



*UK National
Screening Committee*

Review of the UK National Screening Committee (UK NSC)

Recommendations

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Public Health England hosts the UK National Screening Committee

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Foreword

In March 2013 I was asked by the four UK Chief Medical Officers (CMOs) to Chair the UK National Screening Committee (UK NSC).

The UK NSC was established in 1996 to provide clear advice to Ministers and the NHS in all four countries about all aspects of screening. Since this time the UK NSC has developed into a world leader in its field and screening programmes in the UK are among the best in the world. This is by design not accident – the UK NSC brings academic rigour and authority to what is an extremely complex area. Our standards are high and screening programmes are only introduced where they will do more good than harm, saving lives and reducing illness. The UK NSC forms its recommendations based around the principles that interventions which do harm or provide no clinical benefit are eliminated and treatment should begin with the basic proven tests and interventions. That is something I and all those involved in the work of the UK NSC are proud of.

However, that does not mean we should be complacent. Advances in genetic screening and the development of new technologies bring additional complexities and considerations to screening reviews. In addition, there have been a number of changes to the structure of the NHS in each of the four countries, most recently the establishment, in England, of NHS England and Public Health England, the body now responsible for providing Secretariat support for the UK NSC. For these reasons, my first action as Chair was to request an in depth structure and process review to ensure that best practice is applied to all aspects of UK NSC business and that it continues to operate to the most robust evidence base and criteria available internationally.

To support the review, a systematic review exploring screening systems and processes in other countries was commissioned from the University of Warwick. I am delighted that this found the UK NSC compared favourably with other countries and also that the UK had the most integrated and evidence based screening programmes in the world. My thanks go to both the University of Warwick and the PHG Foundation who contributed to this work.

During the review, a House of Commons Science and Technology Committee launched an Inquiry into National Health Screening. This Committee supported the approach that all screening programmes should be grounded in robust evidence and supported the idea that the evidential barrier to entry should remain high. The Committee has also made a number of recommendations on improvements that needed to be made to the structures and processes used by the UK NSC. These have fed into and informed the recommendations from the review.

The review of the UK NSC was overseen by a working group and I am extremely grateful to its members for their contribution and for their time, patience and expertise.

I would also like to thank the 97 respondents who took the time to complete the survey and help inform the recommendations the working group has developed. I believe we have come up with a set of recommendations which can only strengthen the UK NSC's position as a world leader in screening.

A handwritten signature in dark ink, appearing to read 'David Walker', written in a cursive style.

Professor David Walker
Chair UK NSC

Background

The UK NSC was established in 1996. It advises Ministers and the NHS in all four countries on all aspects of screening policy and supports implementation. It assesses the evidence for programmes against internationally recognised criteria, using research evidence, economic evaluation and pilot programmes.

As part of the current governance arrangements for the UK NSC its role, terms of reference and membership are reviewed on a three yearly basis. The review due in 2013/14 provided an opportunity for an in depth structure and process review to ensure that best practice is being applied to all aspects of UK NSC business. This included:

- terms of reference
- membership
- the roles and relationships of different organisations, including Public Health England (PHE), the Department of Health in England, the Scottish Government, the Welsh Government, the Department of Health, Social Services and Patient Safety, Northern Ireland with the UK NSC
- the criteria for appraising the viability, effectiveness and appropriateness of a screening programme to ensure the UK NSC continues to operate to the most robust evidence base and criteria available internationally
- the scope of population screening that should be within the UK NSC's remit

The review was overseen by a working group, which included representatives from each UK country as well as patients and the public, external stakeholders and independent public health screening experts. The group was chaired by Professor David Walker, Chair of the UK NSC. A list of the review group members can be found at Annex B. Sub-groups were established to consider stakeholder engagement and the scope of screening within the UK NSC's remit in more detail.

To support this work a systematic review exploring screening systems and processes in other countries was commissioned from the University of Warwick – *International comparisons of screening policy making: A systematic review*.¹ As a contribution to this work genetic aspects of international screening policy were also reviewed by the PHG Foundation, acting as an independent non-profit organisation focussing on genomics and population health.

The working group was keen to obtain the views and opinions of a range of stakeholders to help inform its recommendations and therefore a public consultation was held between 15th April 2014 – 8th July 2014. The consultation was undertaken through a questionnaire on survey monkey. An e-mail alert was sent to the UK NSC's 250 registered stakeholders requesting their input into the review. A link to the consultation was also placed on the UK NSC's website so that it was available to members of the public and other unregistered stakeholder groups to complete. 97

¹ Seedat F, Cooper J, Cameron L, Stranges S, Kandala NB, Burton H, Taylor-Phillips S. International comparisons of screening policy-making: A systematic review, 2014.

respondents answered one or more of the 22 consultation questions. A summary consultation document together with full responses is available.

All documents relating to the review are available for download from:

<https://www.gov.uk/government/publications/review-of-the-uk-national-screening-committee-2015>

In December 2013, a House of Commons Science and Technology Committee launched an Inquiry into National Health Screening. It received written and oral evidence over the summer and its recommendations were published on 29 October 2014. It is available at:

<http://www.publications.parliament.uk/pa/cm201415/cmselect/cmsctech/244/24402.htm>

The responses to the consultation and recommendations from the House of Commons Science and Technology Committee have materially contributed to the review and informed its recommendations on the UK NSC.

The recommendations from the review group have been accepted by the four Chief Medical Officers in the UK.

Best Practice

The UK NSC is not a statutory body and appointments are not subject to the approval of Ministers, nor is it bound by the Code of Practice issued by the Commissioner for Public Appointments. There is no requirement to inform parliament and the public of its work. For historic reasons, it is not currently recognised as a Scientific Advisory Committee (SAC). Its remit, processes and procedures are documented currently in an agreement between the four UK Health Departments who are responsible for ensuring adherence.

A clear theme running through the review, is the need for the UK NSC, in line with public bodies and other advisory committees, to have clearly agreed and documented lines of accountability, scrutiny of performance, appropriate oversight, support and assistance with clearly set out roles and responsibilities and terms of office for members, and that this should be in the public domain. Although not consulted on specifically, this view was reflected in responses to the consultation where the need for openness and transparency in all aspects of the Committee's work was highlighted.

The review group considers it essential that these processes and procedures should adhere to the *Principles of scientific advice to government* underpinning the *Code of Practice for Scientific Advisory Committees (CoPSAC)*.

In addition, the recent House of Commons Science and Technology Committee Inquiry into national health screening noted that the UK NSC's independence from Government "*was highly valued and gave added legitimacy to its advice*". However, it was concerned that there was a lack of clarity around the current governance arrangements and, in particular, around the UK NSC's relationship with PHE, which is responsible for providing the secretariat to the UK NSC. It noted that the current functions of the UK NSC are broadly consistent with those of a Scientific Advisory Committee and has recommended that "*the UK NSC adopts, and adheres to, the Code of Practice for Scientific Advisory Committees in its full and unchanged form.*" In addition, it has recommended that the working relationship between PHE and the UK NSC "*is formally defined with safeguards to ensure the UK NSC's continuing independence*".

Recommendations

1. *The review group recommends that a Code of Practice should be developed and published to give information on the status, role, responsibility and procedures of the UK NSC; terms of appointment of members of the Committee; the roles and responsibilities of the members of the Committee; the roles and relationships of different organisations, including PHE, the Department of Health in England, the Scottish Government, the Welsh Government, the Department of Health, Social Services and Patient Safety, Northern Ireland with the UK NSC and how the Committee develops its recommendations. This should adhere to the principles of Scientific Advice to Government and CoPSAC.*

- 2. The review group recommends that discussions should take place with the Department of Health with a view to including the UK NSC in the list of its Scientific Advisory Committees subject to CoPSAC.*

Membership

The majority of responses to the consultation indicate that there are areas of expertise missing from current UK NSC membership. Responses show that a key concern is that the UK NSC does not include specialists with expertise in the specific conditions under review. Responses have also highlighted the need for additional expertise to cope with the different set of issues arising from the use of genetic technologies.

The consultation responses also support greater lay representation on the Committee. Most of these responses suggest including those with experience of the condition under discussion. However, just over half of responses to the consultation agree that the balance between, experts, professionals and lay members was right and in line with other expert advisory committees. Some responses suggest the need for greater clarity should be applied to what is meant by lay expert - mostly this is interpreted as providing a patient/public voice.

Some responses emphasise the need to take into account the age, ethnicity and gender of the Committee and that there should be a balance across the four countries.

The review group considers, that given its extensive remit it would not be feasible to widen the Committee to include every interest and this was reflected in some consultation responses. It believes that the overriding principle is that membership should enable the Committee to fulfil its terms of reference and deliver its objectives. It identifies the need for a range of expertise as follows:

- Public Health (screening)
- General Practice
- Paediatrics and Child Health
- Obstetrics
- Cancer
- Genetics
- Ethics
- Health Economics
- Laboratory Services
- Nursing and Midwifery
- Epidemiology
- Representation of Patient and Public Voice
- Medico Legal
- Social Scientist

The review group is clear that membership may change over time as terms of reference continue to evolve and should be reviewed on a regular basis and in the light of final recommendations.

However, the review group considers stakeholder engagement to be a crucial component of all aspects of UK NSC business and acknowledges that it is essential to involve relevant stakeholders, in particular, those with professional or patient

experience of the condition being reviewed, in the review process. It recommends that the UK NSC's review process, which is currently being updated should make clear how stakeholders can input to a screening review.

It also considers that there should be provision to co-opt additional members onto the group where particular expertise on a specific issue is needed. Again, there is some support for this in the consultation.

The review group has also considered the issues raised in the review and its consultation about the complexities arising from genetic screening and advances in technologies and therefore the need for more ethical, legal and social expertise. (More detail on page 13).

Recommendations

3. *The review group recommends that membership of the UK NSC should provide the skill mix necessary to match the UK NSC's needs and enable it to fulfil its terms of reference. Membership should be reviewed by the sponsoring organisations on a regular basis.*
4. *The review group acknowledges the comments made in the consultation that the Committee does not include specialist or patients/parents with experience of particular conditions. Given the wide remit of the UK NSC and the number of different conditions it covers, the review group considers it would not be possible to expand the group in this way. However, the review group agrees that it is essential to involve relevant stakeholders, in particular those with professional or patient experience of the condition being reviewed, in the review process. It recommends that the UK NSC's review process, which is currently being updated should make clear how stakeholders can input to a screening review.*
5. *The review group recommends that there should be provision to co-opt additional members onto the group when particular expertise on a specific issue is needed.*
6. *The review group recognises the importance of lay membership, not only to ensure transparency of process, but to challenge views and bring a wider perspective to any discussion. It recommends the inclusion of an additional lay member, making a total of four and recommends that "lay expertise" should be clearly defined as representing the "patient and public voice".*
7. *The review group recommends that in line with best practice, the diversity agenda and equality of opportunity should be considered in the procedures for making appointments to the UK NSC. In addition consideration should be given to ensure, as far as possible, a balance across the four countries.*

Appointments

The review group agrees that the *Code of Practice* should include clear information on the process for appointing members and terms of appointment.

The majority of responses to the consultation also agree that there should be a formal process with defined stages of application, assessment and appointment.

As above, the House of Commons Science and Technology Committee has recommended that the Committee should adhere to CoPSAC which sets out a clear process for appointing members.

Recommendation

8. *The review group recommends that, in line with best practice, and to provide assurance on the independence and objectivity of the Committee, there is clear separation between members of the Committee, those attending in an ex-officio capacity and observers. It further recommends there should be a formal process for the appointment of members with defined stages of application, assessment and appointment and that this should be included in the Code of Practice.*

Terms of reference

The review group has considered the UK NSC's terms of reference and agrees that in line with best practice set out in CoPSAC terms of reference should be agreed with sponsor organisations and reviewed on a regular basis. In addition, terms of reference should be reviewed in the light of the review group's final recommendations.

Terms of reference for the Committee were not consulted on specifically.

Recommendation

9. *The review group recommends that terms of reference are reviewed in the light of review group recommendations. In line with best practice set out in CoPSAC these should be agreed with sponsor organisations and signed off by the four CMOs. These should be reviewed on a regular basis, by both the UK NSC and its sponsor organisations.*

Social, ethical and legal issues

The review group has considered the many different social, ethical, and legal issues associated with screening, particularly noting that new programmes involving genetic screening and technologies produce complexities that may be novel for society. Whilst these are not confined to genetic screening, relevant issues include consent and autonomy, discrimination and stigmatisation, issues around reproductive choice, privacy and confidentiality, data ownership, storage and sharing. The review group considers it is vital that, alongside the scientific and clinical evidence, these issues receive attention by the Committee in an expert and explicit way.

Responses to the consultation are clear that the UK NSC would benefit from additional ethical expertise, in particular there is support for drawing expert advice from a reference group of experts. Responses vary on whether this should be a standing organisation, a more ad hoc group or referring to external established ethical groups. There was some concern about the bureaucracy, procedure, process and costs of establishing a standing group.

The review group considers that the breadth of experience and knowledge of the UK NSC allows these issues to be considered in general terms; there is an ethicist on the Committee, and the review group is keen that ethical, legal and social issues should not be seen as separate from core business. However, it acknowledges that sometimes particular expertise or a more focused consideration may be required. Given the range and complexity of these issues, the working group considers that the membership of the UK NSC should be extended to include an additional member with expertise on ethical issues (2 in total).

The review group also considers that training should be made available for members of the committee on ethical, legal and social issues.

The review group also considered a number of options for seeking additional expert ethical, legal and social guidance, ranging from the establishment of standing group to seeking advice from groups already set up to provide this type of advice. On the establishment of a standing group there was some concern that this could be bureaucratic, needing its own processes and procedures when there was already a wealth of expertise in already established groups who would be able to provide appropriate advice.

In line with standard practice, set out in CoPSAC, the review group considers that where the Committee is offering advice on ethical considerations, it should make explicit what processes or expertise it has drawn on in reaching its conclusions. Further work was identified for the UK NSC secretariat to develop a checklist for this.

Recommendations

- 10. The review group recommends training is made available for members of the committee on ethical, legal and social issues.*

11. *The review group recommends that the UK NSC should seek expert ethical, legal and social input from groups already established to provide this type of advice. If this approach proves to be neither practical nor effective then the UK NSC should consider setting up a standing reference group in the future.*
12. *The review group recommends that, in line with standard practice set out in CoPSAC, where the Committee is offering advice on ethical considerations it should make explicit what processes or expertise it has drawn on in reaching its conclusions, and that the UK NSC Secretariat should develop a checklist for this.*
13. *The review group recommends the inclusion of additional members with ethical and socio-legal expertise.*

Criteria and evidence assessment

It is important that screening for a condition is introduced only where there is evidence that it will be effective and that the benefits outweigh the harm. The UK NSC forms its recommendations based around the principles that interventions which do harm or provide no clinical benefit are eliminated and treatment should begin with the basic proven tests and interventions. The UK NSC assesses the evidence for screening against a set of internationally recognised criteria. This review provided an opportunity to ensure the UK NSC continues to operate to the most robust evidence base and criteria available internationally

To support it in making its recommendations the review group commissioned work from the University of Warwick "*International comparison of screening policy: A systematic review,*" to compare the policy making process and criteria in the UK to other countries. Findings from an independent review undertaken by the PHG Foundation with respect to genetic screening were integrated with this work. This concluded that the current criteria used by the UK NSC are comparable to those used by other countries. A copy of the UK NSC's current criteria for appraising the viability, effectiveness and appropriateness of a screening programme are available at Annex C. For genetic screening the UK had made some adaptations of the criteria and the review found that the UK was the most prepared for the genomics era. The PHG Foundation report concluded that some of the existing criteria were difficult to meet for rare or genetic diseases. The review also found there is some variation across different countries. Points of difference include:

- ethical issues
- measures of effectiveness
- planning and implementation, and
- considerations of test performances

Most respondents to the consultation felt the criteria needed some amendment. Some respondents felt the criteria needed updating, particularly to reflect advances in genetic and genomic testing. Other responses suggest that the current criteria did not allow for consideration of some types of screening, for example selective screening, or consideration to be given to benefits from potential new treatments or treatment or care that, while not a cure, could improve a patient's physical or psychological health. There was also concern that some conditions are not amenable to randomised controlled trials and allowance should be made for this.

Evidence to the House of Commons Science and Technology Committee varied on whether or not criteria remained fit for purpose with some saying the criteria were still up to date and others questioning their current suitability.

The review group considers that the current criteria are internationally recognised and have broadly stood the test of time. It considers that they represent the gold standard and is reluctant to be seen to downgrade them in anyway. The House of Commons Science and Technology Committee also recognised this "*we agree that all screening programmes should be grounded in robust evidence and, given the difficulty of withdrawing a programme, support the idea that the evidential barrier to*

entry should remain high." The review group also considers, in response to some of the issues raised in consultation, that there is sufficient flexibility within the current criteria to make expert judgement in addition to objective or factual information. For example, how the criteria allows for consideration of those conditions which might not be amenable to randomised controlled trials and to take account of the wider benefits of screening such as the diagnostic odyssey and reproductive choice. The review group has made some amendments to the criteria and these are attached at Annex D.

A key recommendation from the sub-group established to consider stakeholder engagement is for the review process to set out a clear explanation of how the UK NSC uses its criteria to make recommendations. This was also raised in the House of Commons Science and Technology Inquiry where the need for additional clarity regarding how the criteria are evaluated and interpreted was raised. The House of Commons Science and Technology Committee recommended that the UK NSC publishes guidance *"to clarify and add detail to how the UK NSC evaluates the evidence base against its criteria"*.

The review group agrees it would be helpful to develop an explanatory document to accompany the criteria with a clear explanation of how it uses the criteria to make its recommendations.

The supporting work commissioned to provide international comparisons has identified different approaches to decision making in different countries and the review group has considered that the development of a consistent process to appraise new applications would provide a more robust assessment. The review group considers the use of grading tools (used in formal systematic reviews) would not always make sense for the UK NSC, however, a triage approach should be developed to identify those reviews which might benefit from this type of approach.

The House of Commons Science and Technology Committee has recommended that it is important that the review group *"considers if the evaluation of evidence against these criteria is conducted in a rigorous, transparent and consistent manner."*

Recommendations

14. *The review group considers that the criteria have broadly stood the test of time and is clear that because of the potential harms of screening the evidential bar should remain high. It recommends some changes to the criteria as shown at Annex D, reflecting the need to better take genetic and genomic issues into account.*
15. *The review group recommends that a document to accompany the criteria should be developed. This should explain how the Committee assesses the evidence against its criteria in order to make its recommendations. In addition, a manual for reviewers should be developed to enhance consistency of reporting within review documents.*
16. *The review group considers that the grading tools, as used, in some other countries could provide a more robust assessment of the evidence. It*

acknowledges however, that this will not be appropriate for all reviews and recommends that a triage approach should be developed to identify those reviews which might benefit from this type of approach.

Scope of screening programmes

The UK NSC has traditionally considered population screening programmes based on age and gender although there are exceptions, for example, diabetic eye screening, and increasingly the UK NSC has been asked to consider screening in high risk groups. A sub-group set up to consider the scope of screening within the UK NSC's remit concluded that it is very difficult to set a hard and fast set of rules or characteristics that accurately and simply separate a screening programme from one better suited to a public health or clinical programme.

Most consultation responses supported benefits from applying the robust process used by the UK NSC to assess screening programmes, in particular through avoidance of harm and of wasted resources. For this reason, they endorsed the view that screening programmes are defined by factors beyond just age and gender, and can include:

- those defined by ethnicity or genetic risk
- those individuals defined by a condition with recognised complications
- those defined by lifestyle factors
- those identified opportunistically

Fewer responses supported screening where the main benefit is to others rather than the person screened. Some responses felt early diagnosis could be of benefit even if no treatment was available, for example to inform reproductive choice.

Recommendation

17. The review group has considered the scope of screening that should be within the remit of the UK NSC and recommends that topics should be considered on a case by case basis using the following characteristics as a guide:

- *The target population to be screened should be large (ie sufficiently large enough to enable safe, clinically and cost effective screening)*
- *The cohort to be offered screening would regard themselves as not necessarily having symptoms of the disease or to be at risk of the disease – ie the business of the committee should be apparently healthy people*
- *There should be an effective means of identifying and holding a list of the whole cohort to be offered screening*
- *The population should be proactively approached (eg by written invitation, verbal invitation at the time of the contact with the health service, encouraging attendance for screening) among other things this would ensure that those offered screening would be properly informed of the potential benefits and risks in order to help make an informed choice*
- *The primary purpose of screening should be to offer benefit to the person being screened. If there is no possibility of benefit to the person*

being offered screening then it should be considered no further as a screening programme

Annual call for proposals

Currently requests to the UK NSC to ask for screening for a condition come from a number of sources, including users and patient representative bodies, clinicians, Members of Parliament, the four UK Health Departments, drug companies and individuals. Both the stakeholder sub-group and the scope of screening sub-group considered that there might be merit in having a similar system to that in America, Canada and Sweden with an annual call for proposals from stakeholders with key criteria for considering such requests. The stakeholder sub-group felt this would make access to the work of the UK NSC clearer and fairer, but agreed there should be an easy to follow process making clear the need for a reasonable level of evidence to support proposals. This would be a new departure for the Committee and the workload would need to be assessed and taken into consideration before agreeing a final process.

The majority of responses to the consultation supported the idea of a regular, formal call for proposals, although there was some concern that this could swamp the system and create an administrative burden, slowing down the process.

Recommendation

- 18. The review group acknowledges there could be merit in establishing a regular formal call for proposals for screening reviews supported by an easy to understand process with clearly set out criteria for considering such requests. The review group notes concerns raised around the potential workload of such an approach, both from within the group itself and from consultation responses and therefore recommends developing and piloting a process to gauge the volume of work this approach could generate.*

Stakeholder engagement

The review group is clear about the need for transparency in all aspects of the UK NSC's work, and wishes to see work to provide greater clarity on its processes and procedures. The sub-group set up to consider stakeholder engagement proposed a number of actions, in addition to those already covered in earlier recommendations, including:

- Consultation process – it should be emphasised that anyone can respond, and plain English summaries should be provided for both consultation documents and final recommendations.
- Consultation responses - the process for handling detailed comments on consultation responses could be improved and should set out clearly work undertaken with stakeholders and reviewers to ensure reviews are accurate. It should be clear how evidence from stakeholders had been considered as part of the review.

Responses to the consultation suggested that the review process used by the UK NSC to assess the evidence for screening could be more accessible and easy to understand and agreed it would be helpful to provide plain English summaries of evidence reviews and recommendations.

Most responses said that the UK NSC could improve stakeholder engagement and understanding of the work of the Committee. Suggestions included improving publicity of the UK NSC and its upcoming reviews, greater consultation with stakeholders during the review process, which could include better use of social media.

The House of Commons Science and Technology Committee Inquiry has acknowledged the efforts made by the UK NSC to engage with its stakeholders but considers, *“it is vital that the UK NSC looks beyond traditional, large stakeholder groups and seeks to engage with those smaller – often condition specific – groups especially where they offer scientific insight”*.

Recommendations

- 19. The review group recommends that papers should be written in a way that make it easy for members of the public to understand, with plain English summaries of evidence reviews and recommendations.*
- 20. As in recommendation four, the review group recommends that the UK NSC's review process, which is currently being updated, should make clear how stakeholders can input to each stage of a screening review.*
- 21. The review group recommends that the UK NSC communications team considers suggestions made in the consultation on how to engage with stakeholders, for example more effective use of social media, and accessible articles on UK NSC business.*

Annual meeting

The sub-group on stakeholder engagement considered that an annual open meeting for the UK NSC to present its work might help engage with stakeholders. The review group agreed this could be a useful way to help stakeholders gain a deeper understanding on the make-up of the Committee and how it arrives at its recommendations.

Most responses to the consultation supported this approach and agreed this would help build working relationships with stakeholders. The group noted that the aims, objectives and style of the meeting would need to be carefully thought through in order to avoid the possibility that it be costly, exclusive or appear stage managed.

Recommendation

22. The review group recommends that the UK NSC should hold an annual meeting with officers and members to meet with stakeholders, to discuss and take questions on the work of the committee.

Establishment of a multi-agency group

The working group has discussed the role of the UK NSC in making recommendations about possible actions when it recommends that screening is not appropriate, for example, informing and reinforcing guidelines, and highlighting the need for research and wider access to testing. However each body that might receive such recommendations or request has its own governance and method of setting priorities which cannot be set aside for UK NSC requests. The review group discussed the issues and agreed that it would simply forward recommendations to the four UK Health Departments for further consideration and action.

Recommendation

23. The UK NSC often concludes that while there is insufficient evidence that screening for a particular condition will bring more good than harm there may be alternative actions. The review group recommends that such alternative actions be forwarded to the four UK Health Departments for consideration and further action as appropriate.

Cost effectiveness

The review group has discussed how the UK NSC goes about determining cost effectiveness of screening programmes. The terms of reference state that wider societal costs and benefits should be taken into account but often the only evidence available relates to health care costs. The review group asked that the Secretariat and health economists develop a clear statement on how cost effectiveness evidence will be sought, synthesised and reported.

Recommendation

24. The review group considers that there should be greater clarity and transparency about the UK NSC's methodology for assessing the costs and benefits of screening and, where possible, this should be aligned with others used to make national policies. The review group recommends that a clear public statement on the principles and methodologies around cost effectiveness should be developed and made available on the UK NSC's website.

Annex A

Summary of Recommendations

- 1. The review group recommends that a Code of Practice should be developed and published to give information on the status, role, responsibility and procedures of the UK NSC; terms of appointment of members of the Committee; the roles and responsibilities of the members of the Committee; the roles and relationships of different organisations, including PHE, the Department of Health in England, the Scottish Government, the Welsh Government, the Department of Health, Social Services and Patient Safety, Northern Ireland with the UK NSC and how the Committee develops its recommendations. This should adhere to the principles of Scientific Advice to Government and CoPSAC.*
- 2. The review group recommends that discussions should take place with the Department of Health with a view to including the UK NSC in the list of its Scientific Advisory Committees subject to CoPSAC.*
- 3. The review group recommends that membership of the UK NSC should provide the skill mix necessary to match the UK NSC's needs and enable it to fulfil its terms of reference. Membership should be reviewed by the sponsoring organisations on a regular basis.*
- 4. The review group acknowledges the comments made in the consultation that the Committee does not include specialist or patients/parents with experience of particular conditions. Given the wide remit of the UK NSC and the number of different conditions it covers, the review group considers it would not be possible to expand the group in this way. However, the review group agrees that it is essential to involve relevant stakeholders, in particular those with professional or patient experience of the condition being reviewed, in the review process. It recommends that the UK NSC's review process, which is currently being updated should make clear how stakeholders can input to a screening review.*
- 5. The review group recommends that there should be provision to co-opt additional members onto the group when particular expertise on a specific issue is needed.*
- 6. The review group recognises the importance of lay membership, not only to ensure transparency of process, but to challenge views and bring a wider perspective to any discussion. It recommends the inclusion of an additional lay member, making a total of four and recommends that "lay expertise" should be clearly defined as representing the "patient and public voice".*
- 7. The review group recommends that in line with best practice, the diversity agenda and equality of opportunity should be considered in the procedures for making appointments to the UK NSC. In addition consideration should be given to ensure, as far as possible, a balance across the four countries.*

8. *The review group recommends that, in line with best practice, and to provide assurance on the independence and objectivity of the Committee, there is clear separation between members of the Committee, those attending in an ex-officio capacity and observers. It further recommends there should be a formal process for the appointment of members with defined stages of application, assessment and appointment and that this should be included in the Code of Practice.*
9. *The review group recommends that terms of reference are reviewed in the light of review group recommendations. In line with best practice set out in CoPSAC these should be agreed with sponsor organisations and signed off by the four CMOs. These should be reviewed on a regular basis, by both the UK NSC and its sponsor organisations.*
10. *The review group recommends training is made available for members of the committee on ethical, legal and social issues.*
11. *The review group recommends that the UK NSC should seek expert ethical, legal and social input from groups already established to provide this type of advice. If this approach proves to be neither practical nor effective then the UK NSC should consider setting up a standing reference group in the future.*
12. *The review group recommends that, in line with standard practice set out in CoPSAC, where the Committee is offering advice on ethical considerations it should make explicit what processes or expertise it has drawn on in reaching its conclusions, and that the UK NSC Secretariat should develop a checklist for this.*
13. *The review group recommends the inclusion of additional members with ethical and socio-legal expertise.*
14. *The review group considers that the criteria have broadly stood the test of time and is clear that because of the potential harms of screening the evidential bar should remain high. It recommends some changes to the criteria as shown at Annex D, reflecting the need to better take genetic and genomic issues into account.*
15. *The review group recommends that a document to accompany the criteria should be developed. This should explain how the Committee assesses the evidence against its criteria in order to make its recommendations. In addition, a manual for reviewers should be developed to enhance consistency of reporting within review documents.*
16. *The review group considers that the grading tools, as used, in some other countries could provide a more robust assessment of the evidence. It acknowledges however, that this will not be appropriate for all reviews and recommends that a triage approach should be developed to identify those reviews which might benefit from this type of approach.*

17. *The review group has considered the scope of screening that should be within the remit of the UK NSC and recommends that topics should be considered on a case by case basis using the following characteristics as a guide:*
- *The target population to be screened should be large (ie sufficiently large enough to enable safe, clinically and cost effective screening)*
 - *The cohort to be offered screening would regard themselves as not necessarily having symptoms of the disease or to be at risk of the disease – ie the business of the committee should be apparently healthy people*
 - *There should be an effective means of identifying and holding a list of the whole cohort to be offered screening*
 - *The population should be proactively approached (eg by written invitation, verbal invitation at the time of the contact with the health service, encouraging attendance for screening) among other things this would ensure that those offered screening would be properly informed of the potential benefits and risks in order to help make an informed choice.*
 - *The primary purpose of screening should be to offer benefit to the person being screened. If there is no possibility of benefit to the person being offered screening then it should be considered no further as a screening programme.*
18. *The review group acknowledges there could be merit in establishing a regular formal call for proposals for screening reviews supported by an easy to understand process with clearly set out criteria for considering such requests. The review group notes concerns raised around the potential workload of such an approach, both from within the group itself and from consultation responses and therefore recommends developing and piloting a process to gauge the volume of work this approach could generate.*
19. *The review group recommends that papers should be written in a way that make it easy for members of the public to understand, with plain English summaries of evidence reviews and recommendations.*
20. *As in recommendation four, the review group recommends that the UK NSC's review process, which is currently being updated, should make clear how stakeholders can input to each stage of a screening review.*
21. *The review group recommends that the UK NSC communications team considers suggestions made in the consultation on how to engage with stakeholders, for example more effective use of social media, and accessible articles on UK NSC business.*
22. *The review group recommends that the UK NSC should hold an annual meeting with officers and members to meet with stakeholders, to discuss and take questions on the work of the committee.*
23. *The UK NSC often concludes that while there is insufficient evidence that screening for a particular condition will bring more good than harm there may*

be alternative actions. The review group recommends that such alternative actions be forwarded to the four UK Health Departments for consideration and further action as appropriate.

24. *The review group considers that that there should be greater clarity and transparency about the UK NSC's methodology for assessing the costs and benefits of screening and, where possible, this should be aligned with others used to make national policies. The review group recommends that a clear public statement on the principles and methodologies around cost effectiveness should be developed and made available on the UK NSC's website.*

Annex B**Membership of the Review Group**

Name	Role
Professor David Walker (Chair)	Former Deputy Chief Medical Officer for England, Chair UK NSC
Professor Kevin Fenton (Vice-Chair)	Director, Health and Wellbeing Public Health England
Mrs Jane Allberry (up to April 2014) Dr Dorian Kennedy (from April 2014)	Deputy Director Sexual Health, Screening and Early Diagnosis Department of Health
Dr Margaret Boyle	Senior Medical Officer Department of Health, Social Services and Patient Safety, Northern Ireland
Ms Alison Brown	User representative
Dr Hilary Burton	Director PHG Foundation
Dr Jennie Carpenter (up to April 2014)	Consultant in Public Health Department of Health
Professor Aileen Clarke	Professor of Public Health & Health Services Research Director of Warwick Evidence Head of Division of Health Sciences
Dr Simon Cuthbert-Kerr (up to July 2014) Mr Scott Sutherland (from July 2014)	Health Protection Team The Scottish Government
Mr Greg Fell	Consultant in Public Health City of Bradford Metropolitan District Council Public Health Department
Ms Jane Fisher	Director ARC (Antenatal Results and Choices)
Dr Rosemary Fox	Director of Screening Services Public Health Wales

Professor Liddy Goyder	Professor of Public Health and Deputy Dean of the School of Health and Related Research (SchARR)
Dr Sharon Hopkins	Director of Public Health Cardiff and Vale University Health Board Headquarters
Ms Fiona Jordan	Consultant in Public Health Screening and Immunisation Lead South Yorkshire and Bassetlaw Area Team
Dr Anne Mackie	Director of Programmes UK National Screening Committee
Dr Heather Payne	Consultant Paediatrician, Senior Medical Officer for Maternal and Child Health Welsh Government
Dr Sue Payne	Public Health Consultant NHS Lothian
Dr Angela Raffle	Consultant in Public Health Bristol City Council
Ms Farah Seedat	PhD student, Division of Health Sciences, Warwick Medical School, University of Warwick
Professor David Weller	James Mackenzie Professor of General Practice Centre for Population Health Sciences University of Edinburgh

Annex C

Current criteria for appraising the viability, effectiveness and appropriateness of a screening programme

The Condition

1. The condition should be an important health problem
2. The epidemiology and natural history of the condition, including development from latent to declared disease, should be adequately understood and there should be a detectable risk factor, disease marker, latent period or early symptomatic stage.
3. All the cost-effective primary prevention interventions should have been implemented as far as practicable.
4. If the carriers of a mutation are identified as a result of screening the natural history of people with this status should be understood, including the psychological implications.

The Test

5. There should be a simple, safe, precise and validated screening test.
6. The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.
7. The test should be acceptable to the population.
8. There should be an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals.
9. If the test is for mutations the criteria used to select the subset of mutations to be covered by screening, if all possible mutations are not being tested, should be clearly set out.

The Treatment

10. There should be an effective treatment or intervention for patients identified through early detection, with evidence of early treatment leading to better outcomes than late treatment.
11. There should be agreed evidence based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.
12. Clinical management of the condition and patient outcomes should be optimised in all health care providers prior to participation in a screening programme.

The Screening Programme

13. There should be evidence from high quality Randomised Controlled Trials that the screening programme is effective in reducing mortality or morbidity. Where screening is aimed solely at providing information to allow the person being screened to make an “informed choice” (eg. Down’s syndrome, cystic fibrosis carrier screening), there must be evidence from high quality trials that the test accurately measures risk. The information that is provided about the test and its outcome must be of value and readily understood by the individual being screened.

14. There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/ intervention) is clinically, socially and ethically acceptable to health professionals and the public.

15. The benefit from the screening programme should outweigh the physical and psychological harm (caused by the test, diagnostic procedures and treatment).

16. The opportunity cost of the screening programme (including testing, diagnosis and treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (ie. value for money). Assessment against this criteria should have regard to evidence from cost benefit and/or cost effectiveness analyses and have regard to the effective use of available resource.

17. All other options for managing the condition should have been considered (eg. improving treatment, providing other services), to ensure that no more cost effective intervention could be introduced or current interventions increased within the resources available.

18. There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.

19. Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available prior to the commencement of the screening programme.

20. Evidence-based information, explaining the consequences of testing, investigation and treatment, should be made available to potential participants to assist them in making an informed choice.

21. Public pressure for widening the eligibility criteria for reducing the screening interval, and for increasing the sensitivity of the testing process, should be anticipated. Decisions about these parameters should be scientifically justifiable to the public.

22. If screening is for a mutation the programme should be acceptable to people identified as carriers and to other family members.

Annex D

Revised Criteria

Section 1 - Criteria for appraising the viability, effectiveness and appropriateness of a screening programme

The Condition

1. The condition should be an important health problem as judged by its frequency and/or severity. The epidemiology, incidence, prevalence and natural history of the condition should be understood, including development from latent to declared disease and/or there should be robust evidence about the association between the risk or disease marker and serious or treatable disease.
2. All the cost-effective primary prevention interventions should have been implemented as far as practicable.
3. If the carriers of a mutation are identified as a result of screening the natural history of people with this status should be understood, including the psychological implications.

The Test

4. There should be a simple, safe, precise and validated screening test.
5. The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.
6. The test, from sample collection to delivery of results, should be acceptable to the target population.
7. There should be an agreed policy on the further diagnostic investigation of individuals with a positive test result and on the choices available to those individuals.
8. If the test is for a particular mutation or set of genetic variants the method for their selection and the means through which these will be kept under review in the programme should be clearly set out.

The Intervention

9. There should be an effective intervention for patients identified through screening, with evidence that intervention at a pre-symptomatic phase leads to better outcomes for the screened individual compared with usual care. Evidence relating to wider benefits of screening, for example those relating to family members, should be taken into account where available. However, where there is no prospect of benefit for the individual screened then the screening programme shouldn't be further considered.
10. There should be agreed evidence based policies covering which individuals should be offered interventions and the appropriate intervention to be offered.

The Screening Programme

11. There should be evidence from high quality randomised controlled trials that the screening programme is effective in reducing mortality or morbidity. Where screening is aimed solely at providing information to allow the person being screened to make an “informed choice” (eg. Down’s syndrome, cystic fibrosis carrier screening), there must be evidence from high quality trials that the test accurately measures risk. The information that is provided about the test and its outcome must be of value and readily understood by the individual being screened.

12. There should be evidence that the complete screening programme (test, diagnostic procedures, treatment/ intervention) is clinically, socially and ethically acceptable to health professionals and the public.

13. The benefit gained by individuals from the screening programme should outweigh any harms for example from overdiagnosis, overtreatment, false positives, false reassurance, uncertain findings and complications.

14. The opportunity cost of the screening programme (including testing, diagnosis and treatment, administration, training and quality assurance) should be economically balanced in relation to expenditure on medical care as a whole (ie. value for money). Assessment against this criteria should have regard to evidence from cost benefit and/or cost effectiveness analyses and have regard to the effective use of available resource.

Section 2 – Implementation criteria

15. Clinical management of the condition and patient outcomes should be optimised in all health care providers prior to participation in a screening programme.

16. All other options for managing the condition should have been considered (eg. improving treatment, providing other services), to ensure that no more cost effective intervention could be introduced or current interventions increased within the resources available.

17. There should be a plan for managing and monitoring the screening programme and an agreed set of quality assurance standards.

18. Adequate staffing and facilities for testing, diagnosis, treatment and programme management should be available prior to the commencement of the screening programme.

19. Evidence-based information, explaining the purpose and potential consequences of screening, investigation and preventative intervention or treatment, should be made available to potential participants to assist them in making an informed choice.

20. Public pressure for widening the eligibility criteria for reducing the screening interval, and for increasing the sensitivity of the testing process, should be anticipated. Decisions about these parameters should be scientifically justifiable to the public.