Title: Health Protection Notification Regulations 2010: consultation

IA No: 9611

RPC Reference No: N/A

Lead department or agency: DHSC

Other departments or agencies: UKHSA

Impact Assessment (IA)

Date: October 2023

Stage: Consultation

Source of intervention: Domestic

Type of measure: Secondary Legislation

Contact for enquiries:
hpnrconsultation@dhsc.gov.uk

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 Health Protection (Notification) Regulations 2010 (HPNR) are a vital part of England's infectious disease surveillance system. They place a statutory duty on registered medical practitioners to report suspected or known cases of notifiable infectious diseases, listed in schedule 1 of the regulations. They also place a statutory duty on laboratories that test human samples to report positive test results of notifiable causative agents, listed in schedule 2 of the regulations. Causative agents are organisms and chemicals which directly, or indirectly, cause disease.

Although changes have been made to schedule 1 and 2 of the HPNR urgently to strengthen surveillance during outbreaks, including for COVID-19 and Monkeypox, a full review of the regulations has not taken place since 2010. This consultation and any amendments taken forward, will ensure that the regulations reflect current public health needs and can inform effective public health action at a local, national and international level.

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

The overarching objective of this work is to strengthen the HPNR to ensure they are fit for use in the current public health context. This in-turn will support better public health action.

To do this, three proposed amendments to the regulations have been put forward through a public consultation with the goal of understanding stakeholders' views. The three amendments are:

1. That seven infectious diseases could be added to schedule 1 (list of notifiable diseases) of the regulations.
2. That twelve causative agents could be added to schedule 2 (list of causative agents) of the regulations.
3. That laboratory reporting requirements should be expanded to include the reporting of negative and void test results, as well as positive results which are already required.

Notable indicators of success would be identifying outbreaks as they are occurring and using targeted public health action to tackle them. If proposal 3, expanding lab reporting requirements, were to be taken forward this would improve our understanding of testing trends and the evaluation of vaccine programmes. Where stakeholders don't agree, the consultation will provide insight into the barriers to implementing some changes.

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

Option 0: Do-nothing. Not review the regulations at this time and only add diseases to the regulations in emergency scenarios when complete surveillance is required. This would mean adding diseases without consultation and would be a reactive approach. Instead, proactively adding diseases to the regulations mitigates this risk, and facilitates a prompt and effective public health response.

Option 1: Proceed with all amendments. All seven infectious diseases would be added to schedule 1, and all twelve causative agents would be added to schedule 2, alongside expanded reporting requirements for laboratories.

Option 2: Proceed with all amendments other than additions of syphilis and gonorrhoeae (from a non-sterile site) to schedule 2. Including syphilis and gonorrhoeae (from a non-sterile site) in schedule 2 of the regulations may raise concerns around patient confidentiality. Moving forward with the other amendments but removing syphilis and gonorrhoeae (from a non-sterile site) could allow more time to review data collection for these sexually transmitted infections (STIs) while mindful of the risks of unintended consequences from data collection.

Option 3: Proceed with all amendments other than proposal 3 (expanded laboratory reporting requirements). We anticipate that stakeholders may raise concerns with proposal 3 as it will require some additional workload. The details of this will be worked through from consultation responses. Moving forward without proposal 3 may keep additional workload and costs down but will not provide the granularity in surveillance that we are seeking.

Will the policy be reviewed? It will be reviewed as part of future updates to the HPNR				
Is this measure likely to impact on international trade and investment?	**No**			
Are any of these organisations in scope?	**Micro** No	**Small** Yes	**Medium** Yes	**Large** Yes
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: Date: 17/10/2023

Summary: Analysis & Evidence Policy Option 0

Description: Do nothing

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	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	10	£0	£0
High	£0		£0	£0
Best Estimate	£0		£0	£0

Description and scale of key monetised costs by 'main affected groups'
Option 0 has zero monetised costs by convention as the 'do nothing' option

Other key non-monetised costs by 'main affected groups'
Option 0 has zero non-monetised costs by convention as the 'do nothing' option

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	£0	10	£0	£0
High	£0		£0	£0
Best Estimate	£0		£0	£0

Description and scale of key monetised benefits by 'main affected groups'
Option 0 has zero monetised benefits by convention as the 'do nothing' option

Other key non-monetised benefits by 'main affected groups'
Option 0 has zero non-monetised benefits by convention as the 'do nothing' option

Discount rate (%)	1.5

Key assumptions/sensitivities/risks
Not applicable

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: Amend the Health Protection (Notification) Regulations with Proposals 1-3
FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV))		
			Low: N/A	High: N/A	Best Estimate: -£16.6m

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	10	N/A	N/A
High	N/A		N/A	N/A
Best Estimate	£0.2m		£1.7m	**£16.6m**

Description and scale of key monetised costs by 'main affected groups'
Under Proposal 1 there is a cost to registered medical practitioners in sending additional notifications for the seven infectious diseases to be added to schedule 1. There is a cost to UKHSA to update IT systems and process notifications sent by registered medical practitioners and notifications sent by laboratories under schedule 1 and 2.

Other key non-monetised costs by 'main affected groups'
Under Proposal 2 and 3, there is a cost to NHS England and private laboratories to update their IT systems to comply with the amendments. IT costs to the public and private sector are assessed to be small and well below the Equivalent Annual Net Direct Cost to Business (EANDCB) threshold of £5m that would require RPC approval.

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	10	N/A	N/A
High	N/A		N/A	N/A
Best Estimate	N/A		N/A	N/A

Description and scale of key monetised benefits by 'main affected groups'
Option 1 has no estimates for its monetised benefits at the consultation stage

Other key non-monetised benefits by 'main affected groups'
Option 1 enables the prompt response to diseases that pose significant risk to public health. This can prevent mortality and morbidity in the public, mitigating the risk of a pandemic and reducing pressures on the NHS. The additional notification of infectious diseases and causative agents can also improve current public health responses and outcomes, including for vaccine programmes.

Discount rate (%)	1.5

Key assumptions/sensitivities/risks
Key assumptions include the number of annual notifications, the time for registered medical practitioners to send notifications and the time for these to be processed by UKHSA. Key risks include confidentiality concerns on the inclusion of syphilis and gonorrhoeae (non-sterile site) under schedule 2 leading to patients avoiding presenting to healthcare services. Another key risk is greater than expected notification costs in the unpredictable situation of a disease outbreak. Automation processes by UKHSA could reduce UKHSA processing costs but are not accounted for here owing to these projects either being in progress or unconfirmed. Some key assumptions are unknown at the consultation stage and raised in the 'Risks and assumptions' section of this document. We welcome comments on these from stakeholders in the consultation.

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: Amend the Health Protection (Notification) Regulations with Proposals 1-3, excluding syphilis and gonorrhoeae (non-sterile site)

FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV))		
			Low: N/A	High: N/A	Best Estimate: -£13.1m

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	10	N/A	N/A
High	N/A		N/A	N/A
Best Estimate	£0.2m		£1.4m	**£13.1m**

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

Option 2 incurs the same types of costs as Option 1 above, with time costs for registered medical practitioners and UKHSA and an IT cost to UKHSA.

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

Under Proposal 2 and 3, there is a cost to NHS England and private laboratories to update their IT systems to comply with the amendments. IT costs to the public and private sector are assessed to be small and well below the Equivalent Annual Net Direct Cost to Business (EANDCB) threshold of £5m that would require RPC approval.

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	10	N/A	N/A
High	N/A		N/A	N/A
Best Estimate	N/A		N/A	N/A

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

Option 2 has zero monetised benefits at the consultation stage.

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

Option 2 enables the prompt response to diseases that pose significant risk to public health. This can prevent mortality and morbidity in the public, mitigating the risk of a pandemic and reducing pressures on the NHS. The additional notification of infectious diseases and causative agents can also improve current public health responses and outcomes, including for vaccine programmes. The scale of non-monetised benefits under Option 2 are lower than Option 1 due to the exclusion of syphilis and gonorrhoeae (non-sterile site) under schedule 2.

Discount rate (%)	1.5

Key assumptions/sensitivities/risks

Key assumptions include the number of annual notifications, the time for registered medical practitioners to send notifications and the time for these to be processed by UKHSA. Key risks include greater than expected notification costs in the unpredictable situation of a disease outbreak.

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: Amend the Health Protection (Notification) Regulations with Proposals 1-2
FULL ECONOMIC ASSESSMENT

Price Base Year 2023	PV Base Year 2023	Time Period Years 10	Net Benefit (Present Value (PV))		
			Low: N/A	High: N/A	Best Estimate: -£16.4m

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	N/A	10	N/A	N/A
High	N/A		N/A	N/A
Best Estimate	£0.1m		£1.7m	**£16.4m**

Description and scale of key monetised costs by 'main affected groups'
Option 3 incurs the same types of costs as Option 1 above, with time costs for registered medical practitioners and UKHSA.

Other key non-monetised costs by 'main affected groups'
Under Proposal 2 there is a cost to NHS England and private laboratories to update their IT systems to comply with the amendments. IT costs to the public and private sector are assessed to be small and well below the Equivalent Annual Net Direct Cost to Business (EANDCB) threshold of £5m that would require RPC approval.

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	N/A	10	N/A	N/A
High	N/A		N/A	N/A
Best Estimate	N/A		N/A	N/A

Description and scale of key monetised benefits by 'main affected groups'
Option 3 has zero monetised benefits at the consultation stage.

Other key non-monetised benefits by 'main affected groups'
Option 3 enables the prompt response to diseases that pose significant risk to public health. This can prevent mortality and morbidity in the public, mitigating the risk of a pandemic and reducing pressures on the NHS. The additional notification of infectious diseases and causative agents can also improve current public health responses and outcomes, including for vaccine programmes. The scale of benefits under Option 3 are lower than Option 1 due to the exclusion of Proposal 3's expanded reporting changes.

Discount rate (%)	1.5

Key assumptions/sensitivities/risks
Key assumptions include the number of annual notifications, the time for registered medical practitioners to send notifications and the time for these to be processed by UKHSA. Option 3 incurs the same risks as Option 1, relating to potential concerns over confidentiality and disease outbreaks.

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

Problem under consideration and rationale for intervention

1. The Health Protection (Notification) Regulations 2010 (HPNR) are a vital part of England's infectious disease surveillance system. They place a statutory duty on registered medical practitioners to report suspected or known cases of notifiable infectious diseases, listed in schedule 1 of the regulations. They also place a statutory duty on laboratories that test human samples to report positive test results of notifiable causative agents, listed in schedule 2 of the regulations. Causative agents are organisms and chemicals which directly, or indirectly, cause disease.

2. Although additions have been made to schedule 1 and 2 to improve surveillance in emergency scenarios, such as COVID-19 and Monkeypox, a full review of the regulations has not taken place since 2010. This consultation and any amendments taken forward, will ensure that the regulations reflect current public health needs and can inform effective public health action at a local, national and international level.

3. Government intervention is required because, outside of statutory reporting duties, there is no alternative mechanism that could sufficiently guarantee complete surveillance of a disease.

Rationale and evidence to justify the level of analysis used in the IA (proportionality approach)

4. The estimated impact on business is well below the Equivalent Annual Net Direct Cost to Business (EANDCB) threshold of £5m that would necessitate a consultation Impact Assessment, as noted in the government's Better Regulation Framework[1]. The net costs to Government are also well below the DHSC's own threshold for when regulation requires an Impact Assessment based on costs. Instead, the reason we have produced this consultation Impact Assessment is that including syphilis and gonorrhoeae (non-sterile site) under schedule 2 is potentially controversial due to the risks of unintended consequences.

5. Therefore, this consultation Impact Assessment takes a more qualitative approach with a focus on the inclusion of syphilis and gonorrhoeae (non-sterile site) to support stakeholders' responses in the consultation. The level of data gathering and evidence is proportionate at the consultation stage and will inform future analysis. In the limited circumstances where evidence is missing, we have made appropriate judgements on the analytical assumptions that inform modelling. These gaps are to be tested in this consultation, and through further stakeholder engagement, and will be reflected in any subsequent analysis. The 'Risks and Assumptions' section below includes specific areas where we welcome stakeholders' comments on analytical assumptions.

Description of options considered

6. We consider the below options as part of this consultation Impact Assessment. To varying degrees, Options 1-3 strengthen the Health Protection Notification Regulations (HPNR) and ensure they are fit for use in the current public health context. These options deliver the desired outcomes by including additional infectious diseases and causative agents that are of public health concern and improve reporting requirements of these. We do not have a preferred option at the consultation stage. Options 1 to 3 involve a combination of Proposals 1, 2 and 3 which are summarised below and in the consultation[2].

7. Option 0: Do-nothing. Do not review the regulations at this time and only add diseases to the regulations in emergency scenarios when complete surveillance is required (e.g. Mpox). This would mean adding diseases without consultation and it would be a reactive approach. Instead, proactively adding diseases to the regulations mitigates the risk of needing a reactive approach and facilitates a prompt and effective public health response. The regulations have a provision in which registered medical practitioners have a duty to report all cases of a disease not included in

[1] Link to Better Regulation Framework

[2] Link to Health Protection (Notification) Regulations consultation

schedule 1, which they believe presents, or could present, a significant risk to human health. While this provision is useful it does not guarantee complete surveillance and is not a sufficient replacement to updating the regulations.

8. Option 1: Proceed with all amendments. All seven infectious diseases would be added to schedule 1, and all twelve causative agents would be added to schedule 2, alongside expanded reporting requirements for laboratories.

Proposal 1

9. It is proposed that the following seven infectious diseases could be added to schedule 1 and become legally notifiable by registered medical practitioners to the 'proper officer' of the local authority (usually delegated to a UKHSA health protection team consultant). The addition of these seven infectious diseases is referred to as Proposal 1.
    a. Middle East respiratory syndrome (MERS)
    b. Influenza of zoonotic origin
    c. Chickenpox (varicella)
    d. Congenital syphilis
    e. Neonatal herpes
    f. Acute flaccid paralysis or acute flaccid myelitis (AFP or AFM)
    g. Disseminated gonococcal infection

Proposal 2

10. The twelve causative agents proposed to be added to the regulations under Option 1, as part of Proposal 2, are:
    a. Middle East respiratory syndrome coronavirus (MERS-CoV)
    b. Non-human influenza A subtypes
    c. Norovirus
    d. Echinococcus spp
    e. Tick-borne encephalitis virus (TBEV)
    f. Toxoplasma (congenital toxoplasmosis)
    g. Trichinella spp
    h. Yersinia spp
    i. Respiratory syncytial virus (RSV)
    j. Neisseria gonorrhoeae (from a sterile site)
    k. Treponema pallidum (syphilis)
    l. Neisseria gonorrhoeae (non-sterile site)

Proposal 3

11. Proposal 3 of this consultation is to explore the recommendation for all diagnostic laboratories in England testing human samples to be required to report negative and void test results for all causative agents under schedule 2. This is in addition to the reporting of positive test results, which diagnostic laboratories are already required to do in the HPNR.

Remaining options

12. Option 2: Proceed with all amendments other than additions of syphilis and gonorrhoeae (non-sterile site) to schedule 2. Including syphilis and gonorrhoeae (non-sterile site) in schedule 2 of the regulations may raise concerns around patient confidentiality given these are sexually transmitted infections (STIs). Moving forward with the other amendments but removing syphilis and gonorrhoeae (non-sterile site) could allow for more thinking to be done on how to collect data on these sexually transmitted infections (STIs) through an alternative, preferred method.

13. Option 3: Proceed with all amendments other than proposal 3 (expanded laboratory reporting requirements). We expect that stakeholders may raise concerns with this proposal as it will require some additional workload. The details of this will be worked through from consultation

responses. Moving forward without this proposal may keep additional workload and costs down but will not provide the granularity in surveillance that we are seeking.

14. Options 1-3 are regulatory options and will involve the use of secondary legislation to amend the Health Protection (Notification) Regulations 2010. They involve additions to regulatory reporting requirements from registered medical practitioners and laboratories in England.

Policy objective

15. The overarching objective of these amendments is to strengthen the HPNR to ensure they are fit for use in the current public health context and improving disease surveillance systems.

16. Intended outcomes are primarily improved public health outcomes, such as preventing the spread of infectious diseases and causative agents through early and targeted interventions, saving lives and preventing morbidity.

17. Under Proposal 1, amendments to infectious disease reporting by registered medical practitioners under schedule 1 will facilitate prompt public health action and ensures that, if required, timely prevention and control measures can be put in place. This in turn reduces pressures on the NHS. Under Proposal 2, amendments to the reporting of causative agents by laboratories in England strengthen surveillance capabilities for infectious diseases, which is key to detecting outbreaks and understanding outbreak progression and trends.

18. Ensuring that schedule 1 and schedule 2 reflect current public health needs is critical to maintaining strong surveillance systems enabling prompt investigation, risk assessment and response to cases of infectious disease that pose a significant risk to human health. A recent internal review, prior to the consultation, by the Department of Health and Social Care (DHSC) and United Kingdom Health Security Agency (UKHSA) proposed that 7 infectious diseases could be added to schedule 1, and 12 causative agents could be added to schedule 2 of the HPNR.

19. The review also recommended an expansion of the HPNR's laboratory reporting requirements under schedule 2 to include negative and void results, in addition to reporting positive tests, which is already required. Data on negative and void tests supports the monitoring of vaccination programmes and provides information on testing rates to help understand how they may be impacting on the reported incidence of disease. This requirement was introduced for SARS-CoV-2 during the pandemic, which enabled UKHSA to attain greater granularity in data for surveillance.

20. Notable indicators of success would be identifying outbreaks at an early stage and using targeted public health action to tackle them to reduce their spread and protect health. Outbreaks are unpredictable and uncertain events and therefore it is not possible to robustly assign time bound objectives to this policy.

Summary and preferred option with description of implementation plan

21. We do not have a preferred option at the consultation stage.

22. Amendments, if taken forward, will be given effect through secondary legislation. At the consultation stage, the time for when these amendments will come into effect has not been finalised and is dependent on consultation responses.

Options appraisal methodology

23. Each of the three proposals is expected to incur a cost, with the assessment below being incremental to existing HPNR regulations. All costs to various public and private sector stakeholders are summarised in Table 1 below. Before determining the costs and benefits of Options 0-3, we start by determining a methodology for appraising each Proposal.

24. Under Proposal 1, when a patient visits a registered medical practitioner (RMP) and is suspected of being infected with one of the seven infectious diseases proposed to be added to schedule 1, the RMP must take time to notify the 'proper officer' of the local authority. The RMP incurs a time cost to send this notification. Then public health authorities must process the notification. We assume all local authorities have an employee of UKHSA as their proper officer, meaning this process is usually delegated to a UKHSA health protection team consultant. There is a cost to UKHSA to process the notifications sent by RMPs, alongside a one-off IT cost to update UKHSA's infectious disease systems.

25. Under Proposal 2, UKHSA jointly propose adding 12 causative agents to schedule 2. This would make it a statutory duty for all diagnostic laboratories in England to notify UKHSA if they identify any of these causative agents in a human sample. There is a one-off cost to laboratories, both NHS England's and private, to update their IT systems to send this information. This is alongside a one-off cost for UKHSA to update their IT systems to receive this information and process these notifications.

26. Under Proposal 3, all diagnostic laboratories in England testing human samples would be required to report negative and void test results for all causative agents under schedule 2 (diagnostic laboratories are already required to report positive test results in the HPNR). This includes the causative agents already under schedule 2 and those to be added under Proposal 2. There is a cost to laboratories to update their IT systems to automatically send this information and a cost to UKHSA to update their IT systems to receive this information.

27. We do not assess costs to local authorities to take action against infectious diseases and causative agents, such as a Justice of the Peace, on the basis that these measures cannot be directly attributed to these proposed amendments and could happen in the absence of any amendments.

Table 1: summary of cost impacts

Stakeholder	Proposal 1	Proposal 2	Proposal 3
Registered medical practitioners	Time cost	No cost	No cost
NHS Laboratories	No cost	IT systems cost	IT systems cost
Private laboratories	No cost	IT systems cost	IT systems cost
Local authorities	No direct cost	No direct cost	No direct cost
UKHSA (Health Protection Teams)	Time cost and IT cost	Time cost and IT cost	IT systems cost
Individual being tested	No cost	No cost	No cost

Proposal 1 monetised cost appraisal

28. Proposal 1 involves the addition of seven infectious diseases to Schedule 1, with these seven diseases summarised below in Table 2. The costs of Proposal 1 are a time cost to registered medical practitioners in notifying the Proper Officer, an IT cost for UKHSA to update their systems and a time cost by UKHSA to process and respond to the notification. The total annual cost of Proposal 1 equals the number of notifiable cases multiplied by the cost per notifiable case.

Proposal 1: number of notifiable cases

29. We start by determining the number of notifiable cases. As shown in Table 2, the current most plausible estimate is an annual total of 27,540 additional cases. This value has been determined through engagement with UKHSA's public health teams who are responsible for tracking and responding to these diseases and therefore hold expertise in these areas. This is a plausible estimate based on historical levels but is subject to vary annually owing to uncertainty in future infection rates. It is not possible to account for significant peaks in cases, such as in the event of an epidemic, hence this is just one plausible estimate, and it is also not possible to estimate confidence intervals because of the inherent uncertainty in future cases for infectious diseases. Instead, we have tested the number of additional annual notifications under Proposal 1 in sensitivity analysis.

Table 2: total annual notifiable infectious diseases by RMPs under Proposal 1

Infectious Disease	Discussion	Expected number of annual notifiable cases
Middle East respiratory syndrome (MERS)	The additional reporting burden to RMPs of including MERS under schedule 1 is likely to be low since there are existing reporting mechanisms in place which clinicians are encouraged to use, though they are not legally required to do so. These existing mechanisms mirror those used to report under the HPNR.	1,000
Influenza of zoonotic origin	The additional reporting burden should be low.	100
Chickenpox (varicella)	The addition of chickenpox would likely be a minimal burden for each RMP, although workloads for UKHSA teams will increase. There continues to be a year-on-year decline in attendance to primary care for chickenpox, and if a vaccine programme is introduced, long-term case numbers would be expected to fall significantly.	25,000
Congenital syphilis	Reporting additional cases will pose a very small additional burden for RMPs since cases are rare.	40
Neonatal herpes	Cases are uncommon and so the additional reporting burden will be low.	150
Acute flaccid paralysis (AFP) or acute flaccid myelitis	There may be some additional workload on health protection teams who receive AFP notifications. However, the numbers reported are small and so the burden will be low, as evidenced by the current UKHSA incident response.	1,000
Disseminated gonococcal infection (DGI)	The additional reporting burden for medical practitioners is likely to be low as DGI cases are rare.	250
Total	For all seven infectious diseases under Proposal 1	27,540

Numbers may not sum due to rounding

Proposal 1: cost to registered medical practitioners

30. Assumptions are then made on the time cost for the registered medical practitioner to notify the authority. The registered medical practitioner does this by completing a form or giving the required information verbally over the telephone if notification should be made urgently. We have assumed a value of 5-15 minutes, and use the midpoint of 10 minutes as the central estimate. In the absence of newer evidence, this is based on a prior and unpublished DHSC analysis in an Impact Assessment for the 2009 consultation on regulations under the Public Health (Control of Disease) Act 1984, which reviewed updating the list of notifiable diseases. We welcome comments in the consultation response from RMPs as to whether this is an appropriate assumption and will review this for any subsequent analysis.

31. RMPs include general practitioners (GPs) and hospital doctors (junior doctors and consultants). We assume the hourly cost of a registered medical professional's time to be £265 per hour. This

is based on the unit cost of a GP per hour of patient contact, sourced from the Unit Costs of Health and Social Care 2022 Manual[3].

32. To determine the total cost to RMPs, we multiply the number of additional annual notifiable cases sent 27,540 by the time (10 mins = 0.2 hours) and then multiply by the average hourly cost to RMPs (£265 per hour). This is a total of approximately £1.2m as shown in Table 3 below.

Table 3: cost to RMPs

Number of additional annual notifiable cases sent by RMPs	Time to notify by RMP	Average cost of RMP	Total annual cost to RMP
27,540	10 minutes	£265 per hour	£1,216,000

Proposal 1: cost to the UK Health Security Agency (UKHSA)

33. RMPs are required to notify the relevant Proper Officer. We assume that 100% of local authorities in England have appointed an employee of UKHSA as their proper officer. In the unlikely event that this is not the case, local authorities would be expected to incur a similar, or the same, processing cost as UKHSA for each notification. This means that local authorities usually delegate the processing of notifications to UKHSA public health teams. Hence, we assume 100% of notifications are processed by UKHSA based staff and therefore a processing cost is incurred by UKHSA.

34. In Table 3, we estimated an additional 27,540 annual notifications sent from RMPs that UKHSA must process. We repeat a similar process as above to determine the cost to UKHSA to process additional notifications sent by RMPs under Proposal 1. We assume a processing time of 10 minutes as our central estimate, with a range of 5-15 minutes tested in sensitivity analysis. This is based on internal conversations with UKHSA colleagues whose work involves these infectious diseases and aligned with values used in prior and unpublished DHSC analysis in an Impact Assessment which also looked at updating the list of notifiable diseases.

35. We assume the average cost of UKHSA staff who process these notifications to be primarily at an EO level, with an approximate hourly wage of £20 based on internal Department for Health and Social Care (DHSC) pay bands and uplifted to account for additional staffing costs such as overheads and pensions.

36. To determine the total annual cost to UKHSA, we multiply the number of annual additional annual notifiable cases received by UKHSA (27,540 by the time (10 mins = 0.2 hours) and then multiply by the average hourly wage of UKHSA staff of £20. This is an annual total of £92,000, as shown in Table 4 below. Analysis does not account for any automation processes by UKHSA in the ten-year time horizon of this Impact Assessment. Automation would reduce UKHSA's processing costs but is not accounted for on the basis of these projects either being in progress or unconfirmed.

Table 4: annual notification processing cost to UKHSA

Number of notifiable cases received by UKHSA annually	Time to process	Average hourly cost of UKHSA staff	Total annual cost to UKHSA
27,540	10 minutes	£20 per hour	£92,000

[3] Link to Unit Costs of Health and Social Care 2022 Manual

37. Alongside this, under Proposal 1 there will be an IT cost for UKHSA. Changes are required to existing and in-development systems in UKHSA to configure the capture and reporting of the seven additional notifiable infectious diseases. Three systems would need updating through the use of UKHSA's digital and data workforce. Based on engagement with UKHSA staff, the cost to update UKHSA's Notifications of Infectious Diseases (NOIDs) system is estimated as a one-off cost of £2,000. The cost to update UKHSA's HPZone and Case and Incident Management System (CIMS) is unknown at the consultation stage, but is expected to be in the order of £1,000s. Due to its low expected cost we have chosen not to seek a more specific estimate of it at this stage. Instead, we have tested monetised IT costs in sensitivity analysis, and will update estimated IT costs in any subsequent analysis.

Proposal 1: summary of annual costs

38. Costs under Proposal 1 that are faced by registered medical practitioners and UKHSA are summarised below in Table 5. Overall, we expect a total 10-year cost of £12.3m under Proposal 1 of the amendments.

Table 5: summary of costs under Proposal 1

Stakeholder	10-year cost
Registered medical practitioners	£11,386,000
UKHSA notification processing cost	£918,000
UKHSA IT cost	£2,000
Total	£12,304,000

Numbers may not sum due to rounding

Proposal 2 monetised cost appraisal

39. Proposal 2 involves the addition of twelve causative agents to Schedule 2, with these twelve causative agents summarised below in Table 7. Under Proposal 2, all diagnostic laboratories in England would have a statutory duty to notify UKHSA if they identify any of these causative agents in a human sample.

40. The costs of Proposal 2 are a cost to laboratories to update their IT systems to automatically send results to UKHSA. This cost falls on public and private laboratories in England. There is then a cost to UKHSA to update their IT systems to receive this data and a cost to process these notifications sent by laboratories.

41. Under appraisal for Proposal 2, we present impacts with and without the inclusion of syphilis and gonorrhoeae (non-sterile site). These are then used below in the 'Options appraisal' section of this consultation Impact Assessment.

Proposal 2: number of notifiable cases

42. We start by determining the number of notifiable cases under Proposal 2. As shown in Table 6, a plausible estimate is an annual total of approximately 132,000 cases including syphilis and gonorrhoeae (non-sterile site), and an annual total of just under 21,000 cases excluding syphilis and gonorrhoeae (non-sterile site). This value has been determined through engagement with UKHSA's public health teams who are responsible for tracking and responding to these diseases and therefore hold expertise in these areas. These plausible estimates are based on historical levels but levels are subject to vary annually. It has not been possible to estimate confidence intervals and analysis does not account for significant peaks in cases, such as in the event of an epidemic, owing to the inherent uncertainty in infectious diseases. Instead, we have tested the number of additional annual notifications in sensitivity analysis.

Table 6: notifiable cases under Proposal 2

Causative agent	Discussion	Estimated number of notifiable cases
Middle East respiratory syndrome coronavirus (MERS-CoV)	The addition of MERS-CoV to schedule 2 will act as a contingency in case a case is not notified under schedule 1 because it is not identified or suspected by a clinician.	1,000
Non-human influenza A subtypes	A low additional burden is expected since cases are low.	100
Norovirus	Adding norovirus to schedule 2 is expected to have a low additional reporting burden. This is because Laboratories are already set up to report cases of notifiable causative organisms to UKHSA through their Laboratory Information Management Systems (LIMS). Therefore, the additional burden is associated with the initial burden of adding norovirus to the LIMS reporting system, after which reporting would be automated.	6,500
Echinococcus spp	The overall additional reporting burden to the health system is expected to be low as cases are not common.	100
Tick-borne encephalitis virus (TBEV)	The diagnosis of TBEV is currently carried out at the UKHSA Rare and Imported Pathogens Laboratory (RIPL), although other large laboratories may consider introducing the test if there is a clinical demand. However, confirmation of cases at RIPL will not change if TBEV is included in schedule 2 and therefore the additional reporting burden to the health system is expected to be low.	100
Toxoplasma (congenital toxoplasmosis)	The expected reporting burden of inclusion in schedule 2 is low as cases are rare.	100
Trichinella spp	The cases are not common, and therefore the additional reporting burden is likely to be low.	100
Yersinia spp	Although there are existing reporting mechanisms in place in laboratories, there are currently a significant number of cases of gastrointestinal yersiniosis being noted and so, at least in the short term, an increase in reporting burden is likely if yersinia spp is made notifiable.	496
Respiratory syncytial virus (RSV)	An additional burden is expected.	10,000
Neisseria gonorrhoeae (from a sterile site)	A small burden is expected.	2,400
Treponema pallidum (syphilis)	Syphilis and gonorrhoeae are already currently listed as core pathogens for voluntary reporting to UKHSA surveillance systems. They are already reported as pseudonymised, depersonalised data by some laboratories, with data used to provide an early indication of overall trends. As there are existing reporting channels, if any were to be added to schedule 2, the additional reporting burden is expected to be low.	11,500
Neisseria gonorrhoeae (non-sterile site)	Syphilis and gonorrhoeae are already currently listed as core pathogens for voluntary reporting to UKHSA surveillance systems. They are already reported as pseudonymised, depersonalised data by some laboratories, with data used to provide an early indication of overall trends. As there are existing reporting channels, if any were to be added to schedule 2, the additional reporting burden is expected to be low.	100,000
Total including syphilis and gonorrhoeae	**Including Treponema pallidum (syphilis) and Neisseria gonorrhoeae (non-sterile site)**	**132,000**
Total excluding syphilis and gonorrhoeae	**Excluding Treponema pallidum (syphilis) and Neisseria gonorrhoeae (non-sterile site)**	**21,000**

Numbers may not sum due to rounding

Proposal 2: cost to NHS laboratories

43. Under Proposal 2, there is an IT cost to NHS England laboratories to send positive test results for the proposed additional causative agents to UKHSA. Approximately 130 NHS England laboratories must adapt their Second Generation Surveillance System (SGSS) reporting extracts. This is UKHSA's national surveillance system which holds laboratory test results. We do not expect this IT cost to substantially vary with the inclusion of syphilis and gonorrhoeae (non-sterile site). There is also expected to be a further IT cost for 14 of the NHS England laboratories to adapt their reporting extracts to the Respiratory Data Mart system. IT costs are expected to be a one-off cost.

44. At the consultation stage, we do not know what this cost is. We welcome comments in the consultation from NHS England on how to appraise this total cost.

Proposal 2: cost to private laboratories

45. Private laboratories must update their IT systems to send positive test results for these causative agents to UKHSA. We welcome comments in the consultation from private laboratories on how to appraise this cost, either for a single private laboratory or in total.

Proposal 2: cost to UKHSA

46. UKHSA will be responsible for processing these notifications. We make the same time and staff cost assumptions for Proposal 2 as we did under Proposal 1.

47. From Table 6, we expect approximately 132,000 annual notifications from laboratories to UKHSA, including syphilis and gonorrhoeae (non-sterile site), and 21,000 annual notifications from laboratories to UKHSA, excluding syphilis and gonorrhoeae (non-sterile site). Each notification takes 10 minutes to process, at an hourly rate of £20. Therefore, the annual cost to UKHSA under Proposal 2 is £0.4m, including syphilis and gonorrhoeae (non-sterile site), and £0.1m excluding syphilis and gonorrhoeae (non-sterile site). The total discounted ten-year UKHSA processing cost under Proposal 2, including syphilis and gonorrhoeae (non-sterile site) is approximately £4.1m, and approximately £0.7m excluding syphilis and gonorrhoeae (non-sterile site). Analysis does not account for any automation processes by UKHSA in the ten-year time horizon of this Impact Assessment. Automation would reduce UKHSA's processing costs but is not accounted for on the basis of these projects either being in progress or unconfirmed.

48. Under Proposal 2, there is an IT cost for UKHSA to add the additional causative agents to schedule 2. IT costs have been determined through engagement with UKHSA colleagues and based on the staff needed and duration of work to update systems. Firstly, UKHSA's digital and data staff may need to reconfigure the existing Respiratory Data Mart system that captures data from reporting laboratories. This cost is estimated as a total cost of £10,000. This is also a further one-off cost to validate reporting changes made by laboratories. This is estimated as a total cost of £23,000.

49. If syphilis and gonorrhoeae (non-sterile site) are added to schedule 2, there will be a further IT cost of £16,000 to develop and implement robust pseudonymisation processes for all STIs in the Second Generation Surveillance System (SGSS).

50. There are further IT costs expected for UKHSA under Proposal 2, although these are currently unknown at the consultation stage. SGSS is not designed to process and store non-human samples meaning the inclusion of non-human influenza A subtypes under schedule 2 will lead to further IT costs. Secondly, work is required to validate changes to outputs and the new processes put in place to manage potentially identifiable sexually transmitted infection (STI) data. Therefore, the total monetised IT cost to UKHSA under Proposal 2 is at least £49,000 with further IT costs

expected. All IT costs are expected to be one-off costs that do not depend on the number of additional annual notifications. Known IT costs are tested in sensitivity analysis.

Proposal 2: summary of costs

51. Table 7 below summarises the total discounted 10-year costs under proposal 2.

Table 7: summary of 10-year costs under Proposal 2

Stakeholder	10-year discounted cost
NHS laboratories IT cost	Non-monetised
Private laboratories IT cost	Non-monetised
UKHSA IT cost (inc. G&S)	£49,000
UKHSA IT cost (exc. G&S)	£33,000
UKHSA additional IT cost (SGSS and STI validation)	Non-monetised
UKHSA notification processing cost (inc. G&S)	£4,131,000
UKHSA notification processing cost (exc. G&S)	£652,000

Proposal 3 monetised cost appraisal

52. Proposal 3 expands reporting requirement for all diagnostic laboratories in England testing human samples to report negative and void test results for all causative agents under schedule 2. This is in addition to the reporting of positive test results, which diagnostic laboratories are already required to do in the HPNR.

Proposal 3: cost to NHS laboratories

53. NHS England laboratories in England testing human samples would now be required to report negative and void test results for all causative agents under schedule 2. This is expected to impact their Laboratory Information Management Systems (LIMS), with a need to configure these systems to store non-positive test results and report these to UKHSA. This cost is non-monetised at the consultation stage and we welcome comments in the consultation on how to appraise this total cost.

Proposal 3: cost to private laboratories

54. Private laboratories in England testing human samples would now be required to report negative and void test results for all causative agents under schedule 2. As above, this is expected to impact Laboratory Information Management Systems (LIMS). This cost is non-monetised at the consultation stage and we welcome comments in the consultation on how to appraise this total cost.

Proposal 3: cost to UKHSA

55. Proposal 3's expanded reporting requirements will impose an IT cost to UKHSA because of significant increases in data volumes from multiple reporting streams. UKHSA's digital and data staff will need to configure, validate and quality assure processes for the new data reporting streams that result from the proposal. Engagement with UKHSA staff suggests this is a total one-off cost of £145,000.

Proposal 3: summary of costs

56. Table 8 below summarises the 10-year discounted costs expected under Proposal 3. All of Proposal 3's costs are one-off IT costs.

Table 8: summary of 10-year costs under Proposal 3

Stakeholder	Total cost
NHS laboratories IT cost	Non-monetised
Private laboratories IT cost	Non-monetised
UKHSA IT Cost	£145,000

Options appraisal summary

57. With the costs of Proposals 1,2 and 3 modelled above, we move to appraising the costs of the options presented in this Impact Assessment. These options are summarised below in Table 9.

58. All Options are appraised over a 10-year period, and represent economic costs discounted at 1.5%.

Table 9: options summary

	Option 0	Option 1	Option 2	Option 3
Proposal 1	No change to existing regulations	All 7 infectious diseases included	All 7 infectious diseases included	All 7 infectious diseases included
Proposal 2	No change to existing regulations	All 12 causative agents included, including syphilis and gonorrhoeae (non-sterile site)	Only 10 causative agents included. Syphilis and gonorrhoeae (non-sterile site) are excluded	All 12 causative agents included, including syphilis and gonorrhoeae (non-sterile site)
Proposal 3	No change to existing regulations	Negative and void test results reported for all causative agents on schedule 2, including syphilis and gonorrhoeae (non-sterile site)	Negative and void test results reported for causative agents on schedule 2, excluding syphilis and gonorrhoeae (non-sterile site)	No change to existing regulations

Option 0 appraisal

59. Option 0 is known as the ‘do nothing’ or ‘business as usual’ option. It involves continuing with the current arrangements in place and making no amendments to the Health Protection (Notification) Regulations. Common practice in impact assessments, as outlined in the HMT Green Book, is for other options to be compared to Option 0. This means Option 0 is modelled to have zero costs and benefits, serving as the counterfactual with Options 1-3 being assessed against it.

Option 1 appraisal

Option 1 monetised costs

60. Option 1's costs reflect the inclusion of syphilis and gonorrhoeae (non-sterile site) under schedule 2, and the associated cost of notifications. Costs for Option 1 are based on the cost summary tables for each proposal as appraised above. Table 10 decomposes total costs by the 3 proposals and presents the IT costs separately noting these are one-off costs incurred in year 1 of the policy. Overall, we expected a total monetised discounted cost of £16.6m across 10-years for Option 1, as summarised in Table 10 below.

Table 10: Option 1 cost summary

	Y1 IT cost	Annual notification processing cost- discounted at 1.5%											
		Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Total 10 year	TOTAL
Proposal 1	£0.0m	£1.3m	£1.3m	£1.3m	£1.3m	£1.2m	£1.2m	£1.2m	£1.2m	£1.2m	£1.1m	£12.2m	£12.2m
Proposal 2	£0.0m	£0.4m	£0.4m	£0.4m	£0.4m	£0.4m	£0.4m	£0.4m	£0.4m	£0.4m	£0.4m	£4.1m	£4.2m
Proposal 3	£0.1m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.1m
TOTAL	£0.2m	£1.7m	£1.7m	£1.7m	£1.7m	£1.6m	£1.6m	£1.6m	£1.6m	£1.6m	£1.5m	£16.4m	£16.6m

Numbers may not sum due to rounding

Option 1 non-monetised costs

61. Select IT costs to UKHSA under Proposals 1 and 2 are unknown. These are costs to configure UKHSA's HPZone and CIMS systems under Proposal 1 and costs to configure systems for non-human influenza A subtypes under Proposal 2.

62. The cost to NHS England and private laboratories under Proposal 2, to notify for the additional twelve causative agents, is unknown. The cost to NHS England and private laboratories under Proposal 3, to report negative and void test results, is unknown. At the consultation stage, we welcome responses from stakeholders on the estimated amount or scale of these costs.

Option 1 monetised benefits

63. Option 1 does not have any monetised benefits at the consultation stage. Without detailed data on the incidence and diagnosis of the proposed additional notifiable diseases and associated benefits and costs, it is not possible to explicitly quantify these benefits. As we estimate that the additional burdens on registered medical practitioners, laboratories and UKHSA are likely to be small, it would be disproportionate to carry out such detailed analysis at the consultation stage.

Option 1 non-monetised benefits

64. Option 1 has five key benefits discussed below. They are:
    a. Enable the prompt response to diseases that pose significant risk to public health
    b. Prevent mortality and morbidity in the public
    c. Improve current public health responses and outcomes, including vaccine programmes
    d. Mitigate the risk of a pandemic
    e. Reduce pressure on the NHS

65. Overall, placing a legal duty on registered medical practitioners to report suspected cases of notifiable diseases facilitates prompt public health action and ensures that, if required, timely prevention and control measures can be put in place. This enables prompt investigation, risk assessment and response to cases of infectious disease that pose a significant risk to human health.

66. The primary benefit of Option 1 is to prevent mortality and morbidity in the public. Notifications enable prompt risk assessment and post-exposure treatment of the individual and their contacts. Notifying UKHSA's public health teams can prevent the spread of the infectious diseases and causative agents. This may result in saving the lives of members of the public since untreated symptoms can be fatal, or alternatively reducing the burden of long-term sequelae and preventing individuals getting sick in the first place. By preventing or reducing the risk of hospitalisations, Option 1 avoids expenditure on infected and ill patients, thereby saving money for the NHS. At the consultation stage, due to an absence of data this benefit has not been appraised.

67. Another key benefit is improved public health responses and outcomes through improved surveillance. For some infectious diseases and causative agents, the epidemiology of infections is poorly understood. It is therefore not possible to establish changing trends in the epidemiology of infections. Relatedly, the notification to a health protection team facilitates the collection of demographic and other data, to inform the burden of disease and disease trends. This is important because for some diseases, such as Tick-borne encephalitis virus, health protection teams believe there is an underreporting of the true burden. Knowing the burden can identify which individuals are at risk from the disease, enabling government to provide targeted guidance or responses. This could include targeted and/or specialist health services, such as outreach services or disease-specific clinics designed for high-risk groups, preventing ill health and saving lives.

68. Under Proposal 3, the expanded reporting of negative and void test results for causative agents enables better understanding of testing trends. For example, signalling when an apparent increase in disease is actually being caused by an increase in testing. Relatedly it improves understanding of disparities in healthcare access. Under Proposal 3, it would be easier to determine who is accessing testing, improving efforts to tackle disparities in access of healthcare diagnostic testing. Reporting of test results also improves understanding of whether recommendations and guidelines are being followed. It would allow optimising communication and the targeting of diagnostic tests to the individuals who need them. Finally, Proposal 3 leads to an improved understanding of healthcare utilisation resources required for pathology testing. This can be used to determine the optimal pathology services and resourcing for the future, ensuring value for money.

69. Overall, making select infectious diseases and causative agents notifiable under Proposals 1 and 2, and changing the way test results are reported under Proposal 3 would allow for improved understanding and, where necessary, timely public health response.

70. Understanding the burden of disease supports the evaluation of public health interventions, such as immunisation programmes. The Joint Committee on Vaccination and Immunisation (JCVI) advise UK health departments on immunisation. Understanding the burden of disease enables JCVI to consider the cost-effectiveness of potential vaccine strategies and provide advice to government, such as whether a vaccine should be offered for the diseases under Proposals 1 and 2. Information on who does not have a disease is critical for knowing how well a vaccine works. The UK has been world-leading in evaluating COVID-19 vaccines because this negative and void testing feature was introduced during the pandemic. In turn, this protects public health whilst ensuring value for money for the public.

71. For some infectious diseases and causative agents, such as non-human influenza A subtypes, notifications enable a rapid health protection response and can reduce the risk of a pandemic by identifying and containing exposure. In turn, this would avoid negative economic, health and social outcomes, such as non-pharmaceutical interventions in the event of a pandemic and the corresponding reduction in economic activity. In addition, expanding laboratory reporting requirements to include negative and void test results under Proposal 3 will strengthen surveillance preparedness and avoid the need to make belated adjustments to laboratory and reporting systems during the response to a potential health threat.

72. Notifications enable a swift response from health authorities and can reduce the spread of disease and prevent individuals being hospitalised and requiring health care. This protects the capacity of healthcare systems. Beyond hospitals, outbreaks also have a significant impact on social care settings and educational settings, such as with Norovirus. Notifications under Proposal 1 and 2 can improve public health communications of potential increasing risks, allowing hospitals to implement enhanced control measures where necessary and helping to reduce winter pressures on the NHS at a local level.

73. Option 1 includes the notification of syphilis and gonorrhoeae (non-sterile site) under Proposal 2. The inclusion of these provides the key benefit of increased understanding of diagnoses and outbreaks, prompting more effective public health responses. This is particularly important because cases of syphilis are increasing in all areas with historically high numbers of new diagnoses being made. This can subsequently lead to increases in late complications of untreated infections. Similarly, gonorrhoeae increased over the past decade to high levels. It is now the second most diagnosed STI in the UK. There are concerns that strains with antimicrobial resistance (AMR) could spread rapidly before being detected, making it harder to control.

74. The increased diagnoses of these infections coupled with considerations for future-proofing testing surveillance, and monitoring complications requiring follow up treatment, might mean it is no longer sufficient to rely solely on the current systems of reporting. In which case, adding gonorrhoeae (non-sterile site) and syphilis to schedule 2 may support the public health response by improving surveillance of infections and informing more effective public health action. For syphilis and gonorrhoeae (non-sterile site), any potential improvement in surveillance would also improve health practitioners' ability to see the future needs of the population and understand impacts of factors such as ageing. This may again inform more effective public health interventions.

Option 1 net present value (NPV)

75. Option 1 has a 10-year NPV of -£16.6m, calculated by the difference between monetised benefits and costs.

Option 2 appraisal

Option 2 monetised costs

76. Option 2's costs reflect the exclusion of syphilis and gonorrhoeae (non-sterile site) under schedule 2. Overall, we expected a total monetised discounted cost of £13.1m across 10-years for Option 2, as summarised in Table 11 below. Costs and benefits are discounted at a rate of 1.5%, in line DHSC's discount rate for health appraisals and aligned with HMT's Green Book guidance.

Table 11: Option 2 cost summary

	Fixed cost	Annual Cost- discounted at 1.5%											
		Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Total 10 year	TOTAL
Proposal 1	£0.0m	£1.3m	£1.3m	£1.3m	£1.3m	£1.2m	£1.2m	£1.2m	£1.2m	£1.2m	£1.1m	£12.2m	£12.2m
Proposal 2	£0.0m	£0.1m	£0.1m	£0.1m	£0.1m	£0.1m	£0.1m	£0.1m	£0.1m	£0.1m	£0.1m	£0.7m	£0.7m
Proposal 3	£0.1m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.0m	£0.1m
TOTAL	£0.2m	£1.4m	£1.4m	£1.3m	£1.3m	£1.3m	£1.3m	£1.3m	£1.2m	£1.2m	£1.2m	£12.9m	£13.1m

Numbers may not sum due to rounding

Option 2 non-monetised costs

77. Select IT costs to UKHSA under Proposals 1 and 2 are unknown. These are costs to configure UKHSA's HPZone and CIMS systems under Proposal 1 and costs to configure systems for non-human influenza A subtypes under Proposal 2.

78. The cost to NHS England and private laboratories under Proposal 2, to notify for the additional ten causative agents (excluding gonorrhoeae and syphilis), is unknown. The cost to NHS England and private laboratories under Proposal 3, to report positive and void test results, is unknown.

Option 2 monetised benefits

79. Option 2 does not have any monetised benefits at the consultation stage.

Option 2 non-monetised benefits

80. Option 2 has the same type of monetised benefits as Option 1. They are:
    a. Enable the prompt response to diseases that pose significant risk to public health
    b. Prevent mortality and morbidity in the public
    c. Improve current public health responses and outcomes, including vaccine programmes
    d. Mitigate the risk of a pandemic
    e. Reduce pressure on the NHS

81. However, the scale of these benefits is smaller due to the exclusion of syphilis and gonorrhoeae (non-sterile site) from Proposal 2.

Option 2 net present value (NPV)

82. Option 2 has a 10-year NPV of -£13.1m.

Option 3 appraisal

Option 3 monetised costs

83. Option 3's costs reflect the exclusion of Proposal 3. Overall, we expected a total monetised discounted cost of £16.4m across 10-years for Option 3, as summarised in Table 12 below.

Table 12: Option 3 cost summary

	Fixed cost	Annual Cost- discounted at 1.5%											
		Y1	Y2	Y3	Y4	Y5	Y6	Y7	Y8	Y9	Y10	Total 10 year	TOTAL
Proposal 1	£0.0m	£1.3m	£1.3m	£1.3m	£1.3m	£1.2m	£1.2m	£1.2m	£1.2m	£1.2m	£1.1m	£12.2m	£12.2m
Proposal 2	£0.0m	£0.4m	£0.4m	£0.4m	£0.4m	£0.4m	£0.4m	£0.4m	£0.4m	£0.4m	£0.4m	£4.1m	£4.2m
TOTAL	£0.1m	£1.7m	£1.7m	£1.7m	£1.7m	£1.6m	£1.6m	£1.6m	£1.6m	£1.6m	£1.5m	£16.4m	£16.4m

Numbers may not sum due to rounding

Option 3 non-monetised costs

84. Select IT costs to UKHSA under Proposals 1 and 2 are unknown. These are costs to configure UKHSA's HPZone and CIMS systems under Proposal 1 and costs for systems to configure for non-human influenza A subtypes under Proposal 2.

85. The cost to NHS England and private laboratories under Proposal 2, to notify for the additional twelve causative agents, is unknown.

Option 3 monetised benefits

86. Option 3 does not have any monetised benefits at the consultation stage.

Option 3 non-monetised benefits

87. Option 3 has the same type and scale of monetised benefits under Proposal 1 and 2, as Option 1. They are:
    a. Enable the prompt response to diseases that pose significant risk to public health
    b. Prevent mortality and morbidity in the public
    c. Improve current public health responses and outcomes

d. Mitigate the risk of a pandemic
e. Reduce pressure on the NHS

88. Option 3 excludes the benefits of expanded laboratory reporting of negative and void test results, alongside the positive results they already report under the HPNR.

Option 3 net present value (NPV)

89. Option 3 has a 10-year NPV of -£16.4m.

Sensitivity analysis

90. Uncertainty in key parameters has been tested through sensitivity analysis, with ranges of these parameters presented below in Table 13. Our central 10-year discounted cost is £16.6m for Option 1. In the low estimate scenario, total 10-year discounted costs are £6.2m. In the high estimate scenario, total 10-year discounted costs are £43.4m. Therefore, total 10-year discounted costs of Option 1 range from £6.2m - £43.4m. Table 14 models the sensitivity for Option 2 which excludes syphilis and gonorrhoeae (non-sterile site). Option 2's central 10-year discounted cost is £13.1m and expected to range between £4.9m - £34.2m.

Table 13: parameter ranges for Option 1

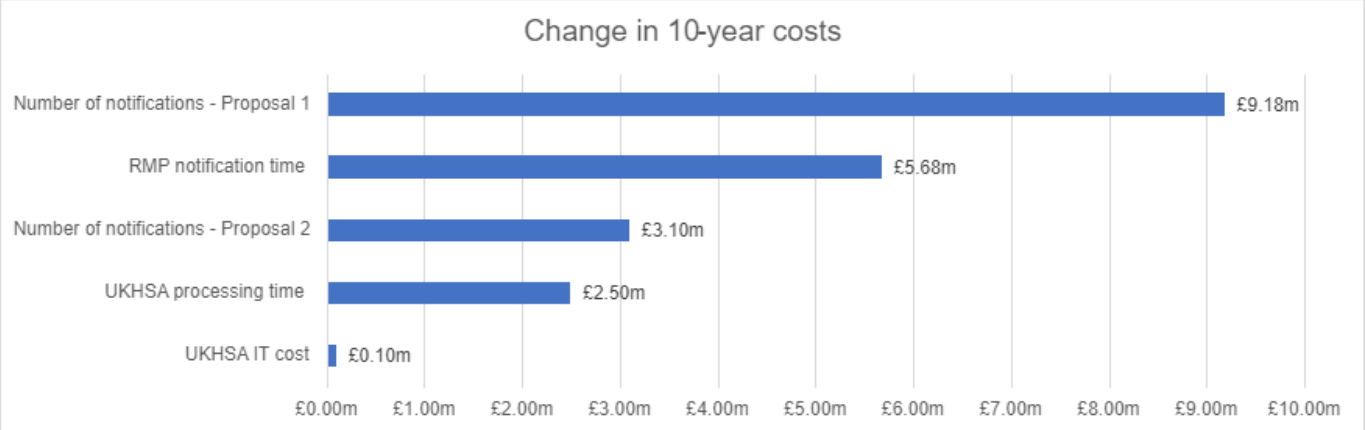
Parameter	Central estimate	Low estimate	High estimate	Sensitivity
Number of notifications- Proposal 1	27,540	20,655	48,195	-25%; +75%
Number of notifications- Proposal 2	132,396	99,297	231,693	-25%; +75%
RMP notification time	10 minutes	5 minutes	15 minutes	± 50%
UKHSA processing time	10 minutes	5 minutes	15 minutes	± 50%
UKHSA IT cost	£196,000	£98,000	£392,000	-50%; +100%
Total 10-year discounted cost- Option 1	**£16.6m**	**£6.2m**	**£43.4m**	**N/A**

Table 14: parameter ranges for Option 2

Parameter	Central estimate	Low estimate	High estimate	Sensitivity
Number of notifications- Proposal 1	27,540	20,655	48,195	-25%; +75%
Number of notifications- Proposal 2 (exc. G&S)	20,896	15,672	36,568	-25%; +75%
RMP notification time	10 minutes	5 minutes	15 minutes	± 50%
UKHSA processing time	10 minutes	5 minutes	15 minutes	± 50%
UKHSA IT cost	£180,000	£90,000	£360,000	-50%; +100%
Total 10-year discounted cost- Option 2	**£13.1m**	**£4.9m**	**£34.2m**	**N/A**

91. Secondly, we have tested the impact of isolated changes in each parameter on total costs to determine which parameters have the greatest impact on costs under Option 1. This is shown in the tornado chart below, in Figure 1, identifying that an increase in the number of notifications under Proposal 1 has the greatest impact on total 10-year costs. This reflects the uncertainty that surrounds the number of notifications for chickenpox. Increases or decreases in the assumed time to notify from the central estimate of ten minutes per notification, has a significant impact on total costs over 10-years. Overall, despite uncertainty in some parameters, sensitivity analysis shows this policy is unlikely to cross the £5m EANDCB threshold to business and the £30m annual cost to government departments.

Figure 1: sensitivity of parameters on total 10-year costs



Direct costs and benefits to business calculations

92. Businesses affected under this policy are private laboratories in England. These businesses will incur a cost to update their IT systems under Proposals 2 and 3 as discussed above. The total cost to businesses (private laboratories) is unknown and is non-monetised at the consultation stage.

93. These IT changes are expected to be relatively simple and we believe all businesses will comply with the regulations. We have therefore not modelled any costs of enforcement activity on non-compliant businesses.

94. The Equivalent Annual Net Direct Cost to Business (EANDCB) does not exceed the threshold of £5m that would necessitate a consultation impact assessment. Instead, we have produced this consultation impact assessment on grounds of syphilis and gonorrhoeae (non-sterile site) potentially being controversial inclusions under Proposal 2.

Risks and assumptions

95. DHSC wishes to make clear that while syphilis and gonorrhoeae (non-sterile site) have been listed alongside other proposed additions, their inclusion will be guided by responses to this consultation and this consultation impact assessment.

96. There may be several risks with the inclusion of syphilis and gonorrhoeae (non-sterile site). The primary risk is a concern over confidentiality. There are additional levels of confidentiality afforded to patients in relation to STI testing. This is an important part of sexual health services and the inclusion of these infections in schedule 2 may raise concerns around an individual's control over anonymity. Under schedule 2, when a laboratory reports a test result to UKHSA they must include the person's name, sex, current address and other personal details. Protecting an individual's right to confidentiality is vital and access to data collected through the HPNR is strictly controlled and only seen by those with a clear need. In turn, concerns over confidentiality may have an impact on individuals' behaviour to be tested for syphilis and gonorrhoeae (non-sterile site), possibly leading to harmful health consequences for the individual and their contacts.

97. There is no qualitative nor quantitative data to back up this assertion. We welcome comments in this consultation on the inclusion of syphilis and gonorrhoeae (non-sterile site). Furthermore, DHSC intends further engagement with stakeholders in this area.

98. The primary assumptions made are those relating to cost appraisal and are discussed above in the 'Options appraisal methodology' section and tested in sensitivity analysis. We welcome comments in the consultation on these, with emphasis on the below assumptions:
    a. What is the total value of IT costs that UKHSA are expected to incur over ten-years, for each of the three proposals, and are these a one-off cost?
    b. How long does it take a registered medical practitioner (RMP) to send a single notification?
    c. What is the total value of IT costs that NHS laboratories are expected to incur over ten-years, for each of the three proposals, and are these a one-off cost?
    d. What is the total value of IT costs that private laboratories are expected to incur over ten-years, for each of the three proposals, and are these a one-off cost?

Impact on small and micro businesses

99. Diagnostic private laboratories, range in size and some may be small businesses. We do not expect a disproportionate impact for small businesses on the basis that IT updates are a one-off cost to adapt existing systems. Because the cost to business falls far below the EANDCB threshold of £5m, we have not analysed this impact in further detail because it would be disproportionate to do so.

Wider impacts (consider the impacts of your proposals)

100. There may be a wider impact on the testing behaviour of those seeking testing for syphilis and gonorrhoeae (non-sterile site), as discussed in the risks section above. No wider impacts are expected from this policy, neither on individuals, the public sector, environment, and competition. We do not expect a disproportionate impact of this policy by protected characteristics because the amendments impact registered medical practitioners, laboratories and UKHSA public health teams, as opposed to English nationals.

A summary of the potential trade implications of measure

101. We do not expect that these amendments will impact trade or investment.

Monitoring and Evaluation

102. UKHSA public health teams will monitor the effectiveness of these amendments through engagement with key stakeholders. External factors are not expected to affect the success of these amendments, noting they fall on a select few stakeholders. Further stakeholder's views will be sought through stakeholder engagement in relation to the inclusion of syphilis and gonorrhoea (non-sterile site), following the consultation. This will further support this policy design and any subsequent analysis. Monitoring of these amendments will continue as part of future reviews of the Health Protection (Notification) Regulations which will seek to assess whether the regulations, and the diseases and causative agents included in them, remain up to date and fit for purpose.