acute symptoms last for about a week, although full recovery may take longer. In most years, influenza occurs predominantly during a six to eight week period during the winter. For most people, this 'seasonal' influenza is an unpleasant but self-limiting and not life-endangering illness, but in some people it may be more severe, or complicated by secondary bacterial infections such as bronchitis and pneumonia. The very young, the elderly and people with underlying diseases such as heart or chest disease are particularly at risk of serious illness from influenza. Without interventions such as annual influenza immunisation, the elderly and those of all ages in disease-based risk groups suffer significant morbidity and mortality even in a non-epidemic year. An estimated 12,000, mainly elderly people die each year from seasonal influenza in England and Wales.

2.2 The objective of the influenza immunisation programme is to protect those who are most at risk of serious illness or death should they develop influenza. Vaccination should be given at the GP's discretion.

2.3 The target groups recommended to receive influenza vaccination in 2005/06 were:

- all those aged 65 and over
- all aged over 6 months in one of the following clinical risk groups: chronic respiratory disease (including asthma), chronic heart disease, chronic renal disease, chronic liver disease, diabetes, immunosuppression due to disease or treatment
- those living in long-stay residential care homes or other long-stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality (this does not include prisons, young offender institutions, university halls of residence etc)
- those who are the main carer for an elderly or disabled person whose welfare may be at risk if the carer falls ill.

2.4 The seasonal influenza campaign in the UK has made considerable progress in increasing coverage for people aged 65 and over, set against the World Health Organization (WHO) 2010 target of 75%. Figure 1 shows influenza vaccine uptake in England.

2.5 The influenza virus strains change annually. The population at risk from influenza must, therefore, be immunised annually with the recommended strains (or variants) for that year.

2.6 The strains of influenza virus to be incorporated into the vaccine to be used in the northern hemisphere are chosen annually in the early spring, and supplies of vaccine are developed by manufacturers for delivery to general practices from September onwards.

2.7 Seasonal influenza vaccination is delivered in England and Wales by a campaign organised primarily through general medical (GP) practices.

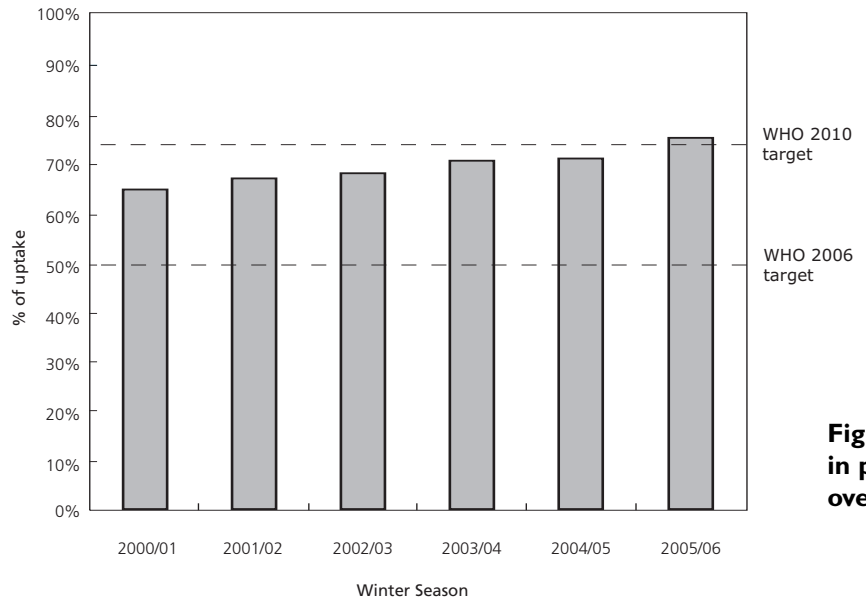

Figure 1 Vaccine uptake in people aged 65 and over in England

2.8 In England, the purchase and supply of seasonal influenza vaccine is a private arrangement between GP practices and vaccine manufacturers.

2.9 GP practices are reimbursed for the purchase cost of the vaccine plus a payment to cover the clinical workload of vaccinating patients in the target population and clerical administration. Many PCTs also award incentive payments if target levels of coverage are achieved in the at-risk population.

2.10 The DH contingency stock is ordered via a European Union tendering process and an advertisement is placed in the Official Journal of the European Union (OJEU) during February. This process takes around three months to complete. Some manufacturers ring-fence an amount of stock for contingency in anticipation of the DH tender. Bids to the DH for contingency supply have usually been received from at least three of the suppliers each year. The bids tend to be price banded and a delivery date is given.

2.11 Prior to placing the OJEU advertisement, the devolved administrations are contacted to determine if they want to elect for a joint tender. Responses differ from year to year. Scotland and Wales participate in the England bid on a regular basis. In the 2005 season, Northern Ireland undertook an independent tender. Both Scotland and Northern Ireland had surplus stock at the end of the campaign in that year, as did England.

2.12 A Directed Enhanced Service (DES) was introduced in 2004 as part of the new General Medical Services (nGMS) contract for the provision of influenza and pneumococcal immunisation for those aged 65 and over and other at-risk groups. The model scheme gives incentives to GPs to provide a proactive and preventive approach by adopting robust call and reminder systems for the patients on their list in the at-risk groups to receive immunisation. Details are included at Appendix 2.

2.13 This arrangement differs from that of the routine childhood programme, which operates as an Additional Service that GPs may choose to opt-out (with a 1% loss of income). A central supply system operates with orders fulfilled to verified customers, based on demographic data on children in the target age groups, practice list sizes and historic baselines of vaccine utilisation.

2.14 The majority of patients receiving influenza vaccine are immunised during the period from September to November, but the campaign is not completed until January. In England, GP practices aim to immunise the majority of the target population within the first six to eight weeks of the campaign, but the programme may not be completed until January.

Section 3

A summary of roles and levels of responsibility

3.1 In this section we describe the roles and responsibilities of the DH, NHS organisations and general medical practices in the delivery of the seasonal influenza programme. We have included a summary of the typical activities within a GP practice that ensure the effective procurement and administration of seasonal influenza vaccine, and summarise the factors that contribute to success.

3.2 We also provide a brief summary of the role of the JCVI, and describe the history and role of the Royal College of General Practitioners (RCGP) Weekly Returns Service (WRS) which is based at The Birmingham Research Unit.

Department of Health

3.3 The DH:

3.3.1 sets immunisation and communicable disease policy in England and directs the provision of immunisation services

3.3.2 ensures that patients and the public can make informed choices about immunisation and provides information resources and national advertising

3.3.3 ensures that NHS organisations are resourced

3.3.4 commissions vaccine research including through the National Vaccine Evaluation Consortium (NVEC)

3.3.5 sets and monitors standards for patient safety (National Patient Safety Agency (NPSA)), procedures (Health Protection Agency (HPA)) and services (Healthcare Commission (HC))

3.3.6 monitors the safety of vaccines (Medicines and Healthcare Products Regulatory Authority (MHRA))

3.3.7 purchases and supplies vaccines (for the seasonal influenza programme only a supply of contingency stock is purchased)

3.3.8 negotiates with the BMA's GPC

3.3.9 provides the secretariat to the JCVI

3.3.10 reviews its own commissioning and provider support function and provides national guidance, learning and resources in order strengthen service design and delivery.

The Joint Committee on Vaccination and Immunisation

3.4 The JCVI is an independent expert advisory committee that was first set up in 1963. Its Terms of Reference are: 'To advise the Secretaries of State for Health, Scotland, Wales and Northern Ireland on matters

relating to communicable diseases, preventable and potentially preventable through immunisation.'

3.5 All aspects of immunisation policy in relation to influenza are examined by the JCVI Influenza-subgroup. This includes detailed scrutiny of the evidence base to expand the at risk groups.

3.6 The DH, acting as the Secretariat for the JCVI puts together a detailed submission of the evidence for the Influenza-subgroup to consider.

3.7 Advice from the JCVI Influenza-subgroup are then sent to main JCVI for consideration and approval.

3.8 The DH collects national vaccine uptake data directly from GP practices and PCTs on a monthly basis (Department of Health/Centre for Infection, 2006). The data are collected by the HPA on behalf of the DH. Vaccine uptake data are available on those over 65 years, those in risk groups under 65 years and health care workers. In addition to these monthly updates, weekly vaccine uptake data from spotter practices are available from the RCGP and QResearch.

The RCGP Weekly Returns Service

3.9 The RCGP, in 1953 established a College Records Unit to enable continued recording of morbidity statistics on a comparable basis throughout the UK and overseas.

3.10 The term 'weekly returns' is first recorded in the twelfth annual report in 1964. Weekly data from the network of practices have now been collected for over 40 years and data as far back as 1967 have now been completely computerised.

3.11 The WRS is funded by the DH and collects weekly data from the network of practices.

Strategic Health Authorities

3.12 As the local headquarters of the NHS, SHAs: provide strategic leadership; develop organisations and the workforce; and ensure local systems operate effectively and deliver improved performance. In discharging these functions, SHAs must work in partnership with their PCTs.

3.13 SHAs are responsible for ensuring that the PCT-led health systems within its area operate effectively, taking account of national guidance. The main way in which SHAs perform this function and drive improvements in equity, quality, responsiveness and efficiency is by assessing and performance managing PCTs to ensure that they deliver their functions effectively.

3.14 SHAs, have the key coordination role to ensure that all organisations work together to manage services throughout the winter months. Effective winter plans include preventative measures, of which the seasonal influenza programme is a key component (Department of Health, 2006).

Primary Care Trusts

3.15 PCTs are responsible for the performance management of local immunisation services and for specifying the level and quality of services provided. As part of the arrangements for the annual influenza and pneumococcal immunisation scheme, each PCT must enter into arrangements to provide immunisation to patients in line with national guidelines.

3.16 PCTs will in turn be held to account by the SHA for their performance, through their commissioning arrangements with contractors.

3.17 The PCT has the responsibility to performance manage its contractors, its provider services arm and its occupational health provider to achieve attainment thresholds in target groups. Each PCT has an influenza coordinator to organise the PCTs seasonal influenza campaign. These coordinators are of varying professional background, experience and seniority within the organisation.

3.18 The attainment targets for the vaccination of target groups may be used by the SHA as a performance indicator.

Financial arrangements

3.19 The PCT has two financial mechanisms for remunerating GPs involved in delivering the seasonal influenza programme. Both remuneration systems require the provision of activity data to the PCT and practices are remunerated for providing these data.

3.19.1 Directed Enhanced Services (DESs) for influenza and pneumococcal immunisation
This payment is overseen by the PCT and relates to members of the population aged 65 and over and those that fall into clinical risk groups as defined in the CMO letter.

3.19.2 Local Enhanced Service (LES) for carers and chronic liver disease
The PCT determines locally whether to support these LESs and any remuneration level for vaccination activity. Some PCTs refer to these payments as a 'Local Incentive Scheme'. The CMO letter gives two definitions of a carer, both of which include 'at the GP's discretion' as a means of identifying and labelling carers.

3.20 The Quality and Outcomes Framework (QOF) offers further indirect payments for vaccinating patients that have coronary heart disease, stroke/ transient ischaemic attack, diabetes and chronic obstructive pulmonary disease.

3.21 Many PCTs provide additional coordination, financial resources and staff time to supporting the practices' seasonal influenza vaccination campaigns. PCTs reimburse practices for the cost of running additional influenza vaccination clinics, usually up to a maximum level (currently around £300 per practice). Additional nursing and administrative staff hours required to support the programme are also reimbursed by the PCTs. The monies are designated as 'pay' and are intended to be passed on to the employee at the full amount. District nurses are able to vaccinate patients in the home on behalf of practices and can claim from the PCT for any extra hours worked in excess of rostered working hours.

3.22 PCTs will usually require weekly or monthly returns from each practice on the uptake of seasonal influenza vaccination amongst the target groups.

General medical practice

3.23 Most general practices have systems in place to:

- identify the target population
- procure seasonal influenza vaccine
- plan clinics for administration, and
- recall patients.

3.24 The new General Medical Services contract (nGMS), and the introduction of the QOF have strengthened these arrangements and have provided incentives for practices to improve performance.

3.25 Practices put in place a variety of systems in organising and delivering their seasonal influenza campaign. Practices may also adapt their methods as they progress through the vaccination campaign to address the specific needs at a given time. Practices may use high volume systems such as mass open access clinics and pre-booked influenza vaccination clinics early in the campaign to meet the high demand and large numbers of patients seeking vaccination. In the later stages of the campaign practices may move instead to systems to individually identify, and vaccinate, high priority target patients. Such techniques include opportunistic vaccination of patients who attend for general medical consultations and more proactive outreach activity such as visiting and vaccinating patients in their homes, places of work or social environments (social clubs for the elderly etc).

3.26 Based on anecdotal information, it appears that patient demand for influenza vaccination during periods where there are reported delays and shortages of supply, may result in additional pressure upon GP practices, impacting on routine surgery workload. Although there is no available evidence to corroborate such comments, this potentially introduces a risk that GP practices might find difficulty applying strict criteria for prioritisation and that some patients outside recommended target groups are immunised.

3.27 We recognise that the workload of general practice has increased. The capacity of general practices to respond to any change to the routine delivery of vaccine is limited by other constraints such as rescheduling clinics, revising staff rosters and

the recall of patients, and possibly during a period when clinical demands are increasing due to winter related illness.

3.28 The management of the seasonal influenza programme by individual practices varies and is dependent upon a number of factors. During the review we collated information from a range of sources including a number of practices and influenza coordinators. The following synopsis is based the reviewers experience of practice systems used within a variety of GP practices and describes the most widely used techniques and timetables as they would be applied within a typical practice. Based on our discussion with a range of stakeholders, we have sought to identify the factors that influence GP practice influenza vaccination attainment levels. For the purposes of illustration, we have categorised these factors as 'high attainment' and 'low attainment' (see Table 1, paragraphs 3.32–36).

A 'general practice' seasonal influenza vaccination programme

3.29 We have attempted to summarise the typical timetable and activities of a general practice, including the procurement of influenza vaccine and the vaccination of the target population within the practice. This is based on a practice serving an inner city population with around 8500 patients.

3.29.1 December to January
The practice reviews the performance during the current influenza season to:

- assess progress against attainment targets in high priority target groups
- identifiy and target any unvaccinated high priority target patients, and
- determine the size of the order for the next influenza season.

Calculation of order size is based on:

- practice population size
- DH/CMO guidance on the target patient groups for the next year's campaign
- number of patients already identified as within the target populations
- performance and attainment levels within target groups during the current influenza campaign
- an adjustment for expanding/shrinking practice registered population and target populations
- any aspirational attainment levels for the next influenza campaign.

3.29.2 January to February
The practice negotiates with the vaccine supplier sales representatives on:

- the size of order
- the timing and phasing of deliveries; and
- the level of discount on list price.

In general, the larger the order and the earlier it is placed, the more favourable the terms that can be negotiated. The negotiations are usually conducted by the practice manager and/or a GP partner. In some areas, GP co-operatives or consortia group together to negotiate more advantageous terms than practices could negotiate separately.

3.29.3 March
The practice reports the final attainment level for the current influenza campaign.

3.29.4 April to September
The practice undertakes a number of planned activities to support effective delivery of the influenza programme:

- identifying and flagging the records of patients within target groups
- adjustment of target groups based on CMO letters and other sources of advice
- negotiation within the PCT of any local influenza vaccination incentive scheme (usually designed as a LES).

3.29.5 August to September
The practice completes planning for the forthcoming influenza vaccination campaign:

- patient identification: final flagging of target patient records
- deliveries: final confirmation of delivery date for vaccines
- operational:
  - details for practice influenza campaign agreed and implementation commences
  - agree prioritisation strategy for patients in target groups

.• if supplies are delayed or compromised the use of early deliveries is restricted to those in the highest priority groups i.e. target highest priority patients first and supply to low priority target patients next. Only supply to non-target patients if there is adequate supply and target patients attainment levels have already been reached
• advertising in the practice of the upcoming campaign including leaflets, posters, messages attached to prescriptions, advice given verbally and in leaflet form from receptionists and all clinicians in the practice
• commence booking nurse-run dedicated mass vaccination clinics. Typically, these would include 2–3 hour-long clinics held one to three times per week, with appointments at 3-minute intervals.
• later in the season, as numbers requiring vaccination decrease, the practice books shorter mass vaccination clinics of 60 to 90 minutes duration
• arrange supplies every day in each clinician's consulting room for opportunistic vaccination of high priority patients, identified by a flag on their clinical computer record
• arrange one or more mass open-access 'walk-in' vaccination clinics on Saturdays and evenings a few weeks after the influenza season commences and advertise/promote these to medium priority target patients.

3.30 Within the first four to five weeks of a campaign, the above methods should have enabled attainment levels of 50% to 60% in the target groups. At this point, the campaign methods move from a reactive programme to a more proactive targeted approach. These proactive targeted methods include:

• telephoning/mailing patients in target groups who still have not received vaccination to arrange attendance at clinic (repeatedly if necessary)
• attaching personalised letters or individualised messages to repeat prescriptions ordered by high priority unvaccinated patients
• visiting nursing homes and house-bound patients at home
• high priority labeling by receptionists of target patients to assist opportunistic vaccination of patients attending clinicians for other reasons
• identify and record all target patients who refused or could not take the vaccination for valid reasons. These records contribute to the exclusion data. Exclusion data are usually not finalised until late in the campaign as most practices seek to minimise the number excluded. High exclusion rates may adversely affect the level of practice remuneration.

3.31 An example of the influenza campaign delivery plans developed by an individual practice is included as Appendix 3.

Factors influencing attainment levels

3.32 The PCTs and other stakeholders that we spoke to were consistent in the factors they identified as crucial to influencing attainment levels in practices. To inform our analysis, a number of PCTs provided anonymised practice information and categorised performance using QOF achievement as a proxy for achievement overall. In general, the more organised and high performing a practice, the more likely it is to have high attainment in influenza vaccination. We found that performance was not related to the contract type (GMS or PMS) as there has been a progressive alignment of contractual requirements relating to seasonal influenza vaccination. Performance appeared largely independent of practice size, depending instead on levels of planning, organisation and teamwork.

3.33 Those contributing to the review indicated that medium to large practices benefit from an increased staffing and administrative structure and, as a consequence, have more flexibility, skill mix and capacity to manage demand, changes in programme scheduling and staff absence. Conversely, small practices, where a member of the team may have to fulfill many roles, may not have that flexibility and resilience.

3.34 The population the practice served was considered to have a significant impact on the workload required to reach stretch targets*. Overall, practice population had a modest correlation with performance, except in the lowest performing practices which appeared slightly less successful in overcoming challenges or adverse events during the vaccination campaign.

3.35 Population factors that appeared to be associated with increased challenges in attaining high performance include:

- low levels of fluency in the English language
- low levels of familiarity with the NHS and the way it works
- some cultural beliefs related to influenza and vaccinations. i.e. a belief that vaccines cause influenza
- high levels of absence amongst target patients during the influenza season. Attainment rates in this group of 'winter expatriates' who live abroad for the winter, might be improved by offering vaccination early in the season, perhaps during September or October before they travel.

3.36 The factors that appear to be associated with high or low performance in seasonal influenza vaccination are summarised in Table 1.

*defined as a target that is achievable but challenging. The target or series of targets requires a cost-effective investment of organisation and resource to achieve, but the targets can be attained by moderate or even poorly performing practices provided they invest a reasonable amount of energy and time.

Table 1 Factors influencing GP practice influenza vaccination attainment level

Factor	High attainment	Low attainment
Clinical and managerial resources devoted to influenza vaccination	Sufficient availability of managerial and senior clinician time protected for influenza vaccination. This is a factor of appropriate staffing levels within the practice rather than size of the practice.	Overloaded or understaffed practices with consequent shortage of managerial or clinician time and energy to devote to influenza vaccination.
Leadership of seasonal influenza campaign	The campaign requires clear leadership, with empowerment to make decisions and, if necessary, alter working arrangements in the practice and commit clinical and managerial resources.	Poor quality leadership, not empowered to make decisions or commit resources.
Teamwork	Good teamwork where influenza vaccination is seen as the responsibility of all members of the team, thereby allowing team members to be engaged in a variety of vaccination delivery strategies to be used. The influenza team is freed from some other responsibilities to create room for influenza programme workload.	Responsibility for the seasonal influenza programme is allocated to an individual or a subset of the team and the remainder of the team abrogates responsibility for delivery of the programme. The influenza team is not released from their pre-existing workload to create space for influenza programme workload.
Operational management and organisation	Clear forward planning of resources required, e.g. timetabling of clinics and staff involvement. Effective balancing of influenza vaccination alongside other clinical workload. Effective skill mixing of the influenza programme delivery team. Good co-ordination of vaccination activity with stock deliveries.	Poor forward planning and operational delivery, poor consideration of opportunity costs. Inefficient communication with patients and poor prioritisation of target groups. Poor skill-mixing with inappropriate use of high skill staff. Vaccination activity is not synchronised with deliveries of stock.
Regular review and performance management of the campaign	Regular reporting of activity and review of progress by the influenza team. Flexibility to respond to unplanned changes in the supply chain.	Lack of regular review of activity. Inflexible arrangements that cannot be altered to address needs.
Key staff	Key managerial, administrative and nursing staff available and involved.	Poor timetabling of vaccination activities, key staff absent or not engaged.

Part B

Review

Section 4 Review of the problems reported in November 2005

Section 4

Review of the problems reported in November 2005

4.1 The key question raised in November 2005 concerned the provision of seasonal influenza vaccine in England. Shortages of supply and delays in supply were being reported in October and November 2005.

4.2 At the time, indicators of uptake pointed to coverage of risk groups then no higher than in previous years, despite a reported supply of influenza vaccine 27% greater than was used in the previous year.

4.3 Concerns were expressed that GPs may not have ordered enough vaccine or had given it to people outside the at-risk and target groups. Contradictory reports from organisations representing primary care asserted that there was a shortage of vaccine and attributed this to the improved identification of patients within target groups, and a consequent expansion in the size of these target populations. The QOF emphasis on detection and identification of target patients was cited as a contributory factor.

4.4 These reported shortages occurred at a time when there was heightened media interest in Government action to address the risks of avian and pandemic influenza.

4.5 Public and professional concerns were heightened by reported shortages and delays in vaccine supply during the early part of the then current influenza campaign. The reports also highlight the problems of delays in supply during 2004, in particular the manufacturing problems by Chiron (now Novartis) and the short term withdrawal of production at their manufacturing plant in Speke, Merseyside due to a production licensing issue.

4.6 In late July 2005, the European Vaccine Manufacturers (EVM) announced that due to one of the three vaccine seed strains for production being provided to vaccine manufacturers by the National Institute for Biological Standards and Control (NIBSC)/WHO later than planned (by three to four weeks); and that the international reagents needed for the quantification of antigen content were received by vaccine manufacturers later than planned for that season, there would be a delay of two to four weeks in the delivery of vaccine to GP practices.

4.7 This statement was refuted by the NIBSC and resulted in a retraction of the statement on the EVM website. NIBSC highlighted:

- that following strain selection by WHO in early 2005, it was necessary to create the reassortment NYMCX-157 strain – an additional step compared with the previous year
- the NYMCX-157 strain was issued from NIBSC on 15 March 2005, only seven days later than the issue of B/Jiangsu in 2004
- the NYMCX-157 reagents were issued from NIBSC from 23 May–2 June 2005, which was only five days later than issue of B/Jiangsu reagents in 2004

- the reagents were issued before calibration was complete to allow vaccine manufacturers to use the reagents for vaccine testing. This was done to minimise delays in vaccine testing. The calibration was completed on 13 June 2005 which was only nine days later than in 2004
- there were no identified delays in shipment of viruses and reagents to individual EVM members
- a delay in production of NIBSC reagents planned for mid-May was delayed due to one of the EVM member's delay in supplying antigen in time for the planned NIBSC freeze drying date.

4.8 The DH recognised that the potential delay would be a problem and contacted practices informing them that they would be contacted by their supplier and informed of revised delivery times.

Review of data

4.9 We have reviewed available data and information sources relating to the supply and demand for seasonal influenza vaccine. However, these data are incomplete and these deficiencies need to be borne in mind when interpreting the findings. The weaknesses in availability of information highlight a need for better data.

4.10 We have looked at the mechanisms for monitoring levels of influenza and influenza-like illnesses, and the data on vaccine supply. National and sentinel vaccine uptake collections monitor vaccine uptake in the risk groups recommended to receive influenza vaccine. Although data are available for vaccine uptake in the general population and those vaccinated outside risk groups, the data source does not provide information on why these individuals were vaccinated. There is currently no routine source of information available about individuals who receive influenza vaccine outside the current recommendations.

Data sources not used in the review

4.11 A number of PCTs operate influenza vaccination incentive schemes and collect data on practice attainment against these incentive targets. We have not included these data in this review as the schemes and data recording methodologies vary significantly between PCTs.

4.12 We have not sought access to individual practice data in England because this information is not routinely available.

4.13 Data from individual vaccine manufacturers on sales, stock returned from GPs and unsold stock are considered commercially sensitive by the manufacturers and were, therefore, not made available to the review.

Data sources used in this review

4.14 Vaccine uptake data are available on those over 65 years, those in risk groups under 65 years and health care workers. In addition to these monthly updates, weekly vaccine uptake data from spotter practices are available from the RCGP and QResearch. In this review, vaccine uptake data from the RCGP have been analysed. It should be noted that this reporting system is based on around 100 GP practices with a population of 900,000 (at the time of writing this report, January 2007) and unlike the national data, cannot be analysed by PCT.

RCGP WRS

4.15 At the time the data were being analysed, we used unpublished data from the 2005 Annual Report (the 2005 report has recently been published). The data were provided as a monthly breakdown. To illustrate the make-up of the RCGP WRS we have used published data from the 2004 report. In 2004, 73 practices contributed to the WRS. These sentinel practices are spread around England and Wales, use the three main GP clinical computer systems in England and Wales (EMIS, Torex / Meditel and In Practice Systems), and have an average of five doctors per practice.

4.16 The sentinel practices in the 2004 study cover a total population of 625,744. Representation as a percentage of the total SHA population ranges from highs of 2.6 % (North East) and 1.8% (West Midlands), to lows of 0.6% (London) and 0.4% (Yorkshire and Humber). The figure for Wales is 1%. The survey population is representative of national population by age and gender. The WRS population is increasing and by late 2006 included almost 100 practices with a population of 900,000.

Prescription Pricing Division (PPD) data on NHS prescriptions

4.17 The Prescription Pricing Division (PPD) of the NHS Business Services Authority (NHSBSA) collects data on NHS prescriptions dispensed by community pharmacists. Reports from frontline NHS organisations and bodies representing pharmacy confirmed that only relatively very small numbers of seasonal influenza vaccines are issued on NHS prescription forms (FP10) and dispensed by community pharmacists. The utility of data from the PPD is limited because the data do not discriminate between vaccines that are personally administered or dispensed on order by prescription.

Contingency stock

4.18 We have examined the ordering and distribution of the central DH contingency stocks in 2005.

DH questionnaire to PCTs

4.19 We examined the collated responses to a DH questionnaire to PCT influenza coordinators issued with the DH letter written to influenza coordinators in PCTs on 3 November 2005.

Findings

4.20 In ideal circumstances, the seasonal influenza campaign starts in mid-September after primary care staff and their patients return from the annual summer vacation period.

4.21 During 2005, deliveries of influenza vaccine to practices took place in mid-September and the majority of patients aged 65 and over received their vaccinations from late September through to November. Coverage in the years prior to 2005 showed achievement figures of over 60% (end of October) and 80% (end of November) of final attainment levels.

Table 2 Influenza vaccination rates for those aged 65 and over during the 2005 programme (source: RCGP)

Month	Monthly number of vaccinations in target populations	Monthly vaccinations as % of final seasonal attainment	Cumulative total as % of seasonal attainment
Sep 2005	837,982	9.5	9.5
Oct	4,560,110	51.4	60.9
Nov	2,234,141	25.2	86.1
Dec	713,297	8.0	94.1
Jan 2006	275,866	3.1	97.3
Feb	111,126	1.3	98.5
Mar	59,367	0.7	99.2
Apr	27,650	0.3	99.5
May	16,016	0.2	99.7
Jun	7626	0.1	99.8
Jul	14,008	0.2	99.9
Aug	6993	0.1	100.0
Total	8,864,182	100.0	

4.22 In general, from early December, clinical workload pressures, and holidays over the Christmas period can force a redeployment of practice staff away from influenza vaccination to mainstream clinical and administration tasks. In January and February some practices make a final effort to vaccinate 'hard to reach' patients to achieve their practice vaccination targets, and use up any spare vaccine on patients in lower priority groups.

4.23 The analysis of influenza vaccination data supplied by the RCGP illustrates that the 2005 campaign started approximately three weeks later than previous campaigns, with deliveries of some limited stock to practices from the third week in September. This analysis is also supported by data and

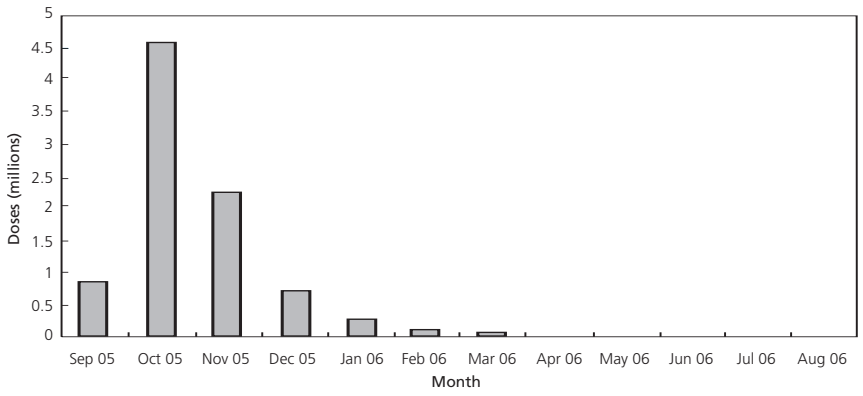

Figure 2 Attainment over the 2005 programme
Data source: PPD

reports from individual practices and PCTs that submitted evidence to the review.

4.24 We spoke to a number of practices and PCTs and they reported the prioritising of high risk patients for these early limited supplies and delaying mass vaccination clinics until they had received the bulk of their orders. In most cases, practices reported receiving large deliveries in early or mid October and, as a consequence, they ran mass vaccination clinics in the second half of October and early November.

4.25 The Prescription Pricing Authority* and RCGP data (Figures 2 and 3 and Table 2) illustrate the activities reported to us by practices and PCTs. Despite the late start, intense catch up activity in late October and during November ensured that by the end of November 2005 attainment levels (86% of final attainment in the 2005 season) had caught up with usual levels.

4.26 This suggested to us that although the majority of practices were able to manage patient demand and ensure vaccine was given, local variations in supply may still have occurred and this could have been misconstrued as indicative of a more general shortage.

4.27 Table 2 and Figures 2 and 3, showing all prescribing activity in England, illustrate a slightly delayed start to the influenza campaign. Only 1.9% of influenza vaccinations were supplied in September. However, there was a rapid catch-up in October (49.5%) and November (34.4%) to match or exceed usual attainment levels by the end of November. These data correlate well with anecdotal reports that practices delayed the start of their campaigns until adequate vaccine supplies were available. When supplies were secured, practices made efforts to vaccinate patients as rapidly as possible, driven by patient demand. Compared to campaigns in previous years, GP practices scheduled additional vaccination clinics and increased opportunistic vaccination of patients attending the practice for other healthcare issues.

Contingency stock

4.28 The data and analysis from the RCGP presented earlier appear somewhat at odds with the media reports during October and November 2005 of a reported shortage of influenza vaccine. In an attempt to clarify this matter, we have examined the ordering and distribution of the central DH contingency stocks in 2005.

4.29 The DH had secured central contingency stock in several, but not all, previous influenza campaigns (Table 3).

*Now the Prescription Pricing Division (PPD) of the NHS Business Services Authority (NHSBSA)

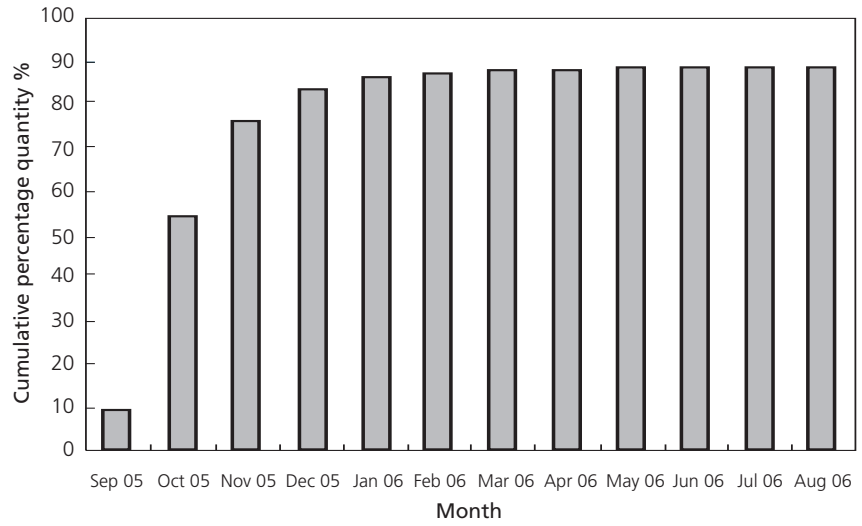

Figure 3 Quantity of influenza vaccine administered (cumulative percentage of final attainment)
Data source: PPD

Table 3 Seasonal influenza vaccine supply 1996 - 2005

Year	DH contingency (Doses)	Direct to GPs from suppliers
1996	0	6,217,875
1997	0	7,249,890
1998	0	7,633,172
1999	0	7,816,013
2000	0	10,900,337
2001	500,000	11,392,920
2002	500,000	11,914,182
2003	0	11,762,514
2004	400,000 rising to 2.9m after Chiron plant licence withdrawn by MHRA	12,391,350
2005	400,000 rising to 1.2m after reported shortages	13,718,352

4.30 Potential shortfalls in the local availability of influenza vaccine are managed by the central procurement of contingency stock. For 2005, the DH initially procured 400,000 doses of vaccine.

4.31 As part of ongoing discussions with suppliers, and responding to reported supply problems, a further 200,000 doses of vaccine for contingency purposes were ordered on 3 November 2005. This increased the planned contingency stock to 600,000 doses.

4.32 As at 24 November 2005, 3354 drawdown orders for seasonal influenza vaccine contingency stock had been received by the DH. Care is needed when interpreting these data, as the amount shown will also include PCTs ordering on behalf of a group of practices or PCTs and practices placing multiple orders.

4.33 On 28 November 2005, a further 600,000 doses were ordered to augment the central contingency stock. This increased the planned contingency stock to 1.2 million doses.

4.34 Despite the concerns that had been expressed about a perceived shortage of vaccine at the start of the campaign, 800,000 doses of central contingency stock were not distributed to the frontline organisations by the end of the campaign.

4.35 To explore the impact of these alleged drivers of increased demand, we examined the collated responses to a DH questionnaire to PCT influenza coordinators issued with the DH letter written to influenza coordinators in PCTs on 3 November 2005. This document had also been copied to: Directors of

Finance at SHAs and PCTs; Nursing, Primary Care and Chief Pharmacists / pharmaceutical advisers of PCTs, informing them of the availability of DH contingency stock (400,000 doses) and how to order from that contingency stock.

4.36 The letter requested feedback on:

- the number of general practices in each area requiring additional vaccine
- what arrangements were in place to identify and re-distribute vaccine
- whether groups have been prioritised
- whether demand was greater than expected and, if so, the reasons leading to that situation.

4.37 The responses to this questionnaire are included in Appendix 4. In summary, the respondent PCTs identified the following:

4.37.1 Variable concerns about vaccine supply ranging from those with no problems at all to those reporting a range of difficulties.

4.37.2 Many practices were prioritising the patients at highest risk for early vaccination. However, some practices were not and were reported to be offering vaccinations to patients outside the risk groups.

4.37.3 Demand did appear to be increased in some areas and there were reported local shortages of vaccine supply. We believe that although the majority of practices were able to manage patient demand and ensure that vaccine was given, there may have been localised variations in supply. This could have been misconstrued as indicative of a more widespread shortage.

4.37.4 A significant number of practices were affected by delays in supply.

4.37.5 The media reports of avian influenza were felt to be resulting in increased demand, converting previous 'refusers' to actually seek vaccination, and fuelling some demand from younger 'non-risk' or 'worried-well' patients. There was also reported increased demand for influenza vaccination from NHS staff and workers in essential services.

4.37.6 Practices were working towards more ambitious attainment targets than in previous years.

4.37.7 The risk groups had increased in scope and identification of patients at risk had increased numbers.

4.38 In an effort to determine whether vaccination usage had increased between 2004 and 2005, we collated data on the number of available doses of seasonal influenza vaccine in each year, i.e. doses ordered by and delivered to frontline organisations and teams through their normal supply chain, and also the total central contingency stock.

4.39 The total available stock between 2004 and 2005 remained steady at around 14 million doses.

Table 4 Summary of total number of doses available in the 2004 and 2005 campaigns

Year	Number of doses available	DH contingency stock	Total number of doses used (excluding unused contingency)	Number of doses used (UK)	Contingency unused
2004	11,735,953	2,900,000	14,635,952	12,391,350	–
2005	13,388,092	1,200,000	14,588,092	13,718,352	813,588

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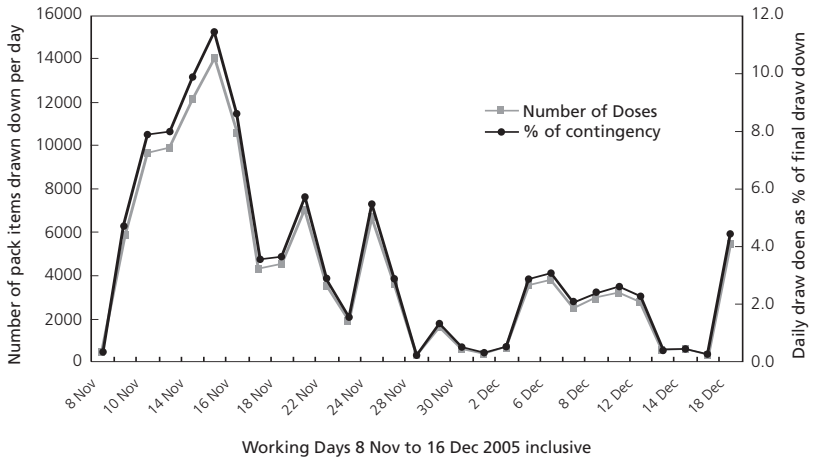

Figure 4 Daily drawdown of DH contingency stock in 2005

In 2005, 387,412 doses of DH contingency stock were distributed to frontline organisations. 812,588 doses remained unused (Table 4) and represents a cost of approximately £5 million (using the average list price excluding VAT).

4.40 In the period between 23 October 2005 and 19 December 2005, 87,412 doses of contingency stock were dispatched to satisfy 4043 drawdown orders (Table 5).

4.41 Data provided by the DH show the number of doses dispatched. 387,412 doses were dispatched which equated to 122,846 packs. It is not known for whom this vaccine was ordered as data on the destination for the drawn down stock are not available. Information collected in the questionnaire issued on 3 November 2005 (Appendix 4), show some local shortages and delays in vaccination associated with increased patient demand. However, this was not universal and some PCTs were reporting no problems in supply.

4.42 Figure 3 and Table 6 show the numbers of pack items dispatched from the distributors on a daily basis from 8 November to 16 December 2005 inclusive. In the first two weeks of dispatch of the contingency stock (the period between the 8 to 18 November inclusive) 71,286 doses were dispatched (58% of the final quantity). This period also includes the dates with the highest dispatch activity. The busiest single day was 15 November 2005 when 14,038 doses (11.4%) were dispatched. It is not clear why activity was highest at this period.

Table 5 Contingency supply, drawdown orders and drawdown doses dispatched in 2005

Date of contingency stock order 2005	Number of doses of contingency stock per tranche	Total number of drawdown orders	Total number of doses dispatched from contingency
Initial contingency stock order	400,000	–	–
Additional order 3 Nov 2005	200,000	–	–
No. of drawdown orders by 24 Nov 2005	–	3354	–
Additional order 28 Nov 2005	600,000	–	–
Number of drawdown orders by 19 Dec 2005	–	4043	387,412
Final data at 19 Dec 2005	1,200,000	4043	387,412

Table 6 Number of doses of contingency stock dispatched in 2005

Date dispatched 2005	Number of pack items drawn down daily	Cumulative total of pack items dispatched	Daily dispatch as % of total	Cumulative %
8 Nov	442	442	0.4	0.4
9 Nov	5808	6250	4.7	5.1
10 Nov	9649	15,899	7.9	12.9
11 Nov	9825	25,724	8.0	20.9
14 Nov	12,117	37,841	9.9	30.8
15 Nov	14,038	51,879	11.4	42.2
16 Nov	10,615	62,494	8.6	50.9
17 Nov	4320	66,814	3.5	54.4
18 Nov	4472	71,286	3.6	58.0
21 Nov	7010	78,296	5.7	63.7
22 Nov	3465	81,761	2.8	66.6
23 Nov	1894	83,655	1.5	68.1
24 Nov	6709	90,364	5.5	73.6
25 Nov	3534	93,898	2.9	76.4
28 Nov	284	94,182	0.2	76.7
29 Nov	1649	95,831	1.3	78.0
30 Nov	580	96,411	0.5	78.5
1 Dec	362	96,773	0.3	78.8
2 Dec	642	97,415	0.5	79.3
5 Dec	3512	100,927	2.9	82.2
6 Dec	3779	104,706	3.1	85.2
7 Dec	2472	107,178	2.0	87.2
8 Dec	2917	110,095	2.4	89.6
9 Dec	3202	113,297	2.6	92.2
12 Dec	2767	116,064	2.3	94.5
13 Dec	511	116,575	0.4	94.9
14 Dec	544	117,119	0.4	95.3
15 Dec	302	117,421	0.2	95.6
16 Dec	5425	122,846	4.4	100.0
Total	122,846	(387,412)*	100.0	

* Dispatches from Healthcare Logistics (formerly Farillon) include multi-dose as well as single dose quantities. Total number of individual doses dispatched is 387,412

4.43 By Friday 25 November 2005, the distributors had dispatched 93,898 pack items (76.4% of total). The second contingency order of 600,000 was delivered on Monday 28 November 2005. It is notable that 97,415 pack items (79.3% of total) of the contingency stock were dispatched by Friday 2 December 2005.

4.44 Requests for draw down of contingency stock were received and collated by the DH. Stock to fulfill the orders was dispatched from the distributor after confirmation by the DH.

4.45 We identified a number of issues relating to the management of the contingency stock that need to be addressed:

• the processing of contingency stock orders was administered by two experienced members of DH staff with additional temporary staff on an ad hoc basis and during a period of intense activity. This represented a heavy workload for those individuals
• there were no control measures on the submission of orders. Despite the DH, in its letter of 3 November 2005, requesting that influenza coordinators from each PCT placed the orders, it appeared that PCTs did not follow the request to route all orders through the local influenza coordinator. In addition, there were no restrictions on the authorisation of orders, nor a requirement to obtain the endorsement from the relevant PCT before submitting the request
• the DH staff coordinating the orders and contingency stock distribution had no means by which they could further assess the severity or potential impact of the alleged shortage prompting the request and, therefore, had no means by which to prioritise requests
• those frontline organisations that drew down contingency stock were not charged for the stock
• records are not routinely and completely collected identifying:
  • the name of the clinical team to be supplied
  • the reason for the drawdown
  • the PCT involved, and
  • whether the same team had also drawn down contingency stock in previous years.

4.46 Four other factors have been postulated by those interviewed as also contributing to the perception of a supply problem at the time and included:

4.46.1 Media reports of the avian influenza 'scares' secondary to avian influenza incidents in South East Asia and the discovery of a dead swan in Scotland.

4.46.2 Media reports of delayed supply of seasonal influenza vaccine and reports that highlighted the risk of avian and pandemic influenza. Some members of the public appeared to confuse elements of seasonal influenza, avian influenza and pandemic influenza and erroneously believed that seasonal influenza vaccination would give some degree of protection against avian and pandemic strains. The media interest seems to have at least accelerated patient demand so that patients proactively requested their vaccinations earlier in the season rather than waiting for a scheduled call from their practices. The media reports may also have helped encourage target patients to seek vaccination who in previous years had neglected, or refused, and the 'worried well' to go for vaccination. These events increased pressure on practices earlier in the campaign when stock was limited. The mismatch of demand and supply forced many practices to prioritise high risk patients and to delay vaccinating lower risk patients resulting in inconvenience to some patients and increasing their concerns. This further escalated perceptions that there was a shortage of vaccine.

4.46.3 The increased numbers of patients identified as members of target and at-risk groups resulting from improved case finding and disease registers in practices relating to the introduction of the QOF and the incentives incorporated within the new contractual arrangements for general practice to immunise certain patient groups.

4.46.4 Further changes to the existing definition of carers. The DH announced a new definition for this target group in the spring of 2005 after the majority of practices had placed their orders for the campaign. We found that there was also some confusion as to how to apply the definition of carers.

Systems analysis

4.47 Despite the reported shortages of influenza vaccine in November 2005, the available data suggest that sufficient vaccine was available overall for at-risk and target groups, even though there were delays in the supply of vaccine to practices and some reports

that people outside the recommended risk groups were receiving vaccine. However, we acknowledge that the data available are of mixed quality and in some instances not available, of very poor quality or incomplete. It has, therefore, not been possible to establish a precise audit of events.

4.48 Taking these issues into account we concluded that the concerns reported in October and November 2005 could not be attributed to a single cause, but identified a number of contributory factors, which may have led to the problems experienced.

4.49 We have based our analysis of the problem on the 'Swiss cheese model' of system accidents developed by Professor James Reason (Reason, 2000). Professor Reason describes defences, barriers and safeguards in systems and how 'holes in defences' arise for two reasons: 'latent conditions' and 'active failures'.

4.50 We identified a number of latent conditions in the seasonal influenza immunisation programme that contributed to system weakness. These include:

4.50.1 Media reports and professional concerns about supply problems in a number of consecutive years have eroded public and professional confidence.

4.50.2 Apart from the annual CMO letter, there appears to be no published long-term strategy for maintaining and improving the seasonal influenza programme, or the planned trajectory of increasing coverage of the target and at-risk population.

4.50.3 Performance management of the programme at all levels is highly variable and local information flows need to be strengthened.

4.50.4 The management of central contingency stocks need to be strengthened. The rationale, management of requests for supplies, and the performance management of the supply need strengthening.

4.50.5 There is limited flexibility to manage unplanned delays in manufacturing, late notification of changes in target groups and increased demands from general practice.

4.50.6 The procurement of influenza vaccine directly by general practices is vulnerable to local variation in the calculation and annual adjustment of orders to meet the needs of the target population and may constrain the effectiveness of local and national population planning.

4.50.7 The seasonal influenza programme requires significant planning by GP practices throughout the year with the clinical workload spread over a fairly limited period during September to December. The capacity to respond to delays in vaccine delivery is limited by the need to reschedule staff time at a time when practice workload is increasing due to winter-related illness.

4.50.8 The nGMS contract and particularly QOF, have assisted in the identification of the at-risk population but, as a result, has increased the number of identified patients in the target population - increasing both workload and the volume of vaccine required.

4.50.9 Changes in the definition of at-risk groups, and changes in the definition of carers, particularly when there is also uncertainty and variation in the application of the definitions, have increased the identified target population.

4.50.10 The DH needs to consider the timing of the advisory letter to the NHS (from CMO, CNO, CPO). Whilst this provides important information on the planned campaign, the publication date does not synchronise with the vaccine ordering schedule for general practice.

4.50.11 The role of the influenza coordinator needs to be strengthened and the interface of roles and responsibilities with immunisation coordinators and pandemic influenza leads needs to be clarified.

4.50.12 Overall there is a need to strengthen communication with influenza coordinators, to coordinate management of the programme locally, and to share learning more effectively across SHA boundaries.

4.50.13 Arrangements for occupational health programmes need to be strengthened. Current coverage is generally low and there is no clear local or national strategy or performance management.

4.50.14 Relationships with a number of key stakeholders need to be strengthened.

4.51 These latent factors represent systemic weaknesses in the programme which, in an environment where a number of active factors can fluctuate, may result in a loss of management control and lead to a rapid shift in confidence in the programme. The active factors appear to have been:

4.51.1 In late July 2005, the EVM announced that due to one of the three vaccine seed strains for production being provided to vaccine manufacturers by NIBSC/WHO later than planned (by three to four weeks); and that the international reagents needed for the quantification of antigen content were received by vaccine manufacturers later than planned for that season, there would be a delay of two to four weeks in the delivery of vaccine to GP practices. Although this statement was subsequently refuted by NIBSC and resulted in a retraction of the statement on the EVM website, the announcement impacted on the confidence in the programme.

4.51.2 Consequent delays in supply of vaccine to general practices.

4.51.3 Increased media reporting of cases of avian influenza.

4.51.4 The timing of an announcement by the Chief Medical Officer (CMO) of the inevitability of a future influenza pandemic and the need for strengthened planning and public awareness.

4.52 It appears that these factors in combination destabilised the seasonal influenza programme and contributed to an erosion in the public and professional perception around the availability of supply. There is some anecdotal information provided to us by several practices and PCTs that this may in turn have contributed to increased demand by patients on GP practices, which could not be matched by immediately available supplies, resulting in the need to reschedule clinics, thereby further leading to some practices experiencing a shortfall in supply and claims that there was a shortage of vaccine despite an adequate supply of vaccine being available overall.

4.53 The latent factors are reviewed in more detail in Section 5.

Part C

Option appraisal

Section 5
Review of the programme

The international context

5.1 The manufacture and supply of seasonal influenza vaccine is a global business. Research and development facilities and manufacturing activities are spread worldwide, particularly in North America, Europe, Australia and Japan.

5.2 The market is worldwide with increasing international competition for the available supply, particularly when there is a delay or shortage in the supply system. The market is dominated by the demands of the northern hemisphere which now consumes over 300 million doses per annum, a scale of demand much greater than the 60 million doses used in the southern hemisphere.

5.3 There is substantial manufacturing capacity in the UK and this supports significant provision for the US market as well as the European market. However, most of the international vaccine manufacturing capacity is based in mainland Europe and Australia.

5.4 Influenza vaccine manufacturing facilities are complex and require: large supplies of fertilised hens' eggs from special protected flocks; approved, licensed, dedicated production facilities; and logistical support systems. The reliance on production facilities outside the UK may increase some of the supply chain risks for the UK. There is a potential risk that countries hosting manufacturing plants could impose special conditions on their manufacturing capacity for preferential supply of product to the host territories.

5.5 Each national territory has its own seasonal influenza strategy and this creates risks for market stability, and potential 'knock-on' effects. Significant increases in a country's supply requirements could cause increased competition on the international market and pressure on other countries' allocation of stock, inflation of prices, or redirection of stock outside the UK's territorial boundaries to address demand in the affected country.

5.6 In 2003, the World Health Assembly urged nations with influenza vaccination policies to increase vaccination coverage of all people at high risk and to aim at vaccination coverage of elderly people of at least 50% by 2006 and 75% by 2010. The 2010 target coverage was achieved for the first time in England in 2005. We recognise this achievement and encourage the DH to undertake further work in order to maintain progress. In addition, the DH should continue to seek the level of coverage of target populations that would make the most effective and efficient use of resources. Targets – both aspirational target levels for coverage, and the planned trajectory for achieving these levels – should continue to be based on the best available evidence.

5.7 The DH should continue to communicate priorities in a timely manner to vaccine manufacturers to assist them to plan adequate future supply.

International decision-making

5.8 Several key steps in decision-making relating to seasonal influenza are effectively addressed internationally through cooperative international organisations such as the WHO. This has advantages in agreeing common approaches and sharing information, but it can also introduce some delay in decision-making.

5.9 We heard evidence of the international collaborative work on influenza, particularly through the WHO, but considered that there was an opportunity to strengthen international collaboration particularly to achieve greater consensus and concordance on risk groups and target levels for coverage. There appears to be limited shared international decision-making on these important elements of vaccination policy even within the European Community. Vaccine production capacity is internationalised and affected by international and national vaccine policy. In our view, a lack of international policy coherence would seem to potentially increase the risk of influenza vaccine supply problems. We concluded that as seasonal influenza vaccine manufacturing capacity is already stretched, there needs to be better international coordination - both in identifying at-risk and target groups and the agreement of aspirational target coverage and the trajectories to attain these targets. We were concerned to hear from some stakeholders that the current manufacturing supply chain may not be capable of matching significant expansion in the definition of risk groups or elevated target coverage rates. We believe that there should be greater coordination to ensure that unilateral territorial decisions do not impact on supply across international boundaries, and particularly within Europe.

5.10 We recognise the crucial role of the WHO within this process, and the reliance on critical consensus decisions on vaccine constituents. In particular, the meetings in each calendar year to review circulating strains and agree strains to be included in the forthcoming season's vaccines are in effect the 'starting gun' for the manufacturing process. We questioned whether the timing of these meetings is optimal or whether it might be feasible to bring these meetings forward earlier in the production timeline. We recognise that we lack both the expertise and breadth of evidence to comment further.

Communications strategy

5.11 Public interest in seasonal influenza was particularly high in 2005, partly fuelled by concurrent scares and media stories about pandemic influenza and avian influenza. There was a high level of coverage of seasonal influenza in the specialist clinical and general lay media in the autumn of 2005.

5.12 It is important to acknowledge that much of the published coverage reinforced positive aspects of the seasonal influenza immunisation programmes and encouraged participation. However, there was also a considerable amount of negative or potentially confusing coverage such as alleged vaccine supply problems, specifically delays and shortages in supply. In particular, the reporting seems to have led to some confusion about the differences between seasonal, avian and pandemic influenza. There were potentially confusing messages about the risks, pathophysiology and the public health implications.

5.13 The DH has a budget for the media and communication campaign related to seasonal influenza. This budget is determined annually and is relatively modest in terms of a national awareness and communications campaign. Many SHAs and PCTs also fund local communication campaigns on seasonal influenza and, therefore, the total combined expenditure of the DH and NHS is difficult to quantify accurately.

5.14 The DH produces publicity materials to support the seasonal influenza programme, including patient leaflets, a poster campaign for health care facilities, and advertisements on television and radio and in the printed media. Press releases and packs are distributed to media contacts. At the time of fieldwork, in May 2006, we were concerned to learn

that the communications budget for the 2006/07 season had not been finalised, and were concerned that this might impact upon delivery of the campaign. We recommend that this should be reviewed and that a decision on available budget should be resolved much earlier.

5.15 There is a DH communications strategy that sets out the nature and content of the seasonal campaign and, in particular, publicity materials and media placement. The DH measures the extent of seasonal influenza coverage in the media but does not appear to discriminate between positive and negative coverage. In addition, the DH reports the coverage attained nationally and in each PCT by target group, but does not analyse the vaccination attainment level and change year-on-year related to the level and format of local media activity on influenza.

5.16 We concluded that there was a need to strengthen media management to deal with adverse media interest particularly where there are alleged supply problems.

5.17 Seasonal influenza coverage rates vary substantially within target groups. Reports on seasonal influenza campaigns in previous years have repeatedly highlighted particular sub-groups of the at-risk and target populations which have lower uptake, even though some of these sub-groups are at particular clinical risk. Examples include black and ethnic minority groups, frequent travellers, drug and alcohol users, people in certain types of residential care (educational or behavioural problems) and those in the custodial system. There is very limited research clarifying the barriers contributing to low uptake in these groups, or evaluating the effectiveness and efficiency of campaigns specifically targeted at these 'hard to reach' groups. We did find some evidence of innovative local campaigns by health care organisations (practices, community health service providers, PCTs) and some charities that were successful in increasing uptake of seasonal influenza immunisation, but the campaigns appeared to have had limited evaluation and little shared learning of successes and failures. There does not appear to be a clear local, regional or national strategy to capture locally successful interventions to address these hard to reach groups and disseminate learning to the wider NHS.

5.18 We could find little evidence of any strategy or mechanism to capture and disseminate best practice. Examples that were cited by the DH were generally from the London area, and this seemed to reflect the ease of geographical access to the organisations concerned rather than the level of innovation or best practise. There did not appear to be any systematic approach to collecting this information, nor an effective means of dissemination. The DH can communicate via the advisory letters to the NHS but there is no regular national discussion forum or web-based discussion site, and no regular national seasonal influenza coordinator meeting. The absence of these fora limits effective communication and the sharing of good practice. Three significant communication channels require particular consideration:

- advisory letter to the NHS (CMO letter)
- national influenza coordinator meetings
- websites/internet resource and discussion forum.

Advisory letter to the NHS

5.19 The advisory letter to the NHS, from the CMO, CNO and CPO, is a key vehicle for communicating policy changes and information on target groups and supply chain issues. Currently, influenza information is usually included in late spring and late summer advisory letters. These timings are not optimal for influencing the most important points in the clinical service's seasonal influenza timetable: the ordering of vaccine supplies in January to February for the next influenza season; and the planning in July/September of the target influenza vaccination patient notification and the organisation of vaccination clinics.

5.20 We understand that the decision on the definition of at-risk groups is made by the JCVI in November of the preceding season. We recommend that the DH reviews the timing of the dissemination of this information, and the timing of publication of the advisory letter to the NHS so that GP practices can review practice population registers, better assess influenza vaccine requirements, and place orders to secure supplies for the practice population.

5.21 We are aware that the DH currently meets with UVIG in January but are mindful of the need to

provide early notification to the NHS of target groups for the following season's influenza campaign, so that vaccine orders can be properly assessed. We recommend that the feasibility of amending the timing of the meeting with UVIG be reviewed.

5.22 We recommend that the first advisory letter to the NHS should be published in January, i.e.8 months before the start of the influenza campaign in September. This letter should clarify the target groups for the following season's campaign, in time to inform clinical services who place their influenza vaccine orders during the period between December and March.

5.23 We recommend that the second advisory letter to the NHS should be published in July. The letter should confirm the final strains that are to be used for the autumn influenza campaign, clarify and update any supply chain issues, lay out the provision and 'drawdown' arrangements for contingency stocks, and 'fine tune' or clarify any definition of target groups.

Risk groups

5.24 GPs are entitled to claim payment under the influenza DES and QOF. The risk groups covered under the DES, which are based on JCVI advice, differ under the QOF. During the 2005 campaign, the QOF definition of asthma was broader than under the DES definition.

5.25 Many of the stakeholders we met cited the inclusion of carers as a new risk-based target group for the 2005 campaign as an example of some of the difficulties in expanding the target groups. There was broad agreement with the decision to include carers in the high risk disease groups, and a recognition that significant influenza activity in this population group would lead to considerable workload on the NHS from both the carer and the person being cared for. A large number of carers (in excess of one million) may be involved if some of the broader definitions of carer are employed.

5.26 However, we found no consistent definition of a 'carer', and noted that the definition used in the seasonal influenza programme differed from the QOF definition, the Department of Work and Pensions definition, and the interpretation of the definitions actually employed by GPs. In our view, this causes unnecessary confusion and is not a sustainable position. We recommend that a single definition be agreed across the NHS and for the purposes of vaccine supply ordering.

5.27 We concluded that the advisory letter to the NHS announcing the inclusion of this target group in the seasonal influenza target population for this year came too late, being issued after most GP practices had already ordered their supplies of influenza vaccine for the 2006/07 campaign. These issues need to be addressed by the DH.

Performance management

5.28 We believe that the performance management of the seasonal influenza immunisation programme should be strengthened. We found that the robustness of performance management was subject to variation. There was evidence that some poorly performing practices and clinical teams are not being monitored or performance managed effectively by their PCT. There was similar variation in the performance management role of SHAs. Performance management arrangements need to be clearly defined, become more consistently and effectively applied, and appropriate sanctions invoked where performance fails to improve. The profile of seasonal influenza within the planning agenda needs to be enhanced within NHS organisations and monitoring of performance requires validated data systems.

5.29 The NHS is currently undergoing a major organisational reform. New SHAs were established in July 2006, and new PCTs in October 2006. We recommend that the DH should take the opportunity to review the governance arrangements for the seasonal influenza programme to take account of these organisational changes and determine the responsibilities and accountability of each tier of management. We believe that this will provide an opportunity to strengthen performance management arrangements at a regional level, and foresee an increased role for SHAs working with PCTs in their health economies. There may also be a an enhanced role for the healthcare regulators, particularly the HC.

5.30 The management of variation in performance between organisations needs to be tempered by balancing the public's right to equity of provision with their right to exercise their free choice. All patients within identified at-risk and target groups should have access to influenza vaccination but should be allowed to exercise their free right to refuse such vaccination. If, because of cultural or belief reasons, they choose to decline vaccination then they have a right to do so but the healthcare organisation must still make strenuous efforts to address and provide appropriate education and support to empower people to make an informed decision.

5.31 The introduction of the QOF as a substantial element of the revised general practice contractual arrangements may benefit the seasonal influenza campaign. QOF enforces tight definitions of target groups and rewards the creation and maintenance of accurate practice registers for these target groups. This would greatly assist the accuracy of local and national data on target groups provided that the definitions of these groups are consistently applied.

5.32 Improved data on target groups should:

- inform procurement
- support manufacturers' ability to match long term demand with production goals
- provide adequate lead time to build capacity
- enhance performance management of the influenza programme
- minimise potential risks of over or under-supply.

Contingency stocks

5.33 For all but one of the last five years the DH has contracted for a central supply of vaccine to act as a contingency stock for England, Scotland and Wales. Northern Ireland has its own arrangements for contingency stocks.

5.34 The decision as to whether to order a contingency stock, the size of that stock and the distribution arrangements for the stock, have been decided annually. Tenders to supply the contingency stock are covered by EU Procurement rules because of the size of the contract. To comply with the legal requirements, advertisements are placed in the OJEU in February and the tenders are opened in early July.

The rationale for the contingency stocks

5.35 A number of NHS organisations arrange their own local contingency stocks, effectively replicating some of the national contingency stock. During the review, a number of PCTs reported ordering in the region of 3,000 to 5,000 doses for local use within their PCT. There is, therefore, a risk of duplication and redundancy of contingency stocks and potential risk of waste or inappropriate use.

5.36 If the concern is to insure against inefficiency in local ordering or local supply chain, linked to poor performance by an NHS organisation or manufacturer, then contingency stock may not be the best solution. Instead steps should be taken to improve performance. This needs to be complemented by a timely and efficient drawdown process with some control by the DH to allow prioritisation against need, rather than a 'first come - first served' drawdown system.

5.37 The addition of new target groups or the extension of existing target groups or target levels would only result in a need for contingency stock if the announcement of these extensions occurred after influenza vaccine orders are submitted by frontline clinical teams, e.g. if the announcements occur later than February. This could be avoided by the timely announcement of target groups by November.

5.38 If it is agreed that a contingency stock is required, then the decision needs to be made as to whether this should be decided and contracted nationally or locally in individual PCTs, or regionally across a consortium of PCTs with arrangements for risk and supply sharing.

5.39 If there is a decision to continue with a central contingency stock then the DH should review:

- the basis for the size of the stock to be held
- the design and implementation of drawdown arrangements

- the identity of practices of the contingency stock, particularly large volume or recurrent users and determine the reasons underpinning such use
- whether contingency stock should be managed at a national or local level.

Potential for rolling contingency stock contracts

5.40 If there is a decision to continue securing large scale contingency stock supplies, held either nationally or regionally, then consideration should be given to the appropriateness and feasibility of securing rolling contracts with suppliers which may achieve better pricing.

Planning assumptions and trajectories

5.41 The decision on whether to continue to procure a contingency stock, its scale and the use of the stock should be based on an assessment of risks, trajectories of influenza vaccine uptake in target groups and vaccine supplier manufacturing capacity and risks.

Potential charges to those outside recommended risk groups – rationale and logistics

5.42 A number of those interviewed raised the issue of potential charges to groups outside the recommended target groups, if supplied with vaccine. We could find no clear rationale to providing seasonal influenza vaccine stock intended for the NHS target groups to other non-target groups. Under the current regulations, a GP that supplies and administers the vaccine to such a person can claim a personal administration fee. The charging of a fee might create a potential perverse incentive for diversion of NHS supply to low risk groups.

Current management arrangements for the national contingency stock

5.43 The current arrangements for managing the delivery of the stock from the manufacturers to the storage facilities, the ordering and the draw down of this stock by NHS organisations and the management of the logistics of delivery to the user organisation are primarily overseen by a small team at the DH. This workload becomes very intensive during the autumn influenza season. There are risks associated with the dependency. We noted that:

- there is very variable awareness amongst frontline organisations of the existence of a contingency stock, its size and the drawdown arrangements
- there are no clear criteria for prioritising the use of the contingency stock - it is currently distributed mainly on a 'first come - first served' basis
- the nature and scope of frontline organisations that request the stock vary enormously: from individual single doctor practices up to, and including, large PCTs
- there are no current arrangements to use PCT influenza coordinators to investigate and validate the actual extent and nature of shortages reported by local organisations before orders are endorsed and provided from national contingency stock.

Perverse incentives

5.44 Organisations that draw down contingency stock are not currently charged for this stock. They essentially receive a free vaccine supply and this could create perverse incentives to overuse, or inappropriately use contingency stock. Essentially:

- using national contingency stock that is provided free of charge reduces the financial risk of the seasonal influenza campaign to GP practices
- inappropriate use of the national contingency supply destabilises any mainstream supply
- inappropriate use of contingency stock introduces inequity in access to influenza immunisation
- inappropriate draw down of contingency stock amounts to an indirect subsidisation of inefficient practice.

5.45 There is a lack of clarity as to how drawn down contingency stock is used by the frontline organisations and, in particular, how much is actually administered to target groups. In some areas, unused contingency stock to occupational groups towards the end of the influenza season. Whilst this increases

coverage rates in these key occupational groups, it is indicative of poor planning and prioritisation.

5.46 Some of those interviewed voiced their concerns that contingency stocks are delivered by manufacturers to the DH later in the influenza season - it was reported that early influenza vaccine supplies are prioritised for frontline organisations. As a consequence, by the time this stock is drawn down and actually delivered to the frontline organisations it is very late in the season and too late to impact significantly on the seasonal influenza programme.

Performance management

5.47 Current arrangements for performance management of the influenza vaccine contingency stock are very limited. There are no robust data on:

- utilisation trends
- which organisations have drawn down contingency stock
- when they drew it down
- why they drew down
- what they did with the supplied stock
- how these organisations perform against target
- what steps these organisations took to prevent a need for draw down in subsequent years and, if so, whether these initiatives were successful.

5.48 We were concerned that the failure to collect such data limits year on year learning and hampers the provision of feedback to local organisations to enable them to manage local procurement more effectively. The lack of robust data on the use of contingency stock, and when it is drawn down by organisations, may disguise potential wastage of some of this stock. Wasted stock not only squanders financial resources but erodes the effectiveness of the contingency reserve, and establishes a pattern of poor management of resources that may be potentially exacerbated in the event of a severe vaccine shortage.

5.49 Events in autumn 2005 demonstrate the fragility of arrangements and the wastage that can occur. During a period of heightened professional and media concern, the DH ordered an additional 800,000 doses during November 2005 to augment the existing central contingency stock of 400,000 doses. Despite the concerns that had emerged, and despite active management of the situation by the DH, it was reported to us that the additional 800,000 doses were not used.

Should contingency stock be held nationally or locally?

5.50 There is considerable debate on the issue of where to hold contingency stock: nationally, regionally or locally within frontline organisations (PCTs). Currently there is no clear evidence as to which is the most appropriate level to hold contingency stock. There is a risk of duplication and inefficient use of resources if contingency stock is procured at both national and local levels.

5.51 The advantages/disadvantages of national stock include:

- large orders provide an opportunity to negotiate favourable financial and delivery arrangements from suppliers
- vaccine can be moved anywhere nationally where there is a shortage
- identification of needy areas may be more complicated and prolonged and delay delivery of product.

5.52 The advantages/disadvantages of local stock include:

- more local knowledge of need and the reasons for need
- more incentive for the PCT to prevent recurrence
- may be more effective at recovering the costs of the products supplied
- more difficulty sharing/redirecting contingency stock to other health economies.

5.53 We recommend the following measures to strengthen management of the contingency stock:

5.53.1 A system should be introduced where the local PCT influenza coordinator must be informed of all contingency draw down orders received from within that PCT area so they can coordinate locally and follow up and manage reported shortages

5.53.2 The system for authorisation of those submitting draw down requests needs to be strengthened

5.53.3 The reasons behind the request for contingency stock, the amount requested and supplied and the usage of the stock supplied should be recorded

5.53.4 Requests for contingency stock need to be prioritised

5.53.5 Consideration be given to charging for contingency stock

5.54 Data on draw down orders should be routinely analysed to identify repeated users and the reasons prompting requests for draw down.

Influenza coordinators

5.55 Influenza coordinators are appointed by primary care organisations to coordinate and lead the seasonal influenza programme at a local level. They have an important role to play in strengthening influenza vaccine management and encouraging improvements in uptake and coverage.

5.56 There appears to be a lack of consensus between PCTs on the roles and responsibility of influenza coordinators and there is great variation in the implementation of the influenza coordinator role. We noted significant differences between influenza coordinator posts including:

- the extent of the role
- the level of seniority of the post holder
- the reporting mechanisms within the organisation to board level
- the background of post holders
- the job descriptions
- the additional non-influenza responsibilities of post holders
- their discretion to manage budgets and the size of those budgets
- their ability to influence allocation of financial and human resource within the PCT
- the input into PCT strategy.

5.57 The managerial level at which post holders are appointed shows considerable variation between organisations. Our enquiries suggest that some of the biggest influences on the success or otherwise of the post are:

- the seniority of the post and the post holder
- the extent of the additional non-influenza workload they have to manage
- the access and influence they can exert on strategy and resource allocation.

5.58 We also noted a lack of coherence between the roles, responsibilities and appointment of:

- influenza coordinators
- immunisation coordinators
- pandemic influenza leads (Directors of Public Health/emergency planning leads).

5.59 We have concluded that there was a general failure to integrate or interconnect these roles, responsibilities and strategies at PCT and SHA level. Communication with these key individuals needs to be strengthened. We recommend that within organisations there should be more coherence and integration, interaction and support between these roles and personnel.

5.60 We concluded that there is a need for improved communication between the DH and local influenza coordinators and for increased networking and peer support amongst local influenza coordinators. Such initiatives would:

- facilitate more timely dissemination of guidance and best practice
- aid the early identification and solving of problems
- facilitate peer support and the personal development of influenza coordinators
- support contingency planning and business continuity.

5.61 We found that there is an over-reliance on informal networks and no apparent structured engagement and programme governance. This leads to inconsistencies in approach, the risk of impaired performance, and introduces considerable variability in the operating methods and effectiveness of influenza coordinators.

5.61.1 Possible solutions that could address these needs might include:

- the DH to hold regular national meetings for seasonal influenza coordinators
- regular national meetings with influenza coordinators to support effective communication about programme objectives and delivery. We recommend that these meetings could be held to coincide with the recommended revised publication schedule of advice to the NHS:
  - January
    To review performance in the previous influenza season and to review the implications of the latest advice on target groups for the forthcoming influenza season.
  - July
    To review plans and performance management arrangements for the forthcoming influenza season, communication strategies, the management of potential interruptions to vaccine supply, and the management of contingency stocks.
- some form of web-based discussion forum available on the internet
- local peer-support groups organised into clusters of primary care organisations.

5.61.2 These communication events would contribute to:

- a two-way exchange of information
- harvesting of local intelligence
- earlier proactive and deeper intelligence
- shared learning
- shared ownership of programme objectives.

5.62 A local mentoring programme that allowed more recently appointed or junior influenza coordinators to be mentored by more senior, experienced and effective colleagues would assist a rapid development of newly appointed staff and build capacity in the service.

5.63 Within their organisations, influenza coordinators need to engage with, and gain support from, senior management, especially at board level. With the multitude of competing demands on NHS organisations, seasonal influenza would benefit having a board level champion. We consider it important that there be board level accountability for delivery of the programme. Natural candidates for such a role would be the Director of Public Health or the Chair of the Professional Executive Committee (PEC).

5.64 Given the importance on increased local accountability, we concluded that the DH should support better engagement and review governance arrangements within the influenza programme.

5.65 We noted the inevitable and appropriate focus on establishing robust plans to manage pandemic influenza, but observed that there have evolved three distinct roles of:

- immunisation coordinators
- influenza coordinators
- pandemic influenza leads

5.66 We believe that there would be benefit in greater coordination. Pandemic influenza leads are in many cases Directors of Public Health and we believe that there would be possible advantages in developing the responsibilities of this role to take overall responsibility for all the influenza programmes. We believe that this will improve the support available to seasonal influenza coordinators and immunisation coordinators, and provide some consistency and coherence in managing these important public health programmes. Such an approach would reinforce the importance of the seasonal influenza programme and provide engagement with the broader public health strategy.

5.67 Data flows on seasonal influenza vaccine ordering and uptake vary considerably in quality, completeness and timeliness between organisations. This can introduce a degree of inaccuracy and uncertainty to the local and national monitoring arrangements for the seasonal influenza campaign.

5.68 As part of the review of governance and performance management, the DH should review data requirements and provide guidance to the NHS on better use of existing data.

5.69 We heard anecdotal reports of an increased lack of lay and professional confidence in the benefit of seasonal influenza programme in some areas. This erosion of confidence appears to be the result of repeated supply problems and negative media coverage in the specialist clinical and general lay media. These reports are difficult to verify or quantify. However, they may point to a need to strengthen public and professional confidence in the programme in a more proactive manner. There is a clear need to promote positive messages and 'good news stories' about the successes of the programme, coupled with clear and transparent attempts to improve management overall.

5.70 The seasonal influenza campaign is largely delivered by clinicians: they plan the local clinics, identify members of the target groups, order the stock and arrange its delivery, immunise patients and record the intervention. While we saw some examples of very progressive and effective interactions between influenza coordinators and frontline clinicians, we also saw significant evidence of failure to communicate with clinicians, and engage them fully in this programme.

5.71 The take-up of seasonal influenza immunisation amongst NHS staff is low – in general less than 30%, and is far from the levels recommended by the DH. Data on take-up amongst other occupational groups, particularly emergency and essential workers and occupational target groups are not currently widely available or considered reliable. In general, PCTs have not prioritised occupational health target groups, nor have they as yet developed strong working relationships with occupational health services.

Non-GP delivery mechanisms

5.72 NHS reform and policy encourages the diversification of the healthcare workforce with greater skill mixing, expansion of the skills of health professionals, and the range of clinical practice.

5.73 The programme of reform in primary care has established new contractual frameworks providing opportunities, flexibilities and incentives for new ways of working. Examples include: the new flexibilities in the contractual framework for community pharmacy enabling the delivery of a wider range of clinical services; and the expansion of nurse and pharmacist prescribing. There is also a commitment to expand access and equity in healthcare, underpinned by a programme of plurality and choice.

5.74 The seasonal influenza supply system should work to reflect these fundamental shifts and the programme should take advantage of the new flexibilities to help manage the capacity of a GP-based supply system to respond to increasing population coverage.

5.75 There are, of course, important clinical governance issues to address, and GPs will need to discuss local initiatives with their respective medical defence organisations to ensure that appropriate indemnity arrangements are agreed.

5.76 The DH has published its guidance, Immunisation against infectious diseases (Department of Health, 2006). The HPA has published national minimum standards for immunisation training (Health Protection Agency, 2005).

5.77 The DH has published a review of the regulation of non-medical healthcare professions (Department of Health, 2006).

5.78 Using alternative providers and new access to deliver seasonal influenza vaccination vaccine would:

- manage increased demand for seasonal influenza vaccine, with additional personnel to supplement current limited delivery capacity through GP practices, which is dependent upon GPs and practice nurses
- improve accessibility by offering new access points, such as community pharmacy. These may respond to the special needs of hard to reach groups.

5.79 However, the introduction of alternative providers and new access points may:

- increase the complexity of calculating influenza vaccine requirements, as patients may be double counted by two delivery teams, e.g. GPs and community pharmacies
- require new incentive and reward systems to encourage collaborative working between the health professions and alternative

providers.

Potential new delivery routes for seasonal influenza vaccination

Community pharmacy

5.80 The new contractual framework for community pharmacy may offer opportunities for innovative practice in seasonal influenza supply such as:

- essential services: signposting of public and patients to access points for seasonal influenza
- advanced services: targeting of information for at-risk and hard to reach groups via community pharmacies rather than general practice
- enhanced services: vaccine administration in the pharmacy (currently being piloted in a number of areas).

5.81 Community pharmacies may be particularly effective for targeting and accessing hard to reach groups who do not usually attend general practices, e.g. carers, employed people, teenage and young adult males.

5.82 We received evidence from a number of pilot programmes in England and Scotland on the enhanced role of community pharmacy in the delivery of the seasonal influenza programme (Hind, 2006) and recommend that the DH evaluates the evidence and determines whether further studies are required.

Community nursing

5.83 Community nursing staff and teams (e.g. district nurses, health visitors, school nurses; practice nurses, community psychiatric nurses) may currently be under-utilised in some areas of the country. In particular, they may be effective at accessing: elderly care centres; vulnerable groups (e.g. mental health patients, drug and alcohol abuse patients, patients with learning difficulties, ethnic minorities, mothers with families etc).

Healthcare assistants

5.84 We reviewed written evidence of a number of pilot programmes utilising trained and accredited healthcare assistants in the administration of influenza vaccine in PCTs in England.

5.85 The Medical Defence Union (MDU) has given advice to members on the role of healthcare assistants; reinforcing the need to assess competence for the role, in line with GMC and Nursing and Midwifery Council (NMC) advice on delegation, and the need to maintain a record of the training programme (Medical Defence Union, 2006).

5.86 The Working in Partnership Programme (WiPP) is currently working on advice for general practice, and developing a protocol template that will help ensure minimum standards are met in relation to healthcare assistants undertaking the role.

Non-GP doctors

5.87 Doctors employed in acute hospitals, mental health trusts and rehabilitation centres, as well as employed doctors in out of hours GP services could be utilised to target hard to reach groups such as inpatients, mental health patients, patients with learning disability, those with other disabilities, and users of emergency services.

New alternative providers

5.88 New providers of health care, including the commercial sector and independent healthcare providers are developing opportunities in primary and community care. Some Alternative Provider of Primary Medical Services (APMS) may be contracted to address seasonal influenza vaccination in particular, especially where there is a record of low levels of performance in general practice-based delivery systems.

Occupational health services

5.89 Occupational risk groups have been identified and targeted in previous seasonal influenza campaigns but the coverage is low – ranging from 15 to 30% in most healthcare organisations. There has been poor progress in achieving significant changes in uptake in this sector. This coverage needs to increase substantially to be effective, and to help maintain an

effective workforce at times of increased influenza activity. In addition, a range of other occupational groups such as emergency services, essential services, and social care may be added as target groups for future campaigns.

5.90 There is likely to be significant expansion in the target levels and the size of the targeted populations within the occupational health sector. NHS data on these occupational groups are incomplete, and need to be enhanced to support any future programme.

5.91 The following issues have particular relevance:

- there is a need for clear and consistent definitions of the target groups
- there is a lack of data on current activity in influenza immunisation in occupational risk groups
- aspirational levels and the trajectory for achievement must be clearly decided and fully communicated
- there is a need to explore incentives to reward achievement in coverage
- performance management systems for the occupational health target group need to be strengthened
- there may be a key role for the HC and other healthcare regulators to develop standards and inspect NHS organisations against the occupational health standards
- there is a need to fully understand the supply routes and their interaction, including the interface between occupational health services, and GPs.

Supply cold chain

5.92 There are currently no available local data on the seasonal influenza vaccine cold chain. Despite there being a number of different logistic or supply companies and strategies there is currently no system for:

- standard audits, or
- targeted visits and spot checks.

5.93 There are a number of factors that determine biological stability, including handling and the age of the vaccine. Stability relates specifically to the efficacy of the product and, generally, manufacturers will state that most seasonal influenza vaccine should be used within one year of manufacture. In general, influenza vaccine appears to be more tolerant of minor short term problems in the cold chain than some other vaccines. The DH provides routine information on the storage, distribution and disposal of vaccines for health professionals in the Green Book (Department of Health, 2006). The only public information on individual vaccine stability is contained within the Statement of Product Classification (SPC) and is also provided by manufacturers.

5.94 We were informed about two specific issues relating to the cold chain that need to be maintained:

5.94.1 *Maximum and minimum temperatures*

Vaccines should be stored in the original packaging at between +2C and +8C and protected from light. Effectiveness cannot be guaranteed for vaccines unless they have been stored at the correct temperature. Freezing may cause increased reactogenicity and loss of potency for some vaccines. It can also cause hairline cracks in the container, leading to contamination of the contents.

5.94.2 *'Cycling'*

The term 'cycling' is used to describe the repeated raising and lowering of temperatures even within the recommended storage temperature band for the cold chain. This can cause damage to the vaccine.

5.95 We concluded that there was currently an over reliance on documentary audit trails to provide assurance on cold chain integrity and recommend that these are enhanced local arrangements by:

- reviewing the distribution logistics, to identify potential system weaknesses in ad hoc distribution mechanisms at a local level
- providing additional guidance
- initiating structured audits by influenza coordinators
- arranging for random spot checks of the cold chain and storage arrangements by influenza coordinators or other appropriately trained and qualified clinical staff

5.96 The DH is undertaking work to assess the benefit of bar coding for batch tracing. The DH recognises the importance of maintaining the cold chain and continues to explore with manufacturers the advantages of using heat sensitive detectors on pack labels.

Healthcare regulation

5.97 The regulation of health and social care has been considerably strengthened in recent years as an integral part of healthcare reform. The opportunities for these regulatory bodies to assess the effectiveness of the seasonal influenza programme in their respective sectors should be further explored.

Healthcare Commission

5.98 The Healthcare Commission (HC) is a key regulator of healthcare and promotes improvement in the quality of the NHS and independent healthcare. It has a wide range of responsibilities, all aimed at improving the quality of healthcare. The HC has a statutory duty to assess the performance of healthcare organisations, award annual performance ratings for the NHS, and coordinate reviews of healthcare by others.

5.99 The HC has a key role in assessing the implementation, effectiveness, access and equity of the seasonal influenza campaign in healthcare organisations. The DH should discuss with the HC how this role could be enhanced.

Monitor

5.100 Monitor regulates NHS foundation trusts, making sure they are well-managed and financially strong so that they can deliver excellent healthcare for patients.

5.101 There is a role for Monitor to assess the delivery of occupational health services in NHS foundation trusts and their implementation of seasonal influenza vaccination in the healthcare workforce.

Commission for Social Care Inspection

5.102 The Commission for Social Care Inspection (CSCI) is the independent regulator of social care and will amalgamate with the HC in 2008. CSCI has a potential role in inspecting seasonal influenza campaign effectiveness in social care environments such as care homes, rehabilitation and day care centres.

5.103 We recommend that the DH should initiate discussion with the regulators to further develop and implement systems to monitor the effectiveness of the seasonal influenza programme in their respective sectors.

5.104 We recommend that the assurance process and performance management of NHS organisations in relation to the seasonal influenza programme should include the following elements:

- board level accountability
- defined accountable officer
- assessment of the robustness of the delivery plan
- actual delivery data compared against targets
- direction and speed of delivery trajectories
- action plans for addressing poor performance and managing risk
- assurance frameworks
- compliance with HC standards.

Regulatory framework

5.105 Influenza vaccines are biological products and their constituents change annually. Influenza vaccines are currently required to undergo evaluation in limited clinical trials prior to licensing. A number of those interviewed questioned the evidence base, role, reason and utility of the current limited clinical trial. Several of those interviewed suggested reviewing the requirement for such trials, as they were perceived to add little value and build in a further delay during vaccine manufacture.

5.106 We recognise that attempts have been made to streamline the regulatory process but, given the increasingly pressured timeline for influenza vaccine

development, manufacture, licensing and supply to market, there is a need to review the timeliness and speed of all elements of the process. This may reveal ways to minimise any potential for avoidable delay and maximise the speed and efficiency of each element in the pathway.

Building relationships

5.107 Seasonal influenza policy is the responsibility of the DH. There is wide recognition of the extent and depth of expertise within the DH and also the expertise of individual members in the specialised area of influenza immunisation. Nevertheless, a number of stakeholders expressed concerns about a perceived 'lack of coherence' between seasonal influenza policy and other health policy and the need to enhance credibility.

5.108 An example of lack of coherence is the definitions of target groups in the seasonal influenza campaign and the QOF section of the GP contract. It would seem logical that these definitions should be identical.

5.109 A significant number of those interviewed highlighted difficulties within the influenza programme in building and maintaining relationships with key stakeholders such as:

- NHS Employers
- BMA GPC
- GPs
- influenza coordinators
- specialist professional media.

5.110 A particularly important aspect of such relationships is the management of public announcements and media statements.

The vaccine industry

5.111 Vaccine manufacture is a global business and vaccine supply manufacturers determine the proportions of their manufacturing output to be provided to each country. Each regional division of a vaccine manufacturing company calculates its seasonal influenza requirement and then effectively competes with the other territorial divisions for its company share of the manufacturing production output.

5.112 In general, the international pharmaceutical industry has, particularly over the past five years, undergone a series of mergers and acquisitions that have reduced the number of competing companies in the pharmaceutical industry. It is unclear what impact this may have for the UK market.

5.113 The manufacturing capacity for seasonal influenza vaccine is based mainly in the UK and mainland Europe and Australia. Unexpected events that affect the manufacturing capacity, including contamination, or a failure to gain manufacturing licenses, can have a significant effect on overall influenza vaccine availability. Some of the UK-based manufacturing capacity has been in place for a considerable time. We were unable to establish a clear understanding of any plans to modernise or upgrade the UK-based facilities or the international facilities.

5.114 Vaccine manufacture is reported to be working at the limits of available capacity. It was reported to us that the lead in time to incorporate the building, equipping, commissioning and licensing of a new manufacturing plant could take three to five years in total. We were unable to ascertain whether existing manufacturing plants could expand their current manufacturing capacity incrementally or whether the industry was at a point where it required a step increase in manufacturing capacity.

5.115 England and Wales have a clear long term commitment to expanding seasonal influenza vaccination coverage. However, a clearer communication of the seasonal influenza vaccination strategy, including projected attainment levels and trajectories, could support the ability of vaccine manufacturers to plan for future demand and provide greater leverage in negotiations with vaccine manufacturers.

5.116 Six competing suppliers currently supply the UK market. There is understandable commercial sensitivity between the competing companies and this significantly hinders assessment of the overall influenza vaccine market in the UK. We experienced difficulties in clarifying:

- the real cost of the influenza vaccine supply (i.e. the discounted cost rather than the NHS reimbursement cost)
- the entire volume of influenza vaccine supplied through all routes
- the quantities of unused and returned influenza vaccine
- the volume of influenza vaccine supplied to occupational health schemes
- the redirection of UK supplies abroad
- the identity of health organisations that persistently over or underuse their influenza supplies
- the reasons behind such over or under use of influenza vaccination supplies.

5.117 The industry representative body (UVIG) functions within the umbrella of the Association of British Pharmaceutical Industries (ABPI). Members include: Baxter Healthcare, Novartis Vaccines & Diagnostics, GlaxoSmithKline, Sanofi Pasteur MSD, Solvay Healthcare and Wyeth Vaccines. The aims of UVIG are to:

- promote the positive benefits of vaccination as a key element in improving the health of the nation
- represent the UK vaccine industry to all interested parties

5.118 The DH is a key stakeholder in this relationship and meets regularly with representatives from UVIG.

5.119 This body is inevitably constrained by its members' commercial sensitivity and this creates barriers to the sharing of financial and sales volume data for individual companies, their strategic plans and the future development of manufacturing capability. The ability of the umbrella organisation to influence its constituent member companies is limited.

5.120 Manufacturing capacity is based in a number of countries. We were unable to obtain data on the volumes produced by each manufacturing facility. There is no overall plan in the public domain for dealing with a partial or total loss of manufacturing capacity across the industry, and no plans in the public arena to build resilience and business continuity in the case of loss of manufacturing capacity.

5.121 In previous years some markets have relied heavily on a small number of manufacturing sites. For example, in 2004 when the manufacturing facility at Speke, Merseyside had licensing problems this significantly affected the US market, as 50% of the US market's total seasonal influenza vaccine supply was produced at the plant. The same plant supplied a less significant proportion of the UK market's demand and, therefore, its closure had considerably less adverse impact in the UK compared to the US.

5.122 Lessons have been learned from this incident and many countries now insist on sourcing their supply from a number of different companies rather than over-dependence on one or two suppliers. We understand that many countries now have response plans for any failure in their planned supply that would enable them to purchase alternative supply on the open market more competitively and aggressively than was the case during this incident.

5.123 Other elements that may impact on the development of manufacturing capacity include:

- commercial priorities, such as the market state for influenza vaccine, and return on investment in the influenza sector, may impact on the willingness to invest in influenza vaccine manufacturing capacity
- lead in times for developing vaccine manufacturing capacity are relatively long and susceptible to considerable risks around obtaining and maintaining production approval from medicines regulatory agencies
- changing technology – some companies are developing cell culture production systems rather than the much more widely used egg culture system. If the cell culture system is demonstrated to be effective and commercially viable then it would substantially accelerate and expand the production capacity for influenza vaccine as it would remove the dependency on the egg-based system
- contingency planning and business continuity are vital for this industry.

5.124 The current manufacturing process has a number of key choke points on the current critical pathways. Two elements require particular comment:

5.124.1 Reagent materials are used by the manufacturers to test and quality control the vaccine material they produce. These materials are produced by a small number of laboratories in the UK, US, Japan and Australia. The first three cater for the northern hemisphere campaign and release their products to the industry from June onwards. Laboratories in Australia cater mainly for the southern hemisphere campaigns. The US and Japanese laboratories mainly cater for their own domestic markets.

5.124.2 The UK laboratory managed by NIBSC, has a major role in supplying reagents for the international market in addition to domestic demand. These laboratories are relatively small and have very small numbers of key staff. If one or more of these laboratories were affected by loss of key staff members or loss of this facility this could have a detrimental effect on the influenza vaccine timelines and capacity.

5.124.3 An important step in the influenza vaccine development programme is the gene splicing of influenza virus strains to identify high yielding influenza virus strains appropriate for use in the manufacturing processes. Once the WHO agrees the constituent influenza virus strains for the northern hemisphere vaccine in March, a small independent laboratory in the US starts to develop and trial variants of the nominated strains through a process of gene splicing. The laboratory is funded by two vaccine manufacturing companies. In several recent years the new strains produced by this laboratory played a major role in securing the production pathway when there were difficulties with the original nominated strains that were found to be low yielding. Any loss of key personnel in this laboratory or of the facility would severely adversely affect the resilience and responsiveness of the manufacturing process.

5.125 Several stakeholders discussed their concerns about understanding the operating environment and decision-making by vaccine manufacturers. Areas of concern included:

- the level of actual competition in the sector may currently be very limited, as there are few players and they have relatively stable market share and similar strategies
- there is a small critical mass of experts in the field of influenza and their careers and affiliations cross policy making, healthcare delivery, research, teaching, academia, regulation and industry. Commercial sensitivity will influence the ability to share information relating to manufacturing capacity, pricing, product stability, market strategy and research and development
- the transparency of communication with the sector as a whole. This is inevitable in a commercially sensitive manufacturing and marketing environment.

5.126 The review has identified a key risk of overdependence on a small number of key individuals or facilities at several important rate-limiting steps of the influenza manufacturing and supply process. Examples of these risks include:

- strain variants are developed by a small laboratory in the US, funded by two pharmaceutical companies
- quality assurance of the vaccine supply depends on the supply of reagent materials that are developed in four laboratories worldwide (in the US, Australia, Japan, and the UK). Of these, the UK facility – NIBSC – is particularly important internationally as it provides reagents to most of the European vaccine manufacturing facilities
- there is a relatively small critical mass of individuals within the DH industry, WHO, healthcare and academia with expertise in the production and supply of influenza vaccine
- contingency and succession planning do not appear to be well developed for these critical resources.

5.127 Individual companies use a variety of distribution and logistic systems. We heard that some have equipped their sales representatives' vehicles with cold chain equipment to enable them to assist in the redistribution of stock when there are shortages. All the distribution systems reportedly meet cold chain requirements but there is no external verification of this assertion, and no sampling or site assessments to check the distribution and logistics system. Consolidation within the distribution and logistics system could impact on the risks within the supply chain.

Vaccine supply issues in 2006

5.128 During 2006 there were further reported delays in the supply of influenza vaccine which has provoked further public, professional and media concern although this has been less than that experienced during 2005.

5.129 There were delays due to a variety of factors including lower than expected yields of the selected strains. This highlights that one of the key challenges in the production of influenza vaccine is the variable yield from the culture of different influenza viruses.

5.130 The reported delays in influenza vaccine availability in the EU during 2006 were reported to be due to poor yielding H3N2 reassortant vaccine strains (IVR-142, X-161) being available to industry at the correct time for vaccine production, only to be replaced by a high yielding strain (X-161B) much later. The situation has highlighted the critical nature of the choice of high growth reassortants and the critical dependence on just two laboratories in the world (CSL Australia and Mount Sinai School of Medicine, USA) for supply. Both of these laboratories are funded by industry. The situation has also highlighted the need for improved communication between the USA and EU on influenza vaccine strain selection.

5.131 In 2006 no company submitted a tender for the contract to supply the DH with a contingency stock of influenza vaccine. This reinforces the need to review the rationale and logistics of a contingency stock.

5.132 The challenges of manufacturing a biological product, such as influenza vaccine, means that irrespective of the other measures to strengthen the seasonal influenza programme outlined in this report, there will continue to be a critical dependence on the processes related to the identification of viral strains and the manufacture of vaccine which may continue to compromise the effective delivery of this programme.

Section 6

Options and recommendations for improvement

6.1 A specific objective of this review was to examine the current seasonal influenza vaccine supply system in place in England and to evaluate alternative systems employed in other UK jurisdictions or elsewhere.

6.2 The current system for the supply of influenza vaccine in England is fully de-centralised, allows general practices to order in a number of flexible ways, carries financial incentives (and some financial risk) for GPs, and exposes the DH to little financial risk. However, the current system exposes the DH to criticism if vaccine demand outstrips availability.

6.3 Incentives are in place to reward good performance and form part of the primary medical care contracts. The continued engagement of GPs remains vital to the successful delivery of the seasonal influenza immunisation programme. It is estimated that the current provision of influenza vaccine contributes up to 1% of GP income. Any decision to change the system would require negotiation with the profession, contractual changes and amendment of the existing Statement of Financial Entitlements (SFEs).

6.4 Potential shortfalls in the local availability of influenza vaccine are managed by the central procurement of contingency stock by the DH. Despite the DH providing guidance about how practices should access this central contingency vaccine supply, it is still vulnerable to: under-utilisation and hence wastage; or over-demand and being inadequate to match demand. This process needs to be reviewed concurrent with any review of options for the future purchase, supply and delivery of influenza vaccine. This will include an assessment of:

- the rationale for a central contingency supply
- the most effective means of distribution and management of stocks.

6.5 The management of contingency stock has already been reviewed in Section 5.

6.6 This review has been prompted by perceived problems in the supply of seasonal influenza vaccine during 2005 but also in the previous year. In considering the options available, we were mindful of the ongoing contractual negotiations with the GP representative body (GPC), and the proportion of general practice income related to the seasonal influenza programme.

6.7 We were also aware of the significant concerns that have been expressed following problems that emerged following the introduction of the revised arrangements for the integrated home oxygen service (HOS) in February 2006. Whilst a formal review of that implementation programme is yet to be reported, it is likely that important lessons will

be learned and that these will help inform the implementation of future programmes. Such lessons will be important in informing any future decision on the seasonal influenza programme, and we have made appropriate recommendations.

6.8 In the course of this review we have sought suggestions from stakeholders on the need for, and possible adaptations to the procurement process in order to improve the overall efficiency and responsiveness of seasonal influenza vaccine supply, and to optimise its preparedness for future expansion in target groups or higher target levels.

Options for procurement and delivery

6.9 In summary, we have identified four main models of influenza vaccine supply. These include three existing models and one potential new model:

6.9.1 Option 1 No change
The system currently in operation in England. General practices are individually responsible for ordering and procuring their seasonal influenza vaccine supplies for the practice population. The DH separately procures a central national contingency stock.

6.9.2 Option 2 Stock order
This is the system for seasonal influenza supply currently used in Scotland. General practices determine their requirements for the forthcoming seasonal influenza programme but instead of placing their orders directly with the manufacturers (as in Option 1) place the orders with their local community pharmacies or hospital pharmacies. These pharmacies then place aggregate orders with the manufacturers and draw down stock and supply vaccine to the clinical teams as required. The Scottish Executive Health Department separately procures a central national contingency stock.

6.9.3 Option 3 National procurement and distribution
This system is currently used for childhood vaccine supply in the UK. The DH would gather data on the influenza vaccine requirements for the entire country. There would be a single central procurement of vaccines by the DH. This central stock would then be supplied to a regional area that would then distribute onwards to frontline clinical teams. Contingency arrangements would be incorporated into the national procurement arrangements. There is currently no national network of regional distribution systems

6.9.4 Option 4 A new model
This model would be based upon the central negotiation of vaccine price combined with devolved procurement and an enhanced quality incentive scheme.

Frontline clinical providers would remain responsible for determining their seasonal influenza vaccine requirements and procuring supplies. A reduced purchase price would be negotiated centrally and the savings, which currently go directly to GPs via a discount on the list price, would be redistributed to GPs and other frontline providers through a new graduated reimbursement scheme. This scheme would incentivise and reward the achievement of agreed targets aligned to a number of factors including: data provision, and target coverage levels of at-risk and target groups, including hard-to reach populations.

There would be an enhanced performance management system for the programme at PCT and SHA level. Contingency stock could be held at PCT level with robust prioritisation and sharing arrangements in case of delay or shortage in supply. Any provider drawing down contingency stock would reimburse the PCT at the cost price. We have not tested the feasibility.

Option 1. No change

6.10 The current system has been in operation in England for almost two decades. During this time the UK has made considerable progress in increasing the coverage of the at-risk and target population. Whilst there have been several years when there were reported problems with influenza vaccine supply, it is arguable that the root cause of these delays in recent years lay primarily in the manufacturing process, rather than in the procurement, distribution and administration elements of the system.

6.11 The key elements of the current system are:

- GP practices identify registered patients in identified target groups within their practice population and calculate the total number of patients in the target population
- GP practices review their actual influenza vaccination achievement levels in the target groups in previous years and estimate their likely achievement rates in the forthcoming campaign
- GP practices use the above two pieces of information to estimate their seasonal influenza vaccine requirements for the forthcoming season
- the practice negotiates availability, delivery times and price with manufacturers or wholesalers. These negotiations are usually led by the practice manager, or alternatively the nurse or GP partner leading the practice's seasonal influenza campaign
- after negotiating a discount, the practice orders their vaccine stock direct from the manufacturer. A number of practices split their order across more than one manufacturer in order to spread the risk of disrupted supply by procuring from multiple sources
- the order is usually placed during January and February. Very few practices place orders after March, and manufacturers are generally reluctant to accept orders after that date
- manufacturers' sales representatives or wholesalers will normally undertake a check of the practices proposed order against previous activity and the robustness of their campaign plans before they agree the final order quantities and staged delivery
- the manufacturers' sales representatives or wholesalers arrange delivery in tranches to the practice during the period from September to November; thereby balancing demand for the vaccine against available supply, and avoiding overloading the practice's refrigerated storage capacity
- manufacturers' sales representatives or wholesalers may be involved in facilitating the redistribution of stock if there are local shortages or oversupply
- payment for the supplied stock is in arrears and normally occurs after the GP practice has been reimbursed for their campaign attainments following the conclusion of the campaign (usually at the end of January)
- some manufacturers and wholesalers have arrangements for GP practices to return unused or excess stock with variable levels of reimbursement of some, or the entire purchase price to the practice.

6.12 The practice generates income from three elements:

- a discount on the vaccine sale price that is negotiated below the list price. The level of discounting varies but we believe that levels may typically amount to 30 to 40% of the NHS price
- an administration fee
- target payments linked to DES, LES and QOF targets.

6.13 The GP practice carries the financial risk for the vaccine stock, sharing some of the risk with the manufacturer through stock return or redistribution arrangements. Therefore, the GP practice, and to a lesser extent the manufacturer, has clear incentives to order accurate quantities of stock, arrange timely staged deliveries and avoid waste. However, the same financial risks may also encourage the GP practice to set conservative, rather than stretching, vaccination target levels.

6.14 Further difficulties may arise from under-ordering, resulting in the practice utilising alternative supply channels such as:

• additional prescriptions on FP10s, necessitating an additional supply channel through community pharmacies. In situations where there are generalised supply problems, the community pharmacy route is also likely to be affected
• reliance on national contingency stocks.

6.15 The potential disadvantages of the existing system include:

• planning, ordering and supply of vaccine stocks may be at risk of being fragmented and uncoordinated because the procurement process is dependent on each individual practice and clinical or occupational health team. Conversely, it could be argued that devolved procurement may improve the accuracy and enhance the resilience of the system by protecting against a single catastrophic error
• some GP practices may lack robust or accurate systems to identify members in the target groups in the practice population to accurately determine their vaccine requirements
• some GP practices or clinical teams may have problems organising effective vaccination clinics
• there is some evidence that a small number of GP practices are less efficient at planning and implementing their campaigns. This relatively poor performance adversely affects equity and choice for the practice population but, if there is over-ordering, it also indirectly affects the general vaccine supply and thereby may damage equity and access for the wider population
• the effectiveness of performance management of seasonal influenza programme by PCTs varies considerably. While some PCTs plan and provide timely, appropriate and effective support to their practices, others are not so well organised and do not challenge poor quality data and fail to implement effective sanctions to address poor performance
• the variable quality of local data reduces the quality and utility of national data
• waste, including the under-use of vaccine and diversion to non-priority groups, is difficult to detect and performance manage
• the system is more reliant on indirect subsidisation through the discount element of the price negotiation. Therefore, the true cost of the programme to the NHS is difficult to measure
• only one of the three payment elements for GPs is incentive based and linked to achievements against targets.

6.16 Possible advantages of the current system include:

• there is a simple supply chain – GP practices and the manufacturers
• the current system has achieved high levels of vaccination and has responded well to the expansion in target groups compared to other countries. There is strong evidence that the existing system has, in general, been effective in meeting challenging targets, delivering enhanced targets with annual incremental growth
• the existing system is flexible and has responded well to delays in supply or shortage of vaccine as a result of the ability of GP practices to reschedule vaccination campaigns and clinics. Data show that several recent campaigns have commenced later than planned due to delayed supplies but have rapidly caught up and completed on time and on target
• there are inherent financial disincentives for under/over-ordering by GP practices. Over-ordering leads to financial loss for the GP practice which, depending on agreed return agreements, has to pay for the unused stock. Under-ordering may lead to loss of potential income
• there are disincentives for inappropriate use of vaccine in non-target groups as such groups that do not attract incentive payments or personal administration fees
• the innovative management techniques used in some of the highest performing PCTs demonstrate there is considerable scope, and front line acceptability, for enhanced performance management of the various

elements of the seasonal influenza programme
• QOF and DES/LES schemes have substantially improved target patient identification and achievement levels
• increasing competition within primary care and the emphasis on equity and choice may further drive improvement.

6.17 In summary:

6.17.1 The advantages of this model would be:

• no risk to GP remuneration
• supply and logistics remain unchanged
• the financial risk remains with general practice.

6.17.2 The disadvantages would be:

• procurement and supply remain fragmented, with limited opportunity to ensure equitable access to this public health programme
• management vulnerability is perpetuated if there are delays in the supply chain
• GPs continue to negotiate significant discounts on vaccine procurement, with limited added value.

Option 2. Stock order

6.18 The NHS in Scotland uses a stock order system for seasonal influenza vaccine supply.

6.19 The key elements of the current system are:

• the GP or clinical team identifies target individuals in the population they serve and calculates vaccine requirements for the up-coming season as in Option 1
• the GP practice orders its vaccine requirements from a community pharmacy
• the pharmacies are required to spread their order across at least three suppliers
• the community pharmacy places an order with vaccine manufacturers. The associated financial risk is mitigated by delayed payments to the manufacturer and agreements on return or redistribution of excess stock
• community pharmacy profits from a negotiated discount on the NHS price and a dispensing fee
• the GP practice generates income from an administration fee and target payments linked with DES and QOF.

6.20 The potential disadvantages of the stock order system include:

• this system, compared with the current system in England, introduces an additional step into both bureaucracy and the cold chain
• procurement is devolved to small local organisations and the system does not have the leverage of a single national purchase
• the negotiated discount on the list price currently secured by GPs in England would transfer instead to community pharmacies.
• GPs deprived of the discount element of their current payments would seek additional alternative income to compensate
• the loss to GPs of the discount element would significantly affect their financial and resource planning relating to the influenza vaccination campaign. The 'hard to reach' patient groups are the element of the population requiring the greatest resource investment to vaccinate and, therefore, are at risk of being labelled as not cost-effective to target
• the responsibilities and obligations of the relationship between practice and pharmacy would have to be defined in contractual terms. This would introduce in the vaccine supply chain another layer of contractual responsibilities and obligations
• community pharmacies would have no direct access to patients and, therefore, no mechanism to ensure uptake of any excess stock. Fear of being left with expensive overstock may lead pharmacies to become risk averse
• there is no evidence that community pharmacies would be any better at cooperating together to address shortfalls in the supply chain by redistributing and reprioritising vaccine supply with any greater success than the existing local arrangements facilitated by PCT influenza co-ordinators and pharmaceutical representatives
• there would be an increased requirement for vaccine cold storage equipment in community pharmacies that would only be used for a very short period each year

• the dispensing fee for the community pharmacy may add costs to the scheme
• there is a risk that GPs may not be as robust in identification and targeting of at-risk groups if the financial risk lies with the community pharmacy
• performance management of the system may be complicated by the extra step of including community pharmacies, with a potential lack of clarity on where responsibility lies should the supply system break down.

6.21 The potential advantages of the stock order system include:

• some pharmacies may be able to encourage and support general practices that are performing poorly in their seasonal influenza vaccination campaigns
• community pharmacy investment in cold chain vaccine storage may limit the investment GP practices have to make in dedicated vaccine refrigerators and cold chain storage
• pharmacies specialising in vaccine sourcing and supply may, if they come to control a sufficient share of the market, negotiate improved supply contracts with the pharmaceutical manufacturers or the logistical transport companies.

Option 3. Central procurement and distribution

6.22 The DH currently centrally plans, procures, purchases and distributes childhood vaccines. The model of central procurement and logistics could be applied to the seasonal influenza programme.

6.23 In the current system for childhood vaccine procurement and distribution:

• the NHS centrally gathers information on all children in the target group using data from the central registration of births and health visitor and GP practice registration data. This information is robust and accurate
• childhood vaccinations are spread evenly over the year and demand is predictable months or even years in advance. This contrasts to the rapid expansion of seasonal influenza target groups and coverage levels
• childhood vaccines have a relatively long shelf life and window for use. This contrasts to the very limited window of September to January for seasonal influenza vaccines
• workload within GP practices for delivering childhood vaccines is relatively low and spread throughout the year. This contrasts to the pattern of workload for GP practices in the episodic population-based programmes and high seasonal workload for seasonal influenza campaigns
• the DH uses long term forecasting to predict accurately demand in entering into long term contracts with vaccine manufacturers
• the logistic support for the programme is relatively limited and evenly distributed over the year, unlike the high seasonal workload associated with the influenza campaign
• performance management of the delivery of childhood vaccinations to GP practices is strong and there are effective alternative delivery mechanisms, including community teams and health visitors, if the GP practice is decommissioned.

6.24 If this model were to be applied to the seasonal influenza immunisation programme:

• central ordering may allow more advantageous contract terms to be negotiated for the NHS: including more competitive prices, phased delivery from manufacturers, and added value services
• the national stock would have to be sourced from a number of manufacturers to safeguard supply and this might affect manufacturers' market volume and competition
• there is a potential for enhanced long term planning for the health service and manufacturers through longer term rolling contracts
• if the market is working at or near capacity, there may be very little potential for improved prices. If there is a widespread shortage of supply there may be no incentive for manufacturers to reduce their prices

• the financial risk is transferred from GP practices to the DH or, more likely, NHS organisations at SHA or PCT level
• if the GP practice is not bearing financial risk, there may be less incentive to manage the programme effectively
• in a centralised system, risk can be increased because one error can have wider consequences
• an extra layer of bureaucracy and logistics is added between the manufacturer and the front line clinical teams in GP practices
• redistribution of excess stock becomes the responsibility of the DH or, more likely, NHS organisations, rather than the GP practices and manufacturers' local sales representatives
• there may still be a need for contingency supply but this could be rolled into the larger contract and the distribution arrangements
• GP practices would lose the discount element of their current payment system. This saving would accrue to the central NHS budget but GPs would inevitably demand renegotiation of their contractual arrangements for the seasonal influenza campaign
• NHS organisations do not have a strong history of managing a centralised procurement and supply system. Recent experience of the implementation of a centrally organised procurement through the implementation of integrated home oxygen service (HOS) highlights the risks of replacing a devolved system with a centralised system
• there is a potential increased role for the DH and the new NHS Logistics agency in managing the procurement and distribution process
• central procurement is very dependent on accurate analysis of need and knowledge of local need and capability. There is little evidence that the current NHS data systems provide the required level of accuracy to support the procurement of seasonal influenza vaccine
• central price negotiation would need to be managed taking due account of relevant legislation.

6.25 In summary:

6.25.1 The advantages of central procurement would be:

• potential for the DH to negotiate an increased discount based on volume
• existing logistics and distribution chain with cold chain integrity
• potential for better planning of a major public health programme to ensure that local population needs are addressed
• potential better alignment with, or removal of the need for, central contingency stocks.

6.25.2 The potential constraints of central procurement are:

• the seasonal influenza programme provides a significant proportion of GP practice income (circa 1%), a large element of which is derived from discount on vaccine costs negotiated with the manufacturers.
• if the DH were to move to a central procurement and distribution model, this would represent a significant logistical and operational change. We were mindful of the problems encountered in February 2006 when new arrangements were put in place for an integrated home oxygen service. We concluded that this was a significant risk, given the need to distribute large volumes of vaccine (circa 10m doses) during a relatively short seasonal timeframe
• financial risk would shift from general practices to the DH or to NHS organisations at SHA or PCT level.
• the data on which to calculate national ordering are currently not robust
• vaccine manufacturers may resist central negotiation and discounting
• risk that management of a no-cost vaccine supply at GP practice level would increase waste.

Developing an alternative model of procurement and delivery

Option 4. Central negotiation of vaccine price combined with devolved procurement and an enhanced quality incentive scheme

6.26 In the course of this review we have sought suggestions from stakeholders on possible adaptations to the procurement process to improve the overall efficiency and responsiveness of seasonal influenza vaccine supply, and to optimise its preparedness for future expansion in target groups or higher target levels. The key messages we received were:

Timeframe for the campaign

6.27 The seasonal influenza immunisation campaign should aim to conclude by the end of October. Analysis of influenza activity reveals epidemics start in the period November to January with the most aggressive epidemics starting earlier in this period, particularly in November.

Attainment targets

6.28 The seasonal influenza campaign in the UK has made considerable progress in increasing coverage for people aged 65 and over, set against the WHO 2010 target of 75%. This has already been achieved in the UK and amongst European countries the UK is one of the highest achievers.

6.29 There are precedents for aiming at, and achieving, higher levels from around the world. The US 'Healthy People 2010' programme has set a target for influenza immunisation of 90% in the over 65s. Influenza immunisation in England exceeded 75% in 2005-6 and in some areas reached as much as 82% of the target population.

6.30 Although a recent review questioned the efficacy of influenza immunisation (Jefferson *et al*., 2005), previous reviews have concluded otherwise and have suggested high cost-effectiveness, particularly among care-home resident populations of elderly people – cost per QALY in the over 65s as £2333, and for care home residents – £769 = cost saving (Turner *et al*., 2003). It is clear that outcomes in terms of benefit and the cost-effectiveness are dependent upon the match of vaccine to circulating strains, and on the incidence and severity of influenza in a particular season. If an immunisation programme is considered effective, it should operate on the basis of clear targets and these should be increasingly ambitious in order to maximise individual benefits.

6.31 The United States now advocates immunisation of all healthy infants aged 6–23 months, and Japanese data suggest that immunisation of schoolchildren had a beneficial effect in reducing influenza among the elderly (Isaacs, 2005; Reichert, 2001).

6.32 These are areas that JCVI is already exploring. The next stated goal in England is to improve immunisation in the under 65 risk groups.

Target groups

6.33 Current target groups are likely to expand by a natural growth in numbers of people affected by the conditions in an ageing population.

6.34 The number of people in disease-related target groups is likely to increase, as the prevalence of diabetes and coronary heart disease, for example, increase.

6.35 The increasing number of patients with multiple pathology and co-morbidities will give rise to difficulties in maintaining up to date and accurate disease registers. In turn, this creates difficulties in identifying and counting the target patients and measuring attainment levels in these populations.

6.36 The inclusion of carers as a target group may significantly increase the target population. The absence of a standard definition will create difficulties in creating a register or database, and keeping it up to date.

6.37 The current low coverage of 15 to 30% among occupational target group coverage should increase substantially.

6.38 Occupational target groups are likely to expand by inclusion of new groups in addition to healthcare workers such as the workforce in emergency and essential services, and social care.

A quality based incentive scheme

6.39 The current level of discount on the list price offered to GPs suggests that the amount paid for influenza vaccine significantly exceeds the realistic market value.

6.40 DH should consider renegotiation of the financial arrangements for the seasonal influenza programme to include a redistribution of the current discount element into a graduated incentive scheme based on target patient identification and coverage levels.

Improved performance management

6.41 Performance management of the seasonal influenza campaign could, and should, be improved in line with the methods used in the best performing NHS organisations.

Workforce development

6.42 Current policy encourages diversification of the workforce, expansion of roles and responsibilities for clinical groups, and improved skill mix within the clinical team. Current access policy would support extended roles for community pharmacists, nurses and others, including healthcare assistants, who could make an effective contribution to the seasonal influenza programme.

Operational delivery

6.43 The national contingency stock is currently procured and managed by the DH. In line with the principles of the DH Supply Chain Excellence Programme it may be more appropriate for the responsibility for the procurement and/or the management of contingency stocks to transfer to NHS organisations, becoming a responsibility of PCTs or consortia of PCTs (Department of Health, 2006), organised regionally with enhanced redistribution and risk sharing arrangements and arrangements to recover the costs of contingency stocks drawn down by frontline organisations.

6.44 Separate consideration should be given to the role and management of a national contingency stock.

Production capacity

6.45 Manufacturing capacity is currently at, or very near, capacity.

6.46 Inefficiencies in the manufacturing timeline must be addressed, partly to deliver adequate vaccine supply during the period from August to October to ensure completion of the campaign by the end of October, and partly to prepare for the demands of a potential pandemic situation. Therefore, the elements dependent on international consensus or agreement, such as the WHO agreement of the variants to be included in the vaccine, should if possible be accelerated and occur earlier in the production cycle.

Developing a new model

6.47 We have attempted to take account of these issues in devising and proposing an alternative new model for the procurement and supply of seasonal influenza vaccine based on the following objectives:

- central renegotiation to achieve a lower purchase price
- maintain the current financial risk sharing arrangements between GP practices and vaccine manufacturers

• avoid introducing extra steps or bureaucracy into the supply system
• avoid introducing significant new risks into the supply system and improve management of the existing risks within the system
• the monies saved by the central negotiation of vaccine price should be reinvested into alternative reward schemes for frontline clinical teams, with flexibility to fund graduated quality incentive schemes to encourage and reward high attainment by GP practices
• improve data completeness and quality on seasonal influenza, as this is essential for effective performance management and planning
• improved performance management arrangements for the seasonal influenza programme
• the responsibility for contingency stock procurement and delivery should be devolved to the NHS - most likely, PCTs or consortia of PCTs
• the majority of seasonal influenza vaccination should be completed by the end of October
• a clear strategic trajectory for target groups and attainment levels should be agreed by the DH and shared with the NHS and the vaccine manufacturing industry to inform their planning
• greater disaster resilience and business continuity arrangements should be built into the current manufacturing and supply systems

Proposed new model for seasonal influenza supply

6.48 Applying the above objectives to the supply systems for seasonal influenza has led us to propose a model that promotes central negotiation of the cost of influenza vaccine between the DH and vaccine manufacturers. GP practices would continue to procure vaccine, but the centrally negotiated discounted price would be used as the reimbursable price applied to GP claims. The discount is likely to be quite significant (estimated between £20m and £30m). It is recognised that there is no desire by the DH to erode GP income, and it is, therefore, proposed that these monies be used to fund a graduated incentive scheme to reward performance. This could be used exclusively for the seasonal influenza programme, or more widely to include other immunisation programmes.

6.49 It is proposed that:

• the DH should renegotiate the purchase price downwards to the level at which vaccine is currently supplied to the GP practices
• the savings should be invested into a new graduated quality incentive scheme for GPs based on incremental attainment levels in coverage of target groups, data quality and completeness, and quality parameters such as assurance of the integrity of the cold chain. This could be used exclusively for the seasonal influenza programme, or more widely to include other immunisation programmes
• more robust cold chain assurance, audit and inspection arrangements should be implemented
• performance management of the seasonal influenza programme should be a responsibility of PCTs and SHAs with oversight from the DH
• procurement should remain the responsibility of GP practices negotiating contracts directly with the manufacturers
• over time the responsibility for contingency stocks could be devolved to PCTs which would be encouraged to establish consortia arrangements to manage the risks associated with supply problems and the management of contingency stock
• when a GP practice draws down contingency stock, they should reimburse the contingency stock supplier for the cost of the vaccine
• the majority of seasonal influenza vaccination should be completed by the end of October
• there should be enhanced governance arrangements for the seasonal influenza programme, setting out roles, responsibilities and accountabilities for the DH, NHS organisations, influenza coordinators and GPs
• there should be improved overall coordination of the seasonal influenza programme

• there should be improved communication, especially with influenza coordinators
• a clear strategic trajectory for target groups and attainment levels should be stated by the DH in order to inform planning and development of capacity
• greater disaster resilience and business continuity arrangements should be built into the current manufacturing and supply systems and should be incorporated within contractual arrangements between the NHS and vaccine manufacturing industry and should be assessed as part of performance management
• the DH should continue its work on assuring a manufacturing and supply system capable of expanding and accelerating to cope with the substantially greater demands
• the opportunities to use alternative providers to deliver the objectives of the seasonal influenza programme should be explored to fully utilise the flexibilities in the new contractual framework for community pharmacy, the expansion of the nursing role, healthcare assistants and other primary care contractual models, such as Alternative Provider of Medical Services (APMS) contracts.

6.50 The proposed changes would require further consideration and consultation with a broad range of stakeholders to develop a robust operational model. The proposed new model would be dependent on:

• renegotiation downwards of the purchase price of influenza vaccine
• agreement to redeploy the monies saved into a new incentive scheme to provide a graduated reward system for improved quality
• the agreement of the GP profession for the introduction of a new incentive scheme to provide a graduated reward for improved quality.

To summarise:

6.51 The advantages would be:

• avoids the risk of destabilising distribution logistics
• maintains GP practice income
• strengthens performance management
• provides an opportunity to improve and incentivise performance, within the existing resource framework
• provides better value for money for the public purse.

6.52 The potential constraints are:

• potential resistance of GPs and their representative body (GPC) to the change of the current GP-led procurement model
• ability to negotiate a graduated incentive scheme
• willingness of vaccine manufacturers to respond to the market change.

Option appraisal

6.53 In order to determine and prioritise the options in terms of potential risks and benefits to the delivery of the seasonal influenza programme, we conducted an options appraisal exercise. The first step in developing the options was to consult relevant stakeholders and seek comments on how the programme could be improved and to identify potential benefits or criteria. This process of iteration enabled us to identify four options for consideration. These four options are described earlier in this section (paragraphs 6.9–52).

6.54 A list of criteria was devised with the assistance of the DH that enabled us to undertake a detailed assessment and to rank benefits. We used a total of twenty criteria and, to simplify analysis, clustered these into nine groups. We assigned weighting criteria to each of these nine criteria clusters based on an assessment of criticality to success. Details of the criteria and weightings used are included in Table 7.

6.55 We reviewed each of the four options using this framework. The results are set out in Appendix 5. We then used this analysis to inform the scoring of each option against these criteria, allocating a value out of 10 according to how well each option addresses a given benefit (10 being very well and 1 poorly). The average of these results was then recorded.

6.56 In order to determine the final score, the weight for each criterion was multiplied by the average score given and then adding up all the values for each option. As a result, the option with the highest score represents the most beneficial option.

6.57 The criteria included benefit areas relating to feasibility of the option, acceptability to stakeholders, performance management, access, and resilience of the provider to be able to cope with changes in demand.

6.58 The results from this option appraisal are set out in Table 8.

Table 7 Option appraisal: criteria and weightings

Criteria cluster	Components	Weighting
Feasibility	• Policy into practice • Policy relevance	15
Acceptability	• Contractual negotiations	15
Procurement	• Purchasing • New distribution routes • Logistics	10
Resilience of model	• Contingency stock	10
Performance management	• Programme management • Performance management • Needs assessment • Reporting • Expansion of targets	15
Quality improvement	• Quality improvement • Independent inspection	10
Financial risk management	• Financial risk management	10
Access to programme	• Clinical delivery to patients • Occupational health delivery	10
Communications	• Communicating policy • Coordination of campaigns • Public and media	5
	Total	100

Table 8 Option appraisal

		Option 1 No change		Option 2 Stock ordering		Option 3 Central procurement		Option 4 Central negotiation	
Criteria	**Weighting**	**Score**	**Weighted Score**	**Score**	**Weighted Score**	**Score**	**Weighted Score**	**Score**	**Weighted Score**
Feasibility	15	8	120	6	90	7	105	7	105
Acceptability	15	8	120	5	75	5	75	7	105
Procurement	10	7	70	6	60	7	70	7	70
Resilience of model	10	7	70	6	60	7	70	8	80
Performance management	15	6	90	6	90	8	120	8	120
Quality improvement	10	7	70	6	60	7	70	9	90
Financial risk management	10	7	70	6	60	7	70	7	70
Access to programme	10	7	70	6	60	8	80	8	80
Communications	5	7	35	7	35	8	40	8	40
Total		64	715	54	590	64	700	69	760

6.59 In summary, the summary weighted score for each of the four options was:

		Weighted score
Option 1	No change	715
Option 2	Stock ordering	590
Option 3	Central procurement	700
Option 4	Central negotiation and incentive scheme	760

6.60 We have, therefore, recommended that further detailed consideration be given to developing Option 4 as an alternative model for the procurement and delivery of the seasonal influenza immunisation programme.

6.61 It should be noted that there is a close clustering of scores for Option 1 and Option 3. Care needs to be taken in interpreting the relative scores for these two options as we are mindful that the weighting for acceptability had a significant impact on the overall weighted score for Option 3. We believe that Option 3 has some operational advantages compared to Option 1, but were aware of the potential difficulties in negotiating such arrangements with GPs and their representative body (GPC).

6.62 The models are not mutually exclusive and there are indeed a number of common features. We would highlight the following issues:

6.62.1 All four models are based on GP practices remaining the most important delivery route for influenza vaccination. The patient's lifelong clinical record is maintained by general practice and this clinical record is the key tool for identifying and contacting target members of the population.

6.62.2 All four models assume expanding patient target groups and increasing attainment levels over time.

6.62.3 In this report we have identified a number of issues that will strengthen the delivery of the seasonal influenza programme. We have assumed that the recommended changes would apply irrespective of the model adopted.

6.62.4 Options 2 (Stock order) and 3 (Central procurement) would require considerable change. Although the stock order system is operational in Scotland, and central procurement and distribution is used for the childhood vaccination programme in England, there are significant logistical challenges in adopting the models for the seasonal influenza programme.

6.62.5 Option 2 (Stock order) would require a significant expansion of the role of community pharmacy in the procurement and distribution of seasonal influenza vaccine.

6.62.6 Option 3 (Central procurement) significantly increases the role of the DH or NHS organisations in procurement and distribution.

6.62.7 Option 4 (Central negotiation and incentive scheme) maintains and adapts most of the existing supply and distribution infrastructure, but offers graduated incentives to improve the targeting of the at-risk population and enhances performance management.

6.63 Furthermore, it should be noted that the models are not rigidly demarcated and elements of each option could be combined to create further options or a new mixed model. In particular, it would be possible to modify Option 4 to incorporate central procurement and distribution.

6.64 We also wish to comment that in this discussion about developing the model for Option 4, we have not explored the broader provider issues and, in particular, the potential to involve alternative providers, including community pharmacy. These issues are discussed in more detail in Section 5 (paragraphs 5.72–88).

Part D

A model for the future

Section 7 Recommendations

Section 7

Recommendations

We have assessed the current service arrangements for delivery of the seasonal influenza programme and have given detailed consideration to alternative models for procurement and supply of influenza vaccine. In undertaking the review we have identified a range of recommendations to strengthen the overall delivery of the programme, and, as a result of a detailed option appraisal, proposed a potential new model for the primary care delivery of the programme.

Measures to strengthen programme delivery

7.1 DH overview

We recommend that the DH continues to monitor the seasonal influenza immunisation programme to ensure that:

7.1.1 The planning and management takes into account planning for avian and pandemic influenza.

7.1.2 At risk and target groups for each programme are clearly identified.

7.1.3 Definitions of target groups, particularly carers, are clearly defined, and standard definitions are agreed.

7.1.4 Any limitations of production capacity for influenza vaccination are identified, particularly where there may need to be a shift in production capacity or priority.

7.1.5 Resources are identified to manage the roles and responsibilities to support the programme.

7.1.6 Future aspirational targets for at-risk and target groups are defined.

7.1.7 Trajectories and timeframes are identified for the achievement of those targets.

7.2 Advisory letter to the NHS

The DH should determine the optimal timing of publication of the advisory letter to the NHS on the seasonal influenza immunisation programme and determine whether it would be more appropriate to provide advice at two separate points so that there is timely advice to the NHS to better inform planning:

7.2.1 January
Detailing recommended target groups for the following season. This will enable those responsible for ordering vaccine supplies to better calculate the amounts required and to optimise the identification of patients in the target groups.

7.2.2 July
As now, provide advice on:
- arrangements for monitoring uptake
- the MHRA role on monitoring safety
- publicity and information materials
- funding and contractual arrangements
- influenza vaccine composition for the forthcoming season
- arrangements for the supply of contingency stocks.

7.3 Performance management

We recommend that the performance management[†] arrangements of the seasonal influenza programme are strengthened to ensure that programme delivery is improved and that there is equity in access to this valuable public health programme in identified at-risk and target groups. We recommend:

7.3.1 The development of better governance[*] within the programme, covering the DH and the NHS, so that roles and responsibilities are clearly defined.

7.3.2 The development of strengthened performance management arrangements.

7.3.3 Better use and scrutiny of existing data and overall management.

7.3.4 Agreement of intervention criteria where performance is found to be poor.

7.3.5 The strengthening of the role specifications and accountability frameworks of programme coordinators.

7.3.6 Further work is undertaken with the Healthcare Commission to inform the assessment methods it will use to assess the performance of NHS organisations.

7.3.7 Further work is undertaken with the Healthcare Commission and other relevant regulators to assess the effectiveness of the seasonal influenza programme within the independent sector.

7.4 Communication strategy

We recognise the good progress the DH has been made in raising public awareness of the benefits of seasonal influenza immunisation, and the consequent increase in coverage rates and recommend:

7.4.1 That a comprehensive contingency plan be developed for use in the event of disruption or delays in the supply of vaccine.

7.4.2 That there is a need to build public and professional confidence in the management of the seasonal influenza programme, and the timely availability of influenza vaccine.

7.4.3 That the annual communication strategy for the seasonal influenza programme should be agreed as soon as practicable each season.

7.4.4 That arrangements for identifying and sharing innovation and best practice are enhanced.

[†]Performance management is the activity of tracking performance against targets and identifying opportunities for improvement - but not just looking back at past performance.

[*]The term 'governance' is defined as the functions, processes, procedures and responsibilities that define how the programme is to be setup, managed and controlled. Programme governance provides the backdrop for all activities of managing the programme and achieving the programme's outcomes.

7.5 Influenza coordinators

We recommend that the DH clarifies the roles and responsibilities of immunisation coordinators, influenza coordinators and pandemic influenza leads to ensure that:

7.5.1 There is strengthened coordination between the three programmes.

7.5.2 Roles and responsibilities are clearly defined.

7.5.3 There is board level accountability for delivery of the programmes.

7.5.4 Senior managerial support is available in primary care organisations.

7.5.5 The developmental and support needs of these staff are identified and supported.

We further recommend that communication with these coordinators is strengthened, and in particular that:

7.5.6 The DH encourages the strengthening of existing network arrangements with these coordinators and improves two-way communication.

7.5.7 The DH establishes more regular meetings with influenza coordinators to support effective communication about programme objectives and delivery. We recommend that these meetings be held to coincide with the recommended revised publication schedule of advice to the NHS:

7.5.7.1 January
To review performance in the previous influenza season and to review the implications of the latest advice on target groups for the forthcoming influenza season.

7.5.7.2 July
To review plans and performance management arrangements for the forthcoming influenza season, communication strategies, the management of potential interruptions to vaccine supply, and the management of contingency stocks.

7.5.8 A website is developed to provide coordinators with information on the programme and to facilitate an e-discussion forum for coordinators so that information and best practice can be identified and shared effectively.

We believe that the performance management of the delivery of programme can be strengthened by:

7.5.9 Defining accountable officer responsibilities, including:

7.5.9.1 assessment of the robustness of local plans

7.5.9.2 delivery against agreed targets and trajectories

7.5.9.3 assessment of variations in performance and the reasons that lie behind such variation.

7.5.10 Establishing local audits of performance and a local assurance of the integrity of the vaccine cold chain and delivery systems.

7.5.11 Targeted and proportionate intervention and support where performance fails to meet planned targets and trajectories.

7.6 Purchase, supply and delivery of influenza vaccine

We recommend that the DH in collaboration with stakeholders examines:

7.6.1 The cost and reimbursement structure for seasonal influenza vaccination.

7.6.2 The planned trajectory of the seasonal influenza immunisation programme and its implications for manufacturing and distribution.

7.6.3 The risks attendant on the internationalisation of production capacity.

7.6.4 With international partners explore methods for accelerating the production process aiming for delivery of vaccine in sufficient time to complete the majority of the seasonal influenza campaign by the end of November rather than the current December/January.

7.6.5 Assesses the manufacturing capacity of vaccine manufacturers and the potential for further growth in production capacity.

7.7 Delivery mechanisms

We recognise the key role of general practice in the delivery of the seasonal influenza immunisation programme and the contribution it has made to achieve a significant increase in population coverage. General practice holds the central patient life-long record and this is key to identifying and maintaining contact with people in the at-risk groups. However, the capacity of general practice to cope with further increases in the necessary improvement of population coverage and the extension of at-risk categories, particularly carers, may be limited. The capacity of general practice to deliver effective services could be weakened during an influenza epidemic. Therefore, we recommend that the DH:

7.7.1 Assesses the role of alternative providers in supporting the delivery of influenza immunisation.

7.7.2 In particular, examines the potential role of community pharmacy to determine whether the flexibilities in the contractual framework for community pharmacy would:

- promote the programme by signposting patients to GPs
- enable the targeting of at risk and hard to reach groups
- increase the primary care capacity for delivering immunisation
- increase patient choice and accessibility.

7.8 Occupational health services

Although the available data are incomplete, it is clear that there is significant variation in the uptake of seasonal influenza immunisation by healthcare workers. The data on uptake by essential workers (including social care, emergency services, and utility services) is even weaker. We recommend that the DH:

7.8.1 Communicates a clear strategy for the immunisation of healthcare staff and essential workers.

7.8.2 Provides a clear definition of healthcare and essential workers.

7.8.3 Models the impact on the supply of seasonal influenza vaccine.

7.8.4 Agrees clear timeframes and trajectories for achieving coverage targets in these occupational groups.

7.8.5 Provides further guidance for the NHS.

7.8.6 Examines the roles of occupational health services and primary care providers in delivery.

7.8.7 Develops strengthened performance management arrangements on the issue of occupational coverage.

7.8.8 Undertakes further work with the Healthcare Commission (HC) to assess the performance of NHS organisations.

7.8.9 Undertakes further work with the HC and other healthcare and social care regulators including Monitor and the Commission for Social Care Inspection to assess the performance of NHS organisations.

7.9 Contingency stocks

We have identified weakness in the management and distribution of DH central contingency stocks. We recommend that a range of measures are introduced to strengthen the use of a contingency supply, in particular to assess:

7.9.1 The triggers for release of the contingency stock and prioritisation arrangements when supplies are scarce.

7.9.2 How planning assumptions can be improved.

7.9.3 Whether there would be benefits in securing rolling contracts with the vaccine supply manufacturing sector to improve stability in supply and whether higher levels of discount could be secured as a result.

7.9.4 Whether there would be advantages in holding stocks at regional or local level, to provide a more equitable and efficient distribution.

7.9.5 How vaccine contingency stocks might be better targeted to match need.

7.9.6 How the timing of distribution might be improved to reduce wastage or delay.

7.9.7 How performance management can be strengthened to identify, address and prevent recurrent shortages in the supply and use of contingency stocks.

7.9.8 How the potential misuse of contingency stock can be minimised.

7.9.9 The appropriateness and feasibility of recovering the costs of contingency stock supplied to practices or primary care organisations if it can be demonstrated that planning and procurement was not robust.

7.10 Supply cold chain

We recommend that further work is undertaken to strengthen local assessment of compliance with the supply cold chain during vaccine transport and distribution, particularly when stock is redistributed locally in times of shortage. We recommend that the current reliance on a documentary audit trail be enhanced locally by:

7.10.1 Conducting an assessment of distribution logistics, and whether there may be potential system weaknesses in ad hoc distribution mechanisms at a local level.

7.10.2 Determining whether additional guidance is required.

7.10.3 Establishing structured audits by influenza coordinators.

7.10.4 Random spot checks of the cold chain and storage arrangements by influenza coordinators or other appropriately trained and qualified clinical staff.

7.11 Contingency planning

The seasonal influenza immunisation programme has a number of critical interdependencies, both national and international, and the manufacturing cycle has a number of critical pathways leading to delivery. The programme requires significant scientific and technical expertise and it is apparent that there is a dependency on a very small number of key individuals and organisations that support critical steps in the pathway. We recognise the constraints and recommend that the DH:

7.11.1 Determines the robustness of contingency plans to respond to any problems in influenza vaccine manufacturing.

7.11.2 Identifies where there is a dependency on key organisations

7.11.3 Ensures that appropriate contingency arrangements are in place, and:

7.11.3.1 where appropriate, there are succession planning arrangements

7.11.3.2 disaster recovery and business continuity arrangements are in place.

7.11.4 With international partners, reviews what steps can be taken to build resilience.

7.12 Regulatory framework

We recommend that the EMEA:

7.12.1 Considers the rationale underpinning the current requirement for limited clinical trials for influenza vaccines to determine their effectiveness.

7.12.2 Explores whether there can be greater international collaboration to strengthen and streamline the process of testing and approving vaccines.

7.13 Strengthening relationships

We recognise the important role the DH has in the formulation of policy but have concluded that relationships with key stakeholders, including other branches within the DH, the NHS, professional representative bodies and pharmaceutical manufacturers, should be strengthened.
We recommend that the DH:

7.13.1 Improves governance structures for the seasonal influenza immunisation programme to ensure that roles, responsibilities and accountabilities are clearly defined.

7.13.2 Improves the relationship with key stakeholders in primary care contracting negotiations, including NHS Employers and the BMA GPC.

7.13.3 Reviews communication with the NHS, particularly influenza coordinators (see recommendation 7.5).

7.13.4 Reviews existing communication strategy (see recommendation 7.4).

7.13.5 Strengthens the media management of adverse events.

Measures to strengthen seasonal influenza vaccine supply

7.14 Proposed new model

7.14.1 We recommend that the DH gives further detailed consideration to all options for the procurement and delivery of seasonal vaccination detailed in section 6 (paragraphs 6.47–52).

7.14.2 Based on the option appraisal exercise (paragraphs 6.9–44), we recommend Option 4. This model promotes central negotiation of the cost of influenza vaccine between the DH and vaccine manufacturers. GP practices would continue to procure vaccine, but the centrally negotiated discounted price would be used as the reimbursable price applied to GP claims. It is recognised that there is no desire by the DH to erode GP income, and it is, therefore, proposed that these savings be used to fund a graduated incentive scheme to reward performance. This could be used exclusively for the seasonal influenza programme, or more widely to include other immunisation programmes.

Appendices

Appendix 1

Stakeholders consulted

A. Manufacturer/sponsors/trade:

- UK Vaccine Industry Group (UVIG)

B. Professional/specialist and patient/carer groups/submission:

- British Lung Foundation (BLF)
- British Medical Association (BMA)
- Department of Health (DH)
- Devolved Authorities
- Health Protection Agency (HPA)
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- National Health Service Employers (NHSE)
- National Institute for Biological Standards and Control (NIBSC)
- Primary Care Trusts (PCTs)
- Purchasing and Supply Agency (PASA)
- Royal College of General Practitioners (RCGP)
- Scottish Executive Health Department (SEHD)
- UK Vaccine Industry Group (UVIG)

C. External expert and patient advocate:

- Alan Russell, PASA
- Alison Lawrence, UVIG
- Associate Nursing Officer, SEHD
- Category Specialist, PASA
- Chairman, BMA GPC
- Chief Executive, LMCA, invited but declined
- Chief Pharmaceutical Officer, SEHD
- Colin Pearson, DH
- Director, RCGP
- Dr Alan Smith, DH
- Dr David Salisbury, DH
- Dr Dorian Kennedy, DH
- Dr Jane Leese, DH
- General Practitioner, Bradford NHSE
- Richard Armstrong, DH
- Gill Littlehales, DH
- GPC Secretariat, BMA
- Head of Primary Care Strategy, Westminster PCT
- Head of Respiratory Division, HPA
- Head of Service HV, Oldham PCT
- Jacqui O'Reilly, Oldham PCT
- Jeannette Howe, DH
- Jeff Porter, DH

- June Boggis, DH
- Kerry Chalmers, SEHD
- Loraine Gershon, DH
- National Project Manager, Health Care Assistant Project, Working in Partnership Programme
- Patient and Carer Representative, BLF
- Paul Vaughan, National Project Manager, WiPP
- Pharmaceutical Adviser, NHSE
- Primary Medical Care Contracting, DH
- Principal Scientist, NIBSC
- Senior Medical Officer, MHRA
- Tim Hodgson, Westminster PCT
- Transitional Chief Executive, Cambridge PCT
- Zoltan Bozoky, DH

D. SHA and Trust respondents

- Avon, Gloucestershire and Wiltshire SHA
- Barking PCT
- Bebington and West Wirral PCT
- Birkenhead and Wallasey PCT
- Birmingham and the Black Country SHA
- Bristol North PCT
- Bristol South West PCT
- Cannock Chase PCT
- Chelmsford PCT
- Cheshire and Merseyside TPCT Network
- Cheshire and Merseyside SHA
- City and Hackney PCT
- Dagenham PCT
- Dudley Group of Hospitals NHS Trust
- Ealing PCT
- Ellesmere Port and Neston PCT
- Essex SHA
- Hambleton and Richmondshire PCT
- Hampshire and Isle of Wight SHA
- Hillingdon PCT
- Knowsley PCT
- Lambeth PCT
- Leeds North East PCT
- Liverpool PCT
- Mid-Essex Hospital Services Trust
- NE London SHA
- North Tees PCT
- North Tyneside PCT
- North East SHA
- NW London SHA
- Pharmacy Practice Unit, Liverpool
- Redbridge PCT
- Scarborough, Whitby and Ryedale PCT
- Selby and York PCT
- Sheffield South East PCT
- Somerset PCT
- St Helens PCT
- Sunderland TPCT
- Tower Hamlets PCT
- Waltham Forest PCT
- Witham, Braintree and Holstead Care Trust

Appendix 2

DES Specification

THE NATIONAL HEALTH SERVICE ACT 1977

The Primary Medical Services (Directed Enhanced Services) (England) Directions 2005

The Secretary of State for Health, in exercise of the powers conferred upon him by sections 17 and 126(4) of the National Health Service Act 1977([5]), and of all other powers enabling him in that behalf, hereby gives the following Directions:

Citation, commencement and application

1.1 *These Directions may be cited as the Primary Medical Services (Directed Enhanced Services) (England) Directions 2004 and shall come into force on 1st April 2005.*

1.2 These Directions are given to Primary Care Trusts in England and apply in relation to England only.

Interpretation

2.1 In these Directions -
"the Act" means the National Health Service Act 1977;

"general practitioner" means a medical practitioner whose name is included in a medical performers list prepared by a Primary Care Trust under regulation 3 of the National Health Service (Performers Lists) Regulations 2004([6]);

"GMS contractor" means a person with whom a Primary Care Trust is entering or has entered into a general medical services contract;

"health care professional" means a person who is a member of a profession regulated by a body mentioned in section 25(3) of the National Health Service Reform and Health Care Professions Act 2002([7]);

"PMS contractor" means a person with whom a Primary Care Trust is entering or has entered into section 28C arrangements which require the provision by that person of primary medical services;

"primary medical services contract" means -

(a) a general medical services contract;

(b) section 28C arrangements which require the provision of primary medical services; or

(c) contractual arrangements for the provision of primary medical services under section 16CC(2)(b) of the Act (primary medical services);

"primary medical services contractor" means-

(a) a GMS or PMS contractor; or

(b) a person with whom a Primary Care Trust is making or has made contractual arrangements for the provision of primary medical services under section 16CC(2)(b) of the Act (primary medical services); and

"Statement of Financial Entitlements" means any directions given by the Secretary of State under section 28T of the Act([8]) (GMS contracts: payments). Establishment etc. of directed enhanced services schemes

3.1 Each Primary Care Trust must exercise its functions under section 16CC of the Act (primary medical services) of providing primary medical services within its area, or securing their provision within its area, by (as part of its discharge of those functions) establishing (if it has not already done so), operating and, as appropriate, revising the following schemes for its area -

(a) *an Improved Access Scheme, the underlying purpose of which is to encourage providers of primary medical services to offer improved and convenient patient access to primary medical services;*

(b) a Childhood Immunisation Scheme, the underlying purpose of which is to ensure that patients in its area -

(i) who have passed their second birthday but not yet their third are able to benefit from the recommended immunisation courses (i.e. those that have been recommended nationally and by the World Health Organisation) for protection against -

(aa) diphtheria, tetanus, poliomyelitis, pertussis and Haemophilus influenzae type B (HiB), and

(bb) measles/mumps/rubella, or

(ii) who have passed their fifth birthday but not yet their sixth birthday are able to benefit from the recommended reinforcing doses (i.e. those that have been recommended nationally and by the World Health Organisation) for protection against diphtheria, tetanus, acellular pertussis and poliomyelitis;

(c) an Influenza and Pneumococcal Immunisation Scheme, the underlying purposes of which is to ensure that patients in its area who are at-risk of influenza or pneumococcal infection are offered immunisation against these infections;

(d) a Violent Patients Scheme, the underlying purpose of which is to ensure that there are sufficient arrangements in place to provide primary medical services to patients that have been subject to immediate removal from a patient list of a primary medical services contractor because of an act or threat of violence; and

(e) a Minor Surgery Scheme, the underlying purpose of which to ensure that a wide range of minor surgical procedures are made available as part of the primary medical services provided within the Primary Care Trust's area.

2 Before entering into any arrangements with a primary medical services contractor as part of one of the Schemes mentioned in paragraph (1), a Primary Care Trust must satisfy itself that the contractor with which it is proposing to enter into those arrangements -

(a) is capable of meeting its obligations under the plan setting out those arrangements; and

(b) in particular, has the necessary facilities, equipment and properly trained and qualified general practitioners, health care professionals and staff to carry out those obligations,

and nothing in these directions shall be taken as requiring a PCT to enter into such arrangements with a contractor if it has not been able to satisfy itself in this way about the contractor.

Influenza and Pneumococcal Immunisation Scheme plans

4.1 *As part of its Influenza and Pneumococcal Immunisation Scheme, each Primary Care Trust may enter into arrangements with any primary medical services contractor, but where it does so, the plan setting out the arrangements that a Primary Care Trust enters into, or has entered into, with the primary medical services contractor must, in respect of each financial year to which the plan relates, include -*

(a) a requirement that the contractor develops and maintains a register (its "Influenza and Pneumococcal Scheme Register", which may comprise electronically tagged entries in a wider computer database) of all the at-risk patients to whom the contractor is to offer immunisation against influenza or pneumococcal infection, and for these purposes a patient is at risk of -

(i) influenza infection if he is -

(aa) aged 65 or over at the end of that financial year,

(bb) suffering from chronic respiratory disease (including asthma), chronic heart disease, chronic renal disease, immuno-suppression due to disease or treatment, or diabetes mellitus,

(cc) living in long-stay residential or nursing homes or other long-stay health or social care facilities, or

(ii) pneumococcal infection if he is -

(aa) aged 75 or over at the end of that financial year, or

(bb) *aged 65 or over at the end of the financial year;*

(b) a requirement that the contractor undertakes -

(i) to offer immunisations against those infections to those at risk patients, and with immunisations against influenza infection -

(aa) to make that offer during the period from 1st August to 31st March in that financial year, but

(bb) to concentrate the immunisation programme during the period from 1st September to 31st January in that financial year, and

(ii) to record the information that it has in its Influenza and Pneumococcal Immunisation Register using any applicable national Read codes;

(c) a requirement that the contractor develops a proactive and preventative approach to offering these immunisations by adopting robust call and reminder systems to contact at-risk patients, with the aims of -

(i) maximising uptake in the interests of at-risk patients, and

(ii) meeting any public health targets in respect of such immunisations;

(d) a requirement that the contractor takes all reasonable steps to ensure that the lifelong medical records held by an at-risk patient's general practitioner are kept up-to-date with regard to his immunisation status, and in particular include -

(i) any refusal of an offer of vaccination,

(ii) where an offer of vaccination was accepted -

(aa) details of the consent to the vaccination or immunisation (where a person has consented on an at-risk patient's behalf, that person's relationship to the at-risk patient must also be recorded),

(bb) the batch number, expiry date and title of the vaccine,

(cc) the date of administration of the vaccine,

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

(ee) any contraindications to the vaccination or immunisation,

(ff) any adverse reactions to the vaccination or immunisation;

(e) a requirement that the contractor ensures that any health care professional who is involved in administering a vaccine has -

(i) any necessary experience, skills and training with regard to the administration of the vaccine, and

(ii) training with regard to the recognition and initial treatment of anaphylaxis;

(f) a requirement that the contractor ensures that -

(i) all vaccines are stored in accordance with the manufacturer's instructions, and

(ii) all refrigerators in which vaccines are stored have a maximum/minimum thermometer and that readings are taken from that thermometer on all working days;

(g) a requirement that the contractor supply its Primary Care Trust with such information as it may reasonably request for the purposes of monitoring the contractor's performance of its obligations under the plan; and

(h) the payment arrangements for the contractor,

and the Primary Care Trust must, where necessary, vary the primary medical services contractor's primary medical services contract so that the plan comprises part of the contractor's contract and the requirements of the plan are conditions of the contract.

(5) 1977 c.49. Section 17 of the 1977 Act is as substituted by the Health Act 1999 (c.8) ("the 1999 Act"), section 12(1), and thereafter amended by the Health and Social Care Act 2001 (c.15), Schedule 5, paragraph 5(3), and the National Health Service Reform and Health Care Professions Act 2002 (c.17) ("the 2002 Act"), Schedule 1, paragraph 7. Section 126(4) of the 1977 Act was amended by the National Health Service and Community Care Act 1990 (c.19), section 65(2). As regards Wales, the functions of the Secretary of State under the 1977 Act were transferred to the National Assembly for Wales by virtue of article 2 of, and Schedule 1 to, the National Assembly for Wales (Transfer of Functions) Order 1999 (S.I. 1999/672), as amended by section 66(5) of the 1999 Act and as read with section 40(1) of the 2002 Act.

(6) S.I. 2004/585.

(7) 2002 c.17.

(8) Section 28T was inserted by the Health and Social Care (Community Health and Standards) Act 2003 (c.43), section 175.

Appendix 3

An example of the seasonal influenza vaccination work plan prepared by an individual practice

This is a copy of the plan used by a practice, which we have renamed 'The Local Practice' and changed staff names (to safeguard their anonymity), to organise their seasonal influenza vaccination campaign. The practice is a PMS practice in a medium-sized PCT serving a rapidly expanding practice population (8600 in October 2006) in an ethnically, culturally and demographically diverse area of suburban London.

Flu Campaign 2006
The Local Practice

General background

There are some delays this year in the delivery of flu vaccine compared to previous years. Deliveries are starting in the second week of October (later than last year) and will be phased over 3-4 weeks. Therefore could clinicians and reception please alert patients that the campaign will not commence until mid October. We have ordered 1400 vaccinations, an increase from last year, because of our growing practice population and increasing numbers in the target groups.

The Torex Clinical Record System identifies and flags all patients in the target groups (by searching for indicator Read Clinical Codes) and all who have received flu vaccines in previous campaigns. When you enter the patient's records a pop-up box in the bottom right of the screen will alert you to Target Patients.

The 'influenza vaccination given' code is .65E and should be recorded in the Immunisation & Vaccination section of the notes and include the batch number of the injection (on the side of the pre-filled syringe). If we fail to record the vaccination we lose potential income and the cost of the vaccination. SO PLEASE RECORD ACCURATELY EVERY TIME.

Alerting patients

The posters are up in the waiting room, leaflets are available, and the reminders are printing on the flysheets of prescriptions from late September. Reception will start telephoning target patients in October and booking them into nurse run flu vaccination clinics.

Organisation

Delivery flu jabs scheduled for week ending 13 October
Start flu clinics from Monday 16 October
Total number ordered 1400

3 minute appointments – max 2 hour session = 20 appointments per hour

Saturday 28 October and Saturday 4 November 9am–11am – open-access walk-in clinic (no appointment required)

2 days of clinics x 2 clinicians/clinic x 2 hours/clinic/clinician x 20 vaccinations/hour = 160+ appts

Flu sessions

Practice nurse A
9.30am–11.30am
17, 24, 31 October, 7 Nov (4 sessions) = 160 appts

4pm–6pm
16, 23 Nov (2 sessions) = 80 appts

Practice nurse B
9.30am–11.30am
19, 23 October, 6, 9 21 November (5 sessions) = 200 appts

26 October (1 session) = 40 appts

Nurse consultant NC

3.30pm–5.30pm
20, 27 October, 17 November (3 sessions) = 120 appts

2.30pm–4.30pm 8 November
(1 session) = 40 appts

Sub total = 640 appts + open access clinics = 160 appts

Total = 800 appointments

'Restful Valley' Care Home (nursing home with 70 elderly residents) – Visit planned for 30 November – Alpha and Beta – 10am–12.30pm = 70 appts

We will review progress in mid November and then set out our plans for the next stage of the campaign.

Opportunistic vaccinations

A small supply of flu vaccines and Pneumovax vaccines will be placed in a coolbox in each GP and nurse's consulting room by receptionists before the start of each session. Further supplies are stored in the small fridge in reception if required (along with a small supply of childhood immunisations).

Flu campaign group

The flu campaign group is nurse consultant NC, J C (GP), and practice manager. They will plan and manage the flu campaign and report regularly to the clinical team meeting and the practice management meeting. NC will report the weekly performance figures to the PCT as they require. We will update everyone regularly on how we are performing.

We did very well against our targets last year. The targets are even more challenging this year, so let's try for a great collective effort and try to break the back of this well before Christmas.

Appendix 4

PCT responses to DH letter

Written responses to letter of 3 November 2005 from Dr David Salisbury regarding the status of local seasonal influenza vaccine supply.

Number	PCT/Area	Response
1	East Lincolnshire	Increase in at risk groups
2	Kingston	Suppliers say they have no further stocks; 'Worried well' referred to private GP clinics or medicentre.
3	Western Somerset	Increase due to media around avian influenza.
4	Broadland	1250 doses required; panic from last year's shortage.
5	Gedling	Only one practice requires vaccine.
6	Derwentside	No extra vaccine required; demand not higher from last year.
7	Bolton	Some resistance over sticking to risk groups.
8	East Surrey	Increase due to media on avian influenza.
9	Greater Peterborough	People think it will protect them against avian influenza.
10	Berkshire	Two practices require extra vaccine.
11	Leeds North east	Two out of three practices require extra vaccine.
12	Gravesend	2000 extra doses needed; some GPs giving vaccine to anyone that wants it.
13	Cheshire West	More demand from 'worried well'.
14	City & Hackney	Extra demand re avian influenza threat.
15	Barnet	5000 doses required.
16	Central Cheshire	15 per cent higher demand.
17	Somerset Coast	Some vaccine still to be delivered week commencing 21 November.
18	South Tyneside	Demand has been extreme; six practices have no vaccine left.
19	Newcastle	Demand greater in affluent areas, less so in deprived areas; waiting list being kept for 'worried well'.
20	East Elmbridge & mid-Surrey	Information given to practices about contingency on 31 October.
21	North Herts & Stevenage	1100 extra doses required
22	Hertsmere	Mixed response. Some GPs okay and require no doses, others require extra to finish 'at risk' groups. Many 'worried well' desperate to get vaccinated and willing to pay
23	Burnley, Pendle and Rossendale	No problems with supply; demand similar to last year
24	North Kirklees	80–100 doses were required for two practices but managed locally by distribution.
25	Wandsworth	1500 doses required.

Number	PCT/Area	Response
26	West Cornwall	Everything okay.
27	North Dorset	1150 doses required.
28	Blackburn & Darwen	200 doses required.
29	South West Kent	Demand exceeded previous years; media on avian influenza.
30	Ashford	25 per cent practices require more vaccine; where necessary groups have been prioritised.
31	Lambeth	2500 doses required; worried about hitting target.
32	Kennet & N Wilts	Practices will be contacted week commencing 14 November to identify any surplus stock.
33	South Bucks (surgery)	100 doses ordered to finish clinics.
34	Hillingdon	At least three surgeries require extra.
35	Welwyn & Hatfield	Demand higher from over-65 risk groups.
36	Plymouth	Stronger local media campaign this year; increase in number of risk groups.
37	Surgery	30 doses required.
38	Hartlepool	1900 given; 500 doses required.
39	Canterbury & Coastal	Wyeth said 'more vaccine could be ordered', then said 'no'; priority given to residential care homes, housebound, over-65s and at risk groups.
40	Surgery	200 doses required.
41	Humber	Four out of nine practices prioritised groups; 650 doses required.
42	Eastern Cheshire	20 out of 23 practices want extra doses.
43	Leeds West	One practice requires 50 doses.
44	Leeds East	Five practices require extra; increase demand re media on avian influenza.
45	Barnsley	Some practices did not prioritise patients.
46	Redbridge	Re-distribution occurring; more stock due to arrive in December.
47	Greenwich	Some practices still waiting to receive their first delivery from suppliers; 23 out of 47 require extra.
48	Kensington & Chelsea	Not sure yet if demand is higher.
49	Surgery in Wales	Trying to order from English stock.
50	Salford	Trying to re-educate patients that it will not protect against avian influenza.
51	Harrow	'Worried well' given prescriptions to go to the chemist.
52	Central Cornwall	3000 doses short; large number of 'carers' coming forward.
53	Shepway	800 doses required.
54	Morecambe Bay	50 per cent of surgeries want extra.
55	Swindon	Think vaccine will protect against avian influenza.
56	Craven & Harrogate	1450 doses required; 16000 carers in area.
57	NE Lincolnshire	Delay to original supply.
58	Basildon	500 doses required; previous refusers coming forward
59	Barking and Dagenham	Previous refusers coming forward.
60	Surgery	New patients added to list after original flu letters sent.
61	Bassetlaw	Four out of 12 want extra vaccine.
62	Durham Dales	Trying hard to reach Quality and Outcomes Framework (QOF); 'worried well' asked to come back late November.
63	Preston	Demand higher from patients and staff.
64	Hyndburn and Ribble Valley	A number of practices have vaccine on order.

Number	PCT/Area	Response
65	S Worcester	2150 doses required; Healthcare Workers (HCWs) demand via Occupational Health service (OHS) higher.
66	Eastern Birmingham	Increased demand re media on avian influenza.
67	Hambleton & Richmond	Some but not all GPs prioritising.
68	Wakefield West	450 doses required.
69	Surgery	Extra demand re avian influenza threat.
70	Surrey Heath and Woking	Increase demand from 'worried well'.
71	Dudley Beacon	3800 doses required; one practice giving to non-risk patients.
72	Thurrock	Some vaccine on order and due in December.
73	Scarborough & Whitby	Demand for vaccine on private basis to those not at risk.
74	Darlington	Demand higher due to avian influenza.
75	Cotswold & Vale	Looking to achieve uptake of approximately 90 per cent.
76	Wigan	2100 doses required; avian influenza media coverage.
77	North & East Cornwall	Demand increase due to avian influenza.
78	Waveney	Some practices require extra.
79	Burntwood Lichfield & Tamworth	1470 doses requested from 10 out of 25 practices.
80	Islington	Delay in supplies arriving; some need extra doses.
81	Bradford	Extra doses required.
82	Suffolk East	Extra doses required.
83	Rotherham	Five practices require extra; more at risk coming forward
84	North Staffs	600 doses required.
85	Rothery	2500 doses required; previous refuser coming forward.
86	Surgery - Horsham	500 doses needed.
87	South Wilts	Planned for 65 per cent uptake but demand is higher.
88	Blackpool	150 doses needed.
89	Wolverhampton	4-6 week delay receiving original order; increased demand due to avian influenza reports.
90	South Warks	Five practices require extra; more at risk groups coming forward.
91	Torbay	200 doses required.
92	Easington	50% require extra doses; demand from younger 'at risk' groups.
93	South Gloucester	All practices affected by delays which put back campaign by 2 weeks; care homes given priority then risk groups & carers.
94	Birkenhead & Wallasey	Worried they will not receive vaccine as letter says Department of Health contingency is limited.
95	Calderdale	1000 doses required.
96	Mid Devon	250 doses required.
97	Broxtowe & Hucknall	Four practices require extra; demand exceeded that for the last 2–3 years.
98	Surgery	200 doses required.
99	Nottingham city	600 doses required.
100	Westminster	4 week delay to receiving vaccine; problem with supplier; will continue to receive supplies in November
101	Central Derby	No extra required.
102	Wyre	Extra doses required.

Number	PCT/Area	Response
103	Fylde	Extra doses required; cannot get any from suppliers.
104	Selby & York	870 doses required.
105	St Albans	700 doses required; groups have shared vaccine.
106	Chorley	Surplus has been offered around the area; 2850 extra doses required.
107	Sunderland	1000 doses required.
108	South Cambs	Small number of doses required.
109	Surgery	Extra doses required.
110	Havering	Practices told to prioritise but British Medical Association (BMA) message not consistent.
111	Great Yarmouth	300 doses required.
112	Chiltern & S Bucks	Nine out of 21 surgeries need extra.
113	E Yorks	Some require extra.
114	Croydon	Some suppliers reneging on reserve orders.
115	SW Staffs	808 doses required.

Appendix 5

Option appraisal

The following table describes the 20 criteria used in the option appraisal.

Criteria	Explanation
Policy into practice	Impact of changing current policy and practice. Challenges of negotiating and agreeing new policy.
Policy relevance	Policy relevance in this area such as access, choice, expanding role for other clinical professions, Practice Based Commissioning, Payment By Results, quality based contracts.
Contractual negotiations	Complexity of negotiating the contractual arrangement resulting from the new policy, e.g. with providers and with Pharma suppliers.
Communicating policy	Identifying the key audiences for new policy. Mechanisms for communicating policy.
Public and media	Arrangements for dealing with inquiries or interest from patients, public, professions, media and other interested parties. Public and patient awareness campaigns.
Management	Management of the seasonal influenza campaign at a national and local level. Management arrangements and responsibilities at each organisational level within the NHS.
Needs assessment	Mechanisms for needs assessment. Accuracy and timeliness of target patient identification and needs assessment.
Financial risk management	Nature and extent of financial risk carried by each element of the system.
Purchasing	Purchasing arrangements for seasonal influenza.
Logistics	Logistic arrangements for transport and delivery of the influenza vaccine supply to frontline clinical teams.
Coordination	Coordination of the national and local campaigns especially across organisational boundaries.
Clinical delivery to patients	Organisation of actual clinical delivery of vaccine to patients.
Occupational health delivery	Organisation of actual clinical delivery of vaccine to occupational health groups.
Reporting	Reporting of attainment data for patient and occupational health campaigns.
Performance management	Performance management responsibilities and arrangements.
Quality improvement	Systems for improving the quality of influenza vaccination activity.
Expansion of targets	Systems for dealing with significant expansion of influenza vaccine targets.
New distribution routes	Systems for developing distribution routes for influenza vaccine to improve access and equity.
Contingency stock	Contingency stock arrangements.
Independent inspection	Arrangements for independent inspection and public transparency within the system.

Option 1

No change: Continue the current arrangements of GP-based supply with GPs ordering their practice supplies directly from pharmaceutical companies. Our appraisal is based on the current system in operation in England, without any potential future adaptations.

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Policy into practice	DH develops policy. Monitors the programme nationally. Sets target groups and attainment levels. Scientific advice for policy mainly sourced from JCVI (its subgroups), HPA and flu experts.	Incorporate flu policy and targets into SHA oversight of PCTs and provider organisations.	Develops local flu strategy and policy. Appoints local flu coordinator (significant local variation in seniority of post holder, job description and lines of accountability).	Majority of programme is delivered by GP practices and most develop internal flu policies. Small elements delivered by district/ community nurses and residential care clinical teams.	Limited interaction with DH Policy into Practice. Industry limits sharing of their strategies on commercial competition and building production capacity.	WHO and international influenza policies strongly influence UK policy.
Policy relevance	Policy relevance in this area such as access, choice, expanding role for other clinical professions, Practice Based Commissioning, Payment By Results, quality based contracts.	SHA provides oversight and strategic leadership.	PCTs have limited local flexibility in negotiating Local Enhanced Services Contracts (LES). Provider choice for patients is limited to their registered GP practice. No alternative NHS vaccination suppliers. Limited scope for Quality Incentive elements.	No added incentives to vaccinate hard to reach subgroups within target populations. No incentives to extend choice or access or strive for stretch attainment levels.		No mechanism for vaccination provision by independent sector or non GP independent contractors. Very limited systems to incentivise community teams to vaccinate.
Contractual negotiations	DH, through NHS Employers, negotiates the contractual arrangements with General Practice Committee of BMA.	No clear SHA role.	GMS contracts are national model. PCTs negotiate local PMS contracts with GPs and potentially APMS contracts with other providers of influenza vaccination campaigns.	Practices negotiate with PCT to agree local PMS contracts and in some cases flu incentive schemes.	Pharma industry does not have a contractual arrangement with DH or NHS apart from the manufacturing of vaccines. Company reps negotiate local supply contract with practices.	No current contracts for non-GPs to routinely deliver seasonal influenza. Pharmacists can dispense, on receipt of prescription, but not administer.

Option 1

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Communicating policy	DH informs flu-coordinators and providers via CMO letters and policy guidance. Regular scheduled meetings with UVIG.	Some facilitate local networks of flu coordinators.	Flu coordinators coordinate and monitor programmes at PCT level. Limited two way communications between flu-coordinators and DH.	GPs receive policy guidance on target groups and attainment levels via CMO, independent of the local procurement cycle.	Pharmaceutical companies are alerted to policy via UVIG.	Pharmacists and non-GP providers receive CMO letter.
Public and media	DH handles queries from national media, professionals, public and politicians. Communications unit plans and implements the National Flu Awareness campaign	SHA handles regional queries from media, professionals, public and politicians.	Handles queries from local media, professionals, public and politicians. Some PCTs run local flu awareness campaigns (usually use DH national materials).	Practices run flu awareness campaigns as part of preparation for seasonal influenza.	Pharmaceutical industry produces and distributes flu awareness materials (mainly to practices). Some companies have considerable interaction with media.	Pharmacists and other clinical teams disseminate flu awareness materials.
Management	DH has limited interaction with local flu coordinators (no national resource website or regular peer meetings for flu-coordinators).	Monitors performance of PCTs against flu targets.	Coordinates local GP provider activity, but impact varies between PCTs. PCTs also deliver vaccination via their provider and occupational health arms.	Practice campaign is led and managed by practice manager and lead clinician (usually GP partner and/or lead nurse.	Pharma companies' local representatives report to national sales directors / company management teams.	
Needs assessment	Target groups decided by DH advised by JCVI (and its sub-groups), the HPA and flu experts.	No clear SHA role.	Few PCTs independently use disease registers and practice databases to calculate vaccination requirements. Most PCTs base need on amalgamated practice submitted figures.	Practices identify target patients and estimate their vaccination requirements.	Some pharma companies assist PCTs and practices in calculating local demand and identifying patients.	Vaccine provision through FP10s and private purchase is not usually measured.

Option 1

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Financial risk management	DH responsible for flu vaccine budget paid through GP reimbursement. Also bears the financial risk of national contingency stock. No national systems to use up unused contingency stock. DH is likely to seek reduction of the NHS reimbursement payment closer to the actual market price.	SHA accountable for the financial performance of their PCTs.	PCTs take risk for their occupational health stock and PCT-run practices. Some PCTs order a small local contingency stock.	Practices carry most of the financial risk. Use or return contracts for stock are rarely available. If DH seeks to reduce the reimbursement payment price the rebate available to GPs will shrink substantially. Current system does not recognise the additional costs of vaccinating hard-to-reach populations or very high attainment levels.	Industry manufactures to meet the demand confirmed by advance orders. Some companies share limited amounts part of risk with GPs through use or return schemes.	Pharmacies carry a small stock to meet FP10 demand.
Purchasing	DH negotiates and purchases contingency stock in some years. Purchase via a formal tendering mechanism. Contract price and any discount level commercially sensitive.	Some SHAs may provide limited oversight.	Some PCTs purchase a small stock for occupational health and internal contingency supply, mainly to cover transient blips in the delivery schedule. Contract price and any discount level commercially sensitive.	Practices order direct from suppliers and negotiate discount, delivery timetables and sometimes contingency arrangements.	Local pharma industry reps negotiate orders with practices. Discounts are offered.	Pharmacies order small amounts of flu vaccine stock for FP10 use (average 30 to 100 doses per pharmacy) and optional access to additional supply.

Option 1

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Logistics	National contingency stock is distributed via a logistics company (additional cost).	No SHA role.	PCT occupational health stock is delivered direct to occupational health by suppliers. PCT staff sometimes required to move around stock between clinical teams or practices.	Practice supplies are delivered direct to practices in a series of phased deliveries from the supplier.	Suppliers arrange the delivery of stock as part of the purchase package. In cases of over or undersupply suppliers move excess stock locally using logistic companies and/or local representatives.	Suppliers arrange the delivery of stock as part of the purchase package.
Coordination	DH responsible for national coordination of campaign via local flu co-ordinators.	Some SHAs may provide limited oversight.	PCT flu coordinators responsible for coordination of internal PCT and independent contractor campaigns. Variable effectiveness in this role.	Practices internally coordinate their practice clinics and performance against target and stock levels. Limited coordination between practices and between practices and PCT.	Supplier representatives coordinate phasing and size of deliveries and reassignment of excess stock.	Pharmacies do not explicitly coordinate with practices or PCT.
Clinical delivery to patients		SHAs may put in place clinical governance protocols.	A small number of PCTs arrange moderate provider activity via community nurse provider arm and occupational health team.	Responsible for significant majority of delivery. Identify target patients. Arrange invited and opportunistic flu vaccination mainly via practice nurse clinics.	Works with providers to estimate requirements and arrange delivery, quantity and timing. No direct access to patients.	Community pharmacies dispense some vaccine on FP10. Some piloting of pharmacy-based administration of flu vaccine.
Occupational health delivery	DH has occupational health vaccination scheme for staff.	Few SHAs arrange an occupational health vaccination scheme for staff.	PCTs responsible for occupational health vaccination of their workforce. Most PCTs have an occupational health flu vaccination programme for clinical staff but low uptake.	Some practices arrange occupational health vaccination for staff; most do not.	Most suppliers arrange occupational health vaccination for all their staff.	Few pharmacies, dentists, optometrists arrange occupational health vaccination for their staff.

Option 1

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Reporting	DH receives regular reports from RCGP Flu Monitoring Unit and weekly PCT vaccination uptake reports during the flu campaign.	SHA monitors PCT vaccination rates as a key performance indicator.	PCTs collate weekly flu vaccination reporting for their practices and forward to SHA and DH.	Practices submit weekly flu vaccination reports to PCT (reimbursement for vaccine and administration is dependent on these returns). Some practices contribute data to the RCGP flu monitoring project.	Suppliers collect delivery / sales data but not administration data. Data is commercially sensitive and not shared with DH or UVIG	Pharmacists do not report vaccine numbers except via the FP10/PPD reporting system (up to 3 month delay in reporting.
Performance management	DH monitors national performance but performance management is responsibility of NHS.	SHAs performance manage PCTs vaccination performance against flu targets.	PCTs monitor practices performance. PCTs can implement incentive programmes and commission or decommission service providers.	Practices self monitor performance of flu campaign against internal and externally set targets.	Pharma companies closely monitor the performance of their representatives.	Pharmacies monitor their sales and FP10 performance.
Quality improvement	DH can change target groups and attainment targets.	No clear SHA role.	PCTs can implement local incentive schemes over and above national targets, e.g. to increase uptake in underserved populations.	Most practices reassess their performance and processes at least annually to control costs and maximise efficiency.	Pharma companies have established quality improvement cycles to optimise their commercial advantages.	Flu vaccine represents a very small area of business for pharmacies.

Option 1

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Expansion of targets	New targets groups or higher performance set by DH will require further funding.	SHA may provide limited oversight.	PCT responsible for implementing targets. Current funding mechanisms do not strongly incentivise stretching performance.	Current funding mechanisms reward performance but there are significant resource demands and financial risks for practices pursuing stretching targets. No additional incentive to achieve stretching targets.	Pharmaceutical company production may already be stretched. Unclear how much additional production capacity current system can deliver or over what timeframe.	
New distribution routes	DH willing to explore and promote new distribution routes (e.g. new providers).	SHAs provide oversight and strategic leadership.	A small number of PCTs are making innovative use of community nursing staff to deliver vaccinations.	Most practices are making innovative use of nurses and health care assistants to increase productivity and reduce costs.		Independent and voluntary sector providers are willing to explore business opportunities of expanded distribution routes.
Contingency stock	DH orders national contingency stock in some years via an EU tendering process. No supplier submitted a bid against the tender invitation in 2006.	SHA may provide limited oversight.	Some PCTs arrange a small local contingency. If contingency is unused in target groups, some PCTs divert to occupational health or non target groups late in the campaign.	Some GPs (very few) arrange a very small contingency supply within the practice. Most practices requiring contingency stock have to compete on the open market for supply.	Suppliers move excess stock around to cover transient shortfalls in the delivery programme.	Some pharmacies will sell a portion of their supply to practices or organisation short of stock.
Independent inspection	DH is conducting an independent review of flu vaccine supply.	SHA may provide limited oversight.	The Healthcare Commission, during their annual inspections, assess flu vaccination performance as a quality indicator for PCTs.			Healthcare Commission independently inspects all provider organisations occupational health vaccination coverage.

Option 2

Stock Order System: community pharmacists receive orders from local GPs, order stock and supply to practices. This is the system currently in use in Scotland for GP administered influenza vaccine. Our appraisal is based on the current system in use in Scotland.

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Policy into practice	DH, through NHS Employers, would have to negotiate new work (or change to existing workload) with representative bodies of GPs (GPC) and pharmacists (PSNC).	Incorporate flu policy and targets into SHA oversight of PCTs and provider organisations.	Local flu coordinator has to liaise with all GPs and all community pharmacists. Need to develop new supply arrangement via pharmacies for PCT clinical / occupational health demand.	Majority of programme is delivered by GP practices. Practices must develop relationship with local pharmacists including risk sharing arrangements. May evolve over time into formal contracts.	Industry will have a view on introducing community pharmacy into the supply chain. Potential for commercial advantages for very large pharmacy chains versus small community pharmacies.	The system was introduced in Scotland when flu vaccination was a tiny proportion of current activity and discounts were much smaller. Introducing the system now to England would significantly alter the financing of flu vaccination.
Policy relevance	Policy relevance in this area such as access, choice, expanding role for other clinical professions, Practice Based Commissioning, Payment By Results, quality based contracts.	SHA provide oversight and strategic leadership.	PCTs have limited local flexibility in negotiating Local Enhanced Services Contracts (LES) Provider choice for patients is still limited to registered GP practice. No alternative NHS vaccination suppliers. Limited scope for Quality Incentive elements.	No added incentives to vaccinate hard to reach subgroups within target populations. No incentives to extend choice or access or strive for stretch attainment levels.		Pharmacists are involved in securing supply but only a limited role in actual provision of vaccination. No mechanism for vaccination provision by independent sector or non GP independent contractors. Very limited systems to incentivise community teams to vaccinate.

Option 2

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Contractual negotiations	Renegotiation of the contractual arrangements with the representative bodies of GPs and pharmacists would be complex and likely to meet opposition from the General Practice Committee of BMA.	No clear SHA role.	PCT would require new contracts with GPs and community pharmacies.	Practices would likely require contractual arrangements with community pharmacies. Risk sharing and reward sharing arrangements likely to be particularly contentious.	Pharma industry unlikely to welcome a more complex supply chain as it is likely to slow growth in demand by emphasising risk minimisation.	Pharmacists may be reluctant to accept the workload and risk of supplying GP requirements and the potential souring of local GP/pharmacist relationships.
Communicating policy	DH informs flu-coordinators and providers of policy via CMO letters and guidance. Regular scheduled meetings with UVIG.	Some facilitate local networks of flu coordinators.	Flu coordinators coordinating and monitor programmes at PCT level would have to deal with a more complex supply chain.	GPs and pharmacist would have to agree and coordinate their joint response to central guidance and targets. Risk of introducing additional delay and risk aversion in decision-making.	Pharmaceutical companies have a more complex supply chain to deal with.	Pharmacists would have to develop significantly enhanced systems to respond to DH guidance.
Public and media	DH handles queries from media, professionals, public and politicians. Communications unit plans and implements the National Flu Awareness campaign.	SHA handles regional queries from media, professionals, public and politicians.	Handles queries from local press, professionals, public and politicians. Some PCTs run local flu awareness campaigns (usually use DH national materials).	Practices run flu awareness campaigns as part of preparation for seasonal influenza.	Pharmaceutical industry produces and distributes considerable flu awareness materials to both practices and pharmacies.	Pharmacists would have to significantly increase their flu awareness activities as they would wish to minimise their exposure to risk.

Option 2

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Management	DH has limited interaction with local flu coordinators (no national resource website or peer meeting for flu-coordinators).	Monitors performance of PCTs against flu targets.	Coordinates local GP provider activity, but impact varies between PCTs. PCTs also deliver vaccination via their provider and occupational health arms.	Practice campaign is led and managed by practice manager and lead clinician (usually GP partner and/or lead nurse). Reduced financial value of campaign and reduced exposure to risk likely to lead to reduced management resources devoted to flu.	Pharma companies' local representatives have to coordinate ordering and delivery via much more complex supply chain.	Pharmacies have to increase management resources devoted to flu, also may put pressure on pharmacy infrastructure (e.g. sufficient cold storage).
Needs assessment	Target groups decided by DH advised by JCVI (and its sub groups), the HPA and flu experts.	No clear SHA role.	Few PCTs independently use disease registers and practice databases to calculate vaccination requirements. Most PCTs base need on amalgamated practice submitted figures.	Practices identify target patients and estimate their vaccination requirements. Calculation of demand may be less accurate and more conservative as rewards and risks to practices decrease.	Some pharma companies assist PCTs and practices in calculating local demand and identifying patients.	Pharmacies dependent on local practices to calculate their need, therefore considerable new risk for pharmacies.

Option 2

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Financial risk management	Introducing a new and additional step to the supply chain is also likely to introduce additional costs and risks. DH may seek reduction of reimbursed NHS price to level closer to actual market price and may question the cost effectiveness of involving pharmacists in the supply chain.	SHA accountable for the financial performance of their PCTs.	PCTs would have to decide how to source, and manage the financial risks, of their occupational health and PCT provider services requirements.	Practices would transfer most of their current financial risks to pharmacies and therefore little incentive or restraints for continuing responsible behaviour. GP income and flu campaign finances are threatened by loss of purchase rebate.	Industry likely to be put under considerable pressure from the large pharmacy chains.	Pharmacies assume most of the financial risks for supply. Dependent mainly on the purchase rebate to pay for their involvement. May also seek a dispensing fee for supply. Both may create additional costs with little added value and therefore may be questioned by DH.
Purchasing	DH would have to decide on additional clauses for possible inclusion in the pharmacy contracts, e.g. risk sharing arrangements, contingency stock procurement etc.	Some SHAs may provide limited oversight.	PCTs and practices may need to agree risk and reward sharing contracts with the community pharmacies.	PCTs and practices may need to agree risk and reward sharing contracts with the community pharmacies. Practices' relationship with manufacturer and local supplier (pharmacy) is likely to change profoundly.	Manufacturers have to cultivate and understand a new set of customers for the flu vaccine market (pharmacists).	Some large chemist chains may negotiate preferential rates from manufacturers and have a significant competitive advantage.

Option 2

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Logistics	National logistics network becomes more complex by inclusion of community pharmacy as an intermediate step between manufacturer and administering clinician.	No SHA role.	PCT may find it more difficult to performance manage a more complex supply chain.	Practices now liaise with pharmacy rather than the pharmaceutical representative; therefore, more scope for communication failures. Deliveries of stock first to pharmacies then additional delivery leg between pharmacy and the GP practice/ clinical team.	Suppliers arrange the delivery of stock as part of the purchase package. Increased competitiveness in this sector may lead to cost cutting of added value services such as redistributing excess stock to meet shortfalls.	Suppliers arrange the delivery of stock as part of the purchase package.
Coordination	DH responsible for national coordination of campaign via local flu coordinators.	Some SHAs may provide limited oversight.	PCT flu coordinators facing challenge of coordinating a significantly more complex supply chain.	GP practices have limited experience of coordinating with local pharmacies on a programme of this size and complexity. Limited communication between practices, pharmacists and PCT are likely to continue and may deteriorate further as information becomes increasing commercially sensitive.	Suppliers' representatives coordinate phasing and size of deliveries and reassignment of excess stock to pharmacies as a proxy of PCTs.	Pharmacies would have to explicitly coordinate with practices and PCT.

Option 2

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Clinical delivery to patients		SHA may put in place clinical governance protocols.	A small number of PCTs arrange moderate provider activity via community nurse provider arm and occupational health team.	Responsible for significant majority of delivery. Identify target patients. Arrange invited and opportunistic flu vaccination mainly via practice nurse clinics.	Works with providers to estimate requirements and arrange delivery, quantity and timing. No direct access to patients.	Pharmacists still only provide limited administration of flu vaccine.
Occupational health delivery	DH has occupational health vaccination scheme for staff.	Few SHAs arrange an occupational health vaccination scheme for staff.	PCTs responsible for occupational health vaccination of their workforce. Most PCTs have an occupational health flu vaccination programme for clinical staff but low uptake.	Some practices arrange occupational health vaccination for staff; most do not.	Most suppliers arrange occupational health vaccination for all their staff.	Pharmacies would likely develop some further staff vaccination but probably towards end of season.
Reporting	DH receives regular reports from RCGP Flu Monitoring Unit and weekly PCT vaccination uptake reports during the flu campaign.	SHA monitors PCT vaccination rates as a key performance indicator.	PCTs collate weekly flu vaccination reporting for their practices and forward to SHA and DH.	Practices submit weekly flu vaccination reports to PCT (reimbursement for vaccine and administration is dependent on these returns). Some practices contribute data to the RCGP flu monitoring project.	Suppliers collect delivery/sales data but not administration data. Data is commercially sensitive and not shared with DH or UVIG.	Pharmacists would need to have access to the ordering data or analysis and would themselves have to report data on 'draw-down' of stock by practices. Such data is likely to become commercially sensitive.

Option 2

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Performance management	DH monitors national arrangements only as performance management is responsibility of NHS.	SHAs performance manage PCTs vaccination performance against flu targets.	PCTs monitor practices performance. PCTs can implement incentive programmes and commission or decommission service providers. These roles become more complex as more teams involved in the chain.	Practices self assess performance of flu campaign against internal and externally set targets.	Pharma companies closely monitor the performance of their representatives.	Pharmacies monitor their, and their customer practices stock order performance.
Quality improvement	DH can change target groups and attainment targets. But has to negotiate changes with a potentially larger number of stakeholders.	No clear SHA role.	PCTs can implement local incentive schemes over and above national targets but these become more complex to recognise inclusion of pharmacists in the chain.	Most practices reassess their performance and processes at least annually to control costs and maximise efficiency. Reduced financial benefit and risks may lead to decreased QI activity.	Pharma companies have established quality improvement cycles to optimise their commercial advantages.	Flu vaccine becomes a more significant area of business for pharmacies.
Expansion of targets	New targets groups or higher performance set by DH will require further funding.	Some SHAs may provide limited oversight.	PCT responsible for implementing targets Current funding mechanisms do not strongly incentivise stretching performance.	What would be the additional incentives to achieve stretching targets?	Pharmaceutical company response to expansion of targets may be delayed or minimised by overly risk-averse approach from pharmacies.	Pharmacies may be conservative and reluctant to set stretching targets as they increase risk to the pharmacy.
New distribution routes	DH is willing to explore and promote new distribution routes (e.g. new providers).	SHAs provide oversight and strategic leadership.	PCTs could negotiate for pharmacies and others to administer vaccine.	Any move to have pharmacies administer flu vaccine would further alienate GPs.		Pharmacies, if they administer, would risk allegations of conflict of interests.

Option 2

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Contingency stock	DH orders national contingency stock in some years via an EU tendering process. No supplier submitted a bid against the tender invitation in 2006.	SHA may provide limited oversight.	PCTs may be reluctant to arrange a local contingency if this creates an additional financial demand from pharmacists.	Most GPs would try to transfer as much risk as possible (including contingency stock provision) to the pharmacists.	Pharma companies would be less likely or able to move spare stock around without payment up front.	Some pharmacies will be reluctant to stock contingency stock when they do not have control over any system to use up that stock and minimise their financial risk.
Independent inspection		SHA may provide limited oversight.	Healthcare Commission, during their annual inspections, assess flu vaccination performance as a quality indicator for PCTs.			Healthcare Commission would have to inspect community pharmacy, particularly large chains. More difficult to inspect the supply chain as it increases in complexity.

Option 3

Central procurement and distribution: DH or its agent would purchase all the seasonal influenza vaccine supply used by the NHS and distribute from this central supply to frontline clinical teams. Central procurement and supply is the current system used for childhood vaccine supply. We have based our appraisal on a model where the current childhood vaccination system would be adapted and applied to seasonal influenza vaccination.

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Policy into practice	DH develops policy. Has to negotiate the system change with the GP and PCT representative groups and likely to face considerable opposition to feasibility of centrally assessing a seasonal demand (in view of oxygen supply problems). May be seen as contradicting policy of locally accountable and locally scrutinised services.	Incorporate flu policy and targets into SHA oversight of PCTs and provider organisations.	PCT would likely raise concerns over the policy's negative effect on GP attitude and also concerns re centralising a currently devolved function, loss of system flexibility, storage and distribution problems.	GPC would strongly oppose any central supply policy. Would be interpreted as an erosion of GP income and independence.	Welcome a centralisation of flu vaccine supply as it creates an explicit monopoly customer situation.	European and UK competition legislation would need to be taken into account.

Option 3

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Policy relevance	Policy relevance in this area such as access, choice, expanding role for other clinical professions, Practice Based Commissioning, Payment By Results, quality based contracts. New system centralises needs assessment and supply and, therefore, decreases local flexibility and ownership of the supply.	SHA provide oversight and strategic leadership.	PCTs have limited local flexibility in negotiating Local Enhanced Services Contracts (LES). Provider choice for patients is limited to their registered GP practice. No alternative NHS vaccination suppliers. Limited scope for Quality Incentive elements.	No added incentives to vaccinate hard to reach subgroups within target populations. No incentives to extend choice or access or strive for stretch attainment levels. Little flexibility for local commissioners to enhance the services provided locally.		No mechanism for vaccination provision by independent sector. Limited role of community pharmacy. Limited systems to incentivise community teams to vaccinate .
Contractual negotiations	DH would negotiate the contractual arrangements with General Practice Committee of BMA and Pharma industry.	No clear SHA role.	PCTs may see risk of considerable disruption of their relationships with GPs and their flu vaccination attainment if central supply is implemented.	Estimated that up to 1% of GP income might be threatened so likely to be considerable opposition to altering GMS and PMS contract clauses.	NHS/DH would tender for a central contract. Need strategy to manage risk (by securing multiple suppliers). Unclear whether central purchase would secure better discount and added benefits from suppliers compared to the current system.	No current contracts for non-GPs to deliver seasonal influenza. Pharmacists can dispense, on receipt of prescription, but only limited administration.
Communicating policy	Such a significant policy change would require considerable negotiation and time to implement.	SHA provide oversight and strategic leadership.	PCT mechanisms and flu coordinator role would require considerable expansion.	Guidance to GPs and pharmacists on changes to procurement and impact assessment for their practices.	Pharmaceutical companies may choose to contest the policy or decline to participate in tendering process.	Need to determine whether flu vaccine would still be available through pharmacies on FP10 or private prescriptions.

Option 3

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Public and media	Likely to be considerable professional, public political and commercial interest in the new policy.	SHA handles regional communication.	Considerable local professional, public and political interest in the new policy.	GP practices might lobby local opinion against the policy.	Pharmaceutical industry could lobby public and political opinion against the policy.	Possible UK or European legal challenge on grounds of anti-competitiveness or misuse of monopoly position.
Management	DH has system for management of childhood vaccines where there is very accurate data on need, limited variability and long lead in times. Seasonal flu has poor data on need, a short compressed season, and large risks of under or over provision.	May need regional or SHA distribution systems.	Role and responsibilities of the flu coordinator would be considerably expanded and would require additional support and resources and much more standardised role descriptions and contracts and enhanced systems to communicate with central supply agency.	Practice may withdraw from active management of flu campaign and transfer considerable responsibilities and workload to the PCT/central vaccine supply agency.	Pharma companies' local representatives would withdraw from involvement and there may, therefore, be a significant decrease in the workforce. The local networks and knowledge built up by the companies would be unavailable to the new system.	Logistics companies would need to be involved at possible additional cost.
Needs assessment	Data available centrally on assessing local need for vaccine is poor and patchy.	No clear SHA role.	Few PCTs independently use disease registers and practice databases to calculate vaccination requirements. Most PCTs base need on amalgamated practice submitted data.	Practices identify target patients and estimate their vaccination requirements. Practices quality monitoring of this system may deteriorate if the new system transfers risk away from them.	Pharma companies would be unlikely to assist PCTs and practices in identifying patients and calculating local demand as they would gain little or no advantage from this.	Vaccine provision through FP10s and private purchase is not usually measured.

Option 3

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Financial risk management	DH becomes responsible for procurement and logistics budget elements as well as the administration element. No national systems to use up unused contingency stock. DH may push for reduction in cost price to closer to market level. Need for DH to finance the expanded delivery team required for seasonal flu.	SHA accountable for the financial performance of their PCTs.	PCTs could be exposed to more risk as the flu elements of their budgets become controlled by a central agency. Practice Based Commissioning consortia may oppose any centralisation.	A significant element of financial risk would be removed from GP practices. Risk that practise changes. Practices lose the price rebate element of their current income and finances of flu campaign may be threatened.	Industry would see little benefit in continuing to carry any significant financial risk and might seek to transfer risk to the central agency.	
Purchasing	DH or their agents would tender for suppliers and negotiate price and value added contracts and include contingency and other arrangements.	SHA provides oversight and strategic leadership.	PCTs would likely transfer as much of their risk as possible to the new central authority and would press hard for significant cost reductions/quality improvements from the new system.	Practices would no longer have any involvement in purchasing or contract negotiation so local flexibility would be decreased.	No compelling evidence or assurances the system would be able to secure discounts from manufacturers or cost savings or quality improvements from the supply system.	Could pharmacies still order small amounts of flu vaccine stock for FP10 or private prescription use and optional access to additional supply?

Option 3

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Logistics	Central procurement agency would have to arrange logistics of supply chain to end users Current logistics for distribution of childhood vaccine could be used, but scale of flu vaccine supply between Sept to Dec would be far in excess of childhood vaccine supply. Potential to create considerable additional cost.	No clear role for SHA.	PCT arrangements for arranging and recording flu vaccine supply to practices would have to considerably expand and improve and this would create financial and technical stresses for the PCT especially for occupational target groups.	Practices would require reassurance that supplies would be delivered direct to practices in a series of phased deliveries from the supplier.	Manufacturers would be keen to totally withdraw from the distribution and delivery of stock.	Suppliers would be keen to withdraw from the logistics elements of flu vaccine distribution.
Coordination	DH assumes full responsibility for national coordination of campaign via local flu co-ordinators and therefore the linked technical and management challenges and political risks.	SHA provides oversight and strategic leadership.	PCT Flu coordinators responsibility for coordination and delivery of supply would be substantially increased.	Practices internally coordinate of campaigns may decrease if they consider themselves inadequately rewarded for their efforts or feel their influence on the campaign has been diluted against target and stock levels. Limited coordination between practices and between practices and PCT.	Supplier representatives who in past coordinated phasing and size of deliveries and reassignment of excess stock will disappear and with tem the knowledge and expertise they had developed. What evidence that this will improve coordination between practices and practice and PCT?	Pharmacies do not explicitly coordinate with practices or PCT.

Option 3

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Clinical delivery to patients	No evidence to suggest central procurement and distribution will significantly improve quality or reduce / contain costs.	SHA may put in place clinical governance protocols.	A small number of PCTs arrange moderate provider activity via community nurse provider arm and occupational health team and will have to develop systems to inform.	Responsible for significant majority of delivery. Any reduction in practice income or control / influence increase pressure to use community rather than practice staff to deliver the vaccinations.	Central procurement and supply may adversely affect local flexibility to estimate requirements and arrange delivery, quantity and timing.	Clinical delivery in the system will still be mainly GP based.
Occupational health delivery	DH has occupational health vaccination scheme for staff. Occupational health coverage is likely to be a growth area over the next few years and central procurement will not positively impact on this.	Few SHAs arrange an occupational health vaccination scheme for staff.	PCTs responsible for occupational health vaccination of their workforce. Most PCTs have an occupational health flu vaccination programme for clinical staff but low uptake.	Some practices arrange occupational health vaccination for staff; most do not.	Most suppliers arrange occupational health vaccination for all their staff.	Few pharmacies, dentists, optometrists arrange occupational health vaccination for their staff.
Reporting	DH will require much more extensive, timely and accurate data on vaccine requirement needs.	SHA monitors PCT vaccination rates as a key performance indicator but this will now potentially be influenced by the central procurement and supply process.	PCTs will have to develop enhanced data gathering systems to inform the central procurement and supply groups and their monitor value for money and effective-ness.	Practices submit weekly flu vaccination reports to PCT (reimbursement for vaccine and administration is dependent on these returns) . Some practices contribute data to the RCGP flu monitoring project.		Pharmacists do not report vaccine numbers except via the FP10 / PPD reporting system (up to 3 month delay in reporting).

Option 3

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Performance management	DH will be responsible for both policy and delivery related to seasonal flu.	SHAs performance manage PCTs vaccination performance against flu targets.	PCTs monitor practices' performance. Will PCTs flexibility to implement incentive programmes and commission or decommission service providers be compromised?	Practices' self monitoring of performance of flu campaign against internal and externally set targets may be reduced or weakened.		Pharmacies monitor their sales and FP10 performance.
Quality improvement	DH can change target groups and attainment targets.	No clear SHA role.	PCTs can implement local incentive schemes over and above national targets, e.g. to increase uptake in underserved populations.	Most practices reassess their performance and processes at least annually to control costs and maximise efficiency. However, affordability of clinical staff to support the campaign may be severely restricted under reduced income secondary to central procurement.	Pharma companies have established quality improvement cycles to optimise their commercial advantages.	Flu vaccine is a very small area of business for pharmacies.
Expansion of targets	New target groups or higher performance set by DH will require further funding and accurate additional data to calculate need.	SHA may provide limited oversight.	PCT responsible for implementing targets. Current funding mechanisms do not strongly incentivise stretching performance.	Central procurement and supply would create significant resource demands and financial risks for practices pursuing stretching targets. No additional incentive to achieve stretching targets.	Pharmaceutical company production may already be stretched. Unclear how much additional production capacity current system can deliver or over what timeframe regardless of the delivery model.	

Option 3

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
New distribution routes	DH is willing to explore and promote new distribution routes (e.g. new providers). This option would not affect distribution routes.	SHA provide oversight and strategic leadership.	PCTs could still skill mix delivery provided they have good data on need.	Most practices are making innovative use of nurses and health care assistants to increase productivity and reduce costs but their costs are recovered partly from the discount element of the flu contract. Central procurement would remove the discount element to be paid centrally.		Independent and voluntary sector providers are willing to explore business opportunities of expanded distribution routes.
Contingency stock	DH orders national contingency stock in some years via an EU tendering process. Future procurement would have to contain a contingency element. Risk of wastage of some of this contingency supply.	SHA may provide limited oversight.	Some PCTs arrange a small local contingency stock. This would be difficult under a central procurement model. Also more difficult to divert unused contingency to occupational health or non target groups late in the campaign.	Practices would depend on central procurement for contingency stock.	DH would need to develop excess stock around to cover transient shortfalls in the delivery programme.	Some pharmacies will sell a portion of their supply to practices or organisations short of stock but at an inflated market price. Such local sharing would be very difficult under central procurement.
Independent inspection	DH is conducting an independent review of flu vaccine supply. Would be much more likely to be under significant external scrutiny.	SHA may provide limited oversight.	The Healthcare Commission, during their annual inspections, assess flu vaccination performance as a quality indicator for PCTs.			Healthcare Commission independently inspects all provider organisations occupational health vaccination coverage.

Option 4

Central procurement and distribution: DH or its agent would purchase all the seasonal influenza vaccine supply used by the NHS and distribute from this central supply to frontline clinical teams. Central procurement and supply is the current system used for childhood vaccine supply. We have based our appraisal on a model where the current childhood vaccination system would be adapted and applied to seasonal influenza vaccination.

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Policy into practice	DH develops immunisation policy. Sets target groups and attainment levels. NHS/DH would design incentive schemes and stretch targets. Scientific advice for policy mainly sourced from JCVI/HPA/flu specialists. Service design advice from NHS Employers and policy teams.	Incorporate flu policy and targets into SHA oversight of PCTs and provider organisations.	Develops local flu strategy and policy. Appoints local flu coordinator who would lead implementation and monitoring of the new quality payments. Close links required between flu campaign team and finance and data monitoring teams in PCT.	Majority of programme is delivered by GP practices and most develop internal flu policies. Small elements delivered by district/ community nurses and residential care clinical teams. Both GPs and community teams should be eligible for quality payments.	Considerable political challenge to significantly renegotiate the NHS price. Industry would welcome DH developing and sharing with industry medium term policy direction for seasonal flu policy to better plan production development.	WHO and international influenza policies strongly influence UK policy. Equity and access are growing influences on policy development. Pressure to incentivise quality and stretching targets for flu campaign within a finite budget.
Policy relevance	Policy relevance in this area such as access, choice, expanding role for other clinical professions, Practice Based Commissioning, Payment By Results, quality based contracts. Local commissioners can enhance flu vaccination programmes beyond the national minimum standard.	SHA provide oversight and strategic leadership.	PCTs have more local flexibility in negotiating Local Enhanced Services Contracts (LES) Provider choice for patients is expanded beyond their registered GP practice. Inclusion of alternative NHS vaccination suppliers. Significant scope for Quality Incentive elements.	Added incentives to vaccinate hard to reach subgroups within target populations. Incentives to extend choice or access or strive for stretch attainment levels.		Mechanism for vaccination provision by independent sector or non GP independent contractors. Systems to incentivise community teams to vaccinate.

Option 4

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Contractual negotiations	NHS Employers negotiate the quality improvement contractual arrangements with General Practice Committee of BMA (GPC). DH also negotiates new lower NHS price with Pharma industry.	No clear SHA role.	New quality improvement contractual arrangements for flu must be a national model applying to GMS, PMS and APMS contracts and to non-GP providers including community nursing teams, pharmacists etc.	Practices and other providers negotiate with PCT to agree local elements of the national quality improvement contracts.	Pharma industry negotiates the process to agree the NHS reimbursement price. Company reps negotiate local supply contract with practices and other providers.	More flexibility to contract non-GPs to deliver seasonal influenza vaccine and to incentivise targeting hard to reach or under-served groups.
Communicating policy	DH informs flu-coordinators and providers via CMO letters and policy guidance. Regular scheduled meetings with UVIG. A new contract framework would require considerable additional communication and guidance.	SHAs would be required to facilitate local networks of flu coordinators. SHAs to monitor PCTs implementation of the new contract.	Flu coordinators coordinate and monitor programmes at PCT level. Much more developed two way communication between flu coordinators and DH.	GPs receive policy and contractual guidance on target groups and attainment levels via regular structured communication linked logically to appropriate points on the procurement cycle.	Pharmaceutical companies are alerted to policy and its implementation via UVIG.	Pharmacists and non-GP providers become an integral part of the delivery system.
Public and media	DH handles queries from media, professionals, public and politicians. DH communications unit plans and implements the National Flu Awareness campaign.	Handles regional queries from media, professionals, public and politicians.	Handles queries from local press, professionals, public and politicians. Some PCTs run local flu awareness campaigns (usually using DH national materials).	Practices run flu awareness campaigns as part of preparation for seasonal influenza.	Pharmaceutical industry produces and distributes considerable flu awareness materials (mainly to practices). Some companies have considerable interaction with lay media.	Pharmacists and other clinical teams disseminate flu awareness materials.

Option 4

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Management	DH develops more extensive interaction with local flu coordinators via national resource website and peer meeting for flu coordinators.	Monitors performance of PCTs against flu targets and implementation of new contract.	Coordinates local GP provider and non-GP provider activity. PCTs also deliver vaccination via their provider and occupational health arms.	Practice and provider campaigns are led and managed by team manager and lead clinician (e.g. GP partner and/or lead nurse or pharmacist).	Pharma companies local representatives report to national sales directors/ company management teams.	Non GP providers develop flu vaccination programmes and compete with GPs.
Needs assessment	Target groups decided by DH advised by JCVI, HPA and expert group. HPA also identifies stretch targets and under-served and hard to reach groups to inform design of the quality improvement element of the contract.	No clear SHA role.	PCTs will have to develop more extensive and accurate systems to monitor local need and providers' performance against these specific national and local targets. Most PCTs are likely to continue to base need mainly on amalgamated practice submitted figures.	Providers identify target patients and estimate their vaccination requirements. Some risk of different providers competing to vaccinate the same patient.	Some pharma companies assist PCTs and practices/providers in calculating local demand and identifying patients.	All providers will require access to sufficient data to accurately and responsibly assess vaccine requirements and take-up. Provision through FP10s and private purchase is not usually measured.

Option 4

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Financial risk management	DH responsible for flu vaccine budget paid out through GP reimbursement. New Quality Improvement contract should be designed to minimise risk of inappropriate use of vaccine and need for contingency stock and to use up unused contingency stock. A reduction in reimbursable cost of vaccine will mitigate the cost of any negotiated incentive scheme, or other reinvestment of savings.	SHA accountable for the financial performance of their PCTs.	PCTs assume some increased risks related to provider performance against the quality improvement contract in the first 1-2 years of implementation. PCTs must closely monitor and manage performance against the Quality Improvement targets during the campaign.	Practices and providers carry most of the financial risk. Use or return contracts for stock are rarely available. Quality Incentive payments would recognise and reward the additional resources required to vaccinate hard to reach groups and reach high attainment levels. Quality Improvement payments keep moneys from the purchase rebate within the system.	Industry manufactures to meet the demand confirmed by advance orders. Therefore clear indication of policy direction would assist manufacturers and providers planning. Some companies share limited amounts part of risk with GPs through use or return schemes.	Pharmacies carry a small stock to meet FP10 demand. New providers may be overly ambitious or conservative entering this market. There may be uncertainty in early years of new quality
contract. Purchasing	DH would withdraw from all purchasing and devolve purchasing to providers (including responsibility for contingency arrangements. DH may purchase additional supplies for its own other purposes.	SHA to provide oversight of arrangements and ensure that appropriate contingency plans are in place.	PCTs may purchase a small stock for occupational health, internal contingency supply, etc. PCT need to reality check and coordinate purchasing of stock by multiple providers including their own provider arms.	Practices and other providers order direct from suppliers and negotiate delivery timetables and sometimes contingency arrangements and added value packages to support quality improvement.	Local pharma industry reps negotiate orders with practices. Discounts are no longer offered but added value packages and contingency and flexible supply arrangements may influence purchasers.	

Option 4

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Logistics	DH no longer holds any stocks; therefore does not require logistics.	No clear SHA role.	Providers' clinical and occupational health stock is delivered direct to teams by suppliers. PCT staff sometimes required to move around stock between clinical teams or practices.	Practice and providers' supplies are delivered direct to practices in a series of phased deliveries from the supplier.	Suppliers arrange the delivery of stock as part of the purchase package. In cases of over or undersupply suppliers move excess stock locally using logistic companies and/ or local representatives.	Suppliers arrange the delivery of stock as part of the purchase package.
Coordination	DH responsible for national coordination of campaign via local flu co-ordinators.	Increased role of SHA in coordinating and performance management of seasonal influenza campaign.	PCT flu coordinators responsible for coordination of internal PCT and independent contractor campaigns. Increased number of providers and stretching targets require PCT to manage and coordinate a more complex system.	Practices and providers internally coordinate their clinics and performance against target and stock levels. Limited coordination between providers and between providers and PCT.	Supplier representatives coordinate phasing and size of deliveries and reassignment of excess stock.	Pharmacies do not explicitly coordinate with practices or PCT. Increased commercial competition between providers may hamper local coordination.
Clinical delivery to patients		SHA provides oversight and strategic leadership.	A small number of PCTs arrange moderate provider activity via community nurse provider arm and occupational health team. This may increase if they become eligible for rewards similar to GPs.	Likely to remain responsible for significant majority of delivery. Quality contract may accelerate performance in coverage of target groups. Identify target patients. Arrange invited and opportunistic flu vaccination mainly via practice nurse clinics.	Works with providers to estimate requirements and arrange delivery, quantity and timing. No direct access to patients.	New providers may have more limited access to data to identify target persons and there is an increased risk of multiple providers targeting the same patients.

Option 4

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Occupational health delivery	New contract includes incentives for providers to vaccinate occupational health target groups. DH may wish to review occupational health strategy for staff.	New contract includes rewards for providers to vaccinate occupational health target groups. SHAs accelerate occupational health vaccination scheme for staff.	New contract includes rewards for providers to vaccinate occupational health target groups. PCTs accelerate uptake of occupational health vaccination of their workforce.	New contract includes rewards for providers to vaccinate occupational health target groups. Practices and providers are incentivised to arrange occupational health vaccination for staff.	New contract includes rewards for providers to vaccinate occupational health target groups. Most suppliers arrange occupational health vaccination for all their staff resulting in significant increased demand for vaccine. Occupational health coverage could be scheduled later in the flu campaign after clinical target group target levels are achieved.	New contract includes rewards for providers to vaccinate occupational health target groups. Likely to result in significant and rapid growth in occupational health coverage of pharmacies, dentists, optometrists and their staff.
Reporting	DH receives regular reports from RCGP Flu Monitoring Unit. Weekly PCT vaccination uptake reports during the flu campaign. Process will have to be enhanced to provide more detailed data to adequately report attainment against the quality element.	SHA monitors PCT vaccination rates as a key performance indicator.	PCTs collate weekly flu vaccination reporting, including quality data, for their practices and providers and forward to SHA and DH.	Practices and providers submit weekly flu vaccination reports to PCT (reimbursement for vaccine and administration is dependent on these returns). Some practices contribute data to the RCGP Flu Monitoring Project.	Suppliers collect delivery/sales data but not administration data. Data is commercially sensitive and not shared with DH or UVIG.	All providers report regularly via the standard reporting system. Pharmacists report vaccine numbers via the FP10/PPD reporting system (up to 3 month delay in reporting).

Option 4

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
Performance management	DH monitors national arrangements but performance management is responsibility of NHS.	SHAs performance manage PCTs vaccination performance against flu targets.	PCTs monitor practices' performance. PCTs have some local flexibility related to the quality component and to commission/ decommission new providers.	Practices and providers self monitor performance of flu campaign against internal and externally set targets.	Pharma companies closely monitor the performance of their representatives.	Pharmacies monitor their sales and FP10 performance.
Quality improvement	DH has increased flexibility to alter target groups and attainment targets and to operate within financial envelopes.	SHA provides oversight and strategic leadership.	PCTs can implement local incentive schemes over and above national targets, e.g. to increase uptake in under-served populations.	Most practices and providers reassess their performance and processes at least annually to control costs and maximise efficiency.	Pharma companies have established quality improvement cycles to optimise their commercial advantages.	Competition from new providers and more stretching targets stimulate performance in local practices. Poor performers can be decommissioned more easily if there are alternate local providers of the service.
Expansion of targets	The new flexibility of the Quality Improvement Contract will allow DH to introduce new targets groups or higher performance targets without significant additional funding.	SHA provides oversight and strategic leadership.	PCT responsible for implementing targets. New Quality Contract provides a mechanism to more strongly incentivise stretching performance.	The new funding mechanisms reward performance and more adequately address the significant resource demands and financial risks for practices pursuing stretching targets. Graduated incremental quality-linked payments incentivise achieve stretching targets.	Pharmaceutical company production may already be stretched. Unclear how much additional production capacity current system can deliver or over what timeframe.	Some providers may opt out of competing for the most challenging patient populations. If that occurs PCT and DH could increase the incentives to attract and reward providers who serve particularly difficult populations.

Option 4

Description	DH	SHA	PCT	Provider	Pharmaceutical company	Other
New distribution routes	DH would have much more flexibility to explore new distribution routes (e.g. new providers) and new target groups.	SHA provide oversight and strategic leadership.	Innovative and entrepreneurial PCTs and clinical teams are rewarded for innovative practices such as use of community nursing staff to deliver vaccinations.	Most practices are making innovative use of nurses and health care assistants to increase productivity and reduce costs.		Independent and voluntary sector providers are willing to explore business opportunities of expanded distribution routes.
Contingency stock	DH no longer has to be responsible for a contingency stock. Appropriate contingency arrangements and reduction of waste are two areas rewarded by the new quality contract.	SHA provides oversight and strategic leadership. SHA ensures that PCTs have robust arrangements.	PCTs implement and monitor local contingency arrangements via the quality contract. If contingency is unused in target groups, quality contract rewards appropriate diversion to occupational health or non target groups late in the campaign.	Providers have to develop and implement contingency plans within and between practices.	Suppliers move excess stock around to cover transient shortfalls in the delivery programme.	Contingency arrangements may encourage cooperation between practices, providers and PCT.
Independent inspection	DH reports nationally on performance against the quality contract.	SHA provides limited oversight.	The Healthcare Commission, during annual inspections, assess flu vaccination performance as a quality indicator for PCTs.	New providers may require an assessment of their competence before they are commissioned to deliver flu vaccination.		Healthcare Commission independently inspects all provider organisations' occupational health vaccination coverage.

Appendix 6
Seasonal influenza programme – timelines

2004

The Joint Committee on Vaccination and Immunisation agreed that those who are the main carer for an elderly or disabled person whose welfare may be at risk if their carer falls ill, be vaccinated at the GPs discretion.

This change was included in the revised Influenza chapter of the Green Book. The link to this chapter was included in the CMO letter to all GPs dated 9 August 2004.

2005

Purchasing vaccine

DH does not purchase influenza vaccine on behalf of GPs. GPs, wholesalers, pharmacists, private companies place orders direct from the supplier of their choice. There are six suppliers of flu vaccine to the UK.

Most orders are placed with suppliers between January and March each year. If a supplier has not heard from a previous year's customer by April, they are contacted as a reminder to see if they wish to place an order. It is not unheard of that some GPs try to place orders as late as June.

Delivery dates to GPs are usually arranged at the time of order. Vaccine can be delivered over two to three stages based on fridge capacity of GP or when clinics are going to be held.

At the time of manufacture, suppliers have the best knowledge available to know how much vaccine they need to produce. This is based on confirmed orders received, amount required previous year and any changes in DH policy plus % of reserve stock.

Details of how much each manufacturer can supply is provided to the DH supply team on an individual company basis. Manufacturers do not know how much their competitors can supply. This figure is a UK total figure and includes GPs, wholesalers, private clinics and devolved administrations.

Suppliers offer GPs a percentage of orders on a sale or return basis, not the whole amount.

The majority of vaccine from suppliers goes to GPs/NHS; only 2–3% is provided for private clinics.

March 2005

23rd DH representatives meet with UK Vaccine Industry Group (UVIG) to discuss policy changes and requirements for the 2005/06 influenza campaign. The addition of carers and those with chronic liver disease was mentioned to build in vaccine manufacture to cover these groups.

July 2005

25th Joint CMO/CNO/CPO letter describing this year's influenza campaign was issued to: all GPs, PCT directors of public health, immunisation coordinators, CCDCs, medical directors of trusts, chairs of PCTs, directors of nursing, lead nurses at PCTs, practice nurses, chief pharmacists/pharmaceutical advisers of SHAs, CEs of SHAs, CEs of NHS trusts for circulation to all occupational health departments and directors of infection and prevention control.

25th UVIG contact DH to say there may be a delay in delivery of first orders. This is due to delay in receiving one of the seed viruses and quantification reagents. Statement is being put on UVIG website.

26th First contact from the profession asking if DH knew of delays and wanted clarification on current position.

DH issue advert advertising for 400,000 contingency stock.

August

1st DH contact all manufacturers to get a picture of how many face delays in order to prepare a letter to influenza coordinators.

4th First e-mail request to order vaccine from DH contingency stock for those GPs who are facing four-week delay.

5th DH letter issued to all influenza immunisation coordinators making them aware that some suppliers announced a delay of 2–4 weeks. Coordinators were asked to ensure all GPs in their area were aware of this situation and to rearrange their influenza clinics around re-confirmed orders from their respective suppliers. DH e-mail account provided

It should be noted that there was delay at the start of the 2004 influenza campaign when one of the suppliers, Chiron, had their licence suspended due to their manufacturing process. Chiron did not supply any of its planned doses that year.

October

21st DH receives first calls asking for vaccine from contingency stock.

November

Throughout November, officials have liaised with UVIG and suppliers on the availability of extra contingency stock.

3rd David Salisbury letter to influenza coordinators informing them of the availability of our contingency stock and how to order from it; seeking feedback on number of surgeries in their area requiring extra vaccine; what arrangements they have in place to identify and re-distribute vaccine; whether groups have been prioritised; whether demand is greater than expected and why.

3rd In addition to 400,000 contingency stock, 200,000 doses ordered.

3-15th Receive data from PCTs (audit).

15th DH receives first monitoring uptake data from HPA.

15th Note to David Harper (Chief Scientist at the Department of Health) from Jane Leese informing him of uptake data and that from the audit being carried out, alerting to potential shortage of vaccine.

16th Note from David Harper agreeing to action being taken.

17th Submission to CMO and PS(PH) informing them of latest information and recommending DH seeking and securing additional contingency stock;

Dr Salisbury to write to GPs reminding them to give priority to over 65s and risk groups.

18th COMMS provide media handling to CMO, PS(PH) and SofS recommending Dr Salisbury gives media briefing.

21st Dr Salisbury gives media briefing to selected journalists at RH.

21st Dr Salisbury letter emailed to 20,000 GPs in 8611 practices announcing current contingency will soon be exhausted and that a further 200,000 doses will be available in January.

22nd Officials brief SofS, PS(PH) and Lord Warner. SofS gives statement on seasonal influenza vaccine in House of Commons

22nd Conclusions from audit and further ring-round sent to PS(PH).

23rd On SofS request, letter sent by e-mail to 20,000 GPs covering 8611 practices and influenza immunisation coordinators asking for further feedback on whether they have sufficient vaccine to complete the clinics; number of doses required to complete their clinics; whether they have surplus available for local re-distribution.

Central Office of Information contacted and agreed to issue letter to GPs, letter also e-mailed to all influenza immunisation coordinators, CCDCs, RDsPH, DAs. Database set up to receive response to survey, generic e-mail account set up to receive queries and two members of staff made available to take telephone queries.

24th Daily update sent to Minister.

25th 23% of practices (1852) had responded to Dr Salisbury's letter of 23 November.

28th The supplier confirms that they can supply 600,000 doses of vaccine by end of January, with possibility of a further 200,000.

29th Farillon contacted and asked to provide despatch data.

5th December

- Briefing for CMOs meeting with Dr Meldrum (Chair of the GPC)
- SoS daily update
- Ad hoc requests/responses to queries from Ministers
- Liaise with Farillon for despatch data
- Liaise with PASA/manufacturers
- Respond to e-mail queries from practices/PCTs

Letters issued to the profession

25 July	CMO Letter
5 August	Jeff Porter to influenza immunisation coordinators
3 November	David Salisbury to influenza immunisation coordinators
21 November	David Salisbury to all GPs
23 November	David Salisbury to all GPs

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Biography of panel members

Dr Ian Spencer

MB BS, MSc (Public Health)
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He graduated from the University of Newcastle upon Tyne in 1974. Following house officer posts in South West Durham he spent one year as a Demonstrator in Pathology (Morbid Anatomy and Histopathology) at the University of Newcastle upon Tyne. He then spent 14 years as a Principal in General Practice from 1976-1990, in a relatively deprived semi-rural community in South West Durham.

He left general practice in 1990 to undertake a public health training programme in the Northern Region and was awarded a Masters Degree from the University of Newcastle upon Tyne in 1992. In 1993 he was appointed to a medical adviser post in Newcastle Health Authority and since that time has held a number of senior primary care managerial posts in the area, including the Director of Primary Care for Newcastle and North Tyneside Health Authority.

In 2002, he was appointed as Director of Clinical Governance to Northumberland, Tyne and Wear Strategic Health Authority where he has held lead responsibility for primary care, clinical governance, medicines management and a number of public health screening programmes.

He undertook a number of reviews as a clinical governance reviewer for the Commission for Health Improvement. He is an Associate of the Healthcare Commission and in his most recent role has had close working relationships with the commission.

He has been working on secondment to the Department of Health since September 2006, and will be retiring from the NHS in February 2007 to establish an independent healthcare consultancy.

Dr James Kennedy

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He graduated from University College Cork, Eire in 1986. Following House Officer posts in the South Charitable Infirmary, Cork City he trained on the Cleveland General Practice Vocational Training Scheme in Stockton-on-Tees, Cleveland.

After further postgraduate training in Accident and Emergency and Paediatrics he was appointed as a Principal in a General Practice in

the east end of Newcastle upon Tyne, and as Lecturer in Primary Care Therapeutics at the University of Newcastle upon Tyne.

In November 1995, he was appointed as Senior Lecturer in General Practice at Imperial College School of Medicine, London and shortly after joined a practice in the multicultural area of Hayes, in the west of London where he has remained.

In early 2000, he was appointed as the inaugural Medical Director and the Chair of the Professional Executive Committee (PEC) at Hillingdon Primary Care Trust, largest of the first wave of PCTs in the UK. In late 2002, he moved from this post to become Primary Care Adviser to the Healthcare Commission.

He is Chair of the prescribing Committee of the Royal College of General Practitioners (RCGP), and has been an adviser or associate to the National Clinical Governance Support Team, the NHS Counter Fraud Agency, the National Clinical Assessment Service, the Department of Health and several international healthcare systems.