

Title: Expansion of the Vaccine Damage Payment Scheme (VDPS) for COVID-19 IA No: 9564 RPC Reference No: N/A Lead department or agency: DHSC Other departments or agencies: DWP	Impact Assessment (IA)			
	Date: 02/12/2020			
	Stage: Final			
	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 2019 prices)			
Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status
-£1.25m	£0m	£0m	Not a regulatory provision

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

In facing the COVID-19 pandemic; safe and effective vaccines will make a significant impact to manage and minimise its harmful effects on the nation's health and economy. Any new vaccine carries a risk of causing very rare adverse events. By including COVID-19 in the Vaccine Damage Payment Scheme (VDPS) this will ensure that in cases where severe disablement is caused by a government run 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 and putting any future government's COVID-19 vaccination programme on an even footing to other government vaccination programmes.

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

The 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 vaccines included in the scheme. When the scheme is expanded to include COVID-19, it will help to provide some support for anyone severely disabled as a result of receiving a vaccination against COVID-19. It 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)

There is a limited number of options possible given the government is employing emergency measures for responding to COVID-19 and there will be great urgency to rollout a COVID-19 vaccine if a safe vaccine is available. Broader changes to the scheme are not considered as they would take time to agree and implement. The preferred option is simply to add COVID-19 to the list of diseases covered by the VDPS, as listed in the Vaccine Damage Payment Act 1979. Redress through litigation will be possible and can be pursued independently of the scheme; with any successful VDPS award deducted from any future damages gained through litigation. The Government could choose the "do nothing" option and not expand VDPS to include COVID-19, so that litigation would be the only route for financial compensation. This would remove the potential benefits of this scheme to recipients.

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

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: 2 December 2020

Summary: Analysis & Evidence

Policy Option 1

Description:

FULL ECONOMIC ASSESSMENT

Price Base Year 2019	PV Base Year 2019	Time Period Years	Net Benefit (Present Value (PV)) (£m)		
			Low: -£0.63	High: -£5.98	Best Estimate: -£1.25

COSTS (£m)	Total Transition (Constant Price) Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low			£0.63
High			£5.98
Best Estimate			£1.25

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

Estimates for the present value of the costs as a result of the addition of COVID-19 to the act only include the administrative costs. These costs are estimated to be £630k in the scenario where there are no successful claims; between £630k to £2.4m in scenarios with successful claims from one round of vaccinations and £6m in the scenario with future rounds of vaccination. Payments are direct transfers to members of the public, so they are not included in the headline costs, but are still a financial cost to Government. These transfers are estimated to equal to £0 in the scenario where there are no successful VDPS claims; between £3.2m to £13.2m in scenarios where there are successful claims from one round of vaccination and £63.2m in the scenario with future rounds of vaccination (3.5% discount rate). Due to the high level of uncertainty the central estimate Scenario 3 has been taken as the best estimate.

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 to £0 in the scenario where there are no successful VDPS claims; between £3.2m to £13.2m in scenarios where there are successful claims from one round of vaccination and £63.2m in the scenario with future rounds of vaccination (3.5% discount rate).

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-run 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

Very rare adverse effects of a COVID-19 vaccine will only be observable when there has been a large-scale roll-out. Examples of rates of disability and numbers of successful claims are drawn from the H1N1 vaccine (H1N1v), giving us several worst-case scenarios. Rates of claimants are assumed to be twice the levels seen from H1N1v (un evidenced assumption). The "best estimate" assumes all priority groups in the adult population, are offered a vaccine, although a scenario where the whole adult population receives a vaccine has been estimated. A 2.5x multiplier has been applied to the high estimate to account for the possibility of future rounds of vaccination. There are further risks to capacity of the scheme, run by DWP, if it were to receive many claims, even if those claims are ultimately unsuccessful. There are further risks to Arm's-length bodies, involved in VDPS, if large number of claims are received.

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. During the H1N1 (swine 'flu) however, the disease was added ahead of time in a similar way to this proposal. The specified diseases to which the Act currently applies to:

- 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)

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 SI 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. There are ongoing discussions about providing indemnity to individual manufacturers of COVID-19 vaccines. Any other scheme set up to accommodate agreements

between the Government and COVID-19 vaccine manufacturers would not be resolved under the VDPS. In practice, any successful litigation following a VDPS claim would have the £120,000 award deducted from the final settlement.

It is proposed that the Department adds COVID-19 to the list of diseases covered by the Vaccine Damage Payment Act by amending the legislation through a negative resolution statutory instrument. In doing so, we ensure there is support, should someone be severely disabled as a result of receiving a COVID-19 vaccination.

Currently, should an individual be severely disabled following vaccination against Covid-19, 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 a severe disablement.

The decision to include the COVID-19 on the list of diseases covered by the VDPS is not in any way related to the pace of COVID-19 vaccine development. Any potential COVID-19 vaccine will go through the same robust clinical trials and will occur the same 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 COVID-19 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

There is still uncertainty in how any potential COVID-19 vaccine will be deployed, and to whom. In a large-scale deployment, any unknown side-effects will only occur on a very rare basis, given that the vaccine will have already been tested on very large numbers of people, across broad cohorts, prior to approval for use. It is common for diseases that are added to the VDPS to have no successful claims. Therefore, this IA will estimate a scenario where there are zero severe side effects from the COVID-19 vaccine, as well a range of other worst-case scenarios, where there is an example of a very rare unknown side effect.

To provide evidence for the worst-case scenarios we can draw upon evidence from other diseases that have been added to the VDPS and saw successful claims. A recent analogous example of a new vaccine being brought to market, and being covered by VDPS, is the *H1N1v*, the vaccine used for H1N1, or Swine Flu. This was an example where there were successful VDPS claims, from which we can draw a number of evidenced worst-case scenarios.

Given the scale of uncertainty, five scenarios will be presented. A scenario where there are zero successful VDPS claims, and four scenarios where there are successful claims. These five scenarios are illustrative. As no vaccine has been approved yet, there is uncertainty in several variables. The purpose of these five scenarios is to illustrate how the number of claims, payments and administrative costs vary when assumptions vary.

Ahead of the Swine Flu vaccination programme in 2009, the Minister of State for Public Health asked for H1N1 to be added to the list of diseases covered by the VDPS scheme until the end of the *H1N1v monovalent* vaccination campaign. The same approach is planned with COVID-19. This will inform the scenarios for the vaccine in terms of the likelihood of severe adverse events occurring, as well as the percentage of those successfully claiming on the VDPS.

From April 2007 to the 31st January 2017, there were a total of 759 claims and 11 awards made¹. It should be noted that an award might have been made in a different year to that which the claim was made. In this time, the rate of successful claims for H1N1 was higher than other diseases on the VDPS. There are several reasons to use it as an example to draw evidence from; the first is that eligibility for H1N1 on the VDPS was extended to adults, this is not the case for several other diseases. Any approved COVID-19 vaccine is expected to be given to an adult population; three out of the five scenarios explored assume that the COVID-19 vaccine will be made available to the interim JCVI priority groups²; scenarios 4 and 5 assume the whole adult population is eligible for the vaccine. H1N1 is also an appropriate example as it is easier to confirm that a claim is related to H1N1v as opposed to other childhood immunisation programmes, which can see multiple vaccines administered within a year. This leads the evidence from the H1N1 vaccine to be the best fit when estimating VDPS claims. However, as there was a high success rate of H1N1 claims compared to other diseases, this will lead to estimates that should be considered as worst-case scenarios for COVID-19.

Scenarios 1-4 of this impact assessment will estimate claims on the VDPS from the initial programme of approved and procured vaccines, recommended by JCVI. However, at this stage, it is unknown whether future rounds of vaccinations will be required. Due to this uncertainty, Scenario 5 will account for the possibility that immunity will not last and that the population will have to take future doses, to boost immunity, should this be scientifically necessary.

In the medium term, there will be more clarity on whether very rare side effects exist. If there are severe side effects, this could mean additional policy considerations beyond VDPS, but it would be premature to consider now what these options are due to lack of evidence.

Description of options considered

There are 2 main policy options:

- a) Do nothing, leaving individuals unable to make a claim on the Scheme should they be affected by vaccination.**

This would still leave options for redress through litigation, if those vaccinated suffered severe side effects as a result of the COVID-19 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.

Questions are likely to be raised about why the vaccine is not present on the VDPS, and public confidence in the vaccine and in government could be impacted by it not being treated like other national vaccination programmes.

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].

² Department of Health and Social Care, 2020. *Priority groups for coronavirus (COVID-19) vaccination: advice from the JCVI, 25 September 2020* [Online]. Available from: <https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-25-september-2020> [Accessed 18 October 2020].

b) Add COVID-19 to the Scheme

3. Policy objective

HM Government have invested in a number of potential COVID-19 vaccines, all still under development or in clinical trials stage, with the explicit ambition to create a national COVID-19 vaccination programme if safety and efficacy standards are met. Given the UK Government has already invested in 6 vaccines with a potential stockpile of 340 million doses, it is hoped that the UK Government may be in a position to roll out a programme that is available to a large proportion of the population. A vaccine that satisfies the safety standards still carries a risk of very rare side effects that only become apparent in large-scale roll-out. As well as the systems for continuous monitoring to identify and respond to any adverse side effects that come to light, it is important that there is some financial support available to those who suffer severe disability from the vaccine. Disability can create additional financial hardship, whether from making adaptations to support independent living, impacting on the ability to work, or impacting on the ability to provide and care for dependants.

The expansion of the VDPS for COVID-19 vaccine will support those, who as a result of taking the vaccine, become severely disabled, above a 60% disability threshold. They will receive £120,000 tax free from the scheme. A VDPS payment will alleviate the additional financial hardship faster than redress through litigation.

If we do not make this change, some people may interpret this as evidence that DHSC is no longer committed to responding responsibly to the rare cases when individuals experience severely disabling side-effects from vaccination.

Whilst the creation of a COVID-19 vaccine has been at great pace, a national programme will not go ahead without serious consideration from HM Government of the safety data. There is therefore no reason that a COVID-19 vaccine should be any less safe than a new vaccine entering our routine programmes, as it will have gone through the same safety requirements as any other new vaccine prior to being put on the market. As for any new vaccine, there may be some very rare population-wide safety events that are not detectable in the clinical trials prior to delivery.

4. Summary and preferred option with description of implementation plan

A negative Statutory Instrument will be laid to amend the 1979 Vaccine Damage Payments Act (VDPA), adding COVID-19 to the list of diseases covered by the Vaccine Damage Payment Scheme (VDPS).

Once the regulatory change is laid and comes into effect, those vaccinated against this disease (by whatever vaccines are eventually chosen) will be covered by the scheme.

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.

There is no prospect for flexibility or trialling. Once included in the scheme it will not be removed, unless there is a future requirement from Ministers for a change in policy.

5. Monetised and non-monetised costs and benefits

5.1 Business as Usual Costs and Benefits

The “Business as Usual” scenario here assumes the presence of a COVID-19 vaccine without COVID-19 being included in the VDPS. 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.

5.2 Expansion of the VDPS for the COVID-19 Vaccine Costs and Benefits

The monetised costs of the preferred option are:

- Administration costs from processing claims – cost to HM Government

There are no monetised benefits of the preferred option.

However, this IA will also show:

- Payments to successful claimants – Transfer from HM Government to Citizens

5.2.1 Methodology

The costs of the policy are from potential future claims with the inclusion of COVID-19 onto the list of diseases. However, the total number of potential claims is very uncertain, particularly if a vaccine is new, or is given to a wider population than we have seen in the past. The analysis is scenario-based, drawing on data from past vaccination programmes and associated claims, while recognising that these do not provide a definitive forecast.

Scenario 5 adjusts for the potential of future vaccinations, so it is calculated differently than the first four scenarios. The methodology for the first four scenarios is as follows:

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. For completeness, the estimated costs of the payments will still be presented.

It is assumed that for every claim there are administrative costs, regardless of whether the claim is successful. Therefore, there are costs associated with both successful and unsuccessful claims. We assume an average administrative cost for all claims, based upon evidence from H1N1 claims. This gives the formula:

$$\begin{aligned} \# \text{ of people vaccinated} \times \text{probability of making a claim} \times \text{average administrative cost} \\ = \text{Total administrative costs} \end{aligned}$$

The rate of claims is assumed to be equal across scenarios 1 and 2, despite there being no successful claims in Scenario 1. It is assumed that there will be a substantial rate of claims due to the high-profile nature of the vaccine; so even in the scenario where there is not a proven severe side effect, the rate of claims is 45 per 1M vaccinations, equal to the rate of claims from H1N1.

In most vaccine candidates, two doses immunisation programmes are being trialled. For simplicity, the calculation is the same whether there is one or multiple doses given in a

programme, for any approved vaccine. At this stage before rollout, there is no evidence of any severe adverse events. Therefore, it is not possible to estimate any differences in the probability of a severe adverse event, between the first and second dose of a programme. For the purposes of this IA, the probability of a severe adverse event relates to each person vaccinated with the full programme of a vaccination.

The cost of payments for successful claims are not included within the final estimates of the net present value, but 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:

$$\# \text{ of people vaccinated} \times \text{probability of severe adverse events} \times \text{probability of eligibility} \times \text{VDPS payment} = \text{Total cost of payments}$$

To adjust for the high profile of the COVID-19 vaccination, increased prominence of vaccine, scenarios 3 and 4 assume the rate of overall claims is **double** the rate in H1N1.

Scenarios 1-3 assume all people in one of the at-risk prioritisation groups numbers 1-10 in interim advice from JCVI³, will be eligible for the vaccine; though the actual availability of vaccine doses is unknown and may be significantly less or more than this. Furthermore, it is unknown at this stage whether any future round of vaccination will be needed to should immunity not last. Rates of uptake are uncertain, and we assume uptake for the vaccine of 75%. This is similar to the uptake of flu vaccine in healthcare workers and the most elderly.

Scenario 4 assumes that all of the adult population will be eligible for the vaccine. This helps account for the uncertainty around how many people will be vaccinated.

The first four scenarios assumptions are summarised in Figure 1:

Scenario	Population vaccinated	Rate of claims	Severe Adverse events - rates	Successful VDPS claims as % severe adverse events
1	20.7M	45 per 1M vaccinations	0 per 1M vaccinations	N/A
2	20.7M	45 per 1M vaccinations	7 per 1M vaccinations ⁴	23%
3	20.7M	91 per 1M vaccinations	29 per 1M vaccinations ³	23%
4	39.5M	91 per 1M vaccinations	29 per 1M vaccinations ³	23%

Figure 1

Although Scenario 3 is used as the best estimate in this IA, it does not suggest that severe adverse events are the most likely outcome. For the purposes of this IA and given the high degree of uncertainty in several variables, the central estimate from the illustrative scenarios estimated has been chosen for this category.

Scenario 5 is estimated to account for the possibility that immunity will not last from any potential COVID-19 vaccine and future booster doses could be needed. To account for this uncertainty, an adjustment factor is placed on the vaccinated population. This is assumed to be

³ Department of Health and Social Care, 2020. *Priority groups for coronavirus (COVID-19) vaccination: advice from the JCVI, 25 September 2020* [Online]. Available from: <https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-25-september-2020> [Accessed 18 October 2020].

⁴ Stowe, Julia et al. "Risk of Narcolepsy after AS03 Adjuvanted Pandemic A/H1N1 2009 Influenza Vaccine in Adults: A Case-Coverage Study in England." *Sleep* vol. 39,5 1051-7. 1 May. 2016, doi:10.5665/sleep.5752

a 2.5x multiplier. This is an unevidenced assumption, chosen for illustration only. Given this scenario involves boosters of a vaccine that has adverse rare events, it is likely that the rare side effects are known by the time of the second cycle of vaccination, and alternatives would be sought. Therefore, this scenario is extremely pessimistic in assuming that rare adverse events persist over multiple cycles of vaccination.

Scenario 5 gives us the adjusted number of vaccination subjects as 98.8m.

Scenario	Population vaccinated	Future doses adjustment factor	Adjusted number of vaccination subjects	Rate of claims	Severe Adverse events - rates	Successful VDPS claims as % severe adverse events
5	39.5M	2.5	98.8M	91 per 1M vaccinations	29 per 1M vaccinations ³	23%

Figure 2

5.2.2 Number of people vaccinated

At present, JCVI have published an interim ranking of priority groups for a COVID-19 vaccine.⁵ It is important to note that this could change substantially depending on the efficacy and safety of the available vaccines which might vary according to recipient’s characteristics such as age. For the purposes of this impact assessment, where we do not yet know the characteristics of a potential vaccine, for scenarios 1-3 we assume that a first vaccine may be suitable and available for anyone aged 50 or over, people at high or moderate risk of COVID-19 and health and social care workers, in line with the priority groups identified in the initial JCVI guidance. We call this the “at risk population”. However, it is possible that an eventual vaccine may not be recommended for all these groups. In scenarios 4 and 5 we assume the vaccine will be available to all adults.

To estimate the number of people in the “at risk” population we add the following figures:

- The number of people aged 50 or over in the UK: 25m⁶
- The number of healthcare workers aged below 50: 1m⁷
- The number of social care workers aged below 50: 1.0m⁸
- The number of people who shielded, aged below 50: 0.06m (as a proxy for ‘at risk’)⁹

To note, the data we use for healthcare workers relates to those in NHS trusts, CCGs, Support Organisations and Central Bodies; as such, not all these workers will be providing front line services. This is also true for social care worker data. Therefore, we may be overestimating the number of people who may be eligible for the vaccine.

⁵ Department of Health and Social Care, 2020. *Priority groups for coronavirus (COVID-19) vaccination: advice from the JCVI, 25 September 2020* [Online]. Available from: <https://www.gov.uk/government/publications/priority-groups-for-coronavirus-covid-19-vaccination-advice-from-the-jcvi-25-september-2020> [Accessed 18 October 2020].

⁶ ONS, 2020. *Estimates of the population for the UK, England and Wales, Scotland and Northern Ireland* [Online]. Available from: <https://www.ons.gov.uk/peoplepopulationandcommunity/populationandmigration/populationestimates/datasets/populationestimatesforukenglandandwalesandscotlandandnorthernireland> [Accessed 1 October 2020].

⁷ NHS Digital, 2018. *NHS workforce statistics – September 2018* [Online]. Available from: <https://digital.nhs.uk/data-and-information/publications/statistical/nhs-workforce-statistics/september-2018> [Accessed 1 October 2020].

⁸ Skills for Care, 2017. *The state of the adult social care sector and workforce in England, September 2017* [Online]. Available from: <https://www.skillsforcare.org.uk/Documents/NMDS-SC-and-intelligence/NMDS-SC/Analysis-pages/State-of-17/State-of-the-adult-social-care-sector-and-workforce-2017.pdf> [Accessed 1 October 2020].

⁹ NHS Digital, 2020. *Coronavirus shielded patient list open data set, England* [Online]. Available from: <https://digital.nhs.uk/dashboards/shielded-patient-list-open-data-set> [Accessed 1 October 2020].

Given there may be health and social care workers who were shielding, and therefore a risk of double counting, we assume about 4% of these groups were shielding. We do not have data on shielding amongst these groups, and therefore this is based on NHS estimates that 4% of the total population in England were shielding – it may be that this proportion is higher or lower amongst health and social care workers.

Therefore, in total this gives an approximate population of 28m who may be eligible to receive a vaccine in scenarios 1-3. In scenarios 4 and 5 we assume all adults, or 52m.

Not everyone who is eligible for a vaccine will take it up. In the current climate it is very difficult to be certain about the public's appetite for vaccination. For the purposes of this analysis, we assume 75% uptake amongst those eligible. Evidence from the 2018/19 flu vaccine suggests that uptake was between 44% to 74%, with the highest uptake in older people and health care workers, corresponding with some of those likely to be prioritised for the COVID-19 vaccine.¹⁰ A recent survey by Ipsos MORI suggested that 85% agreed that if a vaccine for COVID-19 were available, they would get it; reasons for not accessing the vaccine included concern about side effects, doubts about efficacy, not perceiving they are at enough risk from COVID-19 and being generally against vaccines.¹¹ Whilst there have been concerns raised by the anti-vaccination community, the public may be more in favour of vaccination given their experiences living in lockdown as a result of COVID-19; indeed, we are seeing high demand for flu vaccines already.¹²

5.2.3 Number of claims

For scenarios 3 and 4, the rate of claims is assumed to be **double** those for H1N1v (unevidenced assumption) given the heightened public profile of the COVID-19 vaccine. Whilst there is a large degree of uncertainty in this assumption, a cautious approach has been taken to create estimates that are considered to be worst case scenarios.

Based upon internal statistics from DWP on VDPS claims relating to *H1N1v*, we can estimate a success rate for application from the scheme. To do this we take:

- The number assumed to have a severe adverse event
- The number of successful VDPS claims associated with *H1N1v*

From this population who are estimated to have encountered severe side effects, we assume that they would all apply to the scheme. From this, we calculate the success rate of receiving an award. In other words, if a person vaccinated has a severe adverse event, the success rate is the probability they pass the 60% disability threshold for severity and is there adequate evidence, based upon a medical assessment, to make the award.

Overall, this gives the range of estimates of the number of successful claims as shown in Figure 3.

¹⁰ Public Health England, 2020. *Surveillance of influenza and other respiratory viruses in the UK: Winter 2019 to 2020* [Online]. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/895233/Surveillance_Influenza_and_other_respiratory_viruses_in_the_UK_2019_to_2020_FINAL.pdf [Accessed 15 September 2020].

¹¹ Ipsos MORI, 2020. *Three in four adults globally say they would get a vaccine for COVID-19* [Online]. Available from: <https://www.ipsos.com/ipsos-mori/en-uk/three-four-adults-globally-say-they-would-get-vaccine-covid-19> [Accessed 15 September 2020].

¹² Roberts, M., 2020. *Flu jab waits and delays amid high demand* [Online]. Available from: <https://www.bbc.co.uk/news/health-54337585> [Accessed 30 September 2020].

Scenario	Number of successful claims
1	0
2	33
3	136
4	260
5	649

Figure 3

5.2.4 Date of claims

Through analysis of the profile of H1N1 claims for VDPS, we assume a highly simplified version of the pattern of claims over time. In the context of COVID-19, eligibility for the vaccine will last for 6 years from the point of vaccination for a claimant. The first assumption in this context is to assume that the vaccine will be administered at the beginning of the 2021/22 financial year. We expect a lag between the vaccine and the first VDPS claim. It is assumed based upon precedent, that the first claim will occur 80 days after vaccination. From this point we expect both total claims and successful claims to be uniformly distributed across the 6 years. Estimates for Scenario 5 contain a greater degree of uncertainty as the time lag between booster vaccinations is unknown. For simplicity we have profiled them evenly across the 6 years though they might be more skewed to later years.

This gives us the estimates in the following Figure 4:

		Financial year					
		21/22	22/23	23/24	24/25	25/26	26/27
Number of claims	Scenario 1	157	157	157	157	157	157
	Scenario 2	157	157	157	157	157	157
	Scenario 3	313	313	313	313	313	313
	Scenario 4	598	598	598	598	598	598
	Scenario 5	1495	1495	1495	1495	1495	1495
Number of successful claims	Scenario 1	0	0	0	0	0	0
	Scenario 2	5	5	5	5	5	5
	Scenario 3	23	23	23	23	23	23
	Scenario 4	43	43	43	43	43	43
	Scenario 5	108	108	108	108	108	108

Figure 4

5.2.5 Costs

Every claim, both successful and unsuccessful, will incur administrative costs. The cost associated with the Vaccine Damage Payment Unit (VDPU) in DWP is assumed to be at £764 per claim in 2019 prices, based upon evidence from H1N1. This figure is still under review from DWP's finance team, so it is not a confirmed figure. 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.

Total payments are the assumed number of successful claims per year multiplied by £120,000. This payment is assumed to be fixed across the time period in nominal terms. Future payments in the table are shown in 2019 prices, and discounted in line with green book guidance, which is a rate of 3.5% per year. This is not included in the net present value calculation.

3.5% discount rate		Financial year						Total
		21/22	22/23	23/24	24/25	25/26	26/27	
Total payments PV	Scenario 1	£0	£0	£0	£0	£0	£0	£0
	Scenario 2	£608,500	£576,600	£545,500	£516,200	£488,600	£462,300	£3,197,700
	Scenario 3	£2,521,000	£2,388,700	£2,260,100	£2,138,400	£2,024,100	£1,915,200	£13,247,600
	Scenario 4	£4,814,300	£4,561,600	£4,316,100	£4,083,700	£3,865,400	£3,657,400	£25,298,500
	Scenario 5	£12,035,700	£11,404,100	£10,790,200	£10,209,100	£9,663,500	£9,143,600	£63,246,200

Figure 5

Administrative costs are calculated the total number of claims per year multiplied by the estimated admin costs per claim. This is discounted to reach the present value. The present value cost estimates are in 2019 prices, all results have been rounded to the nearest £100.

3.5% discount rate		Financial year						Total
		21/22	22/23	23/24	24/25	25/26	26/27	
Total costs PV	Scenario 1	£113,600	£109,800	£106,100	£102,500	£99,000	£95,700	£626,700
	Scenario 2	£113,600	£109,800	£106,100	£102,500	£99,000	£95,700	£626,700
	Scenario 3	£227,300	£219,600	£212,200	£205,000	£198,100	£191,400	£1,253,500
	Scenario 4	£434,000	£419,400	£405,200	£391,500	£378,200	£365,400	£2,393,700
	Scenario 5	£1,085,100	£1,048,400	£1,012,900	£978,700	£945,600	£913,600	£5,984,300

Figure 6

5.2.6 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.

5.2.7 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-run Health Protection scheme.

There is also a large degree of uncertainty to these figures, so the NPV serves as an illustrative figure only. The table is in 2019 prices, all results have been rounded to the nearest £100.

3.5% discount rate		Financial year					Total	
		21/22	22/23	23/24	24/25	25/26		26/27
Total NPV	Scenario 1	-£113,600	-£109,800	-£106,100	-£102,500	-£99,000	-£95,700	-£626,700
	Scenario 2	-£113,600	-£109,800	-£106,100	-£102,500	-£99,000	-£95,700	-£626,700
	Scenario 3	-£227,300	-£219,600	-£212,200	-£205,000	-£198,100	-£191,400	-£1,253,500
	Scenario 4	-£434,000	-£419,400	-£405,200	-£391,500	-£378,200	-£365,400	-£2,393,700
	Scenario 5	-£1,085,100	-£1,048,400	-£1,012,900	-£978,700	-£945,600	-£913,600	-£5,984,300

Figure 7

6. Risks

It is unknown at this stage what number of doses of vaccine are required per person. Whether as part of an initial programme of vaccinations, or any future vaccination programme should immunity not last. Most COVID-19 vaccine candidates have a two-dose schedule, but for simplicity, the number of doses is assumed to have no impact on the rate of adverse events per person vaccinated.

There is a high degree of uncertainty as to whether future vaccination programmes will be needed. The first human trials in March 2020 and results from these trials cannot give us guarantees of long-term immunity. If immunity does not last, and further vaccinations for the same individuals are required. Given that it is unclear a future booster vaccination is required; how long before immunity would fade and whether the vaccinated population would face the same rate of severe adverse events; the estimates in scenario 5 are highly uncertain and should only be taken as illustrative. There will be monitoring of any adverse events after rollout of a vaccine, it is likely that the rare side effects are known by the time of the second cycle of vaccination. It is extremely pessimistic to assume that rare adverse events persist over multiple cycles of vaccination.

Approved COVID-19 vaccines will be new, which is likely to heighten the public's concerns about any perceived side effects, which may lead to a high number of initial claims. 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. 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.

Any significant increase in workload, such as the number of claims in scenarios 4 and 5, or a disproportionate number of unsuccessful claims made, as a result of high profile of the COVID-19 vaccine, 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 made¹³. Therefore, 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 estimates that there could be 940 additional claims, even if ultimately none are successful. Claims have to be made within 6 years of the vaccination. Assuming a single round of vaccination an even distribution of claims across that time period we

¹³ 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].

would observe an increase from 76 claims per year to an estimated 230 - 670 per year, representing a 3 to 9-fold increase in claims. A scenario where future rounds of vaccination are needed could lead to a higher number of claims.

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. This would present the following number of appeals.

		Financial year						Total
		21/22	22/23	23/24	24/25	25/26	26/27	
Number of appeals	Scenario 1	11	11	11	11	11	11	66
	Scenario 2	11	11	11	11	11	11	66
	Scenario 3	22	22	22	22	22	22	132
	Scenario 4	42	42	42	42	42	42	251
	Scenario 5	105	105	105	105	105	105	628

Figure 8

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 for COVID-19. 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 recommended 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.

The total amount that will be reduced is dependent on the percentage of VDPS recipients that successfully pursue litigation. This is shown in Figure 9. As it is unclear in what year these reductions would take place, the table is in nominal prices and is not discounted.

		Future reductions in compensation				
		Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
Percentage that pursue litigation	10%	-	£393,841	£1,631,627	£3,115,856	£7,789,639
	20%	-	£787,682	£3,263,254	£6,231,711	£15,579,278
	30%	-	£1,181,523	£4,894,880	£9,347,567	£23,368,917
	40%	-	£1,575,364	£6,526,507	£12,463,422	£31,158,556
	50%	-	£1,969,205	£8,158,134	£15,579,278	£38,948,194

	60%	-	£2,363,046	£9,789,761	£18,695,133	£46,737,833
	70%	-	£2,756,887	£11,421,388	£21,810,989	£54,527,472
	80%	-	£3,150,728	£13,053,015	£24,926,844	£62,317,111
	90%	-	£3,544,569	£14,684,641	£28,042,700	£70,106,750
	100%	-	£3,938,410	£16,316,268	£31,158,556	£77,896,389

Figure 9

Due to the uncertainty surrounding these figures, they have not been included in the final NPV calculations. They are just for illustrative purposes.

7. Impact tests

In line with Better Regulation Guidance¹⁴, 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 be severely disabled following vaccination against COVID-19, 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

¹⁴ 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].

the disadvantaged suffered by those who are severely disabled by the vaccine by awarding them a lump payment of £120k. By adding COVID-19 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 COVID-19 will be able to make a claim.

8.5.2 Age:

As part of the expansion it is specified that the COVID-19 vaccine will cover all ages, unlike several vaccines on the scheme, which have an age limit for eligibility of 18. As mentioned in the IA, we assume that the vaccine will be administered to over 50s as part of the initial programme of vaccinations first, and therefore they are more likely to be impacted by these changes. However, this is only an assumption of who will be vaccinated, the VDPS itself will cover all ages.

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 of the COVID-19 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

There is no reason that a COVID-19 vaccine should be any less safe than a new vaccine entering our routine programmes, as it will have gone through the same safety requirements as any other new vaccine prior to being put on the market. As for any new vaccine, there may be some very rare population-wide safety events that are not immediately detectable prior to delivery. Overall, the addition of COVID-19 to 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.