Title:	Impact Assessment (IA)
Developing a new system of financial and other support for people infected with hepatitis C and/or HIV through blood and blood products in the UK **IA No:** 3140	**Date:** 1/7/16
	Stage: Post-consultation
	Source of intervention: Domestic
Lead department or agency: Department of Health	**Type of measure:** Other
Other departments or agencies:	**Contact for enquiries:** DH Infectious Diseases and Environmental Hazards

Summary: Intervention and Options

RPC Opinion: Not Applicable

Cost of Preferred (or more likely) Option				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANCB on 2009 prices)	**In scope of One-In, Two-Out?**	**Measure qualifies as**
-£1.11 million	£0m	£0m	No	NA

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

There is a significant degree of dissatisfaction with the current system of voluntary payments made by government to assist individuals with HIV and/or hepatitis C, who were infected via NHS-supplied blood or blood products before the relevant screening tests for blood donation and methods for inactivating viral contamination in plasma-derived products became available. The first of the current five schemes was established in 1988, with four further schemes following at various intervals, with different criteria for payments. Changes made in 2011 were not acceptable to many.

What are the policy objectives and the intended effects?

The reforms should:

- Be acceptable to a majority of scheme recipients, assessed in terms of their responses to the public consultation
- Be value for money for taxpayers, in terms of economy, efficiency and effectiveness over the SR period
- Not financially disadvantage existing scheme recipients in terms of what they could reasonably have expected to receive under the current, unreformed scheme
- Lie within the Department's tolerance of legal risk, as defined by Ministers
- Be affordable within the budget set for the current Spending Review (SR) period

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

Option 0: Carry on without reforming the existing scheme.

All the reform options include rationalisation of the administration arrangements, maintenance of all existing non-discretionary annual payments, introduction of annual payments for those who currently don't receive them, regular payments linked to CPI, and a special appeals mechanism to determine level of payments. In addition:

Option 1: Would remove the lump sum paid when Hep C infections reach greater severity.

Option 2: Would maintain the lump sum and offer a new lump sum to bereaved spouses and partners but offer lower annual payments in 2016/17 and 2017/18 to recipients with Hep C infections at earlier stages.

Option 3: Would introduce an exit payment for Hep C recipients who are successfully treated

Option 2 is the preferred option on the basis that overall it meets the objectives better than the alternatives. Nevertheless it would raise affordability concerns under certain payment demand scenarios. Option 1 would financially disadvantage recipients compared with what they would have received under the unreformed scheme. Option 3 would present severe affordability problems in the SR period, although it would significantly reduce expenditure in the longer term.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 12/2019

Does implementation go beyond minimum EU requirements?			N/A		
Are any of these organisations in scope? If Micros not exempted set out reason in Evidence Base.	**Micro** No	**< 20** No	**Small**No	**Mediu m**No	**Large** No
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 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:***

Summary: Analysis & Evidence

Policy Option 0

Description: Do Nothing

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2016	Time Period Years 5	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate: 0**

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	0		0	**0**

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

This is the do nothing option. Incremental costs are zero.

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

This is the do nothing option. Incremental costs are zero.

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

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

This is the do nothing option. Benefits are set to zero.

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

This is the do nothing option. Benefits are set to zero.

Key assumptions/sensitivities/risks **Discount rate (%)**

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			In scope of OITO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	No	NA

Summary: Analysis & Evidence

Policy Options 1, 2 & 3

Description: Reform options. Options 1, 2 and 3 have the same quantifiable societal costs and benefits, and hence have been summarised on the same sheet.

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2016	Time Period Years 5	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: -1.11

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low				
High				
Best Estimate	2.00		25.08	**118.83**

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

The transition costs arise through a) winding down some or all of the five existing organisations that currently administer ex-gratia payments and b) establishing a new administering organisation. The average annual cost relates to c) incremental ex-gratia payments made available from the Department of Health's central budget, and d) a small budget to fund medical assessments to determine the level of ex-gratia payments to a minority of scheme recipients.

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

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low				
High				
Best Estimate	0		25.19	**117.72**

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

The average annual benefits comprise savings to the Department of Health from more efficient scheme administration and the additional benefit that scheme recipients receive because of the increase in funding.

To note:

We have concluded that there are no net welfare effects from redistributing existing scheme funds, and allocating new funds. This, together with the finding that all options have the same resource cost and cost-saving implications, explains why the quantifiable social costs and benefits of Options 1, 2 & 3 are the same.

Key assumptions/sensitivities/risks — **Discount rate (%)** 3.5

Our key assumption is that the distributional welfare effects of reallocating parts of the existing budget and of additional spending on ex-gratia payments are neutral. This leads to our conclusion that the redistributions are transfers that have no net welfare effect on society.

A key risk arises because ex-gratia payments are demand led, and hence the annual budgets allocated to ex-gratia payments could be exceeded in the SR period. DH modelling suggests that this is a very significant risk for Option 3 because of the need to pay exit payments to a large number of scheme recipients in the early years of the reformed scheme. Although Option 2 brings lower affordability risks in the SR period, it would nevertheless suffer affordability problems if a large number of recipients were successful in their special appeals to become eligible for higher rates of payment. Option 1 carries the least risk of unaffordability in the SR period and is reasonably robust against demand variations.

BUSINESS ASSESSMENT

Direct impact on business (Equivalent Annual) £m:			In scope of OIOO?	Measure qualifies as
Costs: 0	**Benefits:** 0	**Net:** 0	No	NA

Introduction

1. As a result of treatment with NHS-supplied blood or blood products in the 1970s and 1980s, many thousands of people in the UK were infected with hepatitis C and/or HIV. Over 4,500 people with haemophilia in the UK were infected with hepatitis C through treatment with blood products[1]. Published scientific studies estimate that more than 28,000 other patients might have been infected with hepatitis C by blood transfusions[2]. Around 1,200 haemophilia patients and 100 other patients were similarly infected with HIV. To date, over 5,500 affected individuals have accessed dedicated financial support through seven payment schemes, with five ex-gratia schemes currently operational.

2. Readers of this IA will require an understanding of how the infected blood scheme classifies hepatitis C recipients. Recipients whose infections are pre-cirrhotic and therefore have not reached the most severe stages are called **Stage 1** recipients, while those whose infections have reached the most severe stages (cirrhosis) are called **Stage 2** recipients.

3. This is a post-consultation impact assessment. It has been informed by a public consultation that was held between January and April 2016.

Rationale for intervention

4. The current system has evolved in an ad hoc and incremental manner. The five schemes were established on an infection-specific basis and operate according to their own individual criteria.

5. In recent years, the UK Health Departments have worked to improve the current system, including introducing annual payments for those with HIV (in 2009) and for those most severely infected with hepatitis C (in 2011), and establishing the Caxton Foundation to provide discretionary support for those affected only by hepatitis C, operating alongside the Macfarlane Trust and Eileen Trust, the discretionary schemes already established for those affected by HIV. However, the four UK Health Departments acknowledge that some of those affected still have significant criticisms of the schemes, and the way in which the system is structured. Reform of the system is proposed, to address these concerns in the main and address beneficiaries' criticisms as far as reasonably practical.

6. Over the years, there have been repeated criticisms from different groups within the beneficiary community about the way that the current overall system has been set up and operates. Beneficiaries have conveyed their dissatisfaction through a number of different routes, including through an independent inquiry chaired by Lord Archer, which published its report in 2009; numerous campaigns; letters to the four UK Health Departments and Ministers; and through meetings with Ministers. Although we can only briefly summarise some of the main issues that those affected by HIV and hepatitis C infections have highlighted to us within the consultation document, much more information is available on the websites of the various groups that represent them.

7. Some of the concerns regarding the current payment schemes include:
    - that beneficiaries are not assessed on an individual basis;
    - the needs of some people with chronic hepatitis C infection are not adequately met or are inconsistently met;

[1] Source: UKHCDO Annual Report 2010

[2] Source: Soldan, Robinson et al. The contribution of transfusion to HCV infection in England. Epidemiology and Infection 2002. 128, 587-591 (figure corrected to cover UK).

- infected beneficiaries have to deal with more than one scheme;
- the bodies operate different payment policies;
- the principle of having to apply for charitable discretionary payments that are means tested;

8. These criticisms and concerns have been taken into account when suggesting potential scheme reform.

Policy objectives

9. The reforms should:
   - Be acceptable to a majority of scheme recipients, assessed in terms of their responses to the public consultation
   - Be value for money for taxpayers, in terms of economy, efficiency and effectiveness over the SR period
   - Not financially disadvantage existing scheme recipients in terms of what they could reasonably have expected to receive under the current, unreformed scheme
   - Lie within the Department's tolerance of legal risk, as defined by Ministers
   - Be affordable within the budget set for the current Spending Review (SR) period

10. This impact assessment refers only to the period of the current Spending Review (2016/17 to 2020/21). The government has committed to a review of the scheme reforms at the end of the current SR period, at which point future budgets and longer term affordability will be considered.

Policy Options

Policies considered

11. The development of the options for reforming ex-gratia payments have occurred in four consecutive phases, the first three of which were defined by different assumptions about the available budget. The final phase has been informed by responses from the public consultation.

Phase 1

12. Until Autumn 2014, the Department was working under the assumption that reforms would have to live within the existing budget of the unreformed scheme. Apart from the "do nothing" option, the Department considered reforms to replace the existing system with a new scheme that would make payments to individuals that align with the extent of their ill health.

Phase 2

13. In Autumn 2014, the Department started working on options under the assumption that an additional £25 million could be made available in the first year of reform in order to fund the transition from the existing scheme to the reformed scheme, and to decrease long term costs. The option involved offering all those infected in England with HIV and/or the most severe hepatitis C, and who were currently in receipt of non-discretionary annual payments, the choice of taking a lump sum of £50,000 in exchange for ending their entitlement for all future government funded ex-gratia support in relation to infected blood. Ultimately this option was rejected after feedback suggested that recipients would regard the compensation as too small. Take-up would therefore be very low.

Phase 3

14. Work on a new set of options began in November 2015 when the Secretary of State for Health announced that up to £100 million would be made available for ex-gratia payments over the life of the SR, in addition to the already announced £25 million for expenditure in the first year of reform. This additional funding became necessary when an important new reform objective was added: Reforms should not financially disadvantage existing scheme recipients in terms of what they could reasonably have expected to receive under the current, unreformed scheme. This new objective ruled out the reforms considered in Phase 1 because, without additional funding, some recipients would inevitably have had to accept reduced payments in order for the scheme to be able to afford increased payments to recipients who were suffering more severe ill health.

15. The options that were considered in Phase 3 were those that were consulted on publicly. These were:

    Option 1: Carry on without reforming the existing schemes (do nothing)

    Option 2: System reform, possibly combined with enhanced access to the new hepatitis C treatments, depending upon level of interest expressed through the consultation and weighed against affordability. System reform proposals were to:

    - replace the current five schemes with one operated by a single body
    - retain annual payments for those who currently receive them (for HIV and/or the most severe hepatitis C infections)
    - offer access to new highly effective but expensive hepatitis C treatment for some of those for whom the treatments are clinically appropriate on the basis of a treatment assessment and who are unlikely to receive it soon on the NHS. Access to these treatments would be paid for out of non-NHS funds.
    - introduce individual assessments for Stage 1 (see definition in the introduction section) hepatitis C recipients, to determine levels of annual payment based on the impact of infection on their health
    - similarly assess all new entrants to the scheme – both those with hepatitis C and HIV
    - consider whether to retain the lump sum on entrance to the hepatitis C scheme and remove the differential £50k lump sum paid by the hepatitis C scheme but not the HIV scheme
    - consider continuing with entitlement to discretionary payments or a lump sum payment, or a choice of either to exit the scheme for bereaved family members who currently receive regular support from the charities
    - consider providing newly bereaved partners/spouses of infected individuals with a payment for one further year after the bereavement, equal to the payment they were receiving at the time of death or to provide access to a discretionary element, or a choice of either.

Policies shortlisted (Phase 4)

16. The three shortlisted options that have been developed since the end of the public consultation all have the following features in common:
    - replace the current five schemes with one operated by a single body
    - Maintain the annual payment for those with HIV and Stage 2 hep C recipients but at a higher rate than under the unreformed scheme.
    - Link all regular payments to Consumer Price Index changes.
    - No individual assessments for Stage 1 hep C recipients. A majority of the public consultation responses were against the imposition of health assessments. Furthermore, feedback from clinical experts made it clear that making accurate assessments of the overall effect of less severe stages of Hep C infection on individuals' health would be very difficult.

- A new special appeals mechanism for those in Stage 1 hep C infections who believe their ill-health resulting from infection qualifies them for the higher levels of support (from 2017/18). This has been suggested as one way of mitigating criticisms that the reformed scheme could continue to discriminate against certain groups of recipients who suffer some types of extra-hepatic ill-health, where there may be evidence of association with the infection, but where a causal link has not been clearly demonstrated.
- Continuation of a discretionary scheme. Consultation responses indicated the value that individuals place on discretionary payments. This feature also serves the objective of ensuring that existing scheme recipients are not be financially disadvantaged by the reforms.
- Maintain the £20,000 lump sum for those with Hep C who newly join the scheme.
- No accelerated access to Hep C treatment. Although a majority of consultation respondents wanted treatment, there were objections to funding the new highly effective but expensive treatments out of the reformed scheme budget.

17. The **shortlisted Option 1** has the following additional features:
    - Removal of the previously available £50,000 lump sum on progression to Stage 2 hep C infections. This was considered as a way of improving the affordability of the scheme.
    - A new flat rate annual payment for recipients with Stage 1 hep C infections.

18. In addition to the features common to all the shortlisted options, the **shortlisted Option 2** has the following features:

    - Retain the £50,000 lump sum on progression to Stage 2 hep C infections. Although removing this lump sum would help to address the affordability objective, it would arguably not serve the "no financial disadvantage to existing scheme recipients" objective.
    - A one-off payment of £10,000 to bereaved partners/spouses (Existing and future)
    - In the first two years, lower flat rate payments than Option 1 for people with Stage 1 hep C infections. This feature would help to compensate for the loss of affordability of retaining the £50,000 lump sum and adding payments to bereaved partners and spouses.

19. In addition to the features common to all the shortlisted options, the **shortlisted Option 3** has the following features:

    - New exit payment for those with Stage 1 hep C infections on successful treatment. This feature seeks to address the long term affordability of the scheme by encouraging recipients to accept Hep C treatment offered by the NHS before they progress to the most severe stages of Hep C infection and qualify for lifelong annual payments under the infected blood scheme.
    - In the first two years, lower flat rate payments than Option 1 for people with Stage 1 hep C infections. While the introduction of the exit payment would help to tackle long term affordability it would create a problem of short term affordability. The lower rate of annual payment for recipients with Stage 1 hep C infections would help to overcome this short term problem.

Costs and Benefits of Option 1

20. Option 1 represents the counterfactual – what would happen in the absence of any new policy intervention. We have assumed that the counterfactual involves the continuation of the current schemes for ex-gratia payments.

Costs and Benefits of shortlisted options

Transition costs

21. All of the shortlisted options would create a one-off cost from winding down some of all of the five existing bodies that administer payments to recipients. These costs could include the termination of leases for office space, merging IT services, possible redundancy costs, communications and marketing.

22. Further funding could be required to establish a new administering body.

23. The total transition costs are currently uncertain. However, DH is planning to put aside £1 million for expenditure in 2016/17 and a further £1 million in 2017/18.

Cost of appeals process

24. All of the shortlisted options involve a new special appeals mechanism for those with Stage 1 hep C infections who believe their infected blood related ill-health qualifies them for the higher levels of support.

25. The nature of the assessments that will determine the success of appeals has yet to be determined. One option could be for the individual's GP/consultant to complete an assessment form using existing medical records. Information from the BMA website on Government Agreed Fees suggests a cost of £130 (for 45 minutes with a GP) or £207 (for one hour with a consultant .)

26. To compare this data source, NHS reference costs for 2014/15 found the average cost of a consultant led outpatient attendance was £132 . Evidence from the Unit Costs of Health and Social Care finds the hourly cost of a GP at £175 per hour .

27. Another option could be to operate individual infection impact assessments (IIAs) in a similar way to those undertaken by the Department for Work and Pensions (and their subcontractor MAXIMUS Health and Human Services Ltd) when assessing Employment and Support Allowance and existing claims for Incapacity Benefit.

28. Parliament's Public Accounts Committee found that Atos Healthcare (the previous subcontractor) had been paid £112.4m in 2011/12 to perform 738,000 Work Capability Assessments . This divides into a rate of £152 per assessment, which appears to be consistent with other estimates.

29. To conclude, we estimate a cost of between £132 and £207 with a central (midpoint) estimate of £170 per assessment.

30. The number of scheme recipients who would come forward for an appeal is uncertain. In 2017/18 the Department anticipates that there will be a total of 2,291 recipients who would be eligible for an appeal. There is great uncertainty about how many of these people would come forward with an appeal. The Department is currently working on the assumption that 10% will come forward in 2017/18 and none thereafter.

31. Under this assumption, there would be a one-off cost of approximately £40,000 of running appeals.

Cost of administering payments

32. Under all of the shortlisted options the five existing bodies would be replaced with a single body, and there would be costs to set up a single new organisation (or direct an existing organisation) that would administer a new scheme.

33. The replacement of five schemes with one should cause an overall reduction in the administrative cost, however it is not clear how far costs could be reduced. The estimated administrative cost for England across all the existing schemes is £605,000[3]. There is likely to be some overlap of function between the three charities, so some cost savings are possible. Equally, not all of the £605,000 can be saved as the merged body would still have a function to undertake.

34. As a proxy for the probable scale of savings, we have considered the scale of savings that were achieved during a reorganisation of the Department of Health's arm's-length bodies between 2003/04 and 2009/10. This reorganisation was able to produce a £0.5 billion saving from a total funding envelope of £1.2 billion, or a 40% reduction. This reduction is reported in a National Audit Office document[4].

35. It seems reasonable that this type of reduction reflects the avoidance of duplication of function, while maintaining a core function that still needs to take place. The replacement administrative structure would incur costs of its own. If we assume the same 40% reduction in administration cost should five schemes be replaced with one scheme, this implies that the cost of administration of the new scheme could be around 60% of £605,000 (£363,000).

The value for money of the Option 2 ex-gratia payments

36. The counterfactual (do nothing option) includes annual budgets for the continuation of existing ex-gratia payments to individuals. These same budgets would continue to be used in the reformed scheme, although in Option 1 and, to a lesser extent, in Option 3, some of these budgets would be reallocated to other recipients of ex-gratia payments.

37. Additional sums, which do not feature in the counterfactual, have also been allocated to the reformed scheme. An additional £25 million was allocated by the Department of Health in March 2015 to fund the transition from the old scheme to the reformed scheme in England. Up to a further £100 million will be allocated to the scheme for expenditure in England over the period of the spending review (2016/17 to 2020/21), profiled to spend up to £25m a year for each of the four years.

38. The theoretical value for money implications of spending the existing (counterfactual) budget and the new budgets are different. We have therefore separated our analysis into two distinct parts.

The value for money of spending the pre-existing budget

39. The part of the pre-existing budget that is not reallocated would be spent in exactly the same way as it would have been spent in the counterfactual. The value for money of spending these sums would therefore remain unchanged. This would be the case with all of the spending under Option 2, which maintains all previous ex-gratia payments (albeit some would be increased with the use of new funds).

[3] Adjusted for England from UK costs of £756,000.

[4] Releasing resources to the frontline: the Department of Health's Review of its Arm's Length Bodies, National Audit Office http://www.nao.org.uk/wp-content/uploads/2008/01/0708237.pdf

40. Option 1 would remove the £50,000 lump sum that is paid under the counterfactual to individuals who progress to more serious stages of Hep C infection (Stage 2). The money saved would be reallocated to other recipients in the scheme. Option 3 would remove fixed annual payments to recipients who are successfully treated by the NHS, albeit these recipients would receive some fixed sum compensation for no longer receiving regular ex-gratia payments. The net money saved would be reallocated to other recipients in the scheme.

41. In purely financial terms, these reallocations would balance out – there would be no aggregate gain or loss of money. However, from a societal welfare perspective, there are two possible arguments according to which the social value of such changes might not balance.

42. The first would occur if there were substantial differences in incomes between those who receive more money and those who receive less. As set out in the Treasury Green Book guidance, people with lower wealth generally gain more value (welfare) from a given amount of extra income than is the case for people with higher wealth. In the context of the ex-gratia payments reforms, if those recipients who would gain income from the reallocation of the pre-existing budget are on average less wealthy than those who would lose, then there would be a net welfare gain. However, there is no evidence available that suggests such wealth differentials exist in practice.

43. An additional (and contrary) argument is that, from a given starting point, individuals suffer a greater psychological loss from being deprived of income compared with the psychological gain they would experience from receiving an income increase of the same magnitude. The net welfare impact of redistributing income between two people of equal wealth can therefore be negative. Whilst there is evidence for this effect, standard practice in valuation of public policy is to ignore this differential, which would otherwise lead to a strong bias in favour of the do nothing option. A differential may be applied in decisions that involve prospective prevention of harm to health, but this is not the case here – the harm has already been done.

44. In the absence of further evidence, it is therefore reasonable to assume that the net welfare effect of the redistribution of payments is neutral.

The value for money of additional funds

45. As previously noted, up to an additional £125 million would be spent on the reformed scheme in England over the Spending Review period (2016/17 to 2020/21). In all three shortlisted options, these additional funds would be spent on new ex-gratia payments. They do not appear in the counterfactual and if reform does not go ahead, the funds would be used for other purposes. The use of the additional funds therefore comes with an opportunity cost.

46. The Department of Health would receive no additional funding from the exchequer and hence would have to find the additional funding from within its existing fixed central budget. To do this, the Department would have to forego other health expenditure, the societal opportunity cost of which is unknown. Although it is unlikely that funds would be diverted away from NHS front-line services, if this were to happen, the opportunity costs would be very substantial.

47. The societal benefit from allocating new funds to the scheme would be enjoyed by the scheme recipients. In the absence of evidence to the contrary, we have assumed that on average £1 of new income received by scheme recipients is valued as a £1 benefit by those individuals.

48. In conclusion, we believe that the societal costs and benefits of allocating additional funds are equal. This means that the value for money of spending additional funds would be neutral for all of the shortlisted options.

Summary of costs and benefits

49. The table below summarises the estimates of the societal incremental costs and benefits of the shortlisted options compared with the counterfactual (continuing with the current unreformed scheme). Note that all the options would experience the same resource costs and cost savings. Furthermore our conclusion that the welfare impacts of redistributing existing ex-gratia expenditure and allocating additional funding from the Department's central budget are neutral means that the costs and benefits are the same for all the shortlisted options.

	2016/17	2017/18	2018/19	2019/20	2020/21	Present value
Incremental costs						
New ex-gratia payments	£25,000,000	£25,000,000	£25,000,000	£25,000,000	£25,000,000	£116,826,980
Transition	£1,000,000	£1,000,000	£0	£0	£0	£1,966,184
Costs of appeals	£0	£38,947	£0	£0	£0	£37,630
Incremental benefits						
New ex-gratia payments	£25,000,000	£25,000,000	£25,000,000	£25,000,000	£25,000,000	£116,826,980
Annual admin saving	£0	£242,000	£242,000	£242,000	£242,000	£888,885
Net benefits	**-£1,000,000**	**-£796,947**	**£242,000**	**£242,000**	**£242,000**	**-£1,114,928**

Risks, assumptions and affordability

The effect of demand on affordability

50. Although we have concluded that the value for money implications of reforming ex-gratia payments are neutral regardless of the level expenditure or the distribution of funds between different types of recipient, there remains the risk that a reformed ex-gratia payment scheme could exceed its annual budget allocations. Once the rates of ex-gratia payments are set, spending is demand led and hence unpredictable. The key demand uncertainties are associated with:

- The number of individuals who will join the scheme in the Spending Review period
- The number of Stage 1 hep C recipients who have already been successfully treated
- The number of Stage 1 hep C recipients who will be successfully treated by the NHS within the Spending Review period
- The number of Stage 1 recipients who will be successful on special appeal to be eligible for Stage 2 payments.

New joiners

51. One risk is that publicity around the reform of the payment scheme might be alerting hitherto unregistered infected individuals that they can claim payments. If accepted onto the scheme, these individuals would be entitled to entry lump sums and annual payments.

52. The table below shows the number of Stage 1 payments made by the Skipton Fund from 2006/07 to 2014/15. Aside from a spike in payments in 2011/12 a publicity effect surrounding the 2011 reforms, the number of payments made has been on a relatively steady decline.

Financial Year	Number of Stage 1 payments made
2006/07	223
2007/08	227
2008/09	130
2009/10	163
2010/11	116
2011/12	144*
2012/13	131
2013/14	95
2014/15	102

Table 4: Number of new Stage 1 payments made by Skipton Fund 2006/07-2013/14

(* - The actual figure for 2011/12 was 583. However this included 439 payments made due to a change in criteria announced in January 2011. This change extended Stage 1 payment to individuals who died before the 29th August 2003 and hence there were 439 additional payments in that year.)

53. Eligibility for payment is based on evidence (including medical records) that, on the balance of probability, infection was acquired as a result of treatment with NHS-supplied blood or blood products during the relevant time periods (all prior to Sept 1991). With the passage of time, it is becoming increasingly difficult for new applicants to provide satisfactory evidence that NHS-supplied blood or blood products were the likely source of infection.

54. Over and above the numbers of successful new claimants that we would expect to come forward without the publicity effect, our baseline assumptions for modelling annual affordability incorporate an additional 30 new Stage 1 and 10 Stage 2 recipients in each of the years 2016/17 and 2017/18. These additional figures are based on estimates of the publicity effect during the previous reform process that concluded in 2011.

Already successfully treated Stage 1 recipients

55. About 25% of Stage 1 hep C recipients had already successfully cleared their infections (mostly through treatment with old therapies) by the time they joined the scheme. Unfortunately we do not know how many Stage 1 recipients have successfully cleared their infections *since* joining the scheme.

56. Option 3 introduces a lump sum exit payment for Stage 1 recipients who have been successfully treated. Consequently, even before the NHS rolls out new treatments to other Stage 1 recipients, Option 3 would have to afford payments to at least 25% of Stage 1 recipients who have already successfully cleared their infections. This would create a significant affordability problem in the early years of the reformed scheme. The proposed exit payment is £50,000 (chosen to match the lump sum that is paid on progression to Stage 2) and 25% of Stage 1 recipients is 580. This would mean a one-off spend of at least £29 million. This would create an over-spend even if it could be spread over two years.

NHS treatment

57. The speed with which the NHS will roll out the new Hep C treatments will also affect demand for ex-gratia payments. In Options 1 and 2, successful treatment of scheme recipients who are currently at Stage 1 of their hep C infections will eliminate the progression to more severe stages of illness and therefore reduce demand for the higher rates of ex-gratia payments at Stage 2. This will help to contain risks to affordability. Option 3 explicitly includes exit payments for successfully treated Stage

1 scheme recipients. Although this will help long term affordability, there is a risk that a rapid roll out of NHS funded treatment could lead to unaffordability in the short term.

58. The best information we currently have on how quickly the NHS will be able to treat hep C sufferers whose infections are at the less severe stages leads us to suggest that between 50% and 75% of Stage 1 recipients could be treated by the end of the SR period in 2020/21.

59. PHE estimates that there are about 160,000 people in England with hepatitis C, including those who contracted infection through infected blood. NHS England estimated that in 2015/16, around 150,000 of all those infected were at the less severe stages of disease. Approximately 5,000 of those with the most severe illness were treated in 2015/16, and NHS England's expectation is that a further 10,000 people will be treated in 2016/17, rising to 15,000 treated each year thereafter. This suggests that approximately 60,000 individuals with Hepatitis C will have been treated by 2020/21. Of this total, approximately 10,000 are at the most severe stages of the disease, and these individuals will be (have been) treated first. This means that 50,000 of 150,000 individuals at the less severe stages of the disease are likely to have been treated by 2020/21.

60. From this we might expect that 33% of infected blood scheme's Stage 1 recipients will have been treated by the NHS by the end of the SR period. However, it seems likely that infected blood scheme recipients will be more likely to receive earlier treatment on the grounds that:
- they are already within the care of the NHS, whereas some people in the remaining cohort are unaware of their infections and hence not currently in the NHS hep C treatment system.
- They have been infected for at least 25 years and therefore their infections are likely to be at a more advanced stage than the average in the cohort.

61. Our 50% to 75% assumption leads us to expect the following annual budget balances for Option 3:

		2016/17 (Start-up)	2017/18	2018/19	2019/20	2020/21
				£ million		
50% of Stage 1s treated in SR period	Total expenditure	38.0	74.9	40.6	39.8	38.7
	Annual budget	47.5	47.5	47.5	47.5	47.5
	remaining budget	9.5	-27.4	6.9	7.7	8.8
75% of Stage 1s treated in SR period	Total expenditure	38.0	80.4	45.8	44.2	42.5
	Annual budget	47.5	47.5	47.5	47.5	47.5
	remaining budget	9.5	-32.9	1.7	3.3	5.0

The spreadsheet and assumptions behind these summary figures are available on request.

62. Note that the significant overspend in 2017/18 is caused by giving lump sum exit payments to the 580 Stage 1 recipients who had already cleared their hep C infections on joining the scheme. Also note that this overspend is an underestimate because it fails to account for Stage 1 recipients who have successfully cleared their hep C infections since joining the scheme.

Special appeals

63. The final demand uncertainty concerns the number of Stage 1 recipients who will successfully appeal and be awarded the higher Stage 2 payments. Our baseline modelling uses the assumption that 10% will successfully appeal. However, there is currently a lot of uncertainty about this proportion. The estimated annual affordability of Option 1 is robust against changes in this assumption. However, Option 2's annual affordability is less robust. The table below shows the estimated effect of changing the assumption from 10% to 15% (the figures in red indicate an estimated overspend):

		2016/17 (Start-up)	2017/18	2018/19	2019/20	2020/21
				£ million		
10% of Stage 1s successful on appeal	Total expenditure	43.4	47.8	41.7	40.8	40.0
	Annual budget	47.5	47.5	47.5	47.5	47.5
	remaining budget	4.1	-0.3	5.8	6.7	7.5
15% of Stage 1s successful on appeal	Total expenditure	43.4	54.9	43.3	42.4	41.5
	Annual budget	47.5	47.5	47.5	47.5	47.5
	remaining budget	4.1	-7.4	4.2	5.1	6.0

The spreadsheet and assumptions behind these summary figures are available on request.

Preferred Option

64. The shortlisted Option 2 (described on page 7) is the preferred option because it meets most if not all of the objectives.

65. Depending on how many Stage 1 recipients are successful on appeal and hence are subsequently paid at higher rates, Option 2's performance against the affordability objective may become a cause for concern.

Direct costs and benefits to business calculations (following One-in, Three-Out methodology)

66. Impact Assessments that impose a regulatory impact on business, third sector and voluntary sectors must be assessed using the One-in, Three-out (OITO) methodology.

67. There is no regulatory impact on business or the private sector. Therefore, this policy sits outside the scope of the OITO methodology.

Wider impacts

68. The Department of Health impact assessment guidance requires consideration of wider impacts.

Statutory Equalities Duties

69. Chapter five of the consultation document covers a discussion of the Department's obligations under Statutory Equalities Duties and includes due regard to the Public Sector Equality Duty (PSED).

Small and Micro Business Assessment, Competition, Carbon Assessment, Wider Environmental issues, Rural Proofing, Sustainable Development

70. The Department does not consider there to be any impact on these wider impacts from this policy.

Human Rights

71. In terms of human rights, the policy potentially engages several articles of the European Convention on Human Rights (ECHR). In carrying out this policy the Department will aim to ensure that the policy is compatible with the ECHR.

Health and Well-being

72. The Department of Health has five screening questions in relation to assessing the impacts on health and well-being.

Will the proposal have a direct impact on health, mental health and wellbeing?

73. The process of assessing the degree of ill health among infected individuals may cause stress and anxiety. This is more likely given that the assessment would directly affect the size of payments individuals could receive.

Will the policy have an impact on social, economic and environmental living conditions that would indirectly affect health?

74. Option 2 would reform the size of payments made to infected individuals from infected blood. A change in their income that arises from Option 2 could have an indirect impact on individuals' health. The payments made in future would be a more accurate reflection of the degree of ill health for the infected individual.

Will the proposal affect an individual's ability to improve their own health and wellbeing?

75. It would be up to infected individuals to decide how they wish to use the funds available from this scheme. Under Option 2 there would be no ringfencing or requirement for how the money would be spent.

Will there be a change in demand for or access to health and social care services?

76. The new system would use assessments of infected individual's health to determine the size of the payment they receive. It is probable that the assessments would take place using NHS consultants or local GPs. As the format of assessments is subject to consultation it is difficult to say how the Department of Health would fund them. They could be funded through reimbursement of GP and consultant fees, or they could be paid through a central contract with a contractor.

Will the proposal have an impact on global health?

77. There would be no impact on global health.

Justice System

78. The proposed scheme would have a review mechanism through which individuals could challenge the bands they are placed in. The appeals mechanism would be operated separate to the justice system.

79. In addition, the policy is not regulatory in nature and it does not create offences. In summary, there would be no impact on the justice system from these proposals.