

Title: Expansion of the Vaccine Damage Payment Scheme (VDPS) for adult influenza vaccinations IA No: 9569 RPC Reference No: Lead department or agency: DHSC Other departments or agencies: DWP	Impact Assessment (IA)			
	Date: 27/04/2021			
	Stage: Development/Options			
	Source of intervention: Domestic			
	Type of measure: Secondary Legislation			
Contact for enquiries: Thomas Rowland				
Summary: Intervention and Options				RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option (in 2021 prices)			
Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status
-£0.343m	£0m	£0m	Not a regulatory provision

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

Vaccine Damage Payment Scheme (VDPS) claims for seasonal influenza could only be made by those who were vaccinated before their 18th birthday. Ministers agreed to extend the age range of VDPS for seasonal influenza vaccine cases, due to adults being a large proportion of the total vaccinations on the scheme. By expanding the eligibility of the Vaccine Damage Payment Scheme (VDPS) for those 18 and above, this will ensure that in cases where severe disablement is caused by a government approved vaccination programme, there is financial assistance available. This should be done on the grounds of equity and fairness, in line with the objectives of the original scheme.

What are the policy objectives of the action or intervention and the intended effects?

The VDPS provides a one-off, tax-free, lump sum payment of £120,000 to help ease the burden of those individuals who, on very rare occasions, are severely disabled as a result of vaccines included in the scheme. Children receiving the influenza vaccination are already eligible, whereas adults are not. This policy seeks to expand the eligibility to adults who receive an influenza vaccination. The VDPS is not a compensation scheme and other forms of redress, such as litigation, are available to claimants, though may take several years to complete

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

Option A. Do nothing
Option B. Expand to only include adults receiving the influenza vaccination within the Government's national programme
Option C. Expand to include all adults receiving the influenza vaccination

Does implementation go beyond minimum EU requirements?		N/A		
Is this measure likely to impact on international trade and investment?		No		
Are any of these organisations in scope?	Micro No	Small No	Medium No	Large No
What is the CO ₂ equivalent change in greenhouse gas emissions? (Million tonnes CO ₂ equivalent)	Traded: 0		Non-traded: 0	

Will the policy be reviewed? It will not be reviewed. **If applicable, set review date:**

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

Signed by the responsible Minister: _____ Nadhim Zahawi _____ Date: _____ 26th April 2021 _____

Summary: Analysis & Evidence

Policy Option C

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2021	PV Base Year 2021	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: -£0.23	High: -£3.5	Best Estimate: -£0.34

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	£0.090	£0.019	£0.228
High	£1.15	£0.308	£3.5
Best Estimate	£0.113	£0.030	£0.343

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

Estimates for the present value of the costs as a result of the expansion for those aged 18 and over to the act only include the additional administrative costs of running the scheme with an increased caseload. These costs are estimated to be £343k (£228k-£3.5m) in total over the 10-year time period. This is based upon an average annual cost of between £30k (£19k-£308k) plus an additional £113k (£90k-£1.15m) for backdated claims in the first years after the expansion. The cost to Government of the awards made to successful claimants is estimated as part of the IA, but it is not included in the NPV calculations as it is considered a transfer from government to successful claimants. This is estimated to equal between £68k to £111k per annum with an additional £254k – £414k for the backdated claims.

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

None identified.

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

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

There are no estimated monetised benefits. There are only transfers from government to successful VDPS claimants. The amount per successful claimant is £120,000 tax free. These transfers are estimated to equal between £68k to £111k per annum with an additional £254k – £414k for the backdated claims.

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

The scheme allows financial payment for successful applicants quicker than a litigation process, and hence reduces any impact on people whose financial position is impacted by disability resulting from the vaccine; and the related mental anguish this might create. This policy satisfies a moral duty on government to act in a just way towards individuals who suffer disability as a result of engaging in a government approved Health Protection scheme; and all citizens gain from the knowledge that government would award financial assistance if they were severely affected.

Key assumptions/sensitivities/risks	Discount rate (%)	3.5
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The key assumptions include the rate of claims per vaccination, including how rates of adult claims differ from rates below under 18s; rates of successful claims and the admin costs associated with the additional claims. These assumptions are based on past vaccines, as it is difficult to assess the risks of future vaccines, although rigorous safety and regulation standards are upheld for all authorised vaccines.

There are further risks to capacity of the scheme, if it were to receive many claims, even if those claims are ultimately unsuccessful. There are further risks to Arm's-length bodies such as HM Courts & Tribunals Service, the Centre for Health and Disability Assessments and potentially NHS hospitals, if large number of claims are received.

The award per successful complaint is considered a transfer cost. Therefore this IA does not make a welfare adjustment to reflect NHS opportunity costs, should this spending displace marginal NHS activity.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:	Benefits:	Net:	

Evidence Base

1. Problem under consideration and rationale for intervention

The Vaccine Damage Payment Scheme (VDPS) was established in 1979 and provides a one-off, tax-free, lump sum payment of £120,000 to help ease the burden of those individuals who, on very rare occasions, are severely disabled as a result of a vaccination against diseases listed in the 1979 Vaccine Damage Payments Act (VDPA) or specified since 1979 by various statutory instruments. Severe disablement is defined as being 60% or more disabled, on the scale used by the Department of Work and Pensions (DWP) to administer the Industrial Injuries Disablement Benefit.

Diseases are routinely added to the Scheme when a new programme joins the routine immunisation programme. This is usually done a few years after the introduction of the vaccination. The specified diseases to which the Act currently applies to:

- Coronavirus (COVID-19)
- Diphtheria
- Haemophilus influenzae type b (Hib)
- Human papillomavirus
- Influenza, except for influenza caused by a pandemic influenza virus
- Measles
- Meningococcal group B (meningitis B)
- Meningococcal group C (meningitis C)
- Meningococcal group W (meningitis W)
- Mumps
- Pandemic influenza A (H1N1) 2009 (swine flu) - up to 31 August 2010
- Pertussis (whooping cough)
- Pneumococcal infection
- Poliomyelitis
- Rotavirus
- Rubella (German measles)
- Smallpox - up to 1 August 1971
- Tetanus
- Tuberculosis (TB)

Section 2 of the Act restricts claims to those who were vaccinated before their 18th birthday. In other words, the default is that VDPS is limited to under-18s. However, exceptions have been made for certain diseases whereby adults are eligible, in recognition that these programmes are currently, or were previously, offered to a large proportion of adults. This is true for the following diseases:

- Coronavirus (COVID-19)
- Poliomyelitis
- Rubella
- Meningococcal group C
- Human papillomavirus
- Pandemic influenza A (H1N1) 2009 (swine flu)
- Meningococcal group W before your 26th birthday

The focus of this policy is whether to make this exception for Influenza. Note, eligibility is currently not restricted based on whether the claimant has been recommended the vaccine.

The VDPS is a UK wide scheme that has been administered since its establishment initially by the Department of Health and Social Security (DHSS) and subsequently by the Department of Work and Pensions (DWP).

Since 1 May 2014, the VDPS has been the joint responsibility of DWP and DHSC. DWP remains responsible for assessing claims to the VDPS and making payments; DHSC is responsible for VDPS policy as set out in the 1979 Act, including making changes to the diseases covered by that Act by secondary legislation. Any changes we make to the Scheme will be communicated with colleagues in the Devolved Administrations before any Statutory Instrument is laid.

The VDPS is not a compensation scheme and does not prevent an individual from pursuing litigation separately and in parallel, although any payment made through the VDPS would be deducted from any final settlement whether that be from government or a civil claim made against a manufacturer.

Seasonal influenza was added to the Act in 2015, but no exception was made for the age limit. It is proposed that the Department extends eligibility of influenza on the Vaccine Damage Payment Act by amending the legislation through a negative resolution statutory instrument. In doing so, we ensure there is support for those aged 18 and above, should someone be severely disabled as a result of receiving a seasonal influenza vaccination. This is the only way that the Government acknowledges that a vaccination recommended by the Government may have caused a severe disablement.

Any potential influenza vaccine will go through robust clinical trials and will have to meet stringent safety checks and quality controls. All vaccines are tested through three phases of clinical trials to ensure they meet strict standards. Phase one trials are to test initial safety, phase two is to test the immune response (production of antibodies) to different doses; and phase three is to test very large numbers across broad cohorts for safety and effectiveness in preventing disease. There are extensive checks and balances required by law at every stage of the development of a vaccine, and any influenza vaccine will have passed these extensive checks before being administered to the population.

Independent regulators ensure that all the necessary safety checks are carried out. These decisions will be based on the evidence of vaccine trials involving very large numbers of people. As with any medicine, vaccines are highly regulated products. There are checks at every stage in the development and manufacturing process. We have some of the highest safety standards in the world and the MHRA is globally recognised for requiring the highest standards for quality, safety and medicines regulation.

2. Rationale and evidence to justify the level of analysis used in the IA

From April 2007 to the 31st January 2017, across all diseases on the VDPS, there were a total of 759 claims and 11 awards made¹. It should be noted that an award might have been made in

¹ Department of Health and Social Care, 2017. *FOI 1075690, 22 March 2017* [Online]. Available from: <https://www.whatdotheyknow.com/request/391400/response/955853/attach/html/2/FOI%201075690%20Griffin%20VDPS%20claims%20v2%204.pdf.htm> [Accessed 14 November 2020].

a different year to that which the claim was made. Thus far, across influenza vaccinations given to all ages, disabling side-effects have only been identified on a very rare basis.

Since influenza was added to the scheme in 2015, 38 claims have been made to the VDPS, where influenza was listed amongst the vaccinations received and where the recipient was under 18 at the date of vaccination. One award has been made in respect of influenza in this time period. As children can receive multiple vaccinations for different diseases within a short time span, it is not always clear what vaccine the claim is related to.

The future rate of claims for the adult population is uncertain; this impact assessment will explore a number of options for estimating this, creating a low, central and high scenario in order to account for the uncertainty within these estimates. Evidence can be drawn from the number of childhood flu claims seen on the VDPS since its addition in 2015. There are examples of other diseases listed on the scheme where there has been adult eligibility, these include polio, rubella, COVID-19, meningococcal group C, swine flu (H1N1) and HPV; the H1N1 example from this list is used to assist in the estimation of the scenario within this assessment.

Estimates will be made for the resulting number of claims, successful claims, total payments from successful claims and additional administrative costs as a result of the additional claims. Wider societal benefits of the scheme are not estimated as the marginal benefit of the expansion of the scheme cannot be reliably quantified. However, the expansion will help the scheme meet its objectives of acknowledging and providing financial assistance to those who in very rare cases suffer severely disabling side-effects from vaccination.

One factor that could lead to different rates of claims between adults and children is that different influenza vaccinations are given to children and adults in the main. For example, the Quadrivalent LAIV vaccine (nasal spray) which is licenced from ages 2 to 18, and normally given to 2 and 3 year olds as part of the childhood flu vaccination programme; the recombinant Quadrivalent influenza vaccine is only authorised for 18 and above, and is the most prevalent vaccine given for those between the ages of 18 and 65; the Adjuvanted Trivalent Influenza vaccine is only licensed from 65 years of age. There is evidence to suggest that adverse events vary across these vaccination programmes².

Another factor that could drive higher number of claims is an increased prevalence of co-morbidities in the adult population. Irrespective of vaccination, adults will have a greater chance of developing a comorbidity, therefore post-vaccination there is a greater chance that adults could associate that comorbidity as being related to a vaccine they have been given, resulting in them making a claim on the VDPS. Even if there is no causal link proved, the additional claim will still have to go through the process and the VDPS will incur administrative costs as a result.

3. Description of options considered

There are 3 main policy options:

OPTION A - Do nothing, leaving adults unable to make a claim on the Scheme should they be affected by an influenza vaccination.

Seasonal influenza was added to the Act in 2015, but no exception was made for the age limit, and so currently claims can only be made by those who were vaccinated before their 18th birthday.

² Cross, J.W., Joy, M., McGee, C., Akinyemi, O., Gatenby, P. and de Lusignan, S., 2020. Adverse events of interest vary by influenza vaccine type and brand: Sentinel network study of eight seasons (2010–2018). *Vaccine*, 38(22), pp.3869-3880.

For those 18 and above, this would still leave options for redress through litigation, if those vaccinated suffered severe side effects as a result of the flu vaccine. However, this will be a process that will take longer than the process of receiving a VDPS award, and thus in the interim, these individuals will be left without financial support, outside of typical disability benefit awarded.

OPTION B - Limited adult eligibility i.e., any adult recommended the seasonal influenza vaccine

One option for the expansion of eligibility to only those aged 18 plus, is to limit the eligibility to those who have been recommended the vaccination as part of the Government's Annual National Flu Programme. This would be a novel approach, with other vaccinations that have adult eligibility allowing all vaccinations for a disease listed on the scheme, not only those recommended as part of a government vaccination programme.

Eligibility for the Government's Annual National Flu Programme has, in the past, been based on age (for example all those above the age of 60 years), those with a specified list of health conditions (for example, diabetes), and occupation (which in the past has only included frontline health and social care workers i.e., those with direct contact with patients). Some employees pay for their employees to receive the vaccine, and other citizens pay privately to receive this. For every claim, it would be necessary to establish eligibility under the government programme, which adds an additional step to the administrative process and therefore additional cost and potential time delays.

OPTION C - Allow all adults to claim against influenza

Under this approach all flu vaccinations would be covered, included those purchased privately and those given as part of an occupational health scheme, making eligibility more inclusive. This is particularly important in a period where significantly more are being encouraged have a seasonal flu vaccine, this includes the use of private flu vaccination and occupational health schemes, so treating these on an equal footing has important ramifications for meeting both the scheme's objectives but also the Government's wider objectives for seasonal influenza. The additional cost of C over B is very small at around £10,000 per year.

This option would also provide full consistency with the adult exemptions made for polio, rubella, COVID-19, meningococcal group C, swine flu and HPV, none of which include a restriction based on Government recommendations.

We estimate that there are an additional 10-15% vaccinations administered per flu season through private purchases and through occupational health programmes.

4. Policy objective

Ministers agreed to extend the age range of VDPS for seasonal flu vaccine cases. By extending the eligibility to all ages, VDPS will provide wider support to those, who as a result of taking the vaccine, become severely disabled, above a 60% disability threshold. All will be eligible to claim £120,000 tax free from the scheme.

A VDPS payment will alleviate the additional financial hardship faster than redress through litigation, which can take several years. Assistance for those 18 and above will have the

additional benefit of assisting co-dependants who may suffer as a result of the severe disability of the claimant.

There are previous examples of exemptions to section 2, the part of the act that restricts claims to those who were vaccinated before their 18th birthday. These have been put in place for diseases where a large proportion of the vaccinated population are adults, with the most recent of these exemptions being made for COVID-19. Extending this eligibility in seasonal flu, will bring this in line with those previous examples.

5. Summary and preferred option with description of implementation plan

The preferred option is option C. This is to meet the policy objectives as stated above. This option is preferable to Option B because it provides full consistency with the adult exemptions made for polio, rubella, COVID-19, meningococcal group C, swine flu and HPV, none of which include a restriction based on Government recommendations.

In the immediate future, the scheme will continue to be administered as before, with DWP leading on the assessment and payment of claims, in close collaboration with DHSC, who lead on the VDPS policy. However, the administering of the scheme will soon move to the newly formed UK Health Security Agency.

Once included in the scheme it will not be removed, unless there is a future requirement from Ministers for a change in policy.

6. Monetised and non-monetised costs and benefits

6.1 Business as Usual Costs and Benefits

The “Business as Usual” scenario here assumes that only those under the age of 18 will be eligible for the VDPS going forward.

This scenario is defined as zero costs and benefits for the purposes of the calculations which are all made in relation to this counterfactual. However, as mentioned in the policy objectives section of this IA, there are negative consequences associated with the “Business as Usual” scenario.

6.2 Expansion of the VDPS, Options B and C

6.2.1 Methodology

The only costs that will be included in the headline figures are the administrative costs of running the scheme; this is because payments on the scheme are considered transfers between government and successful claimants and are therefore not considered part of the net present value (NPV) calculation. Additionally, we have assumed that there is no opportunity cost of this transfer displacing NHS activity at the margin, and therefore we have not estimated the wider societal cost of this transfer.

Estimates for the Full time equivalent (FTE) hours associated with the increase in overall claims have been made, it is assumed that 1 FTE for VDPS costs £60,000 per year and running the scheme currently involves 1.7 FTE hours.

The cost of payments for successful claims are not included within the final estimates of the net present value, but for completeness, the value of this transfer will still be estimated. The components to the calculation are exposure to a vaccine; the probability of severe adverse events; the probability of a successful claim; and the fixed claim amount. The formula used is:

$$\# \text{ of people vaccinated} \times \text{probability of claim} \times \text{probability of a claim being successful} \times \text{VDPS payment} = \text{Total cost of payment}$$

6.2.2 Number of people vaccinated

Unlike other vaccinations on the scheme that are only given in a GP setting, there are several locations in which influenza vaccinations are administered. Published data for vaccinations that take place in GP surgeries, schools and for healthcare workers is aggregated in order to give a number of vaccinations that are given as part of NHS eligibility. The eligibility in these groups has changed considerably since 2013/14, with increased number of school years being eligible each year, as well as the extended eligibility to over 50s during 2020/21, as part of the measures against the COVID-19 pandemic

Under 18s

Aggregating the number of past childhood flu vaccinations is required to calculate the rate of claims on the VDPS, which can then be applied to adults. The VDPU has received 38 claims relating to influenza since its addition to the scheme in 2015, and the rate of claims for those below 18 is equal to 38 divided by the total number of vaccinations since the extension of the season flu programme in 2013/14.

Table 1: Vaccine eligibility as part of the Government's Annual National Flu Programme

	2020/21	2019/20	2018/19	2017/18	2016/17	2015/16	2014/15	2013/14
Under 18								
GPs								
Aged 2	✓	✓	✓	✓	✓	✓	✓	✓
Aged 3	✓	✓	✓	✓	✓	✓	✓	✓
Aged 4						✓	✓	
At risk	✓	✓	✓	✓	✓	✓	✓	✓
Schools								
Age 4	✓	✓	✓	✓	✓		✓ (Pilot)	
Age 5 - 7	✓	✓	✓	✓	✓	✓	✓ (Pilot)	
Age 8	✓	✓	✓	✓	✓		✓ (Pilot)	
Age 9	✓	✓	✓	✓			✓ (Pilot)	
Age 10 -11	✓	✓	✓				✓ (Pilot)	
Age 12	✓							

The following aggregated figures are used in the IA in the calculations of the rate per million vaccinations.

Table 2: Estimated total of vaccinations for under 18s

	2020/21	2019/20	2018/19	2017/18	2016/17	2015/16	2014/15	2013/14	Total
Under 18									
GPs	2.1m	1.7m	1.8m	1.8m	1.6m	1.9m	2.0m	1.6m	14.5m
Schools	3.9m	3.4m	3.4m	2.4m	1.3m	0.9m	0.2m	0.0m	15.5m
Total	6.0m	5.1m	5.2m	4.2m	3.0m	2.7m	2.2m	1.6m	29.9m

Seasonal flu was added to the scheme in 2015, with claims backdated to September 2013, before the start of the 13/14 flu season. In this time frame until the 2020/21 flu season there were 29.9m people vaccinated for flu and 38 claims giving a claim rate of 1.3 per million.

Flu Vaccinations in 18-year olds and above

To calculate the additional number of claims in the newly eligible adult population, the number of claims in the past 6 years is needed so that we know how many claims from the past will now be eligible, and we will need to have an estimate for the number of claims we would expect going forward. From this, we can apply a rate of claims to the total vaccinations to estimate a number of claims.

Table 3: Vaccine eligibility as part of the Government’s Annual National Flu Programme

	2020/21	2019/20	2018/19	2017/18	2016/17	2015/16
18+						
GPs						
All Aged 65+	✓	✓	✓	✓	✓	✓
At risk	✓	✓	✓	✓	✓	✓
Pregnant	✓	✓	✓	✓	✓	✓
All aged 50+	✓					
Health care workers	✓	✓	✓	✓	✓	✓

It is assumed that all pregnant women will be part of the adult group. There is data that shows that there were 15,644 pregnancies conceived under the age of 18 in England and Wales in 2018³, but it is not clear what the uptake rate for flu vaccinations was amongst this group. As it represents a small amount of the total immunisation figures, the split between below and above the age of 18 for pregnant women is not estimated.

Table 4: Estimated total of vaccinations for those aged 18 and above

	2020/21	2019/20	2018/19	2017/18	2016/17	2015/16
18+						
GPs	15.9m	12.1m	11.9m	12.1m	11.3m	11.4m
Health care workers	1.0m	0.9m	0.9m	0.8m	0.7m	0.6m
Total	16.8m	13.0m	12.7m	12.9m	12.0m	12.0m

It is uncertain what the eligibility criteria will be going forward, especially with the pandemic ongoing. This makes predicting future number of vaccinations more difficult and by extension, increases the uncertainty in the number of claims for VDPS in the future. Another variable that affects the number of vaccinations is the uptake rates for flu vaccinations. Uptake rates were above average in the most recent 2020/21 flu season, likely due to the pandemic and the increased concern about risk, in combination with additional public health campaigns. It is unclear whether this will continue long term or regress back to the average rate seen in recent years.

To account for this, a range of figures will be presented that show both the number of vaccinations per year anticipated if the policy continues with 2020/21 eligibility criteria and uptake rates, or if both factors are more similar to those in the 2019/20 flu season pre pandemic.

³ Office for National Statistics, 2018. Conception statistics, England and Wales

Private Flu

There is no available data on the total number of flu vaccinations that can be purchased privately, but private vaccination is commonly available through community pharmacies. Occupational health schemes also supply vouchers for employees that can be redeemed at pharmacies. Evidence is available on the number of free NHS eligible flu vaccinations that are administered at community pharmacies, these are then recorded and included in GP vaccination statistics. Through published surveys we can estimate a proportion of vaccinations that take place in community pharmacies that are private and the number that are a part of NHS eligible groups⁴, from this we can determine assumptions for an unofficial estimate of the number of private flu vaccinations we can expect in a given year. From the survey in Anderson and Thornley (2016), Out of an n = 1683 who completed eligibility details, 30.8% were from NHS eligible groups, leaving 69.2% as private vaccinations or as part of an occupation health scheme.

We assume that rates of vaccination administered privately in pharmacy settings will follow a similar trend to the increasing number of eligible vaccines in recent years, especially when it comes to an increased in the most recent financial year. Therefore, we estimate the number of private vaccinations as a percentage of the total number of vaccinations. This percentage assumption is highly uncertain, and therefore will be presented as a range.

Community Pharmacies administered 486,897 flu vaccinations to patients under the national NHS Flu Vaccination Service in 2015/16. Assuming this equates to a 30.8% of the total flu vaccinations in pharmacies that would equal approximately 1.6m private vaccinations which would be an additional 13% on the 12m delivered in 2015/16.

Because there is a high degree of uncertainty to this estimate, we assume only 10% addition vaccinations in the low estimate, and we uplift this to 15% additional vaccinations in the high estimate.

Table 5: Estimated additional private flu vaccinations

Scenario	Additional percentage of claims for Option C
Low	10%
Central	13%
High	15%

6.2.3 Estimate of rate of new claims

The VDPS has received 50 claims since 2015 from adults where the influenza vaccine was listed as having been received, despite not being eligible. This is greater than the 38 claims that were made by those below 18 that were eligible, but as more adults were vaccinated in this time span, the rate of claims per million vaccinations is 0.8 compared to 1.3 per million for children since 2015. To calculate the rate of adult claims once they are eligible, a number of factors are considered:

1. The rate of adverse events that are proved to be side effects caused by vaccination and that would be eligible for VDPS
2. The rate of adverse events that occur in the vaccinated population that could cause a claim to be made
3. The propensity of individuals to make a VDPS claim

We discuss each of these factors in turn below, and where relevant discuss the most relevant evidence from historic VDPS claims to inform an estimate:

⁴ Anderson, C. and Thornley, T., 2016. Who uses pharmacy for flu vaccinations? Population profiling through a UK pharmacy chain. *International journal of clinical pharmacy*, 38(2), pp.218-222.

Rate of adverse events caused by influenza vaccination in adults

We know that there has been only one successful claim for a child receiving the influenza vaccine to date, out of 30 million vaccines administered to children. There is a lack of any evidence for what would be the rate of successful claims in adults. One key uncertainty is that new vaccines are developed for each flu season, and a range of vaccines are procured for adults, with a different range of vaccines being available for children. There is no evidence of an increased risk of severe adverse events following immunisation in the adult population. In general, reactogenicity for vaccinations is greater in children compared to adults, therefore the chance of side effects is lower amongst adults.

any additional evidence to base the rate of adverse events now eligible, we assume the influenza vaccines have the same underlying rate of adverse events for adults as they do for children.

Propensity to make a VDPS claim

We know that adults have more comorbidities than children and therefore, unrelated to receiving the vaccine, adults are more likely to develop a disability post-vaccination. This is likely to cause additional claims to be made, and therefore has been factored into our estimates of the rate of claims in the central and high scenarios, with the assumption that these would not result in a successful claim.

Following vaccination, in those who develop a disabling condition, only a proportion of people will make a VDPS claim. This propensity will be informed by the awareness of the scheme and whether there are any known safety issues with the vaccine. We assume that awareness of the scheme and safety concerns with any future influenza vaccines will be similar to current levels for influenza for children. But the additional impact of higher rates of co-morbidity in adults will increase the rate of claims.

In order to evidence this assumption, we have analysed VPDS claims from Swine Flu (H1N1), which allowed extended eligibility for adults. The Swine Flu vaccine was given to approximately 5 million adults and 900k aged under 18. It was found to be linked to cases of known side effect leading to an increase in propensity to claim, much greater than that of seasonal flu.

To adjust for this and to understand the impact of comorbidities on the propensity to claim in adults, we take the number of H1N1 claims listing side effects that were not deemed to have any causal link by the scheme. This gives an indication of levels of comorbidities in the adult population that could be mistaken for side effects from a vaccine. This rate in the adult population was about 16 per million vaccinations, and 13 per million in the child population.

For our low estimate we assume the same rates of claims in children as we do in adults, which is 1.3 claims per million vaccinations

For our central estimate, we uplift the number of adult claims with the same proportion as seen in the H1N1 claims, increasing the 1.3 claims per million vaccinations seen in under 18s to 1.6 per million.

For the high estimate we assume that the rate of claims for adults is the same as seen in the H1N1 example for unproven side-effects, giving a rate of 16 per million vaccinations.

Table 6: Assumed rate of claims

Scenario	Assumed rate of claims
Low	1.3 per million
Central	1.6 per million
High	16.0 per million

Success rates

Given the assumption that we expect the underlying rates of adverse events to be the same for adults as it is for children, we would expect similar success rates in the low and central scenario. The central scenario has been selected to be equal to the rate of success per claim as seen in childhood claims. The low scenario we adjust down by 10% points to reach a new a new success rate of 2.4%.

In the high scenario there is a greater rate of claims. With a constant rate of adverse events, we would see the rate of successful claims fall. The following success rates are assumed. The low scenario assumes a modest reduction in success rates, the high scenario adjusts for the higher rate of claims overall.

Table 7: Assumed success rates

Scenario	Assumed success rate
Low	2.4%
Central	2.6%
High	0.3%

6.2.4 Number of claims

The overall number of claims is calculated by the total number of vaccinations each year multiplied by the rate of claims we assume. Successful claims are calculated as a percentage of the total number of claims.

Table 8: Estimated total of numbers of claims and successful claims.

Policy Option	Scenario	Number of vaccinations	Assumed rate of claims	Estimated number of claims	Assumed success rate	Estimated number of successful claims
20/21 rates of vaccination Option b	Low	16.8m	1.3 per million	22	2.4%	0.5
	Central	16.8m	1.6 per million	27	2.6%	0.7
	High	16.8m	16.0 per million	269	0.3%	0.8
20/21 rates of vaccination Option c	Low	18.5m	1.3 per million	24	2.4%	0.6
	Central	18.9m	1.6 per million	30	2.6%	0.8
	High	19.3m	16.0 per million	309	0.3%	0.9
19/20 rates of vaccination Option b	Low	13.0m	1.3 per million	17	2.4%	0.5
	Central	13.0m	1.6 per million	21	2.6%	0.7
	High	13.0m	16.0 per million	208	0.3%	0.8

19/20 rates of vaccination	Low	14.3m	1.3 per million	19	2.4%	0.6
Option c	Central	14.6m	1.6 per million	23	2.6%	0.8
	High	14.9m	16.0 per million	238	0.3%	0.9

6.2.5 Costs

The only costs that will contribute to the final calculation of the net present value will be the administration costs as the payment itself is considered as a transfer between HM Government and claimants. Despite this, this impact assessment will list the total award amount expected, for illustrative purposes. As the payment is treated as a transfer, we have not made a welfare adjustment to reflect NHS opportunity costs were this spending to displace marginal NHS activity, which generates an estimated 4:1 societal return.

With the number of claims per year being dependent on the eligibility for influenza vaccinations recommended each winter, the range of annual costs will represent this uncertainty in the number of claims

This section will also estimate the costs associated with the past adult vaccinations that are now eligible, this is presented as a one-off transitional cost, as we would expect an additional increased cost within the first couple of years from the eligibility being expanded.

Administrative costs

Every claim, both successful and unsuccessful, will incur administrative costs. The cost associated with the Vaccine Damage Payment Unit (VDPU) in DWP is calculated in the form of full-time equivalent hours that the additional claims will create. This current system is paper based and will not have a large capacity for expansion. Claims are referred to medical assessors to determine the level of disablement. Therefore, the expansion on claims will lead to costs in the form of additional staff costs.

Estimates will be made for Full Time Equivalent (FTE) workload, in other words how much additional staff members will be required to work in a full time capacity in order to meet the demands of this additional workload, and the costs associated with that, which will include both wages and extra costs needed for that person to fulfil their job (IT, corporate infrastructure etc.). estimated that the cost of an additional 1 FTE would cost £60k per year both relating to staff and non-staff costs of administering the scheme. The current running of the scheme currently is estimated to cost 1.7 FTE hours.

From this, assumptions have been made for the number of additional FTE hours that are needed for the additional claims in DWP, and between the two policy options of limited eligibility for the VDPS and the full eligibility. It is assumed that policy option B will have an increased impact on the FTE required, as fewer claims per year will be able to be processed. Costs per claim made are assumed to be the same between options B and C. Even though there may be some additional steps to establish eligibility in Option B, they are expected to be negligible.

Annual Costs

Total payments to successful claimants are summarised in the table below

Table 9: Estimated total of claims and cost per annum

Policy Option	Scenario	Number of vaccinations	Estimated number of claims	Assumed success rate	Estimated number of successful claims	Estimated costs of payments per year
20/21 rates of vaccination Option b	Low	16.8m	22	2.4%	0.5	£62,072
	Central	16.8m	27	2.6%	0.7	£84,884
	High	16.8m	269	0.3%	0.8	£96,768
20/21 rates of vaccination Option c	Low	18.5m	24	2.4%	0.6	£68,353
	Central	18.9m	30	2.6%	0.8	£95,495
	High	19.3m	309	0.3%	0.9	£111,168
19/20 rates of vaccination Option b	Low	13.0m	17	2.4%	0.5	£62,072
	Central	13.0m	21	2.6%	0.7	£84,884
	High	13.0m	208	0.3%	0.8	£96,768
19/20 rates of vaccination Option c	Low	14.3m	19	2.4%	0.6	£68,353
	Central	14.6m	23	2.6%	0.8	£95,495
	High	14.9m	238	0.3%	0.9	£111,168

As the number of successful claims relating to influenza is lower than one, the expected value of payments is below the cost of one payment. This is an average figure representing the estimate of between 0.5-0.9 successful claims per year. Over the course of 10 years we expect between 5 and 9 successful claims will lead to payments between £600k-£1.08M

This does not include other further knock-on effects that could occur if there are a large number of claims, including to the NHS, the Centre for Health and Disability Assessments (CHDA) and HM Courts and Tribunals Service (HMCTS). This is discussed in the risk section.

Table 10: Estimated admin cost per annum

Policy Option	Scenario	Estimated number of claims	Estimated FTE per year	Estimated admin costs
20/21 rates of vaccination Option b	Low	22	0.4	£23,520
	Central	27	0.5	£28,948
	High	269	4.8	£289,477
20/21 rates of vaccination Option c	Low	24	0.4	£24,050
	Central	30	0.5	£30,240
	High	309	5.1	£308,800
19/20 rates of vaccination Option b	Low	17	0.30	£18,200
	Central	21	0.37	£22,400
	High	208	3.7	£224,000
19/20 rates of vaccination	Low	19	0.31	£18,590

Option c	Central	23	0.39	£23,360
	High	238	4.0	£238,400

Backdated claims

With the expansion of the scheme the previous 6 years of vaccinations will now be eligible to claim on the scheme. By applying the same rate of claims per million vaccinations as we do for the annual costs, we can estimate an expected number of claims from this cohort.

It is unclear when these claims would take place. Looking at the historical examples on the scheme does not show a sudden influx of claims, after an expansion on the scheme, despite there now being 6 years of vaccinations that were not previously eligible. After the expansion of the scheme for Rotavirus, which took place in February 2015, there was not a claim citing Rotavirus until 2017. With childhood influenza there were 9 claims in the first year since its addition to the scheme, with eligibility for claiming on the scheme going back for vaccines administered since September 2013. With a total of 38 claims total in the 6 years since then, this is not a disproportionate amount.

The number cost of payments and administrative costs have been estimated separately from the annual costs.

Table 11: Estimated total number of backdated claims and cost of payments

Policy Option	Scenario	Number of vaccinations	Estimated number of claims	Assumed success rate	Estimated number of successful claims	Estimated costs of payments
Option b	Low	62.6m	81	2.4%	1.9	£231,291
	Central	62.6m	100	2.6%	2.6	£316,295
	High	62.6m	1002	0.3%	3.0	£360,576
Option c	Low	68.9m	87	2.4%	2.1	£254,567
	Central	70.4m	89	2.6%	3.0	£355,705
	High	71.9m	1150	0.3%	3.5	£414,144

Table 12: Estimated admin costs for backdated claims

Policy Option	Scenario	Estimated number of claims	Estimated FTE per year	Estimated admin costs
Option b	Low	81	1.5	£87,640
	Central	100	1.8	£107,865
	High	1002	18.0	£1,078,646
Option c	Low	81	1.5	£89,570
	Central	100	1.9	£112,640
	High	1150	19.2	£1,150,400

6.2.6 Benefits

There are no monetised benefits included in the NPV calculations for this IA. However, there are multiple benefits that have not been monetised, these have been laid out for the purpose of describing the policy objective. The VDPS award, which is paid to successful claimants, is also not included as it is a direct transfer from government. The payment of £120,000 is a direct tax-free transfer from government to the claimant.

6.2.7 Total Net Present Value

The total net present value of the monetised aspects of this IA are negative. We are only left with the cost of running the scheme. It is assumed in this IA that the unmonetised benefits of achieving the policy objective will ultimately outweigh the cost of the monetised NPV. Furthermore, this policy satisfies a moral duty on government to act in a just way towards individuals who suffer disability as a result of engaging in a government approved Health Protection scheme.

For the calculation of Net present value, the preferred Option C (all adult eligibility) is used for the estimation. For the low estimate the 2019/20 rates of vaccination are used, whereas for the central and high estimate, the 2020/21 rates of vaccination are used.

Future years are discounted in line with Green book guidance at 3.5% per year.

Table 13: Estimated net present value

	Low	Central	High
Backdated claims	£89,570	£112,640	£1,150,400
2021/22	£17,585	£29,217	£298,357
2022/23	£16,990	£28,229	£288,268
2023/24	£16,415	£27,275	£278,520
2024/25	£15,860	£26,352	£269,101
2025/26	£15,324	£25,461	£260,001
2026/27	£14,806	£24,600	£251,209
2027/28	£14,305	£23,768	£242,714
2028/29	£13,821	£22,965	£234,506
2029/30	£13,354	£22,188	£226,576
Total	£228,030	£342,696	£3,499,654

7. Risks

It is unknown at this stage what the policy surrounding eligibility for seasonal influenza vaccination will be in the long term, as well as the level of uptake within the population. This creates a degree of uncertainty for the future number of claims.

There is also a degree of uncertainty when assessing the risks involved with future vaccinations. It is only possible to base the assumptions in this impact assessment on past vaccinations. In the future, new vaccinations will be developed, and the vaccinations offered as part of the Annual National Flu Programme will change over time. Nevertheless, any new vaccination will be subjected to extensive checks and balances required by law at every stage of the development of a vaccine, and any influenza vaccine will have passed these extensive checks before being administered to the population.

Any increase in number of claims due to an expansion of the scheme will also result in an increasing workload for the Vaccine Damage Payment Unit (VDPU) in DWP. Currently, the VDPU deal with a small number of potential claims per week.

Any significant increase in workload or a disproportionate number of unsuccessful claims made, as a result of an extra propensity to claim amongst the adult population, could stretch the resources of the scheme. In this case, VDPS is likely to require funding for additional administration. This could lead to a large increase in administrative costs. This would ultimately, due to the nature of the agreement between the DWP and DHSC on the administration of the Scheme, fall to DHSC to cover.

From April 2007 through to February 2017, there was a total of 759 claims and 11 awards made⁵. Before COVID-19 was added to the scheme, VDPS is managing an average of 76 claims a year or approximately 1.5 a week. All claims that meet the application eligibility, will have to be assessed by medical experts. Scenarios in the IA estimate that there could be between 69 -125 additional claims from the backdating of claims and these could all fall in the first years after the expansion, as well as the additional 14-34 additional claims we would see per year.

For claims that are unsuccessful, there is the option of the appeal process. - We would anticipate an increase in the number of claims would result in an associated increase in the number of appeals. Based on data over the last 10 years, this would equate to approximately 7% of the claims intake each year giving rise to additional pressures on HM Courts & Tribunals Service, who deal with the process.

It should be noted that the administrative costs estimated are only for the Vaccine Damage Payment Unit (VDPU). An increased number of claims will also on pressure on the Centre for Health and Disability Assessments (CHDA) and potentially hospitals. Before a claim is referred to medical assessment, a process of gathering medical records is undertaken. The process may have an adverse knock effect on NHS facilities such as hospitals which will not receive additional funding to do so as part of the expansion of the VDPS. Therefore, this could stretch resources already impacted by the pandemic.

As discussed, the option of litigation is available to claimants who have received a VDPS award. This IA does not make assumptions about the impact having the option of pursuing a VDPS award will have on the propensity for individuals who have develop severe side effects to litigate. Even in cases where the damage could exceed the VDPS award of £120,000, the acknowledgement that a vaccination approved by the Government may have caused a severe disablement, could be enough to prevent further action.

It is uncertain how many VDPS claimants will pursue litigation, either concurrently or afterwards. If a claimant receives a settlement of more than £120,000, the VDPS payment will be deducted from the settlement. For these individuals the main benefit of the VDPS is to bring the payment forward.

⁵ Department of Health and Social Care, 2017. *FOI 1075690, 22 March 2017* [Online]. Available from: <https://www.whatdotheyknow.com/request/391400/response/955853/attach/html/2/FOI%201075690%20Griffin%20VDPS%20claims%20v2%204.pdf.htm> [Accessed 14 November 2020].

8. Impact tests

In line with Better Regulation Guidance⁶, we have considered the following issues as part of this appraisal:

8.1 Trade impacts

We do not anticipate that the proposals are likely to impact trade or investment.

8.2 Legislation

The proposals are aligned with the Human Rights Act and should not infringe on any right included in the Act. The proposals should not contravene the Data Protection Act or Freedom of Information Act.

8.3 Competition test

We do not anticipate that the proposals are likely to impact any business or competition

8.4 Rural issues

We do not expect impacts on rural areas in particular.

8.5 Equality – Public Sector Equality Duty

As previously noted, the expansion of the VDPS will directly benefit those who have a disability as a result of a vaccine.

Here we discuss how these factors may differentially impact different groups of society, based on the protected characteristics described in the Equality Act 2010.

8.5.1 Disability:

Currently, should an individual who is 18 and above be severely disabled following vaccination against flu, there would not be any way that an individual would be able to make a claim against the Scheme. This is the only way that the Government acknowledges that a vaccination recommended by the government may have caused severe disablement.

Any person who is severely disabled (as set out in the Act), as a result of receiving a vaccine against a disease covered by the VDPS will be able to make a claim. The VDPS seeks to minimise the disadvantaged suffered by those who are severely disabled by the vaccine by awarding them a lump payment of £120k. By extending influenza to the list of specified diseases covered by the VDPS and ensures that those who are severely disabled as a result of receiving a vaccination against influenza will be able to make a claim.

8.5.2 Age:

By expanding the eligibility to allow for those aged 18 and above, more individuals are supported across all age ranges. A large proportion of the total seasonal influenza vaccinations

⁶ Department for Business, Energy & Industrial Strategy, 2020. *Better Regulation Framework: Interim guidance* [Online]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/872342/better-regulation-guidance.pdf [Accessed 15 September 2020].

are given to adults. To ensure that those with a severe disablement are properly supported, all ages will now be eligible to claim on the scheme.

8.5.3 Religious or belief

Some people may, for religious or other beliefs, decide not to get vaccinated. This SI does not deal with matters related to receipt of or eligibility for vaccines.

8.6 Family test

We assume that the expansion for influenza will support families of individuals who, in rare events, become disabled as a result of a vaccine. By providing a financial award, this will reduce financial pressure on families for whom one member could now be unable to earn an income.

8.7 Sustainable development impact test

We do not anticipate that the proposals are likely to impact sustainable development

8.8 Environmental standards

In line with the wider environmental impacts test, we do not expect the proposed changes to

8.9 Intergenerational impacts

We do not expect significant impacts which may disproportionately fall on future generations.

8.10 Health and safety

Overall, the expansion of the system will not have any impact on the health and safety measures, but signal that the Government has confidence in the current system.

8.11 Regional perspectives

Medicines regulation is a devolved matter in relation to Northern Ireland and a reserved matter (to the UK Parliament) in relation to Scotland and Wales. Despite this, eligibility for the VDPS is for the entirety of the UK or the Isle of Man. Because of this, changes will have to be communicated with the devolved administrations ahead of time.