

‘No-Blame’ Redress Scheme

**A Public Consultation on Draft Proposals for
a ‘No-blame’ Redress Scheme in Scotland for
Harm Resulting from Clinical Treatment**

March 2016

'NO-BLAME' REDRESS SCHEME

A Public Consultation on Draft Proposals for a 'No-blame' Redress Scheme in Scotland for Harm Resulting from Clinical Treatment

Responses are invited by 24 June 2016

**Directorate for Population Health Improvement,
Scottish Government Health and Social Care Directorates**

Responding to this consultation paper

We are inviting written responses to this consultation paper by 24 June 2016.

Please send your response with the completed Respondent Information Form in Part 2 (see "Handling your Response" below)

By e-mail: No-BlameRedressScheme@gov.scot

Or

By mail: No-Blame Redress Scheme Team

Care, Support and Rights Division

Room 2ER

St Andrew's House

Edinburgh

EH1 3DG

If you have any queries please contact Julie Crawford on 0131 244 0355.

We would be grateful if you would use the consultation questionnaire provided in Part Two as part of the **Respondent Information Form** or could clearly indicate in your response which questions or parts of the consultation paper you are responding to as this will aid our analysis of the responses received.

This consultation, and all other Scottish Government (SG) consultation exercises, can be viewed online on the consultation web pages of the Scottish Government website at <http://www.scotland.gov.uk/consultations>.

The Scottish Government has an email alert system for consultations, <http://register.scotland.gov.uk>. This system allows stakeholder individuals and organisations to register and receive a weekly email containing details of all new consultations (including web links). It complements, but in no way replaces SG distribution lists, and is designed to allow stakeholders to keep up to date with all SG consultation activity, and therefore be alerted at the earliest opportunity to those of most interest. We would encourage you to register.

Handling your response

We need to know how you wish your response to be handled and, in particular, whether you are happy for your response to be made public. Please complete and return the Respondent Information Form attached as Part 2 of the consultation document as this will ensure that we treat your response appropriately. If you ask for your response not to be published we will regard it as confidential, and we will treat it accordingly. All respondents should be aware that the Scottish Government are

subject to the provisions of the Freedom of Information (Scotland) Act 2002 and would therefore have to consider any request made to it under the Act for information relating to responses made to this consultation exercise.

Next steps in the process

Where respondents have given permission for their response to be made public and after we have checked that they contain no potentially defamatory material, responses will be made available to the public in the Scottish Government Library. You can make arrangements to view responses by contacting the SG Library on 0131 244 4552. Responses can be copied and sent to you, but a charge may be made for this service.

What happens next?

Following the closing date, all responses will be analysed and considered along with any other available evidence to help us consider the way forward. We aim to issue a report on this consultation process along with our Bill proposals and consultation later in 2016.

Comments and complaints

If you have any comments about how this consultation exercise has been conducted, please send them to the address given above.

If you want additional paper copies of the consultation paper, or if you or someone you care for requires this paper in a different format or language, please contact us at:

*No-Blame Redress Scheme Team
Care, Support and Rights Division
Room 2ER
St Andrew's House
Edinburgh
EH1 3DG*

Or e-mail to: No-BlameRedressScheme@gov.scot

Copies of the documents mentioned in this paper can also be obtained from these addresses.

This consultation is being conducted in line with the Scottish Government's consultation process Consultation: Good Practice Guidance¹

This consultation, and all other Scottish Government consultation exercises, can be viewed online on the consultation web pages at <http://www.scotland.gov.uk/consultations>. You can telephone Freephone 0800 77 1234 to find out where your nearest public internet access point is. There will be no charge for this call.

¹<http://www.scotland.gov.uk/Resource/Doc/1066/0006061.pdf>

A Public Consultation on Draft Proposals for a No-Blame Redress Scheme in Scotland for Harm Resulting from Clinical Treatment

This consultation is for anyone who would be affected in anyway by a change in the compensation arrangements for injuries resulting from clinical treatment. There are a number of interests at stake, for example: NHS and private patients or staff; patient's families; carers; NHS Boards; healthcare professionals; NHS and private healthcare providers, equipment suppliers, regulatory bodies, Royal Colleges, medical defence associations; and the legal profession.

The consultation paper explains the background to the work undertaken by the No-fault Compensation Review Group established by the Scottish Government in 2009. It should be read in conjunction with the Review Group's report², the Researcher's Study report³ and the Scottish Government response⁴ to the consultation on the Review Group's recommendations.

In particular the consultation seeks views on the proposals for:

- principles and eligibility criteria
- scope
- legislation
- continuing care costs
- administration, independence and funding
- appeals process

The consultation questions are included within the text of the paper in Part 1, and for ease these are repeated behind the Respondent Information Form, included at Part 2.

² <http://www.gov.scot/Topics/Health/Policy/No-Fault-Compensation/ReviewGroupVol1>

³ <http://www.scotland.gov.uk/Publications/2012/06/2348> and <http://www.scotland.gov.uk/Publications/2012/06/2048>

⁴ <http://www.gov.scot/Publications/2014/04/6437>

A Public Consultation on Draft Proposals for a ‘No-blame’ Redress Scheme in Scotland for Harm Resulting from Clinical Treatment

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Ministerial Foreword

The Scottish Government is committed to ending the blame culture that exists around medical negligence claiming. We want to develop a new system of compensation that fits with our focus on prevention and improving the quality of care outcomes, as well as our aim to improve openness and transparency across NHS Scotland and promote a culture of constant learning and improvement.

In April 2014, Alex Neil MSP, the then Cabinet Secretary for Health, confirmed our commitment to ensuring that “any patients harmed as a result of poor clinical treatment have access to redress in the form of compensation, where this is appropriate, without the need to go through lengthy court processes”. His announcement also explained that we would seek to explore the complexities of the scope, shape and development of a no-fault compensation scheme for Scotland.

Careful consideration has since been given to possible approaches, which would meet this commitment and provide access to financial redress, where appropriate. Importantly, we are looking to establish a person-centred scheme which is trusted as fair by patients and staff alike, which will reduce legal costs and for the majority of people, the need to go through lengthy and costly court processes. Importantly, it also needs to fit with our existing NHS feedback and complaints procedures.

This consultation paper seeks your views on draft outline proposals which combine a new approach for dealing with compensation for avoidable harm (up to £100,000) with improvements to the existing legal process.

The outline proposals detailed below take account of important changes and improvements introduced since the initial work, undertaken by Professor Sheila Mclean’s No-fault Compensation Review Group, which reported in 2011. For example, our Person-Centred Health and Care Programme, the Patient Rights (Scotland) Act 2011, the Patient Charter, the Courts Reform (Scotland) Act 2014⁵, the review of the NHS Feedback and Complaints procedures, the national approach to learning from adverse events through reporting and review⁶ and the new statutory Duty of Candour⁷ procedure.

All of these policies seek to further develop our NHS to be as person-centred as it can be and to continually strive to improve the patient experience and the safety of the services it provides. Staff are required to be open, honest and transparent. Under the feedback and complaints process, adverse event reporting and the new Duty of Candour arrangements, the patient (and their families) should be informed when and why an error, which has resulted in harm, has occurred.

The draft outline proposals reflect this and seek to ensure that the scheme is easily accessible for those who have been affected and that the NHS shares vital learning through reporting and review, which will in turn reduce the number of adverse events.

⁵ <http://www.legislation.gov.uk/asp/2014/18/contents/enacted>

⁶

http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx

⁷ <http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89934.aspx>

I would welcome your considerations and responses, which will help us refine and finalise a No-blame Redress Scheme for Scotland, to be progressed in the next Parliamentary session.

Shona Robison
Cabinet Secretary for Health, Wellbeing and Sport

1. Introduction

1.1 The existing approach is that “*the NHS does not pay compensation when it has no legal liability for the harm suffered by the patient*”.

1.2 Research suggests that between 10-25% of episodes of healthcare (in general hospital, community hospital and general practice) are associated with an adverse event. One third to a half of these events are thought to be avoidable⁸.

1.3 The definition of an adverse event taken from the National Framework⁹ issued by NHS Healthcare Improvement Scotland (HIS), originally in September 2013, with a second edition in April 2015 is:

‘An adverse event is defined as an event that could have caused (a near miss), or did result in, harm to people or groups of people.’

2. Background

2.1 A No-fault Compensation Review Group, Chaired by Professor Sheila Mclean, Professor of Law and Ethics in Medicine, Glasgow University, established in June 2009, was asked to:

“consider the potential benefits for patients in Scotland of a no fault compensation scheme for injuries resulting from medical treatment, and whether such a scheme should be introduced alongside the existing clinical negligence arrangements.”

2.2 The Review Group reported in February 2011¹⁰ recommending consideration be given to establishing a no-fault scheme to cover all medical injury in Scotland (not just NHS) along the lines of the Swedish no-blame scheme as follows:

“Recommendation 1 - We recommend that consideration be given to the establishment of a no fault scheme for medical injury, along the lines of the Swedish model, bearing in mind that no fault schemes work best in tandem with adequate social welfare provision

Recommendation 2 - We recommend that eligibility for compensation should not be based on the ‘avoidability’ test as used in Sweden, but rather on a clear description of which injuries are not eligible for compensation under the no fault scheme”

(For reference, all 10 original recommendations are set out in **Annex A.**)

⁸ The Health Foundation (2011). Evidence scan: Levels of Harm: 1.8
<http://www.health.org.uk/publications/levels-of-harm/>

⁹

http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx

¹⁰ <http://www.gov.scot/Topics/Health/Policy/No-Fault-Compensation/ReviewGroupVol1>

2.3 A public consultation on the Review Group's recommendations was then undertaken, concluding in December 2012. The responses to that consultation suggested that not all of the original Review Group recommendations were workable or affordable. There were particular concerns about Recommendation 2 and how this might work in practice given that all procedures carried a risk. It was suggested that the 'avoidability' test should be used and that it would be difficult to identify any other just or workable criteria for eligibility. The consultation report and Scottish Government response¹¹ published in April 2014 highlighted this. (The papers published so far in relation to this work are available on the Scottish Government website at: <http://www.gov.scot/Topics/Health/Policy/No-Fault-Compensation>.)

2.4 To coincide with the publication of the Scottish Government consultation report and response in April 2014, Alex Neil MSP, the then Cabinet Secretary for Health, confirmed the Scottish Government's commitment to ensuring that:

'any patients harmed as a result of poor clinical treatment have access to redress in the form of compensation, where this is appropriate, without the need to go through lengthy court processes'

2.5 Work has since been undertaken to explore the complexities in full and to shape and scope a proposed scheme which will sit alongside, rather than replace the existing CNORIS scheme, offering an alternative to litigation. This consultation paper now seeks views on the draft outline proposals from that work.

3. Principles and Eligibility Criteria

3.1 Consideration has since been given to possible approaches, which would meet the Scottish Government commitment, take account of the move to a more 'open culture', and provide quicker access to redress, where appropriate. A person-centred scheme, which is trusted as fair by patients and staff alike, will reduce legal costs and the need to go through lengthy legal processes.

3.2 The Ministerial commitment is that any scheme will also contribute to patient safety, learning and improvement and we would therefore propose to integrate the scheme with the NHS Scotland feedback, complaints, adverse incident reporting and Duty of Candour processes as the scheme is being developed.

3.3 Under the national approach to learning from adverse events, set out in the National Framework issued by Healthcare Improvement Scotland (HIS)¹², and the forthcoming introduction of a statutory Duty of Candour¹³ in health and social care settings, the patient (and their families) should be informed when and why an error, which has resulted in harm, has occurred. A report setting out details of the incident

¹¹ <http://www.gov.scot/Publications/2014/04/6437>

¹²

http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx

¹³ <http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89934.aspx>

and the report of the full investigation will be prepared and will be used in consideration of whether the eligibility criteria for redress has been met.

Question 1: Do you agree that it is appropriate to integrate the process for the redress scheme with the incident investigation, duty of candour and complaints processes to ensure consistency, improvement and shared learning?

Yes No

If you disagree please briefly explain why:

3.4 Eligibility criteria are a feature of all ‘no fault’ or ‘no-blame’ schemes world-wide, with common features including: thresholds, limitations on the extent of cover and additionally limitations or caps are applied to the sums payable. In working to scope and shape a fairer and importantly affordable Scottish scheme a number of approaches were considered. Those options have been narrowed down and our preferred approach for the initial establishment and testing of a no-blame redress scheme in Scotland is set out in this paper.

3.5 Additional information gathered for the NHS in Scotland in relation to complaints, adverse events and claims has been considered. This has permitted further exploration of possible approaches for the development of eligibility criteria which would allow the introduction of a fairer, faster and simpler approach to handling compensation claims and one which is affordable. The proposal is that the scheme will be based on the following broad principles:

- Compensate quickly and fairly for avoidable harm where the investigation establishes the harm would have been avoided by the use of ‘reasonable care’. (Will exclude cases where the unfavourable outcome was one of the unavoidable risks of the procedure.)
- Defend medically reasonable care
- Reduce patient injuries (and therefore claims) by learning from patients’ experiences

Question 2 - Do you agree with these broad principles?

Yes No

If you disagree please briefly explain why:

3.6 Given the concerns highlighted at 2.3 above (in relation to the original Recommendation 2) we would propose that, as in Sweden, the eligibility criteria should be structured around the notion of ‘avoidability’; i.e. the test is whether the harm caused by the treatment was avoidable. The proposed scheme will therefore be ‘no-blame’ rather than a true ‘no-fault’ scheme, which would potentially cover avoidable and unavoidable harm. The Swedish scheme also uses the ‘experienced specialist rule’, under which consideration is given to the risks and benefits of treatment options other than the one adopted and a retrospective approach has been taken in some cases in the evaluation of whether the injury was avoidable.

3.7 The draft proposals for the no-blame redress scheme combine a new approach for dealing with compensation for **causally connected avoidable harm where the harm has been or is likely to be, experienced by the person for a continuous period of at least 6 months** with improvements to the existing legal process.

Question 3 - Do you agree that eligibility should be structured around the notion of 'avoidability'? Yes No

If you disagree please briefly explain why:

Question 4 - Do you support the proposal that the non-retrospective scheme should be restricted to harm which has been or is likely to be, experienced by the person for a continuous period of at least 6 months?

Yes

No

If no, please briefly explain why:

4. Scope

4.1 In the first instance it is proposed that the Redress Scheme would be restricted to payment of compensation **where the harm has been or is likely to be, experienced by the person for a continuous period of at least 6 months** and is as a result of **clinical treatment administered by directly employed NHS staff in Scotland**. The scheme will **not be retrospective** (i.e. will cover clinical¹⁴ events that occur after the date of introduction). It will take account of health and social care integration and therefore clinical treatment provided as part of an integrated service.

4.2 The No-fault Review Group also recommended:

Recommendation 3 - We recommend that the no fault scheme should cover all medical treatment injuries that occur in Scotland; (injuries can be caused, for example, by the treatment itself or by a failure to treat, as well as by faulty equipment, in which case there may be third party liability);

Recommendation 4 - We recommend that the scheme should extend to all registered healthcare professionals in Scotland, and not simply to those employed by NHSScotland.

4.3 However, in response to the earlier consultation¹⁵ a good deal of concern was expressed about the cost and complexity of introducing a scheme which extended beyond the NHS. It is therefore proposed that in the first instance the scheme be

¹⁴ A "clinical" event can be broadly considered to be an incident arising directly from treatment.

¹⁵ <http://www.gov.scot/Publications/2014/04/6437>

limited to clinical treatment provided by directly employed NHS staff in Scotland (independent contractors – GPs, dentists, opticians and pharmacists – would be excluded along with private providers (see definition in Annex D) with options to extend, if considered appropriate, at a later date.

Question 5 - Do you support the proposal that the proposed non-retrospective scheme should in the first instance be restricted to clinical treatment provided by directly employed NHS Staff in Scotland?

Yes No

If no, please briefly explain why:

4.4 Currently around 70% of all awards made under the current system are under £100,000. We are proposing that the redress scheme will handle claims up to £100,000.

4.5 The cap of £100,000 on the level of award payable under the scheme (including cost of care packages and damage for loss of earnings) will effectively eliminate the most severe and complex cases (e.g. brain damaged children) and those cases where continuing care is appropriate. These cases would continue to be handled through the legal system. (Please also see proposals in relation to continuing care costs explained at Item 6 below.)

Question 6 - Do you support a cap of £100,000 on the level of award under the proposed scheme?

Yes No

If no, please briefly explain why:

4.6 The no-fault review Group **Recommendation 5** was:

“We recommend that any compensation awarded should be based on need rather than on a tariff based system.”

4.7 We are proposing that the level of compensation for injuries sustained will be based on existing principles including case precedent and the Judicial College Guidelines (formerly the Judicial Studies Board Guidelines). Compensation for patrimonial loss (e.g. past and future wage loss, care and accommodation costs etc.) will require to be assessed on an individual basis often with regard to expert opinion.

Question 7 - Do you agree that levels of award should be based on the Judicial College Guidelines with patrimonial loss assessed on an individual basis?

Yes No

If you disagree please briefly explain why:

4.8 The Breach of Duty of Care principles would continue to be applied to claims being handled through the legal system. However, these claims will benefit from the introduction and compulsory use of a Pre-action Protocol currently being developed

by The Personal Injury Committee of the Scottish Justice Council. The protocol will be used within the existing Clinical Negligence and Other Risks Indemnity Scheme (CNORIS) and will allow for speedier and more transparent outcomes in clinical negligence legal claims.

5. Legislation

5.1 As it stands, current legislation does not allow Ministers to introduce a redress scheme which makes provision for payment of sums which Health Boards etc. have no legal liability (actual or potential) to pay. Primary legislation giving enabling powers is therefore required as existing provisions within Section 85B of the NHS Scotland Act 1978 <http://www.legislation.gov.uk/ukpga/1978/29/section/85B> only allow Ministers to introduce a scheme to make provision to meet liabilities (i.e. sums of money which are legally due).

5.2 A provisional slot has therefore been identified for the introduction of a bill for Primary legislation for a 'No-Blame Redress Scheme' in early 2017. To allow time for the passage of the bill through the Scottish Parliament and the development of appropriate secondary legislation and guidance, the earliest introduction of such a scheme is likely to be in 2018-19.

5.3 The primary legislation and process will be developed in a manner which would allow the eligibility criteria, cap and scope to be amended at a later date through secondary legislation, if appropriate once the scheme has been established and fully tested.

Question 8 - Do you agree that the primary legislation should be flexible enough to allow the eligibility criteria and scope of the scheme to be extended at a later date?

Yes No

If you disagree please briefly explain why:

5.4 The original No-fault Review Group recommendations included:

Recommendation 6 - We recommend that claimants who fail under the no fault scheme should retain the right to litigate, based on an improved litigation system;

Recommendation 7 - We recommend that a claimant who fails in litigation should have a residual right to claim under the no fault scheme;

Recommendation 8 - We recommend that, should a claimant be successful under the no fault scheme, any financial award made should be deducted from any award subsequently made as a result of litigation;

Recommendation 9 - We recommend that appeal from the adjudication of the no fault scheme should be available to a court of law on a point of law or fact.

5.5 The proposed scheme will be compliant with the European Convention of Human Rights and patients will retain the right to go to Court should they wish. The legislation will, however, protect against 'double dipping' i.e. if a patient accepts an award offered under the new No-Blame Scheme they would not then be able to use that to raise a legal claim for negligence. (Please see Item 8 below in relation to consideration of an appeal process.)

Question 9 - Do you agree that the legislation should protect against 'double dipping'?

Yes No

If you disagree please briefly explain why:

6. Continuing care costs

6.1 The rising costs of continuing care is an area of concern. Some respondents to the previous consultation on the Review Group's recommendations called for the repeal of Section 2(4) of the Law Reform (Personal Injuries) Act 1948¹⁶, which stipulates that personal injury defendants must disregard NHS care when paying compensation. Care costs are expensive because the 1948 law still applies. This means public bodies like the NHS have to fund private care.

6.2 Repealing this section would allow personal injury defendants such as employers, insurers, Medical Defence Unions, and public bodies to buy NHS and local authority care packages rather than pay for private care. This could potentially boost NHS and Local Authority funds and improve services for the benefit of all service users.

6.3 In cases where continuing care is appropriate it would be proposed that an independent assessment of the individual care package requirements would be undertaken in each case and a guarantee of treatment and care by the NHS or local authority provided. In circumstances where the package of care or elements of it cannot be provided by the NHS or Local Authority, the relevant NHS Board will be responsible for commissioning these services from alternative providers.

Question 10 - Would you support the repeal of Section 2(4) of the Law Reform (Personal Injuries) Act 1948 in relation to continuing care costs providing, as proposed, the care package is independently assessed and quality care guaranteed in each case?

Yes No

If no please briefly explain why:

¹⁶ <http://www.legislation.gov.uk/ukpga/Geo6/11-12/41/section/2>

6.4 Consideration is also being given to legislating for the payment of continuing care costs through Periodic Payment Orders to spread the cost for the NHS and to ensure that the money is available to meet the patient's continuing care requirements.

7. Administration, Independence and Funding

7.1 In order to maximise existing expertise we would propose:

- The creation of a scheme, which is essentially a 'fast track' element of the existing NHS compensation scheme the Clinical Negligence and Other Risks Scheme (CNORIS). This would be administered by the Central Legal Office with **independent medical expert input** as appropriate.
- Funding would in the main continue to be through Boards' contributions calculated as at present based on claims history and Boards would retain their existing delegated limits. The current scheme excess of £25,000 would also be retained;
- NHS National Services Scotland, (which currently manages CNORIS) would also manage the new scheme.

Question 11 - Would you support the development of a 'fast track' element of CNORIS, utilising existing expertise with **independent medical expert input**?

Yes No

If no, please briefly explain why:

8. Appeals Process

8.1 The Redress Scheme will be compliant with the European Convention of Human Rights (ECHR) and allow a right of appeal against the decision of the scheme administrator thereby enjoying an adequate level of independence and impartiality and with sufficient 'equality of arms'.

8.2 We are exploring proposals for the creation of an independent appeal panel and how this would fit into the wider courts and tribunals landscape.

Question 12 - Do you agree that the creation of an independent appeal panel combined with independent medical input in consideration of the claim and award would provide the appropriate level of independence?

Yes No

If you disagree please briefly explain why:

Question 12.1 – Do you agree that the independent appeal panel will meet the patient's right to appeal?

Yes No

If no, please briefly explain why:

No-Fault Review Group Recommendations

(Please note these are the original Review Group recommendations – not all will be accepted and are subject to change as some are considered unaffordable and/or unworkable when broader current conditions are taken into account.)

Recommendation 1 - We recommend that consideration be given to the establishment of a no fault scheme for medical injury, along the lines of the Swedish model, bearing in mind that no fault schemes work best in tandem with adequate social welfare provision;

Recommendation 2 - We recommend that eligibility for compensation should not be based on the 'avoidability' test as used in Sweden, but rather on a clear description of which injuries are not eligible for compensation under the no fault scheme;

Recommendation 3 - We recommend that the no fault scheme should cover all medical treatment injuries that occur in Scotland; (injuries can be caused, for example, by the treatment itself or by a failure to treat, as well as by faulty equipment, in which case there may be third party liability);

Recommendation 4 - We recommend that the scheme should extend to all registered healthcare professionals in Scotland, and not simply to those employed by NHSScotland;

Recommendation 5 - We recommend that any compensation awarded should be based on need rather than on a tariff based system;

Recommendation 6 - We recommend that claimants who fail under the no fault scheme should retain the right to litigate, based on an improved litigation system;

Recommendation 7 - We recommend that a claimant who fails in litigation should have a residual right to claim under the no fault scheme;

Recommendation 8 - We recommend that, should a claimant be successful under the no fault scheme, any financial award made should be deducted from any award subsequently made as a result of litigation;

Recommendation 9 - We recommend that appeal from the adjudication of the no fault scheme should be available to a court of law on a point of law or fact.

Recommendation 10 - We recommend that consideration should be given to our analysis of the problems in the current system, so that those who decide to litigate can benefit from them.

Outline of Proposed ‘No-blame’ Redress Scheme

Principles	Supporting Processes
1. Be non-retrospective	
2. Scope will be restricted to cover clinical treatment administered by directly employed NHSS staff currently covered by the existing CNORIS scheme	
3. Will offer redress for eligible cases of causally connected avoidable harm for claims up to £100,000. Harm which has, or is likely to be, experienced by the person for a continuous period of at least 6 months. (70% of awards currently made under CNORIS are settled at under £100,000)	Will ensure consistent investigation, reporting and complaints processes to establish whether harm caused was avoidable (or known risk) and whether treatment fell short of reasonable care. Existing infrastructure will be used and developed to deliver the scheme-administered through NSS-CLO with independent medical input.
4. Patients will retain the right to litigate but will not allow “double-dipping”	Guidance and leaflets will make this clear to patients at outset. Eligible claims will be handled through the no-blame procedure. If a patient accepts an award offered under the new Scheme they would not then be able to use that to raise a legal claim for negligence.
5. NHS Scotland’s focus remains on prevention and patient safety , reducing risks and patient injuries and learning from mistakes and positive patient experience	When things do go wrong and a patient is harmed a fairer, faster simpler system of redress should be available.
6. Move away from the “blame culture” – admitting where we get it wrong, apologising and compensating quickly when appropriate to do so	Fairer, faster simpler system will fit with existing Board processes for handling and learning from feedback, comments, concerns or complaints and proposed new Duty of Candour procedure.
7. Will exclude more complex, higher value claims – which will continue to be handled through the Courts, where patients can be represented appropriately.	Management of cases through the Courts will benefit from improvements made through the Court Reform Act 2014. Compulsory use of a new Pre-Action protocol (imposed by rule of Court) will also speed up claims handling by the Courts.
8. Settlements will be based on Judicial College guidelines (Care costs will also be reduced through proposed repeal of Section 2 of the Personal Injury Act 1948)	Funding will be through a combination of Boards’ contributions to the CNORIS scheme plus additional SG funding. The CNORIS scheme excess of £25,000 will remain.
9. Subject to an independent review and appeals process	A process will be developed to ensure the new scheme is compliant with ECHR and the patient’s right of appeal.

Annex C

Proposed 'No-blame' Redress Scheme

Legislation required to introduce the new scheme

Through the NHS Redress Bill Ministers will:

- Seek enabling powers to make compensation payments without the need to go through court processes;
- Establish a no-blame redress scheme and the systems and processes to support it;
- Seek regulatory powers to set and alter the scope, criteria and value of the cap on claims included (proposed at £100,000 at outset); and
- Seek regulatory powers to extend the scheme to independent contractors and private providers if considered appropriate in the future.

In addition, through the Bill, Ministers will seek to:

- Repeal Section 2(4) of the Personal Injuries Act 1948; and
- Place Periodic Payment Orders on a statutory footing.

Annex D

Definitions

We have set down below some broad definitions for certain words or phrases referred to in this consultation paper in order to set the context for some of our considerations.

Avoidability Test – tests to establish whether the harm would have been avoided by the use of reasonable care.

Causation - As well as proving breach of duty, a pursuer must also prove that the breach of duty caused the loss or harm complained of, or at least materially contributed to it.

CNORIS – Clinical Negligence and Other Risks Indemnity Scheme

Compensation - Compensation is a wider term than damages, and covers the provision of something to the injured person (or the injured person's dependants in the case of death) in consequence of the injury or harm, and for the purpose of removing or alleviating its ill effects.

Delict – in Scots Law is, amongst other things, the responsibility to make reparation caused by breach of a duty of care or, arguably, the duty to refrain from committing such breaches. The equivalent in English law and other common law jurisdictions is known as tort law.

Experienced specialist rule – This rule considers whether injuries could have been avoided under optimal circumstances, in that the injury would not have occurred in the hands of the best health practitioner or health system.

Harm – this may include flawed or inadequate consent; affront/outrage; breach of confidentiality; pain and suffering caused through unnecessary Treatment; loss of a probability of a cure/successful treatment.

Injury - Physical injury (an incident or condition causing physical pain will, in general, be regarded as injury e.g. Inadequate anaesthetisation), psychiatric injury as confirmed by a Consultant Psychiatrist or Consultant Psychologist; wrongful birth (a mother who gives birth following a failed sterilisation to an otherwise healthy baby will be awarded damages for the pain and suffering of the childbirth even although medically, this might not be regarded as “injury”).

Independent contractor - Most GPs, opticians, dentists and pharmacists are independent contractors. This means that they are not employed directly by the NHS but are contracted to provide services to patients for which they are paid by the NHS. In addition, independent contractors may also carry out private work which is not funded by the NHS.

Medical Error - is "the failure of a registered health professional to observe a

standard of care and skill reasonably to be expected in the circumstances". This, by definition, requires proof equivalent to that of proving negligence; that is malpractice, in the same way as a medical malpractice claim under Delict law.

NHS Indemnity - NHS bodies are legally liable for the negligent acts and omissions of their employees or agents in terms of the principle of vicarious liability, and should have arrangements for meeting this liability. NHS Indemnity applies to staff in the course of their NHS employment, as well as GPs or dentists, who are directly employed by Health Boards. It also covers people in certain other categories whenever the NHS body owes a duty of care to the person harmed, including, for example, locums, medical academic staff with honorary contracts, students, those conducting clinical trials on NHS patients, volunteers and people undergoing further professional education, training and examinations. NHS Indemnity does not apply to general medical and dental practitioners (or their employees) working as independent contractors under contract for services. General practitioners are responsible for making their own indemnity/insurance arrangements, as are other self-employed health care professionals such as chiropodists and independent midwives. NHS Indemnity does not apply to employees of private hospitals (even when treating NHS patients) local education authorities or voluntary agencies.

Negligence – failure to exercise a duty required by law to show reasonable care, when doing or omitting to do something, in order to avoid loss or harm to others. It is not always medical practitioners who cause or contribute to injury – nurses, clinical support staff, laboratory staff, blood transfusion staff, pathology staff, administrative support staff may also contribute to injury.

No-fault compensation - we use this to refer to compensation which is obtained without the need to raise legal proceedings against either the person responsible for the harm or their employer.

Redress – this may include investigations when things go wrong, remedial treatment, rehabilitation and care when needed; explanations and apologies; and financial compensation in certain circumstances.

Treatment – includes the giving of treatment; diagnosis of a medical condition; a decision to treat or not to treat; a failure to treat or treat in a timely manner; obtaining or failing to obtain informed consent to treatment; the provision of prophylaxis; application of any support systems including policies, processes, practices and administrative systems which are used by the treatment provider and directly support the treatment. It also includes failure of equipment, devices or tools which are used as part of the treatment process, whether at the time of treatment or subsequently. Failure of implants and prostheses are included, except where the injury is caused by general wear and tear.

Part 2

Respondent Information Form and consultation questions

'No-Blame' Redress Scheme in Scotland for Harm Resulting from Clinical Treatment



RESPONDENT INFORMATION FORM

Please Note this form **must** be returned with your response.

Are you responding as an individual or an organisation?

- Individual
 Organisation

Full name or organisation's name

Phone number

Address

Postcode

Email

The Scottish Government would like your permission to publish your consultation response. Please indicate your publishing preference:

- Publish response with name
 Publish response only (anonymous)
 Do not publish response

We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise?

- Yes
 No

“No-blame” Redress Scheme in Scotland for Harm Resulting from Clinical Treatment

Questions:

1. The Ministerial commitment is that any scheme will contribute to patient safety, learning and improvement and we would therefore propose to integrate the scheme with the NHS Scotland feedback, complaints, adverse incident reporting and Duty of Candour processes as the scheme is being developed.
2. Under the national approach to learning from adverse events set out in the National Framework issued by Healthcare Improvement Scotland (HIS)¹⁷ and the forthcoming introduction of a statutory duty of candour¹⁸ in health and social care settings, the patient (and their families) should be informed when and why an error, which has resulted in harm, has occurred. A report setting out details of the incident and the report of the full investigation will be prepared and will be used in consideration of whether the eligibility criteria for redress has been met.

Question 1: Do you agree that it is appropriate to integrate the process for the redress scheme with the incident investigation, duty of candour and complaints processes to ensure consistency, improvement and shared learning?

Yes

No

If you disagree please briefly explain why:

¹⁷

http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/management_of_adverse_events/national_framework.aspx

¹⁸ <http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89934.aspx>

3. Eligibility criteria are a feature of all 'no fault' or 'no-blame' schemes world-wide, with common features including: thresholds, limitations on the extent of cover and additionally limitations or caps are applied to the sums payable. In working to scope and shape a fairer and importantly affordable Scottish scheme a number of approaches were considered. Those options have been narrowed down and our preferred approach for the initial establishment and testing of a no-blame redress scheme in Scotland is set out in this paper.

4. Additional information gathered for the NHS in Scotland in relation to complaints, adverse events and claims has been considered. This has permitted further exploration of possible approaches for the development of eligibility criteria which would allow the introduction of a fairer, faster and simpler approach to handling compensation claims and one which is affordable. The proposal is that the scheme will be based on the following broad principles:

- Compensate quickly and fairly for avoidable harm where the investigation establishes the harm would have been avoided by the use of 'reasonable care'. (Will exclude cases where the unfavourable outcome was one of the unavoidable risks of the procedure.)
- Defend medically reasonable care
- Reduce patient injuries (and therefore claims) by learning from patients' experiences

Question 2 - Do you agree with the broad principles for the scheme?

Yes No

If you disagree please briefly explain why:

5. Given the concerns highlighted at 2.3 of the consultation document (in relation to the original Recommendation 2) we would propose that, as in Sweden, the eligibility criteria should be structured around the notion of 'avoidability'; i.e. the test is whether the harm caused by the treatment was avoidable. The proposed scheme will therefore be 'no-blame' rather than a true 'no-fault' scheme, which would potentially cover avoidable and unavoidable harm. The Swedish scheme also uses the 'experienced specialist rule', under which consideration is given to the risks and benefits of treatment options other than the one adopted and a retrospective approach has been taken in some cases in the evaluation of whether the injury was avoidable.

6. The draft proposals for the no-blame redress scheme combine a new approach for dealing with compensation for **causally connected avoidable harm where the harm has been or is likely to be, experienced by the person for a continuous period of at least 6 months** with improvements to the existing legal process.

Question 3 - Do you agree that eligibility should be structured around the notion of 'avoidability'? Yes No

If you disagree please briefly explain why:

Question 4 - Do you support the proposal that the non-retrospective scheme should be restricted to harm which has been or is likely to be, experienced by the person for a continuous period of at least 6 months?

Yes

No

If no, please briefly explain why:

7. In the first instance it is proposed that the Redress Scheme would be restricted to payment of compensation **where the harm has been or is likely to be, experienced by the person for a continuous period of at least 6 months** and is as a result of **clinical treatment administered by directly employed NHS staff in Scotland**. The scheme will **not be retrospective** (i.e. will cover clinical¹⁹ events that occur after the date of introduction). It will, take account of health and social care integration and therefore clinical treatment provided as part of an integrated service.

8. The No-fault Review Group also recommended that the scheme should cover all medical treatment injuries that occur in Scotland and should extend to all registered healthcare professionals in Scotland, and not simply to those employed by NHSScotland. However, in response to the earlier consultation²⁰ a good deal of concern was expressed about the cost and complexity of introducing a scheme which extended beyond the NHS. Therefore, it is proposed that in the first instance the scheme be limited to clinical treatment provided by directly employed NHS staff

¹⁹ A "clinical" event can be broadly considered to be an incident arising directly from treatment.

²⁰ <http://www.gov.scot/Publications/2014/04/6437>

in Scotland (independent contractors – GPs, dentists, opticians and pharmacists – would be excluded along with private providers) with options to extend, if considered appropriate, at a later date.

Question 5 - Do you support the proposal that the proposed non-retrospective scheme should in the first instance be restricted to clinical treatment provided by directly employed NHS Staff in Scotland?

Yes

No

If no, please briefly explain why:

9. Currently around 70% of all awards made under the current CNORIS system are under £100,000. We are proposing that the No-blame redress scheme will handle claims up to £100,000.

10. The cap of £100,000 on the level of award payable under the scheme (including cost of care packages and damage for loss of earnings) will effectively exclude the most severe and complex cases (e.g. brain damaged children) and those cases where continuing care is appropriate. These cases would continue to be handled through the legal system. (Please also see proposals in relation to continuing care costs explained at Item 6 in the Consultation paper.)

11. The Breach of Duty of Care principles would continue to be applied to claims being handled through the legal system. However, these claims will benefit from the

introduction and compulsory use of a Pre-action Protocol currently being developed by The Personal Injury Committee of the Scottish Justice Council. The protocol will be used within the existing Clinical Negligence and Other Risks Indemnity Scheme (CNORIS) and will allow for speedier and more transparent outcomes in clinical negligence legal claims.

Question 6 - Do you support a cap of £100,000 on the level of award under the proposed scheme?

Yes No

If no, please briefly explain why:

12. The No-fault Review Group recommended that any compensation awarded under the new scheme should be based on need rather than on a tariff based system. We are proposing that the level of compensation for injuries sustained will be based on existing principles including case precedent and the Judicial College Guidelines (formerly the Judicial Studies Board Guidelines). Compensation for patrimonial loss (e.g. past and future wage loss, care and accommodation costs etc.) will require to be assessed on an individual basis often with regard to expert opinion.

Question 7 - Do you agree that levels of award should be based on the Judicial College Guidelines with patrimonial loss assessed on an individual basis?

Yes No

If you disagree please briefly explain why:

13. As it stands current legislation does not allow Ministers to introduce a redress scheme which makes provision for payment of sums which Health Boards etc. have no legal liability (actual or potential) to pay. A provisional slot has therefore been identified for the introduction of a bill for Primary legislation for a 'No-Blame Redress Scheme' in early 2017. The primary legislation and process will be developed, in a manner which would allow the eligibility criteria, cap and scope to be amended at a later date through secondary legislation, if appropriate once the scheme has been established and fully tested.

Question 8 - Do you agree that the primary legislation should be flexible enough to allow the eligibility criteria and scope of the scheme to be extended at a later date?

Yes No

If you disagree please briefly explain why:

14. The original No-fault Review Group's recommendations included recommendations that: claimants who fail under the no fault scheme should retain the right to litigate, based on an improved litigation system; claimants who fail in litigation should have a residual right to claim under the no fault scheme; should a claimant be successful under the no fault scheme, any financial award made should be deducted from any award subsequently made as a result of litigation; and that appeal from the adjudication of the no fault scheme should be available to a court of law on a point of law or fact.

15. The proposed No-blame scheme will be compliant with the European Convention of Human Rights and patients will retain the right to go to Court should they wish. The legislation will, however, protect against 'double dipping' i.e. if a patient accepts an award offered under the new No-Blame Scheme they would not then be able to use that to raise a legal claim for negligence. (Please see Item 8 in the consultation document in relation to consideration of an appeal process.)

Question 9 - Do you agree that the legislation should protect against 'double dipping'?

Yes No

If you disagree please briefly explain why:

16. The rising costs of continuing care is an area of concern. Some respondents to the previous consultation on the Review Group's recommendations called for the repeal of S2 (4) of the Law Reform (Personal Injuries) Act 1948²¹, which stipulates that personal injury defendants must disregard NHS care when paying

²¹ <http://www.legislation.gov.uk/ukpga/Geo6/11-12/41/section/2>

compensation. This means public bodies like the NHS have to fund private care. Repealing this section would allow personal injury defendants to buy NHS and local authority care packages rather than pay for private care.

17. In cases where continuing care is appropriate it is proposed that an independent assessment of the individual care package requirements would be undertaken in each case and a guarantee of treatment and care by the NHS or local authority provided. In circumstances where the package of care or elements of it cannot be provided by the NHS or Local Authority, the relevant NHS Board will be responsible for commissioning these services from alternative providers.

Question 10 - Would you support the repeal of Section 2(4) of the Law Reform (Personal Injuries) Act 1948 in relation to continuing care costs providing, as proposed, the care package is independently assessed and quality care guaranteed in each case?

Yes No

If no please briefly explain why:

18 In order to maximise existing expertise the No-blame scheme proposed would:

- essentially be a 'fast track' element of the existing NHS compensation scheme the Clinical Negligence and Other Risks Scheme (CNORIS). This

would be administered by the Central Legal Office with **independent medical expert input** as appropriate.

- in the main continue to be funded through Boards' contributions calculated as at present based on claims history and Boards would retain their existing delegated limits. The current scheme excess of £25,000 would also be retained;
- be managed by NHS National Services Scotland, (which currently manages CNORIS).

Question 11 - Would you support the development of a 'fast track' element of CNORIS, utilising existing expertise with **independent medical expert input**?

Yes

No

If no, please briefly explain why:

19. The No-blame Scheme will be compliant with the European Convention of Human Rights (ECHR) and allow a right of appeal against the decision of the scheme administrator thereby enjoying an adequate level of independence and impartiality and with sufficient 'equality of arms'. We will explore the creation of an

independent appeal panel and how this would fit into the wider courts and tribunals landscape.

Question 12 - Do you agree that the creation of an independent appeal panel combined with independent medical input in consideration of the claim and award would provide the appropriate level of independence?

Yes No

If you disagree please briefly explain why:

Question 12.1 – Do you agree that the independent appeal panel will meet the patient’s right to appeal?

Yes No

If no, please briefly explain why:

We are grateful for your response. Thank you.



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