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|--|----------------------------------|--|--|--|
| Title: COVID-19 autumn 2023 booster programme IA No: 9604 RPC Reference No: N/A Lead department or agency: DHSC Other departments or agencies: N/A | Impact Assessment (IA) | | | |
| | Date: June 2023 | | | |
| | Stage: Final | | | |
| | Source of intervention: Domestic | | | |
| | Type of measure: N/A | | | |
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| | |
|-----------------------------------|-----------------------------|
| Summary: Intervention and Options | RPC Opinion: Not Applicable |
|-----------------------------------|-----------------------------|

| Cost of Preferred (or more likely) Option (in 2023 prices) | | | |
|--|----------------------------|-------------------------------|-------------------------------|
| Total Net Present Social Value | Business Net Present Value | Net cost to business per year | Business Impact Target Status |
| N/A | N/A | N/A | N/A |

What is the problem under consideration? Why is government action or intervention necessary?
 The Joint Committee on Vaccination and Immunisation (JCVI) have provided advice that vulnerable individuals and those who care for them should be offered a booster dose of a COVID-19 vaccine in autumn 2023. An autumn booster campaign to vulnerable adults is expected to be the most effective way to reduce the harmful effects of COVID-19 and maintain a high level of protection in the most vulnerable over the winter 2023-24 period.

What are the policy objectives of the action or intervention and the intended effects?
 The policy objective is to reduce future health impacts on the entire population through prevention of severe illness (hospitalisations and deaths) arising from COVID-19 infection in the most vulnerable over the 2023/24 autumn period. This will be achieved via the deployment of a COVID-19 vaccine booster dose to vulnerable individuals and those who care for them.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)
 Option 0 (Do nothing): No autumn 2023 COVID-19 booster programme, resulting in negative health impacts for the English population
 Option 1: accept JCVI advice to offer a vaccine to cohorts outlined in the advice
 Option 2: offer a vaccine to a smaller cohort than JCVI has advised
 Option 3: offer a vaccine to a greater cohort than JCVI has advised

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|---|-------------|----------|-----------------|----------|
| Will the policy be reviewed? It will not be reviewed | | | | |
| 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 CO2 equivalent change in greenhouse gas emissions? (Million tonnes CO2 equivalent) | Traded: N/A | | Non-traded: N/A | |

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: Minister Maria Caulfield  Date: 19 September 2023

Summary: Analysis & Evidence Policy Option 0

Description: "Do nothing" – i.e., no autumn 2023 booster programme

FULL ECONOMIC ASSESSMENT

| Price Base Year 2023 | PV Base Year 2023 | Time Period Years 100 | Net Benefit (Present Value (PV)) | | |
|---|--|--------------------------|---|---------|--------------------------------------|
| | | | Low: 0 | High: 0 | Best Estimate: 0 |
| COSTS (£m) | Total Transition (Constant Price) Years | | Average Annual (excl. Transition) (Constant Price) | | Total Cost (Present Value) |
| Low | 0 | | 0 | | 0 |
| High | 0 | | 0 | | 0 |
| Best Estimate | 0 | | 0 | | 0 |
| Description and scale of key monetised costs by 'main affected groups' | | | | | |
| As per IA convention, the "Do nothing" option has 0 costs | | | | | |
| Other key non-monetised costs by 'main affected groups' | | | | | |
| N/A | | | | | |
| BENEFITS (£m) | Total Transition (Constant Price) Years | | Average Annual (excl. Transition) (Constant Price) | | Total Benefit (Present Value) |
| Low | 0 | | 0 | | 0 |
| High | 0 | | 0 | | 0 |
| Best Estimate | 0 | | 0 | | 0 |
| Description and scale of key monetised benefits by 'main affected groups' | | | | | |
| As per IA convention, the "Do Nothing" option has 0 benefits | | | | | |
| Other key non-monetised benefits by 'main affected groups' | | | | | |
| N/A | | | | | |
| Discount rate (%) | | | | | N/A |
| Key assumptions/sensitivities/risks | | | | | |
| Assumes all spending that has happened to prepare for the autumn 2023 booster programme could be recovered if Government decides not to proceed with a vaccination programme. In reality, some costs could not be recovered but no estimate of this is available. | | | | | |

BUSINESS ASSESSMENT (Option 0)

| Direct impact on business (Equivalent Annual) £m: | | | Score for Business Impact Target (qualifying provisions only) £m: |
|---|---------------|----------|---|
| Costs: N/A | Benefits: N/A | Net: N/A | Not Applicable |
| | | | |

Summary: Analysis & Evidence Policy Option 1

Description: Proceed with JCVI advice for the autumn 2023 COVID-19 booster programme

FULL ECONOMIC ASSESSMENT

| Price Base Year 2023 | PV Base Year 2023 | Time Period Years 100 | Net Benefit (Present Value (PV)) | | |
|---|--|--------------------------|---|---|---|
| | | | Low: [REDACTED] [Negative and middle out of Options 1-3] | High: [REDACTED] [Middle out of Options 1-3] | Best Estimate: [REDACTED] [Middle out of Options 1-3] |
| COSTS (£m) | Total Transition (Constant Price) Years | | Average Annual (excl. Transition) | Total Cost (Present Value) | |
| Low | 0 | 0 | N/A | N/A | |
| High | 0 | | N/A | N/A | |
| Best Estimate | 0 | | [REDACTED] [Middle out of Options] | | |
| Description and scale of key monetised costs by 'main affected groups' | | | | | |
| <p>Deployment cost for the NHS (for the autumn 2023 campaign only) – vaccine costs are treated as sunk. The deployment cost is assumed to be [REDACTED] per dose. This is aligned with historical COVID-19 vaccine deployment costs and internal estimates for autumn 2023. This is an average across the whole programme, reflecting full deployment costs including overheads and set up costs, applied to policy options 1, 2 and 3. The total deployment cost has been calculated by multiplying the assumed average deployment cost per dose by the total doses we expect to deploy in autumn 2023, assuming equivalent uptake as the COVID-19 booster programme in 2022. We have used the average cost per dose in our assessments of overall costs but used the marginal cost per dose in relation to whether certain groups would be cost-effective if added to an existing programme</p> | | | | | |
| 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 | 0 | 0 | [REDACTED] | [REDACTED] | |
| High | 0 | | [REDACTED] | [REDACTED] | |
| Best Estimate | 0 | | [REDACTED] [Middle out of Options] | | |
| Description and scale of key monetised benefits by 'main affected groups' | | | | | |
| <p>This Impact Assessment appraises the health benefits of the COVID-19 booster which include:</p> <ul style="list-style-type: none"> • Preventing symptomatic COVID-19 infections • Preventing hospitalisations primarily due to COVID-19 • Preventing deaths due to COVID-19 • Preventing post-COVID syndrome (long COVID) or prolonged recovery from severe COVID-19 • Benefit to elective care patients who are currently on waiting lists, due to shorter waits <p>The financial savings to the NHS are also appraised and arise from:</p> <ul style="list-style-type: none"> • Preventing hospitalisations due to COVID-19 • Preventing expenditure on post-COVID syndrome rehabilitation | | | | | |

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

Vaccines might prevent post-COVID syndrome for patients who are not hospitalised, and there might be some reduced onward transmission. Vaccines in the vulnerable and frontline staff can contribute to preventing the NHS tipping into over-capacity, particularly in the face of winter pressures.

Discount rate (%)

3.5

Key assumptions/sensitivities/risks

This Impact Assessment uses a one-off methodology adapted from JCVI's standard cost-effectiveness methodology. Key assumptions include assuming similar epidemiology and vaccine effectiveness as in winter 2022. The purchase cost of the vaccine is treated as a sunk cost. Several key modelling assumptions and parameters are tested in sensitivity analysis.

Key risks include uncertain epidemiology of COVID-19 this winter. This may increase or decrease the benefits of this programme depending on the booster's vaccine effectiveness against the dominant circulating variant. Noting this, we model a scenario with lower and higher incidence of COVID-19. There is uncertainty in the deployment cost per dose in autumn 2023, with this dependent on the vaccine type and delivery approach.

BUSINESS ASSESSMENT (Option 1)

| | | | |
|--|----------------------|-----------------|--|
| Direct impact on business (Equivalent Annual) £m: | | | Score for Business Impact Target (qualifying provisions only) £m: |
| Costs: N/A | Benefits: N/A | Net: N/A | Not Applicable |

Summary: Analysis & Evidence Policy Option 2

Description: Reject JCVI advice and offer a vaccine to a smaller cohort for the autumn 2023 COVID-19 booster programme

FULL ECONOMIC ASSESSMENT

| Price Base Year 2023 | PV Base Year 2023 | Time Period Years 100 | Net Benefit (Present Value (PV)) | | |
|--|--|--------------------------|---|---|--|
| | | | Low: ■■■ [Highest out of Options 1-3] | High: ■■■ [Highest out of Options 1-3] | Best Estimate: ■■■ [Highest out of Options 1-3] |
| COSTS (£m) | Total Transition (Constant Price) Years | | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) | |
| Low | 0 | 0 | N/A | N/A | |
| High | 0 | | N/A | N/A | |
| Best Estimate | 0 | | ■■■ | ■■■ [Lowest out of Options 1-3] | |
| Description and scale of key monetised costs by 'main affected groups' | | | | | |
| Deployment cost for the NHS to deploy the vaccine to the specified cohort, estimated in the same way as for Option 1. | | | | | |
| Other key non-monetised costs by 'main affected groups' | | | | | |
| N/A | | | | | |
| BENEFITS (£m) | Total Transition (Constant Price) Years | | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) | |
| Low | 0 | 0 | N/A | ■■■ | |
| High | 0 | | N/A | ■■■ | |
| Best Estimate | 0 | | N/A | ■■■ [Lowest out of Options 1-3] | |
| Description and scale of key monetised benefits by 'main affected groups' | | | | | |
| This IA appraises the health benefits of the COVID-19 booster and NHS savings. These are the same benefits appraised in Option 1, calculated according to age and clinical risk. | | | | | |
| Other key non-monetised benefits by 'main affected groups' | | | | | |
| These are the same as for Option 1, though smaller to the extent that Option 2 is a smaller programme than Option 1. | | | | | |
| Discount rate (%) | | | | | 3.5 |
| Key assumptions/sensitivities/risks | | | | | |
| These are the same as for Option 1 | | | | | |

BUSINESS ASSESSMENT (Option 2)

| Direct impact on business (Equivalent Annual) £m: | | | Score for Business Impact Target (qualifying provisions only) £m: |
|---|---------------|----------|---|
| Costs: N/A | Benefits: N/A | Net: N/A | Not Applicable |
| | | | |

Summary: Analysis & Evidence Policy Option 3

Description: Reject JCVI advice and offer a vaccine to a larger cohort for the autumn 2023 COVID-19 booster programme

FULL ECONOMIC ASSESSMENT

| Price Base Year 2023 | PV Base Year 2023 | Time Period Years 100 | Net Benefit (Present Value (PV)) | | |
|---|--|--------------------------|---|--|---|
| | | | Low: [Redacted] [Negative and lowest out of Options 1-3] | High: [Redacted] [Positive but lowest out of Options 1-3] | Best Estimate: [Redacted] [Negative and lowest out of Options 1-3] |
| COSTS (£m) | Total Transition (Constant Price) Years | | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) | |
| Low | 0 | 0 | N/A | [Redacted] | |
| High | 0 | | N/A | [Redacted] | |
| Best Estimate | 0 | | N/A | [Redacted] [Highest out of Options 1-3] | |
| Description and scale of key monetised costs by 'main affected groups' | | | | | |
| Deployment cost for the NHS to deploy the vaccine to the specified cohort, estimated in the same way as for Option 1. | | | | | |
| Other key non-monetised costs by 'main affected groups' | | | | | |
| N/A | | | | | |
| BENEFITS (£m) | Total Transition (Constant Price) Years | | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) | |
| Low | 0 | 0 | N/A | [Redacted] | |
| High | 0 | | N/A | [Redacted] | |
| Best Estimate | 0 | | N/A | [Redacted] [Highest out of Options 1-3] | |
| Description and scale of key monetised benefits by 'main affected groups' | | | | | |
| This IA appraises the health benefits of the COVID-19 booster and NHS savings. These are the same benefits appraised in Option 1, calculated according to age and clinical risk, hence now include the additional benefits of vaccinating not-at-risk adults aged 50-64. It is a relatively small benefit, owing to this cohort's low risk from COVID-19. | | | | | |
| Other key non-monetised benefits by 'main affected groups' | | | | | |
| These are the same as for Option 1, though larger to the extent that Option 3 is a larger programme than Option 1 | | | | | |
| Discount rate (%) | | | | 3.5 | |
| Key assumptions/sensitivities/risks | | | | | |
| These are the same as for Option 1 | | | | | |

BUSINESS ASSESSMENT (Option 3)

| | | | |
|--|---------------|----------|--|
| Direct impact on business (Equivalent Annual) £m: | | | Score for Business Impact Target (qualifying provisions only) £m: |
| Costs: N/A | Benefits: N/A | Net: N/A | |
| | | | Not Applicable |

Impact Assessment for the COVID-19 autumn 2023 booster vaccination programme

[Some elements of this Impact Assessment have been redacted for publication. These are the estimated average and total costs of deploying the COVID-19 vaccine for autumn 2023, the total quantified benefits of vaccination and the stated willingness-to-pay for individual cohorts. This has been done noting some content is commercially sensitive. This redaction maintains government's negotiating power for COVID-19 vaccines, ensuring value for money, whilst promoting fair and open competition for vaccine manufacturers. Redacted text is blacked out, and in some instances we have provided further explanatory information to aid the reader in the form of italic text bound by square brackets]

Summary

1. The Joint Committee on Vaccination and Immunisation (JCVI) has provided its advice for a COVID-19 booster dose in autumn 2023. JCVI's advice states the following groups should be offered a COVID-19 vaccine in autumn 2023:
 - residents in a care home for older adults
 - all adults aged 65 years and over
 - persons aged 6 months to 64 years in a clinical risk group, as defined in tables 3 and 4 of the COVID-19 chapter of the UK Health Security Agency (UKHSA) Green Book
 - frontline health and social care workers
 - persons aged 12 to 64 years who are household contacts of people with immunosuppression, as defined in the UKHSA Green Book
 - persons aged 16 to 64 years who are carers and staff working in care homes for older adults, as defined in the UKHSA Green Book
2. This Impact Assessment (IA) considers several options for the COVID-19 autumn 2023 booster programme including accepting this advice, offering a booster to a smaller or a larger cohort, or offering no autumn 2023 booster. The analysis examines the autumn 2023 booster programme as a one-time programme, and it does not assess future booster rounds. It uses a bespoke non-standard cost-effectiveness methodology. This departs from the standard methodology for JCVI's vaccine assessments in several key ways (more details are provided in the section 'Changes to standard JCVI cost-effectiveness methodology' of this IA). These are one-off changes made specifically to support decisions on COVID-19's autumn 2023 booster programme.
3. In all other aspects this analysis follows the standard JCVI cost-effectiveness methodology that is outlined in the JCVI Code of Practice¹ and aligns closely with the NICE Health Technology Appraisal (HTA) methodology. Vaccine decisions are evaluated for cost-effectiveness rather than cost-benefit analysis methodology which is usually adopted in the Department for Health and Social Care's (DHSC) Impact Assessments². This is so that vaccine decisions are evaluated in as consistent a way as possible with NICE's decisions on health technologies. The

¹ [Link to JCVI 2013 Code of Practice](#)

² Best practice appraisal for HMG is further outlined in the HMT Green Book. [Link to HMT Green Book](#)

cost-effectiveness approach means this analysis is restricted to the health impacts of COVID-19 vaccination only.

4. This is the first occasion that JCVI have factored cost-effectiveness into its advice on COVID-19 vaccines. DHSC advised JCVI on adjustments to the standard methodology, that were judged to be justifiable given various unique circumstances relating to this decision. DHSC also provided the associated analysis.
5. The same results that were presented to JCVI are presented here. They indicate that the JCVI advice includes some cohorts who are highly cost-effective but also includes some cohorts who are not cost-effective according to the quantification possible. JCVI's advice notes this cost-effectiveness assessment was one of the factors considered by JCVI in the formulation of its advice for autumn 2023, but they also take into account the significant uncertainty in future COVID-19 epidemiology and resulting challenges in quantification. Hence their advice can be justified on a precautionary basis, mitigating this risk of uncertainty.
6. Note, the deployment costs here are based on using the same average price per dose across Options 1-3 of [REDACTED]. This is aligned with historical COVID-19 vaccine deployment costs and internal estimates for autumn 2023, however it is a simple approach and may not fully agree with NHS England's final costs, as their costs were still being estimated at the time of writing.
7. Although total costs are estimated at [REDACTED] per dose [*using the historical average deployment cost per dose*], JCVI evaluated cost effectiveness at the margin at £10 per dose, approximately equal to the amount paid to GPs to deploy the vaccine (£10.06). This is a reasonable approximation of the marginal cost in the absence of an established cost model for COVID-19 vaccines deployment. [*This marginal cost per dose is less than the average cost per dose assumed in this analysis*].

Eligible groups by age (adults only) and risk group

8. In this Impact Assessment, we assess three options for evaluating adults by age and risk group (other cohort groups, such as children and young people, and frontline health and social care workers, are further considered later in this document), against a counterfactual of "do nothing" (no autumn boosters):
 - A) Option 1: accept JCVI advice
 - B) Option 2: reject JCVI advice and deploy autumn 2023 boosters to a smaller cohort.
 - C) Option 3 reject JCVI advice and deploy autumn 2023 boosters to larger cohort (the same as for autumn 2022)
9. The results of the analysis show there that Option 2 is evaluated as having the greatest net monetary benefit (NMB), followed by Option 1, with Option 3 having the lowest NMB.
10. The key reason why Option 1 is evaluated as being less cost-effective than Option 2 is that it includes some cohorts who are not cost-effective according to this evaluation, even at the margin of £10 per dose. These groups are: the at-risk below aged 45 and not-at-risk ages 65-79.

Table 1: Net monetary benefit (NMB) results for Options 1-3, for age (15+) and risk cohorts

| Epi scenario | Option 0 (no vaccination) NMB | Option 1 (JCVI option) NMB | Option 2 (narrow programme) NMB | Option 3 (wide programme) NMB |
|----------------|-------------------------------------|----------------------------------|---------------------------------------|-------------------------------------|
| Most Plausible | £0m | ■ [Middle] | ■ [Highest] | ■ [Lowest & negative] |
| Uncertainty | £0m | ■ [Middle & negative] | ■ [Highest] | ■ [Lowest & negative] |
| High benefits | £0m | ■ [Middle] | ■ [Highest] | ■ [Lowest] |

Government's Options

11. In this Impact Assessment, due to the challenges of quantifying COVID-19's potential future risk and health impacts, we do not specify a preferred option. The analysis indicates that Option 1, of accepting the JCVI advice, is cost-effective overall (although it includes some cohorts who are not cost-effective in isolation), with a positive net monetary benefit in the most plausible scenario. Option 2 is the narrowest modelled option and strictly adheres to cost-effectiveness by stratifying cohorts by age and clinical risk status- atypical of the COVID-19 vaccine programme. Option 2 is the most cost-effective option and has the highest net monetary benefit in each epi scenario. It has lower deployment costs and presents a higher net monetary benefit than accepting the JCVI's advice. However, owing to the uncertainty, risks and additional health impacts of COVID-19 which have not been quantified, it is plausible that vaccinating more individuals could be cost-effective. Therefore, Government could justify the non-cost-effective cohorts in Option 1, or proceed with Option 3, on the precautionary basis of uncertainty in COVID-19's risks and to protect the NHS over winter 2023/24. All options are considered implementable.

Table 2: Options analysis summary

| | Option 1 | Option 2 | Option 3 |
|---|---|--|---|
| Description | Accept JCVI advice and restrict booster vaccines to a smaller cohort than in autumn 2022. | Reject JCVI advice and deploy autumn 2023 boosters to a smaller cohort than JCVI advise. | Reject JCVI advice and deploy autumn 2023 boosters to larger cohort than JCVI advise (the same cohort as for autumn 2022) |
| Not at-risk cohort | All adults aged 65 years and over | All adults aged 80 years and over | All adults aged 50 years and over |
| At risk (exc.IS) cohort | Persons aged 6 months and over | All adults aged 45 years and over | Persons aged 6 months and over |
| Immunosuppressed (IS) cohort | Persons aged 6 months and over | Persons aged 6 months and over | Persons aged 6 months and over |
| Net monetary benefit (NMB) - most plausible | ■ [Second highest] | ■ [Highest] | ■ [Lowest and negative] |
| Averted events- over 6 months in the | Averted deaths: 4,090 | Averted deaths: 4,020 | Averted deaths: 4,100 |

| | | | |
|-------------------------|--|--|--|
| most-plausible scenario | Averted ward hospitalisations: 14,720 | Averted ward hospitalisations: 13,990 | Averted ward hospitalisations: 14,860 |
| | Averted ICU hospitalisations: 1,230 | Averted ICU hospitalisations: 1,180 | Averted ICU hospitalisations: 1,240 |

Option 0: no autumn 2023 programme

12. Government can proceed with Option 0, of no autumn 2023 booster programme. This is the lowest net cost option and hence would release the most savings to spend on other health interventions. By definition this has zero net monetary benefit. However, some options have a positive net monetary benefit (NMB): Option 1 (to follow JCVI advice) has a positive NMB in the “most-plausible” and “high benefit” scenarios and Option 2 has a positive NMB in each of the epi scenarios.
13. In addition, although this is modelled as having zero cost, at this stage in the planning cycle preparations have had to be made for an autumn programme. There have been investments which could not be recouped if no vaccination is undertaken. The size of this commitment is not known, but were this factored in, it would make Option 0 even less favourable compared to the other three options. This option would represent an unprecedented departure from JCVI advice and risks significant negative health impacts alongside reputational risks for the COVID-19 vaccination programme. If Government decides to reject the JCVI advice and not offer vaccination, in the absence of a strong rationale, the risk of any challenge by way of judicial review being successful would be high.

Option 1: accept JCVI advice

14. Option 1 is cost-effective overall. This age-based option has a positive net monetary benefit (NMB) in the “most plausible” and “high benefits” epidemiological scenarios. JCVI advise on an age-based approach for those aged 65 years and above. This group are cost-effective when those in a clinical risk group and those not in a clinical risk group are assessed together.
15. However, JCVI advice includes some cohorts who are not cost-effective in isolation at the marginal £10 deployment cost per dose according to this analysis. These cohorts are adults aged 65-79 who are not in a clinical risk group and at-risk (exc. the immunosuppressed) persons below 45. The inclusion of these groups could be justified on a precautionary basis, given there are circumstances when vaccinating these additional groups could be justified:
 - A) If the marginal costs are found to be lower than the assumed £10 per dose (the results suggest a stated willingness to pay of ■■■ [less than £10 per vaccinated person] for these non-cost-effective groups).
 - B) If there are significant unquantified health benefits from vaccination, such as reduction of Post COVID-19 syndrome or if reducing NHS pressures during winter could avoid tipping the system into over-capacity which would have significant additional impacts on patients across the system.
 - C) If there are judged to be risks of a more significant wave of COVID-19 than the modelled scenarios.

- D) If eligibility based on a universal age-based programme results in better uptake in the at-risk groups as compared to them being eligible only based on their clinical risk³.
16. There may also be programme-wide benefits of following the JCVI advice:
 - A) Aligning with JCVI advice will help maintain public confidence in the programme if Government accept JCVI advice, which in turn supports uptake of the programme in the eligible cohorts.
 - B) If changes to the programme happen at a measured pace, this might maintain long-term confidence in the programme and avoid any reversal of decisions should risks be found to be greater at some point in the future.

JCVI's rationale for supporting Option 1

17. JCVI considered a range of evidence in informing their decision, including the cost-effectiveness analysis presented here. Given that there are potential benefits that the cost-effectiveness analysis cannot quantify, JCVI judged Option 1 to be the preferred option.
18. JCVI's rationale for choosing Option 1 over Option 2 (which they refer to as "a fully incremental assessment") is as follows:

"Given the high proportion of older adults with comorbidities and the higher uptake seen in universal age-based programmes, JCVI considers that for autumn 2023, it is appropriate to offer vaccination to all adults aged 65 years and over. While not a fully incremental assessment, as would be standard [which Option 2 would have been], it is considered appropriate to take such an approach during the current pandemic recovery phase due to the uncertainties in the NNV [Number Needed to Vaccinate] and cost-effectiveness assessment estimates, and because of the expected additional benefits of reducing winter pressures on the NHS."
19. JCVI advice justifies offering a vaccine to not-at-risk adults aged 65-79, who are not cost-effective in this analysis, on the basis that higher uptake is seen in universal age-based programmes. The advice also justifies the inclusion of at-risk (excluding immunosuppressed) persons below 45, who are not deemed cost-effective in the quantification presented here, on the basis that further stratification of risk groups would increase the programme's complexity and could negatively impact uptake.
20. JCVI do not explicitly justify why they have chosen Option 1 over Option 3 (remaining with the same groups as the autumn 2022 booster programme) but choosing to do so is consistent with them considering cost effectiveness as an important contributing factor to this decision.
21. In summary, JCVI advising Option 1 is a step towards a more cost-effective programme while also being precautionary given the limitations and uncertainty of the cost-effectiveness analysis and to protect the NHS over winter 2023/24. Hence the Government can choose to proceed with the broadly cost-effective Option 1, over the more cost-effective Option 2, on a precautionary basis.

³ For example, the seasonal flu vaccine programme has greater uptake in the adult groups who are eligible due to their age, than those adult groups who are eligible due solely to their clinical risk group. However, this difference in uptake could be explained by other factors such as older individuals being more likely to take up a vaccine.

Option 2: narrower autumn 2023 booster programme

22. In this option, to offer vaccines only to cost-effective cohorts at the marginal £10 per dose deployment cost, strictly adheres to cost-effectiveness by stratifying cohorts by age and clinical risk status, as opposed to the broader definitions of eligibility in Option 1. This stratification is atypical of the previous COVID-19 vaccine programmes, but in line with the standard methodology adopted by JCVI. Compared to Option 1, not at-risk adults aged 65-79 and at-risk (excluding immunosuppressed) persons below 45 are no longer eligible for a booster. In this assessment of cost-effectiveness, Option 2 is the most cost-effective option, with the highest net monetary benefit across all the modelled epidemiological scenarios.
23. Government can therefore proceed with this option on the basis that it is likely to be the most cost-effective option and if Government is content to take a less precautionary approach than JCVI. There are likely to be some negative consequences of taking a different and unprecedented approach to JCVI. Primarily, in the absence of a strong rationale, the risk of any challenge by way of judicial review being successful would be high. Further, as noted in JCVI advice, Option 2 increases the complexity of the COVID-19 vaccine programme and could have lower uptake than in an age-based programme, such as Option 1. Finally, there may be a potential consequence on public health messaging, which would need to be carefully managed.

Option 3: expanded autumn 2023 booster programme

24. This option involves offering a booster to the same cohorts as in the autumn 2022 programme. This means the 50-64s who are not at-risk would be eligible.
25. Government can proceed with this option, on the basis that Government is content to take a more precautionary approach than JCVI, noting the risks, uncertainty and wider impacts of COVID-19 in autumn 2023 may be more severe than anticipated in this analysis. However, it would represent an unprecedented departure from JCVI advice and therefore carries a reputational risk, albeit a smaller risk than proceeding with Option 0 or 2. Being the largest programme, Option 3 has the greatest unquantified benefits which include protecting NHS capacity in winter and preventing long COVID-19 in the community, but comes at the highest cost and has a negative Net Monetary Benefit in the “most plausible” scenario.

Additional analysis

Children aged 6 months to 14 years in a clinical risk group

26. We estimate this cohort size to be 0.6m children and assume an uptake of 10%⁴. For children aged 6 months to 14 years in any clinical risk group, Numbers needed to vaccinate (NNVs) were not available to quantify the expected benefits. However, if they are comparable in risk to young people aged 15-19 years, the cost-effectiveness analysis suggested that those who are immunosuppressed are likely

⁴ This assumption is based on uptake in children aged 5 to 11 who are at clinical risk was 10% as of end of October 2022. The vaccine was offered to these children by NHS England since January 2022.

to be cost-effective, whereas those at-risk but not immunosuppressed are unlikely to be cost effective.

27. The at-risk (excluding immunosuppressed) group are a heterogeneous group, and recognising some conditions pose significantly greater risk than others, JCVI intends to further investigate eligible risk groups. In the interim, JCVI want to continue to offer boosters to all the at-risk groups to ensure those who are at high risk are given this protection. Some of this group will receive a paediatric dose of the vaccine, and the average deployment cost might be greater than for the adult population. This has not been considered here.
28. Government can choose to follow JCVI advice and offer vaccination to this group, or offer vaccination to a subset, or choose not to vaccinate these groups.

Other eligible groups

29. The above analysis does not cover:
 - A) frontline health and social care workers
 - B) persons aged 12 to 64 years who are household contacts of people with immunosuppression, as defined in the UKHSA Green Book
 - C) persons aged 16 to 64 years who are carers and staff working in care homes for older adults, as defined in the UKHSA Green Book
30. We estimate the total boosters to be deploy to these cohorts to be 1.6 million.
31. The benefits of these groups are more difficult to assess, and a cost-effectiveness analysis has not been done for these groups, so it is not possible for us to provide a verdict on their cost-effectiveness. On the one hand, these groups are unlikely to be evaluated as cost-effective since they are not considered to be at significantly greater risk from COVID-19 compared to the general population. Secondly, the additional benefit of preventing onward transmission to individuals they care for is expected to be small, since the vaccine's relative effectiveness against transmission is weak and short lasting. Thirdly, our assessment of potential sick days due to COVID-19 is that this is likely to be small. However, given the lack of explicit quantification of the impact on onward transmission and owing to additional unquantified benefits (which are discussed in Annex C) we cannot assess the likelihood of these cohorts being cost-effective.
32. Government can choose to follow JCVI advice and justification to offer vaccination to this group, or offer vaccination to a subset, or choose not to vaccinate these groups.

Summary of JCVI advice

33. Table 3 below summarises the total costs and net monetary benefits across the groups included in JCVI's advice. These are the total costs and benefits of Option 1- to accept JCVI advice. Approximately 17m doses are expected to be delivered, at an average deployment cost of █████ per dose, for a total deployment cost of █████

Table 3: Summary of accepting JCVI autumn 2023 advice

| | Eligible adults by age/risk status | Children aged 6 months to 14 years | HSCWs, carers and household contacts of the IS | Total for accepting JCVI advice (Option 1) |
|-----------------------------------|------------------------------------|------------------------------------|--|--|
| Total doses delivered | 15.2m | 0.1m | 1.6m | 16.9m |
| Total cost (█ per dose) | █ | █ | █ | █ |
| Total benefits | █ | █ | █ | █ |
| Net monetary benefit (NMB) | █ | █ | █ | █ |

Introduction

34. JCVI has provided advice on eligibility for an autumn booster in 2023. Ministers are not bound in regulation to implement JCVI's advice, since it does not contain the necessary conditions of a binding recommendation⁵.
35. The main change in JCVI advice, compared to autumn 2022's booster programme, is towards 50–64-year-olds outside of clinical risk cohorts: now only all 65-year-olds and over are eligible on the basis of age, as opposed to the autumn 2022 programme where all 50-year-olds and over were eligible. Other changes include household contacts of people with immunosuppression, who were previously offered a booster if aged 5 or over. For the autumn 2023 programme, this will be limited to those aged 12 and over. Finally, the clinical risk cohorts will now go down to 6 months and above to reflect that an infant vaccine is available for those eligible. There is no change to the eligibility of other cohorts.

Problem under consideration

36. In this Impact Assessment we explore the potential costs and benefits of accepting the JCVI advice, and of other appropriate alternatives. For autumn 2023, JCVI considered cost-effectiveness as one factor in its decision on who should be eligible for a COVID-19 booster. This was the first of any of its COVID-19 vaccine decisions that considered cost-effectiveness. DHSC provided the cost-effectiveness advice, using a one-off adjusted cost-effectiveness methodology. This IA explains the methodology employed and the results provided to JCVI in making this decision.
37. The cost-effectiveness methodology applied in this instance is not the standard JCVI methodology. Instead, a bespoke one-off methodology was designed in conjunction with JCVI to reflect the ongoing uncertainty around COVID-19 in autumn 2023. Changes made to the methodology are discussed in the 'Changes to the standard JCVI cost-effectiveness methodology' section.
38. This IA presents the costs and health benefits of different options for the COVID-19 booster programme and therefore seeks to evaluate which, if any, of these options are cost-effective, or if the equivalent funds would be better spent elsewhere in the health and social care system. This does not preclude applying the precautionary principle in deciding the most appropriate way forward: considering the potential value of any unquantified benefits arising from the mitigation of unquantified risks.
39. The following analysis is limited to England only, with healthcare a devolved matter in the UK. The analysis covers individuals who are not at-risk (not in a clinical risk group) and breaks down the clinical risk group into the at-risk (excluding immunosuppressed) group⁶ and the immunosuppressed group.

⁵ The JCVI can choose, where a series of pre-conditions have been met including a full cost effectiveness exercise having been carried out, to issue a formal recommendation on vaccination which is binding on SoS for health in England. For COVID the JCVI have not been able to issue binding recommendations, as there has been no full cost effectiveness exercise meeting the criteria laid out in the JCVI terms of reference. Even if a cost effectiveness exercise is carried out, the JCVI doesn't have to send a binding recommendation and cannot do so unless the five pre-conditions set out in their Code of Practice are met.

⁶ This is based on CAAS cohorts (created autumn 2022 for the booster): asplenia, chronic heart/vascular, chronic kidney/liver/digestive, chronic neurological, chronic respiratory, diabetes and endocrine, morbid obesity, severe mental illness, serious genetic abnormalities, Immunosuppression, severely immunosuppressed

40. JCVI's advice on offering a vaccine to other groups, such as frontline health and social care workers, other carers and households of the immunosuppressed, is discussed in Annex C. The JCVI advice of switching the primary course offer to a single dose is analysed separately in Annex D.

Rationale for intervention

41. Policy intervention is primarily needed to prevent morbidity and mortality in the most vulnerable.

Policy objective

42. The primary policy objective is the prevention of severe illness (hospitalisations and deaths) arising from COVID-19 infections.

Standard JCVI cost-effectiveness methodology

43. The standard JCVI cost-effectiveness methodology is used for all routine vaccine decisions. This methodology is detailed in Annex A.
44. The key metric of cost effectiveness is the incremental cost-effectiveness ratio (ICER) which evaluates each decision incrementally for how much it costs to gain one quality adjusted life-year (QALY). There will in most cases be a distribution of estimates of the ICER. Firstly, the "most plausible" ICER is compared to JCVI's stated willingness-to-pay threshold of £20,000 per QALY for the "most plausible" scenario. Secondly, the 90th percentile ICER is compared to JCVI's stated willingness-to-pay threshold of £30,000 per QALY for the 90th percentile ICER. An intervention is cost-effective if in both instances the ICER is less than or equal to the relevant threshold.
45. An alternative application of this threshold is to multiply each QALY gained by the relevant threshold and calculate the benefits per dose as a monetary value which we call the "stated willingness to pay (WTP) per dose". This is then compared to the estimated average cost per dose to assess whether the option is cost-effective. The two methods are identical in their conclusions, but this second method is preferred as a clearer means of communicating the results given the dimensions of uncertainty that are explored in this analysis.
46. Cost-effectiveness differs from cost-benefit analysis (CBA) used across Government, by only analysing the health impacts and excluding wider societal impacts. More typically, in standard HMT Green Book appraisal, which is not applied to vaccines, QALYs are given a societal value of £70,000 in CBA, wider costs and benefits are considered, and the intervention is compared with other spending decisions across the public sector. Many of COVID-19's impacts, in the absence of a new and significant variant of concern, are now limited to health impacts, similar to other health interventions, as opposed to the significant non-health impacts it had during the pandemic. Broadly, this supports treating COVID-19 vaccines the same as other vaccines.

Changes to the standard JCVI cost-effectiveness methodology

47. There are several factors that are unique to COVID-19 this autumn that necessitate an adapted approach to cost-effectiveness. Hence, several key changes have been made to the JCVI standard cost-effectiveness methodology. These are one-off changes, specific to COVID-19's autumn 2023 booster programme and not applicable, nor indicative, of future vaccine cost-effectiveness analysis. The changes are:
- A) Assuming sunk purchase costs for the vaccine, reflecting the unique situation for autumn 2023 where there are some contracted vaccines that have been pre-purchased and could be deployed in the autumn 2023 campaign without additional procurement cost, whilst meeting expected vaccine uptake.
 - B) Including wider health benefits from elective care. This is to reflect higher than usual pressures on healthcare resources while the NHS is in a recovery phase from COVID-19
 - C) In acknowledgement of the ongoing uncertainty in COVID-19 epidemiology, modelling three plausible scenarios given equal consideration instead of the standard methodology that evaluates the "most plausible" (50th percentile) at £20,000 and the 90th percentile at £30,000 per QALY.
 - D) Not having a fixed deployment cost, instead using an average and a marginal cost.
48. The remainder of the methodology adopted in this Impact Assessment is the same that JCVI advises and used in other vaccine analysis. For example, within the standard JCVI methodology, all QALYs are valued at the cost-effective threshold set by JCVI of £20,000 per QALY, and all benefits are discounted at 3.5%. JCVI's Code of Practice advises the use of the £20,000 per QALY value to reflect "the current estimate of the opportunity cost elsewhere in the NHS of allocating resources to the programme in question from a fixed NHS budget". There was no strong rationale to depart from these parameters for COVID-19, noting that COVID-19 is no longer quite as exceptional in its impacts as it was earlier in the pandemic.
49. The remainder of this Impact Assessment applies this adapted bespoke methodology for COVID-19 to the autumn 2023 booster programme only. Noting this is atypical for vaccine analysis.

A. Sunk purchase costs

50. We treat the purchase cost of the COVID-19 vaccines as sunk for the autumn 2023 programme. This means the purchase cost per dose of the vaccine is assumed to be £0 in economic terms. Therefore, the only cost of the autumn 2023 programme is that of deploying the vaccine. This cost is incurred by the NHS.
51. This is due to a unique situation for COVID-19 vaccines currently. Some COVID-19 vaccines have been procured prior to JCVI advice being available on who should be offered a vaccine, with existing contracts with manufacturers. These contracts, managed by UKHSA, mean there are existing COVID-19 doses in freezers and more doses coming this autumn that are pre-purchased. These doses could be deployed in the autumn 2023 campaign without any additional procurement cost. There are sufficient doses for the autumn 2023 campaign and no need to procure further doses in any of the options considered. To decide on

treating the purchase cost as a sunk cost in economic terms, we have explored the alternative uses of the existing doses if they are not used in an autumn 2023 campaign.

52. One use is to save the doses for a potential spring 2024 campaign. This is not a feasible alternative because current doses have an expiry date, with many doses set to expire before a potential spring 2024 campaign can commence. Another alternative use is to donate doses internationally. This too is infeasible since international demand for donations has been very low or nil. The final alternative use is to save the doses for a potential surge campaign, in the event of a severe variant of concern. However, there are already doses earmarked for a surge campaign and no need for additional doses.
53. Therefore, these doses have no feasible alternative use, and it is appropriate to treat the purchase cost as a sunk cost for the autumn 2023 programme. Without being used in the autumn 2023 booster programme, these doses would expire. In making this change to the methodology, we have assumed there is no impact on future COVID-19 vaccine spend. This is an important departure from the standard JCVI cost-effectiveness approach where the purchase cost of the vaccine is included. Even though vaccine purchase costs are set to £0, there is still a cost to deploy the vaccines, hence the cost-effectiveness is framed as the stated willingness-to-pay (WTP) for the deployment per vaccine dose. This can be interpreted as the cost-effective price for deployment.

B. Elective care benefits

54. Secondly, we have appraised benefits of vaccination from avoiding a COVID-19 hospitalisation to include benefits to non-COVID patients who are on waiting lists for elective care. This is included because of the unique pressures the NHS is currently under during its 'COVID-19 recovery phase'. The NHS is constrained in being unable to significantly increase its capacity, while also having significant elective care backlogs and other indirect impacts of COVID-19 still playing out. Predicting that these challenges are likely to persist until at least mid-2024, the modelled period up to which the autumn booster programme can reduce COVID-19 admissions, we decided to factor in the indirect impact of COVID-19 admissions on other patients requiring healthcare.
55. A simple proxy model appraises the reduced health state experienced by elective care patients whilst they wait longer for treatment that was displaced by unplanned COVID-19 admissions. This implies healthcare resources cannot be expanded before mid-2024. The modelling assumes the impact of these admissions on elective waits is negated by more capacity being created in 2025.
56. An adjustment such as this is non-standard in that it has not been done before in previous vaccine evaluations. It is justifiable here because the 'recovery from COVID-19' has created exceptional pressures in the NHS, and because this is a one-season only decision. That means we are confident that the exceptional pressures in the NHS will be relevant to this decision. Other vaccine decisions are taken in advance and are usually for creating a long-running programme, hence the pressures on the NHS in one particular year would not be taken into account.

C. Plausible scenarios approach

57. We evaluated the results in three plausible scenarios for COVID-19 epidemiology to accommodate the greater uncertainty in COVID-19 epidemiology and impacts. Paragraph 31 explains JCVI's standard methodology's stated thresholds.
58. In the case of COVID-19, we ran results for three plausible epidemiology scenarios instead.
- A) Most plausible scenario: this is also known as the central scenario; this is based on equivalent COVID-19 risks as for the Autumn boosters 2022. QALY health benefits are valued at the standard JCVI's cost-effective threshold of £20,000 per QALY to calculate the "cost effective price per dose".
 - B) High benefits scenario: here all QALY benefits from the most-plausible scenario are doubled. All QALY health benefits are valued at the standard JCVI's cost-effective threshold of £20,000 per QALY to calculate the "cost effective price per dose". This represents a scenario where there is double the incidence of COVID-19 compared to the "most plausible" scenario. In this scenario, the vaccine has greater health benefits by averting more hospitalisations and deaths. This scenario is not as extreme as a variant of concern scenario, which is not assessed here.
 - C) Uncertainty scenario: this scenario has half the incidence of COVID-19 as the "most plausible" scenario, hence has half the health benefits. Now the QALY benefits are valued at a cost-effective threshold of £30,000 per QALY, thereby loosely aligning with the JCVI standard methodology which requires there to be a small decision risk that the ICER is above £30,000 per QALY.
59. Results of all three of the epidemiological scenarios were presented and given equal attention. Whereas the standard JCVI methodology would generate one cost-effective (CE) price (the minimum of the "most plausible" appraised at £20,000 per QALY or the "90th percentile" appraised at £30,000 per QALY), in this methodology we did not impose that only one CE price is used. Continuing to present the results for the three scenarios separately was due to the significant uncertainty that remains for COVID-19's epidemiology as compared to other vaccine programmes.

D. Deployment costs

60. Historically, the COVID-19 vaccine has been relatively expensive to deploy compared to other vaccines. Fixed costs associated with establishing the COVID-19 vaccination programme were significant, including creation of new IT systems, storage and distribution systems. Running costs were also high in some instances as new capacity had to be found and some delivery methods that were tried had a much higher unit cost than others. The average deployment cost per COVID-19 vaccine dose, taken from past NHS England business cases, have ranged from [REDACTED]. These are higher than the payment made for routine immunisations where GP practices are paid £10.06 per dose.
61. We do not have a deployment cost estimate for the autumn 2023 programme for each of the options in this IA. NHS England are currently considering methods of deployment and how to minimise deployment costs. This winter may see the co-administration of COVID-19 vaccines with flu vaccines, leading to potentially lower costs of deployment. The deployment cost also depends on the type of vaccine being delivered, with mRNA vaccines being more costly due to special

temperature requirements. At the time of writing, JCVI have not advised on the vaccine types to deploy this autumn, meaning no adjustment can be made in modelling.

62. We expect that vaccine deployment costs for autumn 2023 programme will be similar to previous rounds of COVID-19 vaccine programmes, which have been made up of high fixed programme costs which will be incurred regardless of the size of the programme. Ideally, we would have a cost estimate agreed with NHS E for each of the options we have modelled in this IA but given the uncertainty that still exists in the deployment programme this has not been possible to secure. Therefore, we employ a simplistic approach and use a fixed value. This means using the average cost per dose across all options, calculated by taking the total cost divided by the total doses deployed, accepting this is not a good indicator for the cost per vaccine at the margin (the added cost of deploying one more dose). Without an agreed cost model, we have not been able to establish how the average cost per dose will vary according to the programme size.
63. Our own estimates based on draft NHS E costings suggest that the average cost per dose deployed are expected be around █████ per dose (when including all fixed and marginal costs). We know that the deployment programme involves paying primary care providers the standard item of service of £10.06 per dose deployed. Therefore, we still consider it to be appropriate to estimate the total cost at █████ per dose [*average cost per dose*], but cost (or saving) at the margin of doing one more (or one fewer) dose for a programme of this size to be £10 per dose for each option.
64. Therefore, we have used █████ [*average cost per dose*] per dose in our assessments of overall costs but used £10 per dose in relation to whether certain groups would be cost-effective if added to an existing programme.

Options considered

65. In this Impact Assessment, we explore different options based on age and clinical risk factors for adults. There is the 'not at-risk' group, who are not in a clinical risk group, and two clinical risk groups: the 'at-risk (excluding the immunosuppressed)' and the 'immunosuppressed' group. We have therefore modelled three options for eligibility based on age and clinical risk factors. In Annex C, we explore the costs and benefits of eligibility for: residents in a care home for older adults; frontline health and social care workers; persons aged 12 to 64 years who are household contacts of the immunosuppressed; persons aged 16 to 64 years who are carers and staff working in care homes for older adults.
66. In Table 4, we formulate Options 1 to 3. Option 1 involves accepting the JCVI advice. Option 2 offers vaccination to a smaller cohort, restricting the offer to those who are cost-effective at the marginal deployment cost of £10 per dose. These cohorts have been chosen by using the cost-effectiveness results found in Table 15. Option 3 offers a vaccine to the largest cohort of the three options, that is the same cohort as in the autumn 2022 booster programme. These options focus on the age and risk cohorts, excluding other cohorts such as frontline health and social care workers who are analysed in Annex C.

Table 4: Impact Assessment Options

| | Option 0 (Do nothing) | Option 1 | Option 2 | Option 3 |
|---------------------------------|----------------------------------|---|--|---|
| Description | No booster programme this autumn | Accept JCVI advice and restrict booster vaccines to a smaller cohort than in autumn 2022. | Reject JCVI advice and deploy autumn 2023 boosters to an even smaller cohort than JCVI advise. | Reject JCVI advice and deploy autumn 2023 boosters to larger cohort (the same as for autumn 2022) |
| Not at-risk cohort | None | All adults aged 65 years and over | All adults aged 80 years and over | All adults aged 50 years and over |
| At-risk (exc. IS) cohort | None | Persons aged 6 months and over | All adults aged 45 years and over | Persons aged 6 months and over |
| Immunosuppressed cohort | None | Persons aged 6 months and over | Persons aged 6 months and over | Persons aged 6 months and over |

67. These three options are evaluated against a “Do Nothing” option (Option 0) where there is no autumn 2023 booster programme.
68. Options 2 and 3 would be unprecedented if Government decide not to follow JCVI advice for COVID-19 vaccines and this could have very significant and far-reaching consequences including impacting on the trust in national vaccination programmes and in the Government and the JCVI. In the absence of a strong rationale if offering vaccination to a smaller cohort, the risk of any challenge by way of judicial review being successful would be high. Therefore, any options not to follow JCVI advice should be taken very seriously. Options 2 and 3 have not been suggested by any bodies and are presented by analysts to demonstrate important aspects of the results; and other combinations of age and risk groups could be considered.

Eligible cohort size and uptake

69. Table 5 breaks down the English population, based on the National Immunisation Management System (NIMS), as of January 2023. The modelling below excludes individuals aged 6 months to 14 years, for whom numbers needed to vaccinate (NNV) estimates were unavailable. The at-risk children are a relatively small cohort of 0.6m individuals. They are discussed in the ‘Additional analysis’ section above. This does not affect the cost-effectiveness outputs, with the cost-effectiveness of cohorts below 15 years not modelled.
70. Table 5 forms the input for Table 6 which details the eligible cohort sizes for the three options. In Option 1 of accepting JCVI advice, the total cohort size is approximately 18.4m. Option 2 has a smaller cohort size of 12.1m, whilst Option 3 has the largest at 26.9m individuals.
71. These cohort sizes are subject to small changes as individuals enter and leave age cohorts and risk groups over time. Those eligible based solely on being health and social care workers, carers and household contacts of the immunosuppressed are excluded from Table 6 and estimates are provided in Annex C instead.

Table 5: English population by risk status

| Age | Not at-risk | At-risk (exc. IS) | Immunosuppressed | Total |
|--------------|-------------------|-------------------|------------------|-------------------|
| 15-19 | 3,299,000 | 273,000 | 26,000 | 3,599,000 |
| 20-24 | 3,666,000 | 305,000 | 35,000 | 4,006,000 |
| 25-29 | 4,265,000 | 379,000 | 50,000 | 4,695,000 |
| 30-34 | 4,479,000 | 452,000 | 68,000 | 4,998,000 |
| 35-39 | 4,237,000 | 489,000 | 84,000 | 4,809,000 |
| 40-44 | 3,821,000 | 549,000 | 103,000 | 4,472,000 |
| 45-49 | 3,226,000 | 624,000 | 121,000 | 3,972,000 |
| 50-54 | 3,213,000 | 871,000 | 169,000 | 4,253,000 |
| 55-59 | 2,933,000 | 1,069,000 | 203,000 | 4,206,000 |
| 60-64 | 2,325,000 | 1,159,000 | 213,000 | 3,697,000 |
| 65-69 | 1,669,000 | 1,156,000 | 214,000 | 3,039,000 |
| 70-74 | 1,277,000 | 1,225,000 | 232,000 | 2,733,000 |
| 75-79 | 914,000 | 1,271,000 | 239,000 | 2,424,000 |
| 80-84 | 415,000 | 936,000 | 158,000 | 1,508,000 |
| 85-89 | 188,000 | 658,000 | 95,000 | 941,000 |
| 90+ | 87,000 | 413,000 | 46,000 | 545,000 |
| Total | 40,014,000 | 11,829,000 | 2,056,000 | 53,897,000 |

Table 6: autumn 2023 cohort sizes

| Group | Option 1 | Option 2 | Option 3 |
|--|---------------------|--------------------|---------------------|
| Not at-risk | 4.5m (Aged 65+) | 0.7m (Aged 80+) | 13.0m (Aged 50+) |
| At-risk (exc. IS) | 11.8m (Aged 15+) | 9.4m (Aged 45+) | 11.8m (Aged 15+) |
| Immunosuppressed (IS) | 2.1m (Aged 15+) | 2.1m (Aged 15+) | 2.1m (Aged 15+) |
| Total cohort size exc. staff and children | 18.4m | 12.1m | 26.9m |

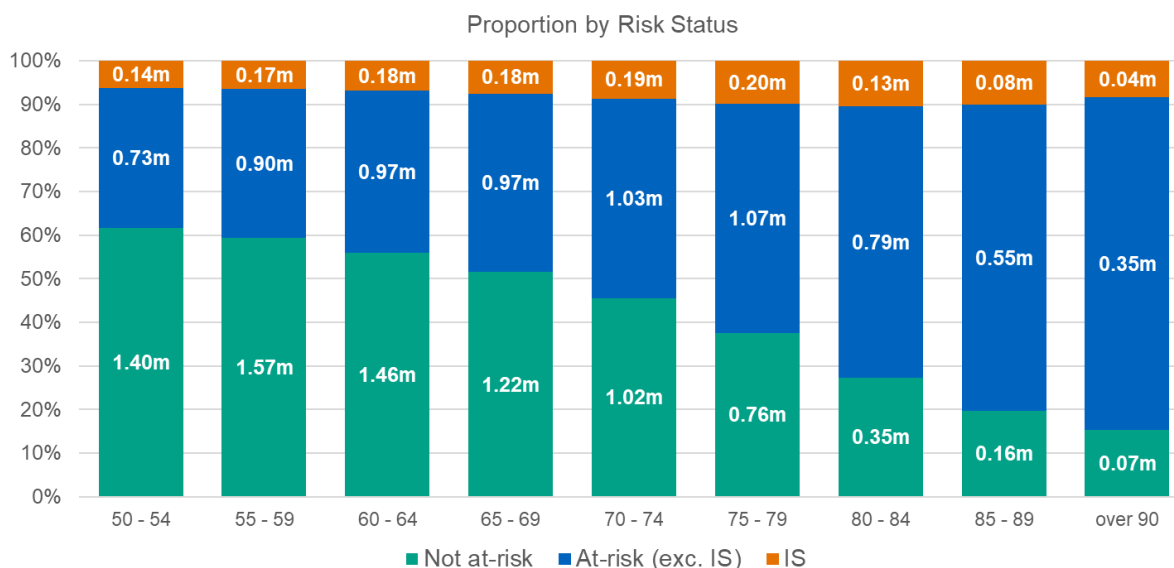
72. The uptake assumptions are taken from the last autumn 2022 COVID-19 booster campaign by age group and clinical risk group. Table 7 details these results across the three options. Note, assumptions in vaccine uptake do not impact on final cost-effectiveness results because the costs and benefits are all modelled as being linearly related with uptake. In reality, if a lower uptake is achieved to what is planned for there is likely to be greater wastage and hence a less cost-effective programme; however, the modelling done here is all based on average costs per dose. Given that the cost-effectiveness is not sensitive to uptake and using the autumn 2022 campaign uptake is considered a good basis for the estimate of uptake for autumn 2023, we do not include an alternative set of uptake assumptions.

Table 7: assumed autumn 2023 uptake⁷

| Group | Option 1 | Option 2 | Option 3 |
|------------------------------|--------------|--------------|--------------|
| Average Not at-risk | 79% | 83% | 79% |
| At-risk (exc. IS) | 84% | 84% | 84% |
| Immunosuppressed | 84% | 84% | 84% |
| Total doses delivered | 15.2m | 10.2m | 19.7m |

73. Figure 1 below shows the cohort distribution across the three risk groups that this analysis explores. As age increases, the proportion of the at-risk (exc. IS) and the immunosuppressed cohorts collectively increase. For the 70-74 cohort and above, those two at-risk groups make up over 50% of the total eligible cohort.

Figure 1: autumn 2023 cohort sizes



Cost appraisal

74. The deployment cost per dose of the COVID-19 vaccine is uncertain as discussed above in the 'Changes to the standard JCVI cost-effectiveness methodology' section. This means we cannot precisely forecast the deployment cost of the autumn 2023 booster programme.
75. Instead, we use an average deployment cost per dose of [REDACTED] when estimating the total cost of each option. This is approximately equal to the historical deployment cost of COVID-19 vaccines, such as in the autumn 2022 booster campaign. This deployment cost includes the core delivery cost of the booster, but also includes significant technology and data costs, staffing costs and market engagement costs. These costs are likely to still be applicable to the autumn 2023 booster programme. The total deployment cost differs for each option, increasing when the

⁷ Sourced from National flu and COVID-19 surveillance report. [Link to National flu and COVID-19 surveillance report](#)

eligible cohort size expands. The total deployment cost of each option is the same across the three modelled epidemiological scenarios: the most-plausible scenario, high benefits scenario and uncertainty scenario. Instead, these epidemiological scenarios only affect the total benefits.

76. We assume the marginal deployment cost is £10 per dose. This means we assume it costs an additional £10 to vaccinate one additional individual or saves £10 to do one fewer vaccination. By comparison, the amount paid to GPs practices to deploy routine immunisations is £10.06, paid per item of service.
77. Table 8 outlines the total costs of Options 1-3. As aforementioned, this is for risk and age cohorts only, excluding children under 15 and other groups such as healthcare staff. We expect the total cost to be approximately █████ for Option 1 of following the JCVI advice. This total cost is the same across the three modelled epidemiological scenarios: the most-plausible scenario, high benefits scenario and uncertainty scenario. Instead, these epidemiological scenarios only affect the total benefits.

Table 8: autumn 2023 costs

| Total cost | Option 1 | Option 2 | Option 3 |
|------------------------|---------------|---------------|----------------|
| Doses delivered | ████ [Middle] | ████ [Lowest] | ████ [Highest] |
| Cost at █████ per dose | ████ [Middle] | ████ [Lowest] | ████ [Highest] |

78. This Impact Assessment does not explore any other costs of vaccination beyond the deployment cost, such as costs to the individual to attend their vaccination appointment both in terms of time and financial cost. This is in line with standard JCVI methodology, as discussed in Annex A.

Benefits appraisal

79. JCVI’s Code of Practice details which benefits are to be assessed in standard cost-effectiveness analysis. As aforementioned, cost-effectiveness analysis is a value for money assessment that only examines health benefits of vaccination, excluding wider societal benefits.
80. In the standard methodology, three types of benefits are assessed:
 - A) Direct health benefits to the individual vaccinated: these are the health benefits of preventing illness and/or death in the vaccinated individual
 - B) Financial savings to the NHS: these are financial savings accruing to the NHS from preventing a hospitalisation and the need to utilise resources to care for hospitalised patients.
 - C) Indirect health benefits to the broader population: vaccines are infectious diseases, meaning an individual who is vaccinated can reduce the risk of transmission, thereby protecting both unvaccinated and vaccinated individuals.
81. Benefits not assessed in standard cost-effectiveness analysis include:
 - A) Indirect health benefits to other healthcare seeking patients: vaccines can support healthcare services by preventing services being otherwise overwhelmed.

- B) Direct non-health benefits to the individual: by reducing the risk of illness, vaccines enable individuals to carry on without disruption to their daily activities.
 - C) Societal non-health benefits: by reducing infections, vaccines prevent work absence and support labour force participation and economic productivity.
82. This Impact Assessment assesses the three standard benefits plus the indirect health benefit of COVID-19 on other healthcare seeking patients: in this instance using a proxy model for the impact on patients awaiting elective care.
 83. Benefits are appraised over six months, noting that the booster's incremental vaccine effectiveness is highly uncertain beyond six months, hence is assumed to wane to zero. These benefits are appraised in the three COVID-19 epidemiological scenarios which are detailed above in part C of the 'Changes to the standard JCVI cost-effectiveness methodology' section.
 84. We do not appraise the benefits of vaccination against a variant of concern scenario. This is because the COVID-19 surge programme, separate to the booster programme, exists and intends to mitigate the impact of a variant of concern. Additionally, the broad range of possibilities of an unknown future variant of concern makes quantification implausible. In practice, the booster vaccine may provide some precautionary protection against a variant of concern. However, the challenge is of how to attribute benefits to seasonal vaccination versus the surge vaccination programme. For these reasons, we do not appraise the benefits against a variant of concern.

Averted hospitalisations and deaths

85. UKHSA performed data linkages between vaccination data, hospitalisation data and death records from the autumn boosters 2022. This is to establish rates of adverse COVID-19 events and the vaccine effectiveness of the booster. These events are hospitalisations not requiring ICU, ICU-hospitalisations and deaths due to COVID-19. The analysis was stratified by age and risk group and the results were presented to JCVI on 9th May 2023. This was expressed in terms of an overall "Number Needed to Vaccinate (NNVs) to prevent one adverse event" and was calculated separately for 5-year age bands and for three categories of those: not at-risk, at-risk (excluding the immunosuppressed) and the immunosuppressed.
86. These NNV estimates were based on the rates of COVID-19 in the period mid-November 2022 to mid-January 2023, and the incremental vaccine effectiveness of the autumn 2022 booster. Hospitalisations are based on those having a positive COVID-19 test and primary respiratory discharge code or a primary COVID-19 code to make it likely that they are due to COVID-19, rather than incidental admissions and tests. Further details on this are provided in Appendix 1 of the published JCVI Advice on the COVID-19 vaccination programme for autumn 2023.
87. We apply these same NNV results to autumn 2023 boosters. In doing so, we are assuming the level of COVID-19 will be the same in the 6-month period post vaccine use in 2023 as in the November 2022-January 2023 period, and that incremental vaccine effectiveness of the 2023 boosters will be the same as that of the 2022 boosters.

88. These are reasonable “most plausible” assumptions but there is significant uncertainty and there are many equally plausible scenarios. For example, COVID-19 peaks have been falling slightly over time and could continue, or there could be a new dominant sub-variant which has a more significant peak. UKHSA, JCVI and DHSC agreed that two additional plausible scenarios should be considered: one is halving of the COVID-19 incidence (and hence halving the COVID-19 health benefits), the other is doubling the COVID-19 incidence (and hence doubling the COVID-19 health benefits of vaccination).
89. Utilising these NNVs and expected uptake, we have modelled the number of averted hospitalisations and deaths we expect the autumn 2023 programme to prevent. This is compared to a counterfactual where we assume there is no autumn 2023 booster programme.
90. Alongside this, we model the number of symptomatic non-hospitalised infections we expect the COVID-19 booster to prevent over 6-months. We utilise incidence rates over winter 2022 to forecast the number of infections without a booster over 6 months. Based on ONS data for the Omicron period⁸, we assume 61% of cases would be symptomatic. Then we adjust for vaccine uptake and the vaccine effectiveness, of a bivalent vaccine, against symptomatic infection. Assumptions for this are taken from the latest UKHSA consensus vaccine effectiveness estimates⁹.
91. These values form the input into cost-effectiveness modelling and are presented below in Table 9, for the most-plausible scenario. Compared to Option 1, Option 3 prevents slightly more adverse events when extending the eligible not at-risk cohort to include the 50-64s.

Table 9: averted events from vaccination, over 6 months in the most-plausible scenario

| Averted events | Option 1 | Option 2 | Option 3 |
|--|-----------------|-----------------|-----------------|
| Averted ward hospitalisations | 14,720 | 13,990 | 14,860 |
| Averted ICU hospitalisations | 1,230 | 1,180 | 1,240 |
| Averted deaths | 4,090 | 4,020 | 4,100 |
| Averted non-hospitalised symptomatic infections | 1,118,000 | 733,000 | 1,436,000 |

92. The averted events in Table 9 are converted into QALY benefits and financial savings, discussed below.

A. Direct health benefits, quantified in QALYs

93. Five direct health benefits are modelled in the analysis and are detailed below in Table 10. These benefits are quantified in QALYs. Further details on QALYs can be found in Annex B.

⁸ [Link to ONS Source](#)

⁹ [Link to UKHSA COVID-19 vaccine surveillance report Week 14, page 10](#)

Table 10: Health benefits of the COVID-19 vaccine

| Benefit | Description | Methodology |
|---|--|--|
| A1. Averted deaths | <p>The booster prevents individuals dying from COVID-19.</p> <p>This means vaccinated individuals have more years of life.</p> | <p>This uses life-expectancy and quality of life (QoL) for those with at least one comorbidity. This is to account for those who would have died from COVID-19, without a booster, having on average shorter life expectancy and lower QoL than typical for their age and gender. The use of life-expectancy for those with at least one comorbidity is atypical for standard vaccine analysis, but is used here to more accurately reflect the benefit of COVID-19 vaccines.</p> |
| A2. Averted ward hospitalisations | <p>The booster prevents individuals being ill and hospitalised in a ward due to COVID-19</p> | <p>We assume there is a loss of QoL, that persists during the length of stay in hospital. This QoL loss is taken from academic literature and is consistent with the assumptions in the NICE COVID-19 Therapeutics appraisal¹⁰.</p> |
| A3. Averted ICU hospitalisations | <p>The booster prevents individuals becoming severely ill and being hospitalised in an intensive care unit (ICU) due to COVID-19.</p> | <p>We assume there is a loss of QoL, a loss greater than that for a ward hospitalisation, that persists during the hospital length of stay. The QoL loss is from academic literature and is aligned with the NICE COVID-19 Therapeutics appraisal.</p> |
| A4. Averted post-COVID Syndrome (long COVID) or prolonged recovery from severe COVID-19 among those who would have been hospitalised | <p>As well as preventing a hospitalisation, the booster prevents the sequelae of hospitalisation, whether it is post-COVID syndrome or other cause of a poor health condition requiring recovery and outpatient treatment post-hospitalisation.</p> <p>Post-COVID syndrome is clinically defined by NICE as: signs and symptoms that develop during or after COVID-19 and continue for more than 12 weeks and are not explained by an alternative diagnosis¹¹.</p> <p>For the purposes of this analysis, we have not made a distinction between long-COVID versus post-COVID syndrome (PCS), accepting that COVID-19 might result in sequelae other than PCS.</p> | <p>We assume without the vaccine, all hospitalised patients who survive and are discharged would suffer from post-COVID syndrome or an equivalent lower health state during a prolonged recovery from severe COVID-19. For simplicity, we assume post-COVID symptoms begin immediately upon discharge. In practice, some patients may face an unexpected rebound of symptoms, days or weeks after discharge.</p> <p>The lower health state post-hospitalisation is assumed to persist for an average of 6 months. This duration is based on recovery times for pneumonia and clinical input from JCVI. This average duration is assumed to apply for all patients. In practice, some patients' symptoms will persist for less than 6 months, whilst other patients may suffer symptoms for two years and beyond with some living with permanent organ damage.</p> <p>An average of 6 months was taken noting heterogeneity in symptoms which creates uncertainty in the duration of symptoms and in the impact of vaccination. Also, we recognise that patients' symptoms and their severity can change over time, with new symptoms developing. This assumption is tested in the 'Sensitivity' analysis section.</p> <p>We assume post-COVID syndrome or prolonged recovery from severe COVID-19 cause an average QoL loss of 0.13. This is based on academic literature and is taken from a study of</p> |

¹⁰ [Link to NICE COVID-19 Therapeutics Appraisal](#)

¹¹ [Link to further information for post-COVID syndrome](#)

| | | |
|---|--|--|
| | | long-COVID patients in the UK ¹² . Some patients may face a greater health loss than this average, noting the wide range of symptoms. |
| A5. Averted symptomatic infection for the non-hospitalised | <p>The booster prevents individuals being infected from COVID-19 and suffering symptoms.</p> <p>These are the standard COVID-19 symptoms, such as fever, fatigue, cough etc.</p> | Symptomatically infected individuals would suffer a small QoL loss for this without the booster, proxied by flu evidence at 0.00167 QALYs. |

94. The autumn 2023 boosters will provide an incremental effect on immunity, on top of existing hybrid immunity from previous doses and infections. Although there is now a plethora of evidence around COVID-19 vaccines overall, there are limitations in the literature, especially in accounting for the impact of prior immunity for the eligible population who have all had a primary course and the vast majority of whom have had 2 or more boosters.
95. Where appropriate, parameters have been taken from NICE's COVID-19 Therapeutics appraisal, modelled in conjunction with the School of Health and Related Research (ScHARR) at the University of Sheffield. Their analysis had undergone significant public consultation. However, their work mostly concerned COVID-19 in a naïve population. In contrast, this analysis of autumn 2023 boosters is in relation to a population who have hybrid immunity. We have used some of the same parameters as NICE's work where appropriate, but in other instances, key parameters are sourced from other academic evidence and clinical input to ensure appropriateness to the context of the autumn 2023 boosters as far as possible.
96. Noting the high level of uncertainty in many of the parameters for health benefits, key parameters have been tested for sensitivity analysis. This is discussed in the sensitivity section below in this Impact Assessment.
97. Table 11 below summarises the total direct health benefits, quantified in QALYs. The table shows the majority of QALY benefits are derived from averting deaths from COVID-19. In the 'Uncertainty' and 'High benefits' epidemiological scenarios, the direct QALY benefits are doubled.

Table 11: Direct health benefits, all values in discounted QALYs

| Epi Scenario | QALY benefits | Option 1 QALYs | Option 2 QALYs | Option 3 QALYs |
|-----------------------|--------------------|----------------|----------------|----------------|
| Most-plausible | A1. Averted deaths | 14,290 | 13,790 | 14,390 |

¹² Evans et al. (2021). Clinical characteristics with inflammation profiling of Long-COVID and association with one-year recovery following hospitalisation in the UK: a prospective observational study. 10.1101/2021.12.13.21267471.

| | | | | |
|----------------------|---|---------------|---------------|---------------|
| | A2. Averted ward hospitalisations | 130 | 120 | 130 |
| | A3. Averted ICU hospitalisations | 10 | 10 | 10 |
| | A4. Averted post-COVID Syndrome or prolonged recovery from severe COVID-19 among those who would have been hospitalised | 770 | 720 | 780 |
| | A5. Averted symptomatic infection for the non-hospitalised | 1,870 | 1,220 | 2,400 |
| | Total QALY benefits (A1 to A5) | 17,060 | 15,870 | 17,700 |
| Uncertainty | Total QALY benefits | 8,530 | 7,940 | 8,850 |
| High benefits | Total QALY benefits | 34,120 | 31,740 | 35,400 |

Numbers may not sum due to rounding

Direct health benefits not modelled

98. There are two direct health benefits that have not been modelled. This means they are not included in the cost-effectiveness assessment. The first is onward transmission of COVID-19. This does not benefit the individual themselves, however, there is some benefit to others. This occurs if the individual transmits the virus to others who in turn may become infected and be symptomatic, therefore suffering a loss of quality of life. We also do not model nosocomial infections, that is transmission within the hospital setting where health effects may be greater.
99. The second direct health benefit not modelled is post-COVID syndrome (or long COVID or prolonged recovery from COVID-19) to the non-hospitalised. The booster vaccine is expected to stop some individuals developing post-COVID syndrome (PCS), principally by reducing overall infections, but there are no reliable estimates of the vaccine effectiveness against PCS in non-hospitalised cases.
100. Without this evidence it is not possible to say whether this would be a large or small impact. This is therefore noted as a non-monetised benefit. In NICE's Therapeutics appraisal, NICE assumed '10% of patients experiencing COVID-19 who did not require hospitalisation would experience long COVID'¹³. We did not take forward this assumption because we do not know the impact of the autumn

¹³ [Link to NICE COVID-19 Therapeutics Appraisal](#) Section 4.2.6.16 page 110

2023 booster in a population that has hybrid immunity. Current evidence is limited, relating to early stages of the pandemic with an unvaccinated or partially vaccinated population, and is therefore inapplicable here.

101. Instead, we quantify post-COVID syndrome (or long COVID or prolonged recovery from COVID-19) only if the individual was hospitalised. We assume all hospitalised patients that recover have on average 6 further months in a lower health state, whether from PCS or another post-hospitalisation condition requiring recovery. This duration is based on recovery times for pneumonia and clinical input from JCVI. It contrasts with NICE's assumption that PCS has an average duration of 2 years; based on patients who developed PCS early in the pandemic.
102. As the estimates here are for new cases of PCS and there is significant uncertainty in average durations for new cases in those who have received at least one vaccine and may have had multiple prior exposures to infection, and what proportion of those hospitalised will have PCS, we cannot find any data to support this assumption. Due to this large uncertainty, we test this in the sensitivity analysis.

B. Financial savings to the NHS

103. The autumn 2023 booster provides financial savings to the NHS through two channels. The first is by directly preventing COVID-19 hospitalisations. Published NHS England cost data suggests each COVID-19 ward hospitalisation costs NHS England £2,592 in total. This is a weighted average, based on NHS Health Resource Groups (HRGs). It covers the currency codes prefixed by 'DX', in the FY21/22 National Cost Collection dataset¹⁴. Additional analysis in the Hospital Episodes Statistics (HES) database indicates this comprehensively covers all patients hospitalised due to COVID-19. A severe hospitalisation in ICU/CCU, requiring oxygen ventilation, is assumed to cost an additional £1,787 per day in ICU.
104. The second type of NHS saving is through preventing post-COVID syndrome or post-COVID-19 hospitalisation recovery. We assume without vaccination, all hospitalised patients who survive are assumed to require further care from the NHS. NICE used rehabilitation for chronic fatigue syndrome as an appropriate proxy, modelling a financial cost of £2,267 per year.
105. Based on clinical input from JCVI members, we modelled the average duration of post-COVID syndrome or other post-COVID recovery to be six months; and the average cost for post-hospitalisation NHS care to be half of the estimate for annual treatment costs chronic fatigue syndrome, at £1,134. This is avoided for each avoided hospitalisation.
106. In practice, heterogeneity in the symptoms and their severity will influence the care that individuals receive, with not all patients being in a fatigue-driven symptom cluster. In the absence of further evidence, we have taken forward this saving assumption to reflect the impact of post-COVID syndrome/post-COVID recovery. Additionally, since we were unable to model cases of post-COVID syndrome that the booster may prevent in the non-hospitalised group, we have not modelled the

¹⁴ [Link to FY21/22 NHS E National Cost Collection data](#)

financial saving attributable to this group. Although, we would expect this group to face a lower cost of rehabilitative care, on the basis that hospitalised patients typically have more severe complications.

107. Taken together, these mean every hospitalisation the booster prevents saves the NHS approximately £3,726 by preventing expenditure on hospital care and on post-hospitalisation rehabilitation.

C. Wider health benefits

108. Cases of infectious diseases generally cluster in time and location. They have a potentially significant impact on healthcare resources and impacting access for other patients seeking healthcare. By reducing the number of hospitalisations, vaccines provide wider health benefits beyond the condition in question. These benefits have not before been incorporated into any vaccine evaluations to date. As aforementioned, they have been appraised here to account for the unusually high pressures on the NHS as it is recovering from the pandemic phase of COVID-19. These pressures are felt across the system, with impacts including high rates of chronic diseases due to missed opportunities for early intervention due to COVID-19; and significant elective care backlogs due to this activity being postponed dealing with COVID-19 admissions and to minimise infections in vulnerable patients. Hospitalisations due to COVID-19 continue to add demands on the NHS which we anticipate might again be working close to its full capacity in winter 2023/24. When a system is working in this way, a small additional extra can tip the system into over-capacity and result in significant additional impacts elsewhere. Vaccines can reduce the risk of this.
109. To model the impact of preventing a COVID-19 hospitalisation in 2023/24 on non-COVID-19 healthcare, we use a simple proxy model. This models a constrained NHS capacity that either treats elective care patients or COVID-19 hospitalised patients (the number of patients are balanced so both groups have the equivalent treatment cost). We assume COVID-19 admissions displace elective care treatment. This means individuals must wait longer for their elective care treatment. Whilst they wait, they spend a longer time in a lower health state. Indicative analysis, using the most appropriate data available, estimates individuals lose 0.1 QALYs every year they spend on an elective care waiting list¹⁵.
110. When COVID-19 hospitalisations are prevented, NHS resources are freed to see more elective care patients instead. Using the average cost of a COVID-19 hospitalisation, the model assumes the freed resources can be fully used to deliver the equivalent costing elective operations. In turn this reduces the time patients spend waiting and improves their health quicker. We model that, in the counterfactual of no vaccines, it would take the system one year to compensate for the lost capacity by increasing throughput of elective care patients. This benefit is measured in terms of QALYs.

¹⁵ This assumption is based on DHSC internal calculations. It is a broad assumption, calculated using two data sources. The first is research by the University of York ([link to University of York research](#)). Based on a small number of elective procedures, this research suggests the health status change before and after elective treatment is 20%. The second is a research paper from New Zealand, published in 1999 ([link to New Zealand paper](#)). Although an older dataset, and for a different population, without further evidence we believe this provides a reasonable central estimate. This paper suggests the initial health status when waiting for an elective procedure is 50%. Combining these two estimates implies a 10% reduction in health status whilst waiting for elective treatment, or 0.1 QALYs lost per year waiting.

111. This is only a proxy model and there are other healthcare activities that would likely be impacted by COVID-19 admissions, such as non-elective (emergency) patients taking longer to receive care or being turned away. There may also be larger, disproportionate impacts if the health system is tipped into over-capacity as a result of COVID-19 admissions. However, although this is a proxy model, it provides some “order of magnitude” guide to the potential impact on non-COVID-19 healthcare. In this sense it is helpful to include. Table 12 summarises the QALY benefits from elective care.

Table 12: Elective care QALY Benefits

| Epi Scenario | Option 1 | Option 2 | Option 3 |
|-----------------------|----------|----------|----------|
| Most-plausible | 2,190 | 2,090 | 2,210 |
| Uncertainty | 1,100 | 1,040 | 1,110 |
| High benefits | 4,390 | 4,170 | 4,430 |

112. Further wider health benefits not appraised include the impact on primary care. By reducing illness from symptomatic infection, the booster may reduce the need for individuals to seek healthcare. This has not been modelled because no reliable published estimates, or data points, exist for how long GPs currently spend on COVID-19 treatment. Instead, the simple elective care proxy model assumes the entire benefit of freed NHS resources is directed to elective care patients.

113. Another impact is the opportunity cost of GP practices’ time in deploying COVID-19 booster vaccines, rather than providing other forms of care. This opportunity cost could lead to a worsening of the management of health conditions. This disbenefit is also not modelled, owing to an absence of evidence and because this is not routinely included in vaccine evaluations.

114. Another benefit not appraised is that of the booster providing peace of mind to vaccinated individuals, providing reassurance both to them and those who care for them. This is a potential benefit of all vaccines and is noted in the JCVI Code of Practice as such, however it is only quantified in exceptional cases. For this stage of the COVID-19 pandemic, the risks to those falling outside the eligibility criteria are not exceptional as compared to other vaccine programmes, hence there is no strong rationale for quantifying peace of mind for this decision.

D. Non-health benefits

115. There are non-health benefits such as preventing work absence and supporting productivity in the economy, however no non-health benefits were appraised. There are two reasons for this. Primarily, cost-effectiveness analysis only examines the health benefits of an intervention. This is true for vaccines, outlined by JCVI’s Code of Practice¹¹. By adhering to this principle, it enables decision makers to have a consistent framework with which to assess different health interventions. In turn, this ensures limited healthcare funds are spent on treatments that offer the best value for money.

116. The second reason for not appraising these benefits is that they are expected to be relatively small for the autumn 2023 boosters. Although non-health benefits were significant during the pandemic, hybrid immunity from prior vaccination and infection mean these benefits are not as significant as they once were. These benefits would only likely be significant again in the emergence of a variant of concern, which is addressed by a surge policy and not evaluated here. This means that non-health benefits are not unique to COVID-19 vaccines. There is therefore not a special reason to depart from standard practice of not appraising non-health benefits for the autumn 2023 cost-effectiveness analysis.

Methodology for calculating “stated WTP cost”

117. We model the stated WTP cost in the following way:
118. QALY benefits are modelled and where appropriate they are discounted at the standard 3.5% discount rate. Discounting is only applied to the QALY benefits from averted mortality since these benefits can persist for more than one year. Direct health QALY benefits and wider health QALY benefits (from elective care) are summed.
119. QALYs are then converted into monetary values by valuing each QALY at the JCVI cost-effective threshold of £20,000, noted in JCVI’s Code of Practice. This is the discount rate and threshold as per JCVI guidance, and the standard approach in all vaccine Impact Assessments. That is, a vaccine that costs up to £20,000 per QALY is considered cost-effective for use. In turn, this enables a fair comparison of vaccines.
120. In the ‘Uncertainty’ scenario’ of this Impact Assessment, QALYs are valued at the JCVI cost-effective threshold of £30,000. This is loosely aligned with JCVI’s 90th percentile condition which cannot directly be applied to COVID-19, noting uncertainty in its epidemiology and impacts.
121. Table 13 presents the total benefits (in £ million) for the age cohorts across the three risk groups, in the most-plausible scenario. Table 13 shows that total benefits increase as age increases. This is caused by older cohorts generally being at higher risk than younger cohorts. Total benefits for the not at-risk cohort are relatively small, including for older not at-risk cohorts aged 65 and above.
122. These values are also modelled for the other epidemiological scenarios: the ‘Uncertainty’ scenario and ‘High benefits’ scenario. These results are summarised in Table 14 for the three options discussed in this analysis, and across the three epidemiological scenarios. Noting that the wider health benefit of COVID-19 vaccination on elective care is a non-standard benefit in JCVI cost-effectiveness analysis, we have also presented this result separately. Table 14 shows that the standard health benefits appraised in JCVI’s cost-effectiveness methodology remain the key drivers of the total benefits of COVID-19 vaccination in autumn 2023. [*Option 3 has the highest monetised benefit across each epidemiological scenario. This is because it is the largest option and offers the most doses, maximising the benefits of vaccination. Option 1 has the second highest monetised benefit across each epidemiological scenario, followed by Option 2.*]

Table 13: Total monetised benefits, most plausible scenario only. All values in £ million

| Age cohort | Not at-risk | | | At-risk (exc. IS) | | | Immunosuppressed (IS) | | |
|------------|--------------------|------------------|---------------------|--------------------|------------------|---------------------|-----------------------|------------------|---------------------|
| | QALY benefits (£m) | NHS Savings (£m) | Total Benefits (£m) | QALY benefits (£m) | NHS Savings (£m) | Total Benefits (£m) | QALY benefits (£m) | NHS Savings (£m) | Total Benefits (£m) |
| 15-19 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 20-24 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 25-29 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 30-34 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 35-39 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 40-44 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 45-49 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 50-54 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 55-59 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 60-64 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 65-69 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 70-74 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 75-79 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 80-84 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 85-89 | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |
| 90+ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ | ■ |

Numbers may not sum due to rounding

Table 14: Total monetised benefits, across the three options

| Epi scenario | Benefit type | Option 1 | Option 2 | Option 3 |
|----------------|--|------------|------------|-------------|
| Most-plausible | Total benefits | ■ [Middle] | ■ [Lowest] | ■ [Highest] |
| | Of which standard cost-effectiveness benefits (direct health benefits and NHS savings) | ■ | ■ | ■ |

| | | | | |
|----------------------|---|---------------|---------------|----------------|
| | <i>Of which non-standard cost-effectiveness benefits (elective care)</i> | ■ | ■ | ■ |
| Uncertainty | Total benefits | ■ [Middle] | ■ [Lowest] | ■ [Highest] |
| | <i>Of which standard cost-effectiveness benefits (direct health benefits and NHS savings)</i> | ■ | ■ | ■ |
| | <i>Of which non-standard cost-effectiveness benefits (elective care)</i> | ■ | ■ | ■ |
| High benefits | Total benefits | ■ [Middle] | ■ [Lowest] | ■ [Highest] |
| | <i>Of which standard cost-effectiveness benefits (direct health benefits and NHS savings)</i> | ■ | ■ | ■ |
| | <i>Of which non-standard cost-effectiveness benefits (elective care)</i> | ■ | ■ | ■ |

Numbers may not sum due to rounding

123. Monetised QALY benefits and NHS savings are summed, and then divided by the total doses delivered. This provides the stated willingness-to-pay (WTP) price for deployment. It can also be referred to as the cost-effective price per dose for deployment. The stated WTP is modelled separately across three different risk groups (not at-risk, at risk (excluding the immunosuppressed), and immunosuppressed) and by 5-year age groups.
124. To determine which cohorts are cost-effective, the stated WTP price is compared to the deployment cost per dose. Two different deployment costs per dose are used as a comparison. The marginal deployment cost per dose of £10 is used as the lower estimate and the average deployment cost per dose of ■ used as the central estimate. This is different to the standard vaccine approach, since here the WTP price is only compared to the deployment cost per dose, with the purchase cost per dose treated as a sunk cost.
125. For a given cohort, if the stated WTP price exceeds, or is equal to, the deployment cost per dose, the autumn 2023 booster is cost-effective. If the stated WTP price is less than the deployment cost per dose, the booster is not cost-effective.

Stated WTP price results

126. In Tables 15 and 16 below, stated WTP prices are provided, and colour coded to denote cost-effectiveness. ■ Results in yellow mean the booster is cost-effective at £10 per dose (the marginal

deployment cost), [REDACTED]. Results in red mean the booster is not cost-effective at £10 per dose. [Cohorts which are cost-effective at the average cost per dose have been redacted. Instead, we have only denoted cohorts who are cost-effective at £10 per dose].

127. For example, a [hypothetical] WTP price of £50 for not at-risk individuals aged 90+ means that the benefit is £50 for each vaccinated 90+ individual who is not at-risk. Vaccination is only cost-effective to this specific cohort if the vaccine can be offered at a cost lower than £50 per dose. Noting the deployment cost is the only relevant cost and is assumed to lie between £10-[REDACTED] this suggests it is cost-effective to offer a vaccine to individuals aged 90+ who are not at-risk. Since the WTP price exceeds the [REDACTED] [marginal] deployment cost of [REDACTED] [£10] per dose, the result for this cohort is coloured in [REDACTED] [yellow]. This same logic is applied to all risk groups and ages.
128. The [REDACTED] category groups [groups who are cost-effective at the average deployment cost], taken alone, would make up a programme of [REDACTED] million doses and have a total quantified health benefit of [REDACTED]. Our informal analysis suggests this size of benefits could justify approximately [REDACTED] of fixed costs for the autumn booster campaign, which is similar to our estimate of the actual fixed costs associated with one season's programme. These estimates are approximate and uncertain. However, they support the general approach of evaluating remaining cohorts at a marginal cost rather than an average cost across all programme costs.
129. Table 15 details the modelled results for the risk groups, in the most-plausible scenario only. In general, cost-effectiveness increases for older cohorts and as risk status increases, since these individuals are more likely to suffer adverse health consequences without a COVID-19 booster. [Table 15 focuses on cohorts who are cost-effective at the marginal deployment cost per dose of £10. Cohorts who are cost-effective at the average deployment cost per dose have not been identified here].
130. Focusing in on the three risk cohorts shows that the not-at risk cohort is the least cost-effective, with only the 80-year-olds and above at £10 per dose. The at-risk (excluding the IS) cohort are only cost-effective for the 45-year-olds and above at a marginal deployment cost of £10 per dose. Younger at-risk age groups, those below 45, are not cost-effective. One explanation for this is that the at-risk (exc. IS) cohort includes a range of clinical conditions, some of which do not expose the individual to a notable risk from COVID-19 infection. These individuals reduce the overall cost-effectiveness of the at-risk (exc. IS) cohort. Finally, the immunosuppressed cohort (IS) are highly cost-effective, noting they are most at-risk from COVID-19.

Table 15: Stated WTP price results for the most-plausible scenario only

| | Most plausible | | |
|-------|----------------|-------------------|----|
| | Not at-risk | At-risk (exc. IS) | IS |
| 15-19 | | | |
| 20-24 | | | |
| 25-29 | | | |
| 30-34 | | | |
| 35-39 | | | |
| 40-44 | | | |
| 45-49 | | | |
| 50-54 | | | |
| 55-59 | | | |
| 60-64 | | | |
| 65-69 | | | |
| 70-74 | | | |
| 75-79 | | | |
| 80-84 | | | |
| 85-89 | | | |
| 90+ | | | |

| Colour Coding Key | | |
|-------------------|---|--------------------------------|
| Interpretation | Not cost-effective at the marginal (£10) deployment cost per dose | Cost-effective at £10 per dose |

131. Table 16 includes the two further epidemiological scenarios- the high benefits scenario and uncertainty scenario. In the high benefits scenario, which corresponds to a scenario with more infections over autumn and winter:

- A) Not at-risk cohort: 75s and over are cost effective at the marginal £10 per dose.
- B) At-risk (exc. IS) cohort: now the 25s and over are cost effective at £10 per dose.
- C) IS cohort: the entire cohort is cost-effective at £10 per dose.

Table 16: Stated WTP price results for all epidemiological scenarios

| | Not at-risk | | | | At-risk (exc. IS) | | | | IS | | |
|-------|-------------|----------------|---------------|-------|-------------------|----------------|---------------|-------|-------------|----------------|---------------|
| | Uncertainty | Most plausible | High benefits | | Uncertainty | Most plausible | High benefits | | Uncertainty | Most plausible | High benefits |
| 15-19 | | | | 15-19 | | | | 15-19 | | | |
| 20-24 | | | | 20-24 | | | | 20-24 | | | |
| 25-29 | | | | 25-29 | | | | 25-29 | | | |
| 30-34 | | | | 30-34 | | | | 30-34 | | | |
| 35-39 | | | | 35-39 | | | | 35-39 | | | |
| 40-44 | | | | 40-44 | | | | 40-44 | | | |
| 45-49 | | | | 45-49 | | | | 45-49 | | | |
| 50-54 | | | | 50-54 | | | | 50-54 | | | |
| 55-59 | | | | 55-59 | | | | 55-59 | | | |
| 60-64 | | | | 60-64 | | | | 60-64 | | | |
| 65-69 | | | | 65-69 | | | | 65-69 | | | |
| 70-74 | | | | 70-74 | | | | 70-74 | | | |
| 75-79 | | | | 75-79 | | | | 75-79 | | | |
| 80-84 | | | | 80-84 | | | | 80-84 | | | |
| 85-89 | | | | 85-89 | | | | 85-89 | | | |
| 90+ | | | | 90+ | | | | 90+ | | | |

132. Table 17 summarises this in terms of which groups are evaluated as being cost effective at the £10 per dose (marginal cost) and average programme cost basis.

Table 17: Summary of cost-effective cohorts

| Deployment Cost | Scenario | Risk group | Age |
|-------------------------------------|----------------|------------------|-----|
| £10 per dose (marginal cost) | Most Plausible | Not at-risk | 80+ |
| | | At-risk (exc.IS) | 45+ |
| | | Immunosuppressed | 15+ |
| | Uncertainty | Not at-risk | 80+ |
| | | At-risk (exc.IS) | 55+ |
| | | Immunosuppressed | 15+ |
| | High benefits | Not at-risk | 75+ |
| | | At-risk (exc.IS) | 25+ |
| | | Immunosuppressed | 15+ |

Options analysis

133. Results for the three vaccination options, compared to “Do nothing” (no vaccination) are presented in Table 18 below. Total health benefits consist of QALY benefits, which are valued at the JCVI cost-effectiveness threshold of £20,000 (£30,000 in the uncertainty scenario) and financial savings to the NHS. The net monetary benefit (NMB) has been generated by subtracting total deployment costs from the total monetised benefits.

Table 18: Results for Options 1-3 compared to Do Nothing (Option 0) at [redacted] [average deployment cost] per dose

| Scenario | Area | Option 1 (JCVI option) | Option 2 (narrow programme) | Option 3 (wide programme) |
|--------------------------------|-----------------------------|--------------------------|-----------------------------|---------------------------|
| Most Plausible Scenario | Total benefits | [redacted] [Middle] | [redacted] [Lowest] | [redacted] [Highest] |
| | Total deployment costs | [redacted] [Middle] | [redacted] [Lowest] | [redacted] [Highest] |
| | Net monetary benefit | [redacted] [Middle] | [redacted] [Highest] | [redacted] [Lowest, <£0] |
| Uncertainty Scenario | Total benefits | [redacted] [Middle] | [redacted] [Lowest] | [redacted] [Highest] |
| | Total deployment costs | [redacted] [Middle] | [redacted] [Lowest] | [redacted] [Highest] |
| | Net monetary benefit | [redacted] [Middle, <£0] | [redacted] [Highest] | [redacted] [Lowest, <£0] |
| High Benefits Scenario | Total benefits | [redacted] [Middle] | [redacted] [Lowest] | [redacted] [Highest] |
| | Total deployment costs | [redacted] [Middle] | [redacted] [Lowest] | [redacted] [Highest] |
| | Net monetary benefit | [redacted] [Middle] | [redacted] [Highest] | [redacted] [Lowest] |

134. The results of the analysis showed that Option 2 is evaluated as having the greatest net monetary benefit (NMB) in each of the epidemiological scenarios, followed by Option 1, with Option 3 having the lowest net monetary benefit (NMB).

135. The key reason why Option 1 is evaluated as being less cost-effective than Option 2 is that it includes some cohorts who are not cost-effective, according to this evaluation, at the average deployment cost per dose. These groups are the at-risk below aged 45 and not-at-risk ages 65-79.

Other options

136. For simplicity, Options 2 and 3 were derived to contrast against Option 1, but other variations of age cut-offs are available to Government on a more or less precautionary basis.

Further details on stated willingness to pay

137. The stated WTP price can be decomposed to identify its drivers, as in Figure 2. The stated WTP price is presented for the age cohorts of an 'All' group, which combines the three risk groups into a weighted average. There is a steep gradient in the stated WTP price, which rises rapidly for older cohorts. Figure 2 also shows that averting mortality (in blue) remains the biggest driver of benefits, constituting on average [redacted] of the total vaccine benefits. This is because averting mortality provides extra years of life to the individual, whereas the impact from averting hospitalisations is a smaller one-off health benefit. Financial savings to the NHS (in brown) are a considerable benefit too, and the knock-on benefit of supporting

elective care patients (in orange). However, these two benefits are minimal for the younger cohorts, since the vaccine averts relatively few hospitalisations for them.

Figure 2: Decomposed stated WTP price¹⁶ (Most plausible scenario) (at-risk, immunosuppressed, and not-at-risk groups combined)

[Figure 2 has been redacted]

Sensitivity analysis

138. Uncertainty in key parameters has been tested through sensitivity analysis. We conducted this analysis for the not at-risk and at-risk (exc. IS) group, omitting the immunosuppressed group because they have high stated WTP across all age groups. These sensitivities are modelled in Figure 3 and Figure 4 below, for the not at-risk and at-risk (exc. IS) cohorts respectively. They are applied to the most-plausible scenario. The cohort's current stated WTP is denoted on the right-hand side of the figure. Meanwhile, the x-axis denotes to what extent the sensitivity changes the stated WTP.
139. Broadly, the sensitivity analysis shows that the ranges tested for key parameters has very few instances where it would change whether the stated WTP price is cost-effective at either £10 or █████ [average deployment cost per dose]. One example where it makes a difference, for example, would be █████ where parameters for post-COVID syndrome (PCS) and/or hospital savings could make these groups cost-effective at the marginal £10 cost point.
140. A fuller discussion of these particular parameters is provided below.

Figure 3: Sensitivity modelling for the not at-risk
[Figure 3 has been redacted]

Figure 4: Sensitivity modelling for the at-risk (exc. IS)
[Figure 4 has been redacted]

A. Increasing the duration of post-COVID syndrome/post-COVID recovery to 2 years

141. There is large uncertainty surrounding the impact and duration of post-COVID syndrome/ post-COVID recovery. This is a very uncertain parameter and we have reflected this by varying the duration of symptoms and NHS costs to range from 6 months to 2 years. There is limited evidence for this parameter since not all hospitalised survivors will face these symptoms for 2 years, and the type and severity of symptoms may alleviate over this time. Testing this in sensitivity analysis, we see that this has the biggest potential to improve WTP, compared to other sensitivities.
142. The impact of inclusion in isolation is a change in cost-effectiveness █████ who would now be cost-effective at the marginal deployment cost of £10 per dose if the duration is assumed to be 2 years.

B. Doubling NHS hospitalisation savings

143. The most plausible scenario assumes that each hospitalisation the booster vaccine prevents saves the NHS approximately £2,600, and an additional £1,800 per day in ICU. These savings are doubled to illustratively account for hospitalisation costs

being higher than anticipated. This could occur if patients hospitalised for COVID-19 have more complications and require more resources for their care.

144. There is no evidence to support the case for greater savings from hospitalisations. In fact, the direct costs of a COVID-19 hospitalisation have fallen from FY20/21 to FY21/22, from approximately £3,800 to £2,600. Nevertheless, the sensitivity analysis is useful in highlighting that doubling hospitalisation savings has no impact on the cost-effectiveness of the not-at risk and at-risk (exc. IS) cohort in isolation.

C. Removing elective care benefits

145. The cost-effectiveness analysis values the knock-on benefit of preventing a COVID-19 admission on elective care. This contravenes the standard cost-effectiveness methodology. Therefore, as part of the sensitivity analysis we explore the impact of removing its benefit.
146. The removal of this benefit in isolation has a negative impact on WTP. However, it does not change the cost-effectiveness of any of the cohorts who are not cost-effective, either at the marginal or average deployment cost per dose. The reason for this is similar to the above, with limited hospitalisations averted in those cohorts. Ultimately, this means although the inclusion of elective care benefits departs from the standard cost-effectiveness methodology, by itself it is not significant enough to sway the cost-effectiveness results.

D. Adjustment for COVID-19 mortality

147. COVID-19 deaths may occur in patients with significant comorbidities, who have few years of expected life remaining. The analysis already accounts for this but can be made stricter. In this sensitivity, we focus on those aged 75 and above. The average life expectancy was taken from ONS analysis of life expectancy for those aged over 75 with 2 or more co-morbidities. This value is approximately four additional years of life.
148. In this sensitivity, we now assume 15% of individuals aged 75 and above only have 1 year of life remaining. This is an illustrative scenario based on the fact that 15% of COVID-19 deaths occur in care homes, where due to the frailty of care home residents, average life expectancy is lower than in the general populace at the same age. This scenario reduces the WTP price, decreasing the mortality benefits the booster provides.
149. This sensitivity does not change the cost-effectiveness of the not at-risk cohort in Figure 3. It also does not change the overall cost-effectiveness of the at-risk (exc. IS) cohorts in Figure 4. All of the at-risk cohorts aged 75 and over remain cost-effective at a deployment cost [redacted] [average deployment cost] per dose, even with this sensitivity applied.

Limitations to this analysis

Epidemiological uncertainty

150. The primary risk remains the uncertainty surrounding COVID-19's epidemiology over the 2023/24 winter period, with the potential for new sub-types and variants. In turn, this means vaccine effectiveness against hospitalisations and deaths, and therefore the benefit of vaccination is uncertain. The benefit of vaccination could be higher if the vaccine offered for autumn 2023 is a good match for the dominant circulating subvariant, and if prior hybrid immunity against this subvariant is low. The latter would increase the vaccine's incremental/relative vaccine effectiveness, which is the additional protection the vaccine offers, in turn increasing the number of averted hospitalisations and deaths.
151. Furthermore, the NNV estimates are uncertain owing to uncertainty in vaccine effectiveness and future COVID-19 rates, alongside difficulties in reliably identifying all COVID-19 related health outcomes. This means estimates of benefits are uncertain, as are any estimates of benefits of vaccines going forward. This is mitigated by modelling an uncertainty and high benefits scenario, corresponding to a doubling and halving of QALY benefits.

Uncertainty in role of vaccines on post-COVID syndrome

152. JCVI's statement says "*There remains considerable uncertainty regarding the prevalence and health impact of sequelae reported following acute COVID-19 infection. Case-control studies have provided more robust data than the initial cohort studies, but the high prevalence of most of the reported persistent symptoms among cases and controls complicates any firm attribution of causality to the initial SARS-CoV-2 infection. Until more and better data are available, the impact of vaccination on the risk, progression and/or outcome of post-COVID syndromes remains difficult to assess or quantify objectively*".
153. In addressing post-COVID-19 syndrome, this Impact Assessment has attempted to include a plausible estimate of the impact of booster vaccines on post-COVID syndrome following hospitalisation, though due to the challenges in quantification this is an uncertain estimate. To mitigate this, we have included sensitivity analysis on the duration of post-COVID-19 syndrome.
154. In this Impact Assessment we have not appraised the benefit of preventing post-COVID syndrome in patients who are not hospitalised due to the challenge of quantifying this benefit, the scale of which is unknown. This has therefore been denoted as a non-monetised benefit.

Deployment Costs

155. The deployment cost per dose used is uncertain. We have modelled a range of £10 to [redacted] [average deployment cost] per dose, with £10 corresponding to the GP fee for routine immunisations and [redacted] being the historical COVID-19 deployment cost per dose when including all capital and one-off costs of setting up a pandemic response programme. £10 per dose is assumed as the marginal deployment cost, that is the additional cost to vaccinate one further individual. This is a wide range and makes it challenging to ascertain which cohorts are cost-effective.
156. Actual deployment costs will depend on factors including the timing of the programme and the opportunities to co-administer with flu vaccines. These factors

and the planning will be firmed up over the summer of 2023.

Definition of the at-risk group

157. The at-risk group currently defined in the UKHSA Green Book is a broad category that includes a wide range of clinical conditions. These conditions are noted by JCVI as being highly heterogeneous, with risks of serious disease varying substantially between clinical risk groups. Further disaggregation has not been possible at this time, but it would be desirable to evaluate the separate risk groups separately for future decisions on COVID-19 vaccines.

Unintended consequences

158. There may be unintended consequences from this policy. For example, utilising this non-standard JCVI cost-effectiveness methodology might lead to manufacturers setting their prices in future negotiations with the UK Government on a different basis to what they otherwise might have done, making vaccines cheaper or more expensive. This risk may have been reduced by not publishing any information that would disclose the decision-making process in JCVI or HM Government. However, it is in the public interest to provide transparency on the decision-making process due to improving confidence in these institutions and the decisions made by them. This risk is likely to be small as COVID-19 vaccines are procured under strict rules to ensure competition, and in addition there are many manufacturers of COVID-19 vaccines who may compete in bidding for new contracts.

Conclusion

159. This Impact Assessment details a one-off cost-effectiveness methodology that has been developed by DHSC analysts to be applied specifically to the autumn 2023 booster decision. This is an adaptation of JCVI's standard cost-effectiveness methodology for evaluating vaccines.

160. The analysis presented here was also shared with JCVI prior to them formulating their advice. This cost-effectiveness assessment was one of the factors considered by JCVI in the formulation of its advice for autumn 2023. They have concluded their advice to ministers. We have evaluated this option and two other options, one with a narrower eligibility and one with a broader eligibility.

161. The analysis shows there is significant uncertainty in many of the key aspects that determine which option would be preferable in terms of having the greatest net monetary benefit. The two most important uncertainties to influence the cost-effectiveness and net monetary benefit are (1) deployment costs, and (2) uncertainty in COVID-19 epidemiology.

162. Our results show that:

- A) Option 2 (narrower eligibility) has the highest net monetary benefit across all three epidemiological scenarios. It is the most cost-effective option.
- B) Option 1, accepting JCVI's advice, has the second highest net monetary benefit across all three epidemiological scenarios

- C) Option 3 (wider eligibility) does not have the highest net monetary benefit in any scenario modelled. It only has a positive net monetary benefit in the 'High benefits' scenario.

163. In this Impact Assessment, due to the challenges of quantifying COVID-19's potential future risk and health impacts, we do not specify a preferred option. The analysis indicates that Option 1, of accepting the JCVI advice, is cost-effective overall (although it includes some cohorts who are not cost-effective in isolation), with a positive net monetary benefit in the most plausible scenario. Option 2 is the narrowest modelled option and strictly adheres to cost-effectiveness by stratifying cohorts by age and clinical risk status- atypical of the COVID-19 vaccine programme. Option 2 is the most cost-effective option and has the highest net monetary benefit in each epi scenario. It has lower deployment costs and presents a higher net monetary benefit than accepting the JCVI's advice. However, owing to the uncertainty, risks and additional health impacts of COVID-19 which have not been quantified, it is plausible that vaccinating more individuals could be cost-effective. Therefore, Government could justify the non-cost-effective cohorts in Option 1, or proceed with Option 3, on the precautionary basis of uncertainty in COVID-19's risks and to protect the NHS over winter 2023/24. All options are considered implementable.

Option 0: no autumn 2023 programme

164. Government can proceed with Option 0, of no autumn 2023 booster programme. This is the lowest net cost option and hence would release the most savings to spend on other health interventions. By definition this has zero net monetary benefit. However, some options have a positive net monetary benefit (NMB): Option 1 (to follow JCVI advice) has a positive NMB in the "most-plausible" and "high benefit" scenarios and Option 2 has a positive NMB in each of the epi scenarios.
165. In addition, although this is modelled as having zero cost, at this stage in the planning cycle preparations have had to be made for an autumn programme. There have been investments which could not be recouped if no vaccination is undertaken. The size of this commitment is not known, but were this factored in, it would make Option 0 even less favourable compared to the other three options. This option would represent an unprecedented departure from JCVI advice and risks significant negative health impacts alongside reputational risks for the COVID-19 vaccination programme. If Government decides to reject the JCVI advice and not offer vaccination, in the absence of a strong rationale, the risk of any challenge by way of judicial review being successful would be high.

Option 1: accept JCVI advice

166. Option 1 is cost-effective overall. This age-based option has a positive net monetary benefit (NMB) in the "most plausible" and "high benefits" epidemiological scenarios. JCVI advise on an age-based approach for those aged 65 years and above. This group are cost-effective when those in a clinical risk group and those not in a clinical risk group are assessed together.

167. However, JCVI advice includes some cohorts who are not cost-effective in isolation at the marginal £10 deployment cost per dose according to this analysis. These cohorts are adults aged 65-79 who are not in a clinical risk group and at-risk (exc. the immunosuppressed) persons below 45. The inclusion of these groups could be justified on a precautionary basis, given there are circumstances when vaccinating these additional groups could be justified:
- A) If the marginal costs are found to be lower than the assumed £10 per dose (the results suggest a stated willingness to pay of less than £10 per vaccinated person for these non-cost-effective groups).
 - B) If there are significant unquantified health benefits from vaccination, such as reduction of Post COVID-19 syndrome or if reducing NHS pressures during winter could avoid tipping the system into over-capacity which would have significant additional impacts on patients across the system.
 - C) If there are judged to be risks of a more significant wave of COVID-19 than the modelled scenarios.
 - D) If eligibility based on a universal age-based programme results in better uptake in the at-risk groups as compared to them being eligible only based on their clinical risk¹⁶.
168. There may also be programme-wide benefits of following the JCVI advice:
- A) Aligning with JCVI advice will help maintain public confidence in the programme if Government accept JCVI advice, which in turn supports uptake of the programme in the eligible cohorts.
 - B) If changes to the programme happen at a measured pace, this might maintain long-term confidence in the programme and avoid any reversal of decisions should risks be found to be greater at some point in the future.

JCVI's rationale for supporting Option 1

169. JCVI considered a range of evidence in informing their decision, including the cost-effectiveness analysis presented here. Given that there are potential benefits that the cost-effectiveness analysis cannot quantify, JCVI judged Option 1 to be the preferred option.
170. JCVI's rationale for choosing Option 1 over Option 2 (which they refer to as "a fully incremental assessment") is as follows:
- "Given the high proportion of older adults with comorbidities and the higher uptake seen in universal age-based programmes, JCVI considers that for autumn 2023, it is appropriate to offer vaccination to all adults aged 65 years and over. While not a fully incremental assessment, as would be standard [which Option 2 would have been], it is considered appropriate to take such an approach during the current pandemic recovery phase due to the uncertainties in the NNV and cost-effectiveness assessment estimates, and because of the expected additional benefits of reducing winter pressures on the NHS."*
171. JCVI advice justifies offering a vaccine to not-at-risk adults aged 65-79, who are not cost-effective in this analysis, on the basis that higher uptake is seen in universal age-based programmes. The advice also justifies the inclusion of at-risk

¹⁶ For example, the seasonal flu vaccine programme has greater uptake in the adult groups who are eligible due to their age, than those adult groups who are eligible due solely to their clinical risk group. However, this difference in uptake could be explained by other factors such as older individuals being more likely to take up a vaccine.

(excluding immunosuppressed) persons below 45, who are not deemed cost-effective in the quantification presented here, on the basis that further stratification of risk groups would increase the programme's complexity and could negatively impact uptake.

172. JCVI do not explicitly justify why they have chosen Option 1 over Option 3 (remaining with the same groups as the autumn 2022 booster programme) but choosing to do so is consistent with them considering cost effectiveness as an important contributing factor to this decision.
173. In summary, JCVI advising Option 1 is a step towards a more cost-effective programme while also being precautionary given the limitations and uncertainty of the cost-effectiveness analysis and to protect the NHS over winter 2023/24. Hence the Government can choose to proceed with the broadly cost-effective Option 1, over the more cost-effective Option 2, on a precautionary basis.

Option 2: narrower autumn 2023 booster programme

174. In this option, to offer vaccines only to cost-effective cohorts at the marginal £10 per dose deployment cost, strictly adheres to cost-effectiveness by stratifying cohorts by age and clinical risk status, as opposed to the broader definitions of eligibility in Option 1. This stratification is atypical of the previous COVID-19 vaccine programmes, but in line with the standard methodology adopted by JCVI. Compared to Option 1, not at-risk adults aged 65-79 and at-risk (excluding immunosuppressed) persons below 45 are no longer eligible for a booster. In this assessment of cost-effectiveness, Option 2 is the most cost-effective option, with the highest net monetary benefit across all the modelled epidemiological scenarios.
175. Government can therefore proceed with this option on the basis that it is likely to be the most cost-effective option and if Government is content to take a less precautionary approach than JCVI. There are likely to be some negative consequences of taking a different and unprecedented approach to JCVI. Primarily, in the absence of a strong rationale, the risk of any challenge by way of judicial review being successful would be high. Further, as noted in JCVI advice, Option 2 increases the complexity of the COVID-19 vaccine programme and could have lower uptake than in an age-based programme, such as Option 1. Finally, there may be a potential consequence on public health messaging, which would need to be carefully managed.

Option 3: expanded autumn 2023 booster programme

176. This option involves offering a booster to the same cohorts as in the autumn 2022 programme. This means the 50-64s who are not at-risk would be eligible.
177. Government can proceed with this option, on the basis that Government is content to take a more precautionary approach than JCVI, noting the risks, uncertainty and wider impacts of COVID-19 in autumn 2023 may be more severe than anticipated in this analysis. However, it would represent an unprecedented departure from JCVI advice and therefore carries a reputational risk, albeit a smaller risk than proceeding with Option 0 or 2. Being the largest programme, Option 3 has the greatest unquantified benefits which include protecting NHS capacity in winter and

preventing long COVID-19 in the community, but comes at the highest cost and has a negative Net Monetary Benefit in the “most plausible” scenario.

Impacts to businesses

178. There is no direct nor indirect regulatory cost nor benefit to businesses. There are no direct impacts expected, noting this Impact Assessment does not analyse the procurement of COVID-19 vaccines.

Operational risks

179. Beyond the decision risks, there are operational risks that this programme does not deliver the expected benefits within the costs estimated.
180. Given that there is surplus vaccine supply, there is no significant risk from vaccine wastage. However, spend on deployment could be wasted if there is low uptake of available appointments. This means some fixed costs of deployment are spread across fewer vaccines delivered. This raises the cost per dose and reduces cost-effectiveness.
181. Some factors that influence the benefits of the programme are:
- A) Which vaccine is deployed – JCVI will decide this in June 2023
 - B) Timing of vaccine to maximise protection of the most vulnerable during the season of high social mixing (around Christmas time) when there are many indoor social gatherings. The intention is to optimise timing, if at all possible, without being at the cost of uptake.
182. There are also operational risks that are beyond our considerations here. An important risk relates to future vaccine cost-effectiveness assessments for other immunisations. There remains a risk of setting a precedent for other vaccine analysis by including the wider benefits of elective care. This departs from the standard cost-effectiveness approach. We have mitigated this risk by noting this approach is a one-off specific approach to the COVID-19 autumn booster programme. This approach is not indicative of the approach DHSC is to take for future vaccine analysis, both for COVID-19 and other vaccines.
183. The coadministration of some COVID-19 and flu doses may lead to a lower deployment cost per dose. This cost is unknown and not appraised. However, we do not expect it to be below the lower threshold of £10 per dose used in this analysis.
184. Finally, payments could be required in the rare possibility of an adverse reaction to a COVID-19 vaccine. Individuals can access financial assistance through the Vaccine Damage Payments Scheme (VDPS). This cost has not been factored into this analysis.

Monitoring and Evaluation

185. UKHSA surveillance data monitors rates of COVID-19 admissions and ONS records deaths due to COVID-19. Using this data, and developing published literature, JCVI will continue to consider COVID-19 booster eligibility for future campaigns. As COVID-19 transitions from pandemic to endemic, and the

purchasing of COVID-19 vaccines can be done with a shorter lead time whilst securing supply, the programme would be expected to become a routine programme. JCVI would need to consider the cost-effectiveness evidence in order to ensure their recommendations meet standard criteria, in line with other vaccination programmes.

Annex A: Overview of the standard JCVI cost-effectiveness methodology

186. JCVI's cost-effectiveness methodology is detailed in its 2013 Code of Practice¹⁷. Cost-effectiveness is a form of health economic evaluation that analyses the health benefits relative to the costs of a vaccination policy. JCVI's standard methodology is largely aligned with that of the National Institute for Health and Care Excellence (NICE) health technology evaluations, although, there are several key differences between them.
187. Key features of the JCVI standard methodology are outlined below in Table A1 and discussed below in further detail.

Table A1: Key features of JCVI's standard methodology

| Key feature | Approach |
|--------------------------------|--|
| Perspective on benefits | Direct for patient and indirect for the population, measured in QALYs |
| Perspective on costs | Costs for the healthcare system (NHS) |
| Time horizon | Lifetime of the vaccinated population (often up to 100 years) |
| Discount rate | 3.5% for costs and health benefits |
| Summary measure | Main measure of cost-effectiveness is the Incremental Cost Effectiveness Ratio (ICER), measured as £ per QALY, and compared to the cost-effectiveness (CE) thresholds (below). |
| CE Threshold | Most plausible ICER is assessed at £20,000 per QALY "Uncertainty" ICER is assessed at £30,000 per QALY Both conditions should be met |

Perspective on benefits

188. The perspective for benefits is for health benefits only. The cost-effectiveness methodology does not permit the appraisal of non-health benefits. This means non-health benefits of vaccination to the individual and society, such as to economic productivity, are not assessed.
189. The clinical outcome measures assessed relate to impacts of the vaccine on mortality and morbidity, typically measured in quality of life (QoL) and adjusted by the duration of the outcome to determine quality adjusted life years (QALYs).
190. One QALY represents a year of perfect health, and QALYs are valued equally. That is, they are not weighted depending on to whom they accrue. By measuring the difference in the health and life expectancy, from those who suffer the illness

¹⁷ [Link to JCVI Code of Practice](#)

and those who do not, we can estimate the QALYs gained from vaccination. QALYs are used as a standardised measure to compare the severity of different diseases and the benefits of health interventions.

191. JCVI's Code of Practice states the 'perspective on outcomes should be all direct health effects, whether for patients or, when relevant, other people (principally carers)'. Within scope of QALY estimates are both the positive benefits from vaccination and the negative health benefits in terms of side effects following vaccination, though these are often considered sufficiently minor to justify exclusion.
192. The Code of Practice also permits the appraisal of indirect health benefits to the unvaccinated population. One way this occurs when vaccinated individuals reduce the spread of the virus, thereby protecting unvaccinated members of society. These unvaccinated members of society therefore avoid a QALY decrement which can be valued in the same way as the direct health benefits.

Perspective on costs

193. JCVI's Code of Practice states 'the perspective adopted on costs should be that of the NHS and Personal Social Services'.
194. Typically, when evaluating the cost of vaccines, we consider the cost to deploy or administer the vaccine by the NHS. We also consider the cost of purchasing the vaccine. This cost is a commercially sensitive piece of information and is not presented to JCVI. Instead, JCVI may consider the cost-effective price per dose of the vaccine for the given cohort. The combination of the deployment cost and purchase cost determines the total cost of the vaccination programme.
195. We do not assess the cost to the individual to be vaccinated, such as the time cost or financial cost to attend their appointment. The perspective on costs relates to financial costs, net of any savings.
196. We evaluate savings to the healthcare system from vaccination. As for NICE, the scope of these savings is that to the NHS and Personal Social Services. Typically, this includes preventing hospitalisations for an infected individual and/or the cost to provide remedial treatment to the individual, such as drugs and rehabilitative care. These costs are intended to be comprehensive, for example including staff time, a contribution to overheads, and the cost of any health treatments. These healthcare savings are subtracted from gross vaccination costs to identify the total net vaccination cost.

Time horizon for appraisal of costs and benefits

197. JCVI's Code of Practice is not explicit on the time horizon to be taken to assess costs and benefits of vaccination. However, it generally seeks alignment with NICE's health technology evaluations. Therefore, to be aligned with NICE, the time horizon taken is to 'be sufficiently long to reflect all important differences in costs or outcomes between the technologies being compared'.

198. Noting that vaccines have an impact over a vaccinated individual's lifetime, a lifetime (often approximated as 100 years) is considered an appropriate time horizon. This does not mean it needs to model 100 years of an intervention: it might only model as short as one round of an intervention, but it will count health impacts that happen far into the future of those interventions.

Discount rate

199. A discount rate of 3.5% is used in JCVI's cost-effectiveness methodology to ensure consistency with NICE. NICE use the 3.5% discount rate based on the recommendations of UK Treasury (HMT). Discounting is applied to future costs and benefits to convert them into a present value. This is important because costs and benefits can occur at different points in the future, and therefore discounting enables a fair comparison of costs and benefits. Further information on discounting and the components of the 3.5% discount rate can be found in HMT's Green Book, Annex A6.
200. The 3.5% discount rate is a specific discount rate agreed with HMT to use for NICE and JCVI's cost effectiveness assessments and differs from the 1.5% discount rate used for health values that DHSC applies to most health interventions when following standard evaluation methods, in line with HMT Green Book's recommendations. The 3.5% discount rate is also used in NICE's health technology evaluations.

Summary measure

201. The summary measure used is the incremental cost-effectiveness ratio (ICER), which is calculated in terms of the cost per QALY. The ICER compares one possible intervention to another. The comparison option, also known as the counterfactual, can be an alternative vaccination approach or no vaccination at all. The ICER is determined by calculating the net cost difference between the option being evaluated and the counterfactual, then dividing by the net health difference between the two options.
202. Vaccine programmes should be analysed in an incremental approach where there are meaningful increments of policy. This might mean starting appraisal of an option to vaccinate the most cost-effective cohorts only, such as the most at-risk; and thereafter the ICER is evaluated for policy options involving adding additional cohorts to the programme and comparing to the thresholds. This is to ensure the increased cost is justified by the additional health benefits. In this example, the incremental approach supports the decision maker in identifying a cohort cut-off for vaccination, but in other policies the incremental approach might be applied to decide on the type of vaccine to administer, the timing of doses, the number of doses and more.

Cost-effectiveness threshold

203. The incremental component of a vaccine programme is cost effective if its ICER is below the thresholds specified in the methodology.

204. There are two thresholds, both of which need to be met:
- A) £20,000 per QALY for the central or most plausible estimate
 - B) JCVI generally considers that ‘a vaccine should not be accepted as cost-effective if there is an unacceptably high chance that its ICER (adjusted as appropriate) exceeds £30,000’
205. These thresholds align with NICE who have an ICER threshold range of £20,000 to £30,000.
206. JCVI’s Code of Practice notes the £20,000 figure “reflects the current estimate of the opportunity cost elsewhere in the NHS of allocating resources to the programme in question from a fixed NHS budget”. The opportunity cost is a distinct concept to the cost-effectiveness threshold. The cost-effectiveness threshold is the maximum cost government is willing to pay to gain one extra QALY. It is used as a rule by decision makers and is informed by the opportunity cost of expenditure.
207. This threshold means that an incremental change to a vaccine programme must be expected to not cost more than £20,000 to gain a QALY. If the change to the vaccine programme is evaluated to exceed the £20,000 per QALY threshold, it will theoretically displace superior health interventions and fail to maximise public health.
208. JCVI’s Code of Practice also suggests JCVI should ‘consider the degree of certainty in that ICER’. This uncertainty can arise through uncertainty in how to model epidemiology and uncertainty in the value of parameter inputs into the model. Noting that NICE has a threshold ranging from £20,000 to £30,000 per QALY, JCVI generally considers that ‘a vaccine should not be accepted as cost-effective if there is an unacceptably high chance that its ICER (adjusted as appropriate) exceeds £30,000.
209. To assess this, JCVI typically considers whether there is ‘more than a 10% likelihood that the ICER might exceed £30,000’. Although the 10% is not a technical parameter, it serves as a reasonable recommendation and starting point. This modelling occurs in JCVI’s ‘uncertainty case’. This is a separate scenario to the ‘most plausible case’ discussed above. By modelling the ‘uncertainty case’, JCVI has confidence that given the uncertainty, the risk of the programme being not cost-effective is acceptable. Simply put, that JCVI are ‘almost sure’ that the vaccine offers a positive net health benefit.
210. ICERs are modelled for the ‘most plausible case’ and ‘uncertainty case’ and tested against the respective £20,000 and £30,000 per QALY threshold, with both conditions needing to be met.

Application of the methodology

211. JCVI applies this cost-effectiveness methodology to assess which cohorts are cost-effective, to inform their advice. There may be relevant non-quantifiable costs, benefits, and risks for a vaccination programme. In some cases, these are considerable and are therefore brought into the decision-making process. This might mean the conclusions from the standard methodology are not strictly adhered to by JCVI and/or by Government. In these instances, a clear rationale for departure is provided by JCVI and/or Government.

Annex B: Estimating QALY benefits for avoided COVID-19 fatalities

212. QALYs are used to measure the health state of an individual in terms of length of life, adjusted for the quality of life (QoL). One QALY represents one year of life in perfect health. When estimating QALYs from a direct COVID-19 death, we consider the expected years of life an individual would have remained, and the QoL they were expected to have.
213. To calculate QoL, we use data from the Health Survey for England (HSE) 2017. The HSE asked adults 16 and over to complete the EQ-5D-5L, a tool used to describe an individual's health state based on 5 dimensions; mobility, self-care, usual activities, pain/discomfort and anxiety/depression.
214. We utilise QoL for individuals with at least one comorbidity. Certain co-morbidities are especially common in those who contract COVID-19, including heart disease and respiratory illnesses including asthma, and diabetes. These diseases are chronic and have a significant effect on QoL. In the absence of COVID-19, individuals with these conditions would not have experienced a QoL of 1 corresponding to perfect health. The risk profile of individuals is therefore accounted for when estimating harms.
215. ONS life expectancy data for individuals with 2 comorbidities is used for each age/gender group. For the 2017 HSE cohort we generated a quadratic best-fit line to the average QoL by age (in single years). Combining life expectancy data and the average QoL by age band, we estimate the average discounted QALYs for a COVID-19 death in each age and gender group. QALYs are discounted at 3.5%, as per JCVI methodology. The methodology and assumptions used to estimate the QALYs gained from averting a COVID-19 death are largely consistent with those used in a joint piece of work between DHSC, ONS and GAD in a commission by SAGE in December 2020.

Annex C: Costs and benefits of vaccinating frontline health and social care workers; household contacts of people with immunosuppression; and carers

Summary

216. In the main body of this Impact Assessment, we explored the cost-effectiveness of clinical and age-based groups. In this annex, we focus on the remaining groups included in JCVI advice. This is because cost-effectiveness was not considered by JCVI and did not inform their advice. These additional groups are:
- Residents in care homes for older adults
 - Frontline health and social care workers
 - Persons aged 12 to 64 years who are household contacts of people with immunosuppression
 - Persons aged 16 to 64 years who are carers
 - Staff working in care homes for older adults
217. We estimate the total doses to be deployed to these cohorts to be 1.6m million. At average deployment costs of █████ per dose, this is an estimated █████ cost of deployment.
218. The benefits of these groups are more difficult to assess, and a cost-effectiveness analysis has not been done for these groups, so it is not possible for us to provide a verdict on their cost-effectiveness. On the one hand, these groups are unlikely to be evaluated as cost-effective since they are not considered to be at significantly greater risk from COVID-19 compared to the general population and the additional benefit of preventing onward transmission to individuals they care for is expected to be small, since the vaccine's relative effectiveness against transmission is weak and short lasting. Further, our assessment of the potential impact of vaccines on sick days due to COVID-19 is that this impact is likely to be small. However, given the lack of explicit quantification of the impact on onward transmission and owing to additional unquantified benefits (which are discussed further below) we cannot assess the likelihood of these cohorts being cost-effective.
219. Government can choose to follow JCVI advice and offer vaccination to this group, or offer vaccination to a subset, or choose not to vaccinate these groups.

Cohort size and uptake

220. Table C1 below has estimates for cohort sizes and uptake of these groups. We deduplicate the cohort sizes of these groups from the eligible clinical risk and age groups modelled in the main body of this Impact Assessment. We do this by removing individuals in these groups who are aged 65 and above and those at clinical risk from COVID-19. Without further data on the clinical risk status of these groups, we assume they have the same proportion as the English population. Analysis of NIMS data suggests 34% of the English population are aged 65 and over, or in a clinical risk group for COVID-19. We adjust this estimate by the same percentage to reach a de-duplicated estimated of this cohort. This adjustment avoids the double counting of costs and benefits from those modelled above.

221. Data on uptake of the autumn booster 2022 suggests there was approximately 20% uptake in the eligible social care workers and 50% in the eligible healthcare workers¹⁸. There are no available data sources for uptake in the remaining categories. In the absence of further data, we assume that uptake is 35% and we perform sensitivity around 20% to 50%.

Table C1: Analysis of the frontline health care workers, social care workers, carers and household contacts of the IS

| | Frontline health and social care workers ^{19, 20} | Persons aged 12 to 64 years who are household contacts of people with immunosuppression ²¹ | Persons aged 16 to 64 years who are carers ²² | Total |
|--|--|---|--|---------------------|
| Cohort Size | 2.1m | 0.2m | 3.5m | 5.9m |
| Deduplicated cohort size (individuals aged below 65 who are not at clinical risk from COVID-19) | 1.4m | 0.2m | 2.9m | 4.5m |
| Vaccines delivered | 0.5m (0.3m-0.7m) | 0.1m (0m-0.1m) | 1m (0.6m-1.4m) | 1.6m (0.9m-2.2m) |
| Total cost of vaccination (deployment cost of █████ per dose) | █████ █████ | █████ █████ | █████ █████ | █████ █████ |

222. Assuming an average deployment cost of █████ per dose, we estimate the total additional cost to offer approximately 1.6m million vaccines to this cohort is approximately █████ as a central estimate and expected to range from █████.

Residents in care homes for older adults

223. We assume that there are a negligible number of residents in care homes for older adults who are below the age of 65. The latest published data from January 2023²³ suggests there are approximately 330,000 individuals aged 65 and above in a care home for older adults. 'Older adult care homes' are defined here as care homes serving any older people (aged 65+) as identified from the latest Care Quality Commission data on care homes in the Older People Service user band. Since

¹⁸ COVID-19 Weekly announced vaccinations 26 January 2023

¹⁹ Frontline Health Care Workers (HCW) Date of publication (31 December 2022)

²⁰ COVID-19 Weekly announced vaccinations 26 January 2023

²¹ Based on unpublished data

²² Unpaid care by age, sex and deprivation, England and Wales - Office for National Statistics (ons.gov.uk)

²³ Residents of Older Adults (OA) Care homes; Date of publication (26 Jan 2023)

these individuals are aged 65 and over, they are already included in the JCVI advice. Although there may be a few individuals who are not included in those groups, we assume the numbers are small.

Frontline health and social care workers; and all staff working in care homes for older adults

224. There are an estimated 1,180,000 front line health care workers, consisting of clinical staff and support to clinical staff.
225. For frontline social care workers, the UKHSA Green Book Chapter 14a defines this group as including: *'those working in long-stay residential and nursing care homes or other long stay care facilities where rapid spread is likely to follow introduction of infection and cause high morbidity and mortality. It also includes other front-line social care workers who regularly provide close personal care to those who are clinically vulnerable'*.
226. We therefore model frontline social care workers to also include staff working in a residential care home for older adults (490,000), younger adults (90,000) and domiciliary care staff (430,000). This may include some non-frontline staff, that is staff who are not involved in face-to-face contact with patients during their duties.
227. JCVI advice specifically includes staff working in care homes for older adults as well as frontline social care workers. Within the estimate provided above of frontline social care workers we have included within this all staff working in care homes for older adults, therefore this does not need a separate estimate.
228. The total cohort size for frontline health and social care workers of 2.1m is adjusted to be 1.4m individuals who are aged below 65, and not at clinical risk from COVID-19.

Household contacts of people with immunosuppression, aged 12-64 years

229. This total cohort size estimate of 0.24m is provided by NHS England based on case finding exercises performed earlier in COVID-19 vaccine deployment.

Persons aged 16 to 64 years who are carers

230. ONS census data estimates there were 4.7 million unpaid carers in England on census day 2021 of whom 3.5 million are aged 18 to 64 years. We are unable to assess how many carers are aged 16 to 64. This is adjusted to be 2.9m carers aged 16-64 who are not in a clinical risk group for COVID-19.

Benefits

231. COVID-19 vaccines provide protection against severe disease and death; however, these individuals are no longer considered to be at much greater risk of severe COVID-19 compared to the rest of the population. They are also not considered to be at significantly greater risk from a mild infection of COVID-19 compared to the general population. The rationale for including them is the benefit of preventing onward transmission to individuals they care for. COVID-19 vaccines

provide some protection against infection, so must provide some benefit against transmission, even if modest.

232. Vaccine effectiveness against onward transmission is very uncertain so no modelling is possible to quantify this benefit. The latest available UKHSA estimate of relative vaccine effectiveness against symptomatic disease is 30% from month 0 to 1 and to decline to 0% by the end of month 6, however this estimate has low confidence²⁴. JCVI acknowledge that the vaccine's relative effectiveness against transmission is weak and short lasting.

Wider benefits

233. For frontline health and social care workers (HSCW) and carers, JCVI state that "There remains potential benefit in offering vaccination to HSCWs in order to protect health services from staff absences due to COVID-19 during the winter months."
234. By preventing staff absence due to COVID-19 infection, offering a vaccine to these groups could protect the resilience of health services in the winter months when the NHS is at risk of being overwhelmed. Latest published data from 5 April '23 gives the rate of COVID-19 related absences among healthcare workers to be 0.4%²⁵, and only 20% of these are estimated to be PCR-positive at the time of absence²⁶ (it is unclear what the reasons are for the remainder absences, this might be due to a range of issues including long-lasting symptoms of prior infections).
235. Given the estimate of vaccine effectiveness against infection, vaccines are expected to have only a very modest impact on staff absences. Although the equivalent data was not available for social care workers, we would expect booster vaccines to also have a very modest impact on staff absences. This potential benefit across both groups is therefore small unless there is a very significant COVID-19 wave of infections; or if they contribute to preventing the NHS and social care system tipping into overcapacity where the impacts are significantly amplified.
236. Equivalent analysis has not been performed for informal carers. However, informal carers may be less able to be replaced as paid staff if unable to perform their caring responsibilities. This may have a significant impact on some vulnerable individuals, thereby being a potentially significant benefit at an individual level.
237. An additional rationale to proceed with offering a vaccine to health and social care workers (HSCWs) is outlined in JCVI's advice. This notes 'Whilst vaccines are still only available through nationally funded mass vaccination programmes, JCVI considers it is appropriate to continue the offer of vaccination in HSCWs for autumn 2023'.
238. JCVI's rationale given for vaccinating otherwise healthy household contacts of immunosuppressed individuals is due to "the high risk of severe COVID-19 amongst immunosuppressed individuals, and the limited protection that

²⁴ [Link to UKHSA COVID-19 vaccine quarterly surveillance reports](#), Week 23

²⁵ NHS Digital Workforce Statistics

²⁶ Internal estimate based on unpublished sources

immunosuppressed persons gain from vaccination themselves”. Therefore, offering a vaccine to household contacts of immunosuppressed individuals may provide the best protection to the highly vulnerable immunosuppressed cohort. This could provide wider benefits to these household contacts, such as peace of mind and enabling them to reduce protective measures, such as isolating.

239. Noting the challenges in modelling benefits for these cohorts, no cost-effectiveness analysis was presented to JCVI. Cost-effectiveness analysis did not inform the decision to include these groups and estimates of the benefits from vaccinating these groups are not available.
240. Government can choose to follow JCVI advice and offer vaccination to these groups, or offer vaccination to a subset, based on a precautionary approach; or choose not to vaccinate these groups.

Annex D: JCVI advice on changing the primary course offer to a single dose

241. JCVI advised on changing the primary course offer from two doses to a single dose. This change will apply to those who are eligible for the autumn booster 2023 campaign, as it has already been established that the primary course offer is only open to those eligible for the autumn booster programme.
242. To analyse this, we appraise two options for England. In Option 0, we consider a 'do nothing' approach where the primary course offer would remain unchanged at two doses. This option forms the counterfactual. In Option 1, we consider accepting JCVI advice to utilise a single dose for the primary course.

Cohorts affected

243. JCVI's advice will affect the groups eligible for an autumn 2023 booster. Their advice is to offer vaccines to:
- Residents in a care home for older adults
 - All adults aged 65 years and over
 - Persons aged 6 months to 64 years in a clinical risk group
 - Frontline health and social care workers
 - Persons aged 12 to 64 years who are household contacts of people with immunosuppression
 - Persons aged 16 to 64 years who are carers
 - Staff working in care homes for older adults
244. For this cost-effectiveness analysis, we only consider adults aged 65 years and older. This is because published data does not stratify uptake of the second dose by JCVI cohorts. This means the impact of the change to partially vaccinated at-risk cohorts aged below 65 years old is not possible to ascertain.
245. This exclusion may not significantly impact results. Firstly, since the cohort size of at-risk individuals below 65 years old is relatively small. Secondly, this cohort is likely to already have had their second dose, owing to their increased risk from COVID-19, and therefore would not be significantly affected by this change.
246. Table D1 based on published UKHSA²⁷ data indicates that as of May 2023, approximately 79,000 individuals aged 65 and over have had 1 dose but not had a second dose of the COVID-19 vaccine. These individuals are in scope of the JCVI advice, although not all of these partially vaccinated individuals would choose to come forward for a second dose. It is likely that only a small subset of these individuals would choose to come forward for their 2nd dose, noting the time individuals have had to come forward.

Table D1: Individuals who have not had one dose but not a second dose

| Age cohort | % Uptake (2 doses) | Individuals vaccinated with 1 dose only (yet to have 2 nd dose) |
|------------|--------------------|--|
| 65-69 | 92% | 30,000 |
| 70-74 | 94% | 21,000 |
| 75-79 | 96% | 14,000 |

²⁷ Link to [National flu and COVID-19 surveillance data report: 25 May 2023 \(week 21\)](#)

| | | |
|--------------|-----|--------|
| 80+ | 96% | 15,000 |
| Total | - | 79,000 |

247. Data from the Coronavirus dashboard²⁸ indicates approximately 1,100 individuals aged 65 and over are coming forward per month for a second dose of the COVID-19 vaccine in England. Assuming this trend continues for the remaining 12 months, approximately 13,200 second doses would be delivered, as shown in Table 5 below. Consequently, the number of individuals who have not had a second dose after their first would fall from 79,000 to 66,000. This is an optimistic uptake assumption because uptake tends to decline over time since those who are more willing to receive their second dose come forward earlier. Nevertheless, over one year, the move to a single dose for the primary course is expected to impact approximately 13,200 individuals aged 65 and over.

Cost Saving

248. Option 0 of making no change to the primary course offer incurs a total annual cost of [REDACTED]. This is solely a cost for deploying the vaccine and is based on the average deployment cost per dose which is estimated to be [REDACTED] per dose. Therefore, if choosing to accept JCVI advice in Option 1, changing the primary course offer from two doses to a single dose, Option 1 results in a financial cost saving of [REDACTED].

Table D2: Change to the primary course

| | Option 0: do nothing | Option 1: accept advice |
|---|-------------------------|----------------------------|
| Second doses delivered per month | 1,100 | 0 |
| Second doses delivered over 12 months | 13,200 | 0 |
| Total deployment cost to deliver second doses over 12 months ([REDACTED] deployment cost per dose) | [REDACTED] | £0 |

²⁸ Source: [Coronavirus Dashboard](#), new people vaccinated for a 2nd dose by vaccination date. Average of March to May 2023 used.

Health impact

249. JCVI's advice includes evidence for unvaccinated individuals where a "single dose of vaccine given on a background of naturally acquired immunity (hybrid immunity) generates at least as good an immune response as two primary doses of vaccine". This suggests a single dose does not lead to worse protection against COVID-19 than two doses in a primary course offer.

Cost-effectiveness

250. The reduction in the primary course offer from two doses to one can save money by only needing to deploy the vaccine once to individuals. This reduces the total deployment cost for the primary course. This reduction in costs, combined with potentially little to no disbenefit for protection against COVID-19, suggests that JCVI's advice for moving to a single dose for the primary course is a cost-effective measure. Although, in the absence of epidemiological modelling, we cannot quantify this further.