| *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<br>**IA No:** 3140 | **Date:** 21/01/2015 |
| | **Stage:** Consultation |
| | **Source of intervention:** Domestic |
| **Lead department or agency:**<br>Department of Health | **Type of measure:** Other |
| **Other departments or agencies:** | **Contact for enquiries:**<br>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** |
| Not available | £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. Only government can make changes, and this government has committed to consult on reforming the current schemes.

**What are the policy objectives and the intended effects?**

The policy objective is to provide a more accessible and equitable system of care and support, that focuses on the welfare of infected individuals. The intended effects are to safeguard the interests of all those who are/were chronically infected and currently receive annual payments; and for those not in receipt of annual payments: to link the level of financial assistance to the current impact that infection is having on their health. This would make the system more responsive to individual circumstances than currently, and could offer better value to the taxpayer.

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

Option 1: Carry on without reforming the existing scheme.
Option 2: Replace the existing 5 schemes with one scheme, maintain annual payments to those who already receive them, reform the rest of the payment system so that payments are based on severity of illness and potentially introduce enhanced access to hepatitis C treatment for some individuals.

**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 1

**Description:** Do Nothing

**FULL ECONOMIC ASSESSMENT**

| Price Base Year 2015 | PV Base Year 2015 | Time Period Years 10 | 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. Costs are set to zero.

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

This is the do nothing option. Costs are set to 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 Option 2

**Description:** Replace the existing 5 schemes with one scheme; maintain fixed annual payments to those who already receive them; reform the rest of the payment system for those current registrants with hepatitis C stage 1, and for new entrants with hepatitis C and/or HIV, so that annual payment amounts are determined by the outcome of periodic assessment of each person's health; and potentially introduce enhanced access to hepatitis C treatment for some individuals.

**FULL ECONOMIC ASSESSMENT**

| **Price Base Year** 2015 | **PV Base Year** 2015 | **Time Period Years** 10 | **Net Benefit (Present Value (PV)) (£m)** | | |
|---|---|---|---|---|---|
| | | | **Low:** | **High:** | **Best Estimate:** |

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

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

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

If only the pre-existing budget were available, reallocation would mean that, compared with Option 1, some individuals could receive lower payments in future than they would otherwise have done. This may be prevented by additional funding. Costs of providing enhanced access to Hepatitis C treatment would be borne by the Department in terms of funding treatment from its central budget, and funding ex-gratia payments for some individuals for longer. This would entail significant opportunity cost.

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

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

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

Compared with Option 1, some individuals will receive higher payments in future than they would otherwise have done. Benefits from enhanced access to treatment would be enjoyed by successfully treated individuals in terms of better health. Enhanced access benefits could also accrue to the Department of health in terms of cost savings from funding lower future rates of ex-gratia payments.

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

The key assumptions are (a) that additional funding allocated to this scheme will not impact on NHS budget and (b) that if enhanced access to hepatitis C treatment is included, this can be implemented without disadvantaging other patients who may receive such treatment. If these conditions are not met, expenditure on the scheme may result in significant net public disbenefit. All funds received by individuals are evaluated on a pound-for-pound basis, as are variations in the amounts received.

**BUSINESS ASSESSMENT (Option 2)**

| **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. This is a consultation stage impact assessment. It should be read alongside the consultation document which discusses the principles of system reform.

# Rationale for intervention

3. 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.

4. 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.

5. 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.

6. 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;
    - 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;

[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).

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

# Policy objectives

8. The policy objectives is to provide a more accessible and equitable system of care and support, that focuses on the welfare of infected individuals, and in which:
    - the assistance a person receives would be linked to the impact that infection is having on their health
    - the interests of infected individuals who already receive annual payments would be safeguarded
    - better value could be provided to the taxpayer.

# Policy Options

## Policies considered

9. A range of options had been considered and discarded in the development of this policy including those outlined below.

### Remove the funding for discretionary payments

10. One option was simply to discontinue those payments which are discretionary. However, this was not considered sufficient to remedy the inequity in the different bases on which payments are made to affected individuals.

### Replacing the three discretionary schemes with one

11. This option would mean that those who are eligible for discretionary payments in a new scheme would all be treated on the same basis. This would require complete overhaul of the current system of discretionary payments and it would not address concerns about current non-discretionary payments to infected individuals.

### Increase the payment available to individuals at Stage 1

12. Another option was to increase the size of the one-off payment available to individuals with Stage 1 hepatitis C. The payment would rise from £20,000 to £50,000, in line with the payment available to individuals with Stage 2 hepatitis C. Preliminary analysis found that this option would not reflect the wide spectrum of ill health in this group

### Make annual payments to all infected individuals

13. Under this option the annual payment of £14,749 would be extended to include individuals with Stage 1 hepatitis C. This would mean all infected individuals would receive the same level of annual payment. Preliminary analysis found that this option would not reflect the spectrum of ill health amongst recipients.

### Restructure annual payments on the basis of impact of infection on health, and extend eligibility to all infected individuals

14. Under this option, long-term financial assistance would be re-targeted so that all those infected or suffering residual side effects from treatment would become eligible for assessment for annual payments. The highest level of payment would be directed to those whose health was most affected, based on individual assessment, and health would be reviewed periodically to ensure assistance

remained linked to impact over time. This would result in a single payment per person, rather than a payment per infection as now. In considering this option, it was assumed that the amount of money available in future years would remain at the same level as the current budget. Analysis found that while this option would provide access to annual payments to the non-cirrhotic hepatitis C cohort, it would also result in a reduction in payments for all beneficiaries already in receipt of two annual payments, and likely also for some in receipt of a single annual payment, and that payments for dependants, spouses and widows would need to be tapered down before stopping in order to prioritise available funding for infected individuals.

## Policies shortlisted

15. There are two options shortlisted for more detailed consideration.

### Option 1: Carry on without reforming the existing schemes

16. Under Option 1, the current ex-gratia payment system for individuals affected by hepatitis C and/or HIV infection continues. The level of payments made for the different degree of ill health will continue to be those described in Chapter 1 of the consultation document. This option is included as the counterfactual against which the impacts of Options 2 are compared.

### Option 2: System reform, combined with enhanced access to the new hepatitis C treatments

17. The main elements of the proposed reformed scheme are to:

a) replace the current five schemes with one operated by a single body
b) retain annual payments for those who currently receive them (for HIV and/or hepatitis C stage 2 infection)
c) offer access to new 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.
d) introduce individual assessments for those with hepatitis C stage 1, to determine levels of annual payment based on the impact of infection on their health
e) similarly assess all new entrants to the scheme – both those with hepatitis C and HIV
f) 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
g) 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

*Explanation of "individual assessment" proposal*

18. Individuals whose hepatitis C infection is in stage 1, and all new entrants to the scheme, would be assessed to determine the impact their infection is having on their health, or the residual ill-health after treatment. The outcome of an individual assessment would be used to determine the allocation of each individual into a payment band. Details would need to be formulated, but it is anticipated that there would likely be a number of broadly defined bands of ill health with different levels of annual payment attached to each. The greatest impact of infection on health would attract the highest annual payment.

19. It is likely that individuals would be re-assessed at regular intervals, and an individual would be able to request an early re-assessment at any time if their condition deteriorated. A request for early re-assessment would likely require support from an individual's clinician. Individuals could be moved into a different payment band if their assessment indicated that they met the criteria. It is anticipated

that health professionals may be asked to provide information to enable any new scheme to assess to which payment band an individual would belong.

*Explanation of the hepatitis Caccess treatment proposal*

20. The NHS is currently rolling out new, highly effective but expensive HCV treatment. NHS budget constraints mean that treatment will be offered to the most severely ill patients first. The treatment of patients whose condition has advanced to the cirrhotic stage and beyond will therefore be prioritised. Consequently, some non-cirrhotic hepatitis C sufferers may have to wait several years before they can benefit from the new treatment. Under Option 2, the Department of Health could potentially fund an enhanced access scheme for non-cirrhotic individuals infected with hepatitis C through treatment with NHS-supplied blood or blood products. This would focus on those who fall just outside of the current NHS roll out plans. The implementation of any Department of Health-funded scheme would be designed as far as possible to ensure that NHS patients whose conditions are not associated with infected blood would not be disadvantaged in any way. Going forward with this part of the proposal would be dependent on gaining assurance that this can be achieved.

# Costs and Benefits of Option 1

21. 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. In addition it involves the roll out of new hepatitis C treatments by the NHS.

22. In theory we could have chosen a counterfactual that would have involved starting from a zero base – ie no payments to any recipients. However, such a scenario would prove politically unworkable and hence does not present a realistic counterfactual.

23. The schedule for the roll out of treatment of NHS England funded treatment is not currently known. However, we understand that patients with the most advanced infections will be offered treatment in the next year or two. Patients with less severe cases may have to wait several years longer before they are offered treatment.

# Costs and Benefits of Option 2

### Transition cost of cessation of funding for the five existing bodies

24. There would be a relatively small one-off cost from ending the funding of the five existing bodies. These costs could include the termination of leases for office space, merging IT services, possible redundancy costs, communications and marketing etc. These costs have not been quantified.

### Cost of the individual health assessments

25. A key feature of Option 2 would be the introduction of individual assessments. These would be used to determine to which payment band infected individuals are allocated.

#### Number of assessments

26. All infected individuals who do not continue on existing annual payments would be invited to undergo an assessment of the impact of infection on their health.

27. The table below gives the number of infected individuals from the latest data available to DH in November 2015. There are a total of 3,058 infected individuals in England[3].

| Hepatitis C infection Stage | HIV: Yes | HIV: No | TOTAL |
|---|---|---|---|
| **No Hepatitis C** | 61 | | 61 |
| **Stage 1**[4] | 181 | 2,221 | 2,402 |
| **Stage 2**[5] | 63 | 532 | 595 |
| **TOTAL** | **305** | **2,753** | **3,058** |

**Table 1: Breakdown of infected individuals, November 2015 (England)**

### Cost of assessment

28. The individual assessment process could work in different ways. This is discussed in Chapter 3 of the consultation document. Possible options for the cost of the assessment are considered here. The cost of the assessments for individuals infected in England will be borne by DH within the current financial resources available.

29. 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[6].)

30. To compare this data source, NHS reference costs for 2014/15 found the average cost of a consultant led outpatient attendance was £132[7]. Evidence from the Unit Costs of Health and Social Care finds the hourly cost of a GP at £175 per hour[8].

31. 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.

32. 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[9]. This divides into a rate of £152 per assessment, which appears to be consistent with other estimates.

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

### Frequency of assessment

34. Clearly the total cost of assessments depends directly on how frequently they occur. The (hypothetical) assumption in this impact assessment is that assessments would take place every three years. It may be the case that re-assessment intervals differ between different groups of

[3] This number covers all primary beneficiaries who are not known to be dead (that is, we do not know if the recipient is alive or not; as a conservative estimate in this analysis we assume all recipients are alive)

[4] Stage 1 refers to hepatitis C infections that are not currently associated with cirrhosis

[5] Stage 2 refers to hepatitis C infections that are associated with cirrhosis

[6] Based on "Medical examination and report or complex written report and opinion (eg 45/60 mins)" http://bma.org.uk/practical-support-at-work/pay-fees-allowances/fees

[7] National Schedule of Reference Costs: the main schedule, consultant led outpatient attendances: https://www.gov.uk/government/publications/nhs-reference-costs-2014-to-2015

[8] Page 195, per hour of patient contact, without qualification costs and excluding direct care staff costs. http://www.pssru.ac.uk/project-pages/unit-costs/2014/

[9] Source: House of Commons Committee of Public Accounts, Department for Work and Pensions: Contract management of medical services, paragraph 48 http://www.publications.parliament.uk/pa/cm201213/cmselect/cmpubacc/744/744.pdf

infected individuals. Decisions on re-assessment intervals would be informed by expert clinical advice.

**Cost estimates**

35. The table below estimates the range of costs that might be incurred for completing infection impact assessments.

| | Total cost (minimum) | Average cost (mid-point) | Total cost (maximum) |
|---|---|---|---|
| **Cost of assessment** | £315,000 | £405,000 | £495,000 |

Table 2: Cost estimates for infection impact assessments (England)

## Cost of administering payments

36. Under Option 2 all five 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.

37. 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[10]. 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.

38. 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[11].

39. 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**

40. The counterfactual (Option 1) includes a budget for the continuation of existing levels of ex-gratia payments to individuals. This same budget would continue to be used in the reformed scheme (Option 2), although some of it would be reallocated. The part of the budget that would not be reallocated would be used to maintain the annual payments that some individuals already receive. For ease of reference, we refer to these payments in this impact assessment as "fixed annual payments". The current annual cost of the existing annual payments is approximately £13 million.

41. Most of the remainder of the Option 1 budget is currently used for lump sum and discretionary payments (approximately £9 million in 2015)[12]. Lump sums of £20,000 would continue for those newly accepted onto the scheme and views are being sought on the retention of the £50,000 lump sum on progression to advanced stage of liver disease. We are consulting those already bereaved

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

[11] 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

[12] The balance is made up of administrative costs.

and receiving means-tested discretionary payments whether they would like to retain access to a discretionary scheme or receive a final lump sum, or the choice between both.

42. An additional £25 million was allocated by the Department of Health in March 2015 to manage 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).

43. The division of these additional funds between new ex-gratia payments and any hepatitis C treatment is currently unknown. We are therefore only able to provide qualitative analyses of the value for money of spending funds on ex-gratia payments and enhanced access to treatment.

44. The value for money implications of spending the existing (Option 1) budget and the new budget are different. We have therefore separated our analysis into two distinct parts.

## Value for money of spending the pre-existing budget

45. The part of the pre-existing (Option 1) budget that is not used to fund continuation of fixed annual payments and other payments, such as lump sums, would be reallocated in a way that is designed to meet the objectives of creating a simpler scheme and linking new annual payments on the impact of infection, including as a result of treatment, on each person's health. If only the pre-existing budget were available, this reallocation would mean that, compared with Option 1, some individuals could receive higher or lower payments in future than they would otherwise have done. In purely financial terms, these changes would necessarily balance out. There are two possible arguments according to which the *social value* of such changes might not balance out, neither of which apply here. The first would occur if there were substantial differences in incomes. As set out in the Treasury Green Book guidance, people with lower incomes in general gain more value from an extra pound of income. The Department of Health does not hold data on the income of individuals who receive ex-gratia payments. One of the objectives of Option 2 is to link the assistance a person receives to the impact that infection is having on their health We would therefore expect those gaining most to comprise individuals who have lower health related quality of life. Research conducted by the University of Sheffield's School of Health and Related research (ScHARR) has measured the link between health related quality of life, age and productivity. Unsurprisingly, productivity declines with age and increases with health related quality of life. To the extent that productivity determines workplace earnings, we would expect that people with lower quality of life will have lower earnings. However, workplace earnings are only one aspect of an individual's income. Among other things, state welfare payments, returns on investments and, in the case of infected blood, ex-gratia payments all contribute to income. There is thus an argument that the proposed redistribution would lead to a net increase in social value, but it is far from conclusive. An additional (and contrary) argument is that in general losses from a given starting point are psychologically valued more highly than gains, so that redistribution will in general reduce net value. 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 status quo. A differential may be applied in decisions that involve prospective prevention of harm to health, but this is not the case here.

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

47. To safeguard the interests of individuals who already receive annual payments, under the reformed scheme (Option 2), a large part of the pre-existing (Option 1) budget would continue to be spent on making payments to recipients who already receive these payments under the current scheme

(Option 1). However these payments would not, under current proposals, be linked to inflation. Index linking has been a feature of the current scheme and we have no reason to believe that this would not continue to be the case if scheme reform were not to take place.

## The value for money of additional funds

48. 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). Some of these additional funds would be spent on new ex-gratia payments in England. These additional funds 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.

49. 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 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.

50. The opportunity cost of the foregone health expenditure represents the societal cost of allocating new funds to the infected blood payment scheme Option 2. The societal *benefit* from allocating new funds to Option 2 would be enjoyed by the scheme recipients. In the absence of evidence to the contrary, we have assumed that on average £1 received by scheme recipients is valued as a £1 benefit by those individuals.

51. With the evidence currently available, we can only conclude that the balance between the societal costs and benefits of allocating additional funds to the infected blood scheme is uncertain.

## The value for money of enhanced access to hepatitis C treatment

52. The benefits from enhanced access to hepatitis C treatment fall into four categories:
    a. Quality of life benefits to those who are treated. Successfully treating patients earlier than would be possible under the NHS would allow individuals to enjoy the health benefits of successful treatment for longer and would also reduce the probability that individuals' health would deteriorate further as a result of their hepatitis C infections.
    b. Department of Health cost savings on future ex-gratia payments. Under Option 1 (and even more so under Option 2), eligible individuals would be entitled to higher rates of ex-gratia payment when their hepatitis C infection causes specific worsened states of ill health. Stopping this health deterioration through successful treatment would remove the need for higher levels of payment, although would not remove the need for payments for remaining ill health effects once the hepatitis C virus has been cleared from the body.
    c. Ex-gratia payments may continue for longer for some individuals. To the extent that successful hepatitis C treatment extends the life of individuals, the period during which ex-gratia payments are disbursed could also be extended.
    d. Cost savings for the NHS. Every course of hepatitis C treatment that the Department of Health funds from its central budget would remove the need for the NHS to fund a course of treatment. This would have been either the relatively cheap pre-existing treatment or one of the expensive new forms of treatment.

53. The costs of an enhanced access scheme would fall into three categories:

    e. The cost to the Department of Health of funding treatment from its central budget.

f. The cost to the Department of Health for funding ex-gratia payments for longer for some individuals. This is the counterpart to "c" above.
g. The cost to individuals from receiving lower future rates of ex-gratia payment. This is the counterpart to "b" above.

54. An important assumption in assessing the costs and benefits of accelerated access to treatment is that the intervention could be designed in such a way that the scheme would not compete with the NHS for scarce resources. For instance if enhanced access took expert clinicians away from their normal NHS activities, it would be at the expense of NHS patients in general. The net health benefits in the UK as a whole would be lower and there would therefore be an extra societal cost associated with the enhanced access to treatment.

55. With further information, we could estimate the costs and benefits to provide a more complete picture of the value for money of enhanced access to treatment. The NHS has yet to decide specific roll out plans for the new hepatitis C treatments. Without this information we do not know for whom, and by how much treatment could be brought forward. However, we expect that by the time the final analysis of value for money gets underway after the public consultation, more information should be available to allow quantitative estimates of costs and benefits.

56. For the time being we can only comment qualitatively on the possible balance between costs and benefits.

*Health benefits*

57. The more individuals that Option 2 could provide enhanced access to treatment for, the greater would be its health benefits. The greatest constraint on the Department's ability to fund treatment is the pressure on the Department's central budget spending. If few patients receive Department-funded treatment significantly in advance of when they would have received treatment on the NHS, the health benefits would be modest.

*Lower ex-gratia payment rates after successful treatment*

58. Similar considerations apply to changes in ex-gratia payments that would occur due to successfully treated individuals becoming ineligible for higher rates of payment. Again, the scale of the changes could be modest. The cost-saving to the Department of Health would, at least in financial terms, be equal to the cost to the individuals who receive lower rates of payment.

*Increased length of ex-gratia payment period after successful treatment*

59. Although it seems reasonable to believe that successful treatment would extend the life of a patient, we could find no empirical evidence on what the effect is. We are therefore unable to judge the extent to which the period that ex-gratia payments to individuals could be extended. In financial terms, the cost to the Department of Health of funding ex-gratia payments for longer would be equal to the benefits to the individuals who receive those payments for longer.

*Differences between the cost per treatment funded by the NHS and by the Department*

60. As noted above, the money that the Department spends on a course of treatment is counted as a cost, while the money that the NHS no longer has to spend on a course of treatment is counted as a benefit. In the case of patients who would otherwise have been treated by the NHS with the relatively cheap pre-existing treatment, the net treatment cost would be considerable. This would be because the new treatments are much more expensive than the pre-existing treatments.

61. In the case of patients who would otherwise have been treated by the NHS with the new expensive treatments, NHS treatment costs would still be lower than Department of Health funded treatments.

Because of its scale of operations and its purchasing power, the NHS can generate cost efficiencies. This means that it can purchase and deliver a course of hepatitis C treatment more cheaply than a Department funded scheme could achieve. Our estimates suggest that on average a course of the new hepatitis C treatment delivered by the NHS costs between £32,000 and £42,000, while the cost to the Department would be between £35,000 and £54,000[13]. The difference in cost could therefore be as much as £12,000[14].

*Balance between costs and benefits*

62. Without more information than is currently available, it is difficult to judge the balance between costs and benefits of enhanced access to treatment. The key determinants are likely to be:

- How many of the more serious cases the NHS would treat. If the NHS (rather than the Department's enhanced access scheme) treats the cases that are most in danger of progressing to greater ill-health, then "enhanced access" would bring limited health benefits and ex-gratia payment savings.
- The difference between the NHS costs of treatment and the Department scheme costs of treatment. The greater the difference in cost, the lower would be the value for money of "enhanced access".

# Risks and assumptions

## Demand effects

63. One risk is that announcements of the reform of the payment scheme might result in more infected individuals coming forward to claim payment, who have not received a payment before. These individuals would be entitled to payment as much as those who are already registered. However, since the policy needs to be sustainable to Government in financial terms, this means the size of payments available may be smaller when divided across a larger group of people.

64. The table below shows the number of Stage 1 payments made by the Skipton Fund over the past few financial years. Aside from a spike in payments in 2011/12 caused by the extension in criteria for payment, 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** | 583* |
| **2012/13** | 131 |
| **2013/14** | 94 |

**Table 4: Number of Stage 1 payments made by Skipton Fund 200607-2013/14**

(* - This figure is higher as a response to the change in criteria announced in January 2011. This change extended Stage 1 payment to individuals who died before the 29th August 2003.)

[13] The higher estimate of the Department treatment cost reflects the possibility that VAT will have to be paid.

[14] Note that the lower estimates and higher estimates are linked, so that, for instance, lower estimates for NHS and DH should be compared with each other but not with higher estimates.

65. 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.

### Financial risk

66. The number of individuals likely to be eligible for the highest band for new annual payments is unknown. Coupled with the demand effect above, there is a risk that the total sum of payments made exceeds the financial envelope that is available for this scheme. Before assessments take place, Government would set the total amount available dependent on financial pressures in that year. Once assessments take place, and after the numbers of individuals within each band are confirmed, the payments could be set to try to ensure the total does not exceed the financial envelope.

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

67. 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.

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

## Wider impacts

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

### Statutory Equalities Duties

70. 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

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

### Human Rights

72. 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

73. 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?*

74. 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?*

75. 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?*

76. 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?*

77. 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?*

78. There would be no impact on global health.

## Justice System

79. 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.

80. 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.