UK National Screening Committee (UK NSC)

Note of the meeting held on the 19 November 2015

at

Goodenough College - London

This meeting provided recommendation on the following conditions;

- Hearing loss in adults
- Glaucoma
- Oral cancer
- Prostate cancer
- Cervical screening (HPV)
- Bowel screening (FIT)
- Diabetic Eye Screening (intervals)
- NIPT
- Congenital adrenal hyperplasia (CAH)
- Mucopolysaccharidosis (MPS I)
- Neuroblastoma

Members

Professor David Walker (Chair)	Medical Director, University Hospitals of Morecambe Bay Foundation Trust
Dr Sunil Bhanot	GP
Ms Alison Brown	Patient and Public Voice
Dr Paul Cross	Consultant Cellular Pathologist, Queen Elizabeth Hospital Gateshead Health NHS Foundation Trust
Professor Alan Cameron (Telecon from 1230-1300)	Consultant Obstetrician at Southern General Hospital, Glasgow
Dr Hilary Dobson	Consultant Radiologist and Clinical Director of the West of Scotland Breast Screening Service and Honorary Senior lecturer, University of Glasgow
Professor Stephen Duffy	Director of the Policy Research Unit in Cancer Awareness, Screening and Early diagnosis and Professor

	of Cancer Screening, Centre for Cancer Prevention, Wolfson Institute of Preventive Medicine
Professor Gareth R Evans	Consultant in Genetics Medicine, St Mary's Hospital, Manchester
Ms Jane Fisher	Patient and Public Voice
Professor Alastair Gray	Director at the Health Economics Research Centre, Nuffield Department of Population Health and Professor of Health Economics at the University of Oxford
Dr John Holden	Joint Head of Medical Division, Medical and Dental Defence Union of Scotland
Dr Surendra Kumar	GP, Widnes
Mrs Margaret Ann Powell	Patient and Public Voice
Dr Graham Shortland	Consultant Paediatrician, Cardiff and Vale University Health Board, Noah's Ark Children's Hospital for Wales and Executive Medical Director, Cardiff and Vale University Health Board, University Hospital for Wales

Observers;

Mr Andrew Anderson	PHE Communication lead
Dr Hilary Angwin	Screening & Immunisation Lead, NHS England/PHE Chair of FMCH
Ms Aleksandra Blawat	DH
Dr Margaret Boyle	Department of Health, Social Services and Public Safety Northern Ireland
Dr David Elliman	Clinical lead for Newborn Infant Physical Examination and Newborn Blood Spot, PHE
Mr Tim Elliott	DH Senior Cancer Policy
Dr Nick Hicks	National Co-ordinating Centre for HTA

Dr Rosemary Fox	Director of Screening Division, Public Health Wales
Dr Dorian Kennedy	Deputy Director, Sexual Health, Screening and Sponsorship Team, Department of Health
Dr Janet Little	Consultant in Public Health, Northern Ireland
Ms Natalie Owen	DH
Dr Heather Payne	Senior Medical Officer for Maternal and Child Health, Welsh Government
Dr Sue Payne	Scottish Government
Ms Marianne Scoles	DH
Ms Jo Taylor	Sexual Health, Screening and Sponsorship Branch Department of Health
Ms Julia Thompson	PHE Communications, Senior lead
Secretariat	
Dr Anne Mackie	Director of Programmes - UK National Screening Committee
Mr John Marshall	Evidence Lead, PHE
Miss Zeenat Mauthoor	Secretariat, PHE
Mr Nick Johnstone- Waddell	Public and Professional Information Lead
Apologies	
Ms Majella Bryne	Acting Director, National Cancer screening service, the Republic of Ireland
Dr Roger Brownsword	School of Law, Kings College London
Ms Sam Cramond	NHS representative
Presenters;	
Ms Sally Cartwright	Specialist Registrar

Mrs Anne Stevenson National Lead for Adult Screening Programmes

Welcome and Introductions

1. The Chair welcomed all to the meeting and a round of introductions were given including;

New members

All seven new members were welcomed onto the committee; Dr Paul Cross, Dr Hilary Dobson, Professor Stephen Duffy, Professor Alastair Gray, Dr John Holden, Mrs Margaret Ann Powell and Dr Graham Shortland.

Agenda Item Presenters

Dr Sally Cartwright invited to present NIPT

Professor Sue Moss to present the findings of the UK Age trial on breast screening at 40

Mrs Anne Stevenson to present screening intervals in the Diabetic Eye Screening Programme (DES)

Resignations

The Chair informed members of Professor Martin Buxton, Emeritus consultant of health economist, resignation from the committee having provided the committee with invaluable input over the last six years. The post for health economist has since been filled by new member Professor Alastair Gray.

Action; The Chair to send letter of appreciation to Professor Martin Buxton

Observers

The Chair informed the committee of the increased interest received from observers to attend UK NSC meetings. The Chair confirmed that the committee is happy to accommodate representatives from other organisations who may have a specific interest on the agenda, however, highlighted that it may not always be possible to accommodate all interested parties. It was agreed that in order to balance attendance to the committee meetings, organisations who have been invited to present will be given priority whilst interested parties who have requested to attend will be put on a waiting list and will have their attendance confirmed nearer the time by the Secretariat.

Apologies were noted.

Minutes and Matters arising

2. Minutes were confirmed as a true and accurate record

11 actions points were identified from the June meeting; many had been completed with only three outstanding;

Directors update

Dr Mackie to bring a detailed English paper on Inequalities to a future UK NSC meeting- to be presented to the UK NSC in 2016

Review of the UK National Screening Programme

Ms Taylor, Dr Angwin and Mr Marshall to take forward work on governance arrangements for the FMCH- ongoing

HTA Presentation

Dr Ulph to forward on pre-consultation report on antenatal information to the NSC- UK NSC awaiting document and publication date

Director's Update

3. Dr Mackie gave an update as follows

Pulse Oximetry

3.1 The pilot is progressing well and will be looking to move to the evaluation phase. Interim data was presented to the group and will be published and shared further in the coming weeks. The pilot has so far screened almost 25,000 babies of which around 160 were screen positives. Of these three had critical congenital heart disease.

Action; Secretariat to share interim data once available

Residual Blood spot

3.2 The Newborn Blood spot programme currently screens for nine conditions. A public consultation on how residual blood spot samples from screening should be kept, stored and used for public health monitoring and health research will be published shortly in a joint consultation. There was an outstanding issue in relation to finding funding for long term storage for research.

Inequalities

3.2 Dr Mackie informed the Committee that a PHE workshop was held in October to address the issues of inequalities across all screening programmes. The event was attended by a range of representation including NHS, LA and voluntary sector attendees. The event focused upon outlining, addressing and providing solutions to these shared issues. It was agreed that a shared national network of good practice should be developed. As mentioned at a previous meeting, a literature synthesis undertaken by Prof Stephen Duffy is being compiled and the findings of the report will be shared at a later date. A number of key actions for both national and local level had been identified at the workshop. These included: developing a network, sharing good practice, developing networks for particular groups (those with learning disabilities), developing a measure of inequalities for monitoring purposes, including evidence based standards in screening pathway standards.

Action: Dr Mackie to share information from the workshop with members and bring the literature synthesis to the UK NSC in 2016

Terms of Reference

3.3 The UK NSC terms of reference have been revised and approved by the four Chief Medical Officers and are available on the gov.uk website.

Evidence Review

3.4 The UK NSC evidence review process document is now available on the gov.uk website. The document formally outlines the process used by the committee and in particular the Evidence team on how the committee reviews evidence relating to the introduction, modification or cessation of a national screening programme. The document also builds upon the process of rapid reviews, the upcoming annual call for topics as well as increased stakeholder engagement.

Adult Screening

Screening for Hearing loss in adults

4 Mr John Marshall presented this item to the committee. The UK NSC last reviewed hearing loss in adults in 2009 and recommended that a population screening programme should not be offered due to a lack of evidence around the test and treatment as well as the availability of any randomised control trials (RCT).

4.1 The current review focused upon these three areas and concluded that an absence of RCTs remained and thus the evidence relating to the type of test which would be used within a population screening programme remained unanswered. Furthermore, the use of hearing aids as treatment was discussed and was agreed that it was not an effective treatment with many individuals having been assigned the use of hearing aids not using them. The GPs of the committee highlighted that this was an ongoing issue particularly in the elderly however recognised that the aids were improving though the newer aids were not available to all. The committee discussed that many individuals once diagnosed with hearing loss had an expectation not to want to wear them and to avoid the stigma. This notion was supported by both the Cochrane and the American systematic review which both indicated that once hearing loss had been diagnosed the use of hearing aids was used infrequently and did not increase the uptake of the treatment.

4.2 The committee noted the mixed opinions received from the consultation following the literature review which took into account evidence from 2009-2014. It recognised that there was a significant difference between being tested and being treated and the use of a hearing aid was down to personal choice as well as social and cultural difference. The committee raised the need for further public education on this condition.

4.3 The committee agreed that although hearing loss in older adults is a serious public health problem it upholds its recommendation not to offer population screening for hearing loss in adults as;

- the evidence is too limited to establish the type of screening test to be used, the severity of hearing loss to target, the age of the population to be screened and the frequency of screening
- Uncertainty on the effectiveness of the long term use of hearing aids and on the effectiveness of additional interventions aimed at improving the duration of hearing aid use is uncertain
- The absence of RCTs-in the general population. Screening has not shown to provide any hearing related improvement in the quality of life in comparison to hearing loss identified in other ways

Criteria	UK NSC Comments
The Test	
There should be a simple, safe, precise and validated screening test.	Due to limited evidence they type of screening test cannot be identified
The Screening Programme	

There should be evidence from high quality Randomised Controlled Trials that the screening programme is effective in reducing mortality or morbidity.	Absence of RCT in the general population.

Screening for Open Angle Glaucoma (OAG)

5 This item was presented by Mr John Marshall who reminded the committee that this was last reviewed by the UK NSC in 2007 which concluded that population screening for glaucoma should not be offered. The HTA review in 2007 concluded that population screening for glaucoma was not cost effective but highlighted that a targeted approach for high risk people could be both clinically and cost effective.

5.1 The 2014 review found that of the possible screening tests to be used to detect glaucoma none would be adequate for the use within a population screening programme. The committee noted that there was a significant lack of high quality evidence relating to treatment and RCTs to support screening for Glaucoma, however agreed that a more pragmatic approach would be to test high risk groups, as currently recommended. The group discussed the importance of regular eye checks and raised the need for public education.

All responses to the public consultation agreed that the absence of a test suitable for whole population screening was an obstacle to recommending the introduction of a screening programme.

5.2 The UK NSC agreed that a population screening programme for glaucoma should not be recommended as;

- a suitable population screening test has not been identified
- while there is some evidence to suggest that early treatment of OAG is useful this has not been established in screen detected populations
- there is no evidence from RCTs to appraise the effectiveness of a general population screening programme in reducing morbidity
- there is concern that treatment may cause harm

Criteria	UK NSC Comments
The Test	
There should be a simple, safe, precise and validated screening	A suitable test for general population has not been

test.	identified
The Treatment	
There should be an effective treatment or intervention for patients identified early detection, with evidence of early treatment leading to better outcomes than late treatment.	While there is some evidence to suggest that early treatment of OAG is useful thus has not been established in screen detected populations
There should be agreed evidence based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.	
The Screening Programme	
There should be evidence from high quality Randomised Controlled Trials that the screening programme is effective in reducing mortality or morbidity.	There is no evidence from RCTs to appraise the effectiveness of a general population screening programme in reducing morbidity

Screening for Oral Cancer

6 Mr Marshall said that oral cancer is the 16th most common cancer in the UK with survival rates varying on the type of oral cancer one is diagnosed with. The main risk factor associated with oral cancer is smoking.

6.1 The UK NSC last reviewed screening for oral cancer in 2010 and concluded that a population screening programme could not be introduced due to the uncertainty around the prediction of oral lesions becoming cancerous.

6.2 Mr Marshall informed the committee that due to the lack of history, progression, test and treatment as well as management of oral cancer it was incredibly difficult to offer a national screening programme. The lack of a suitable biomarker to be used in general population could not reliably predict the progression of lesions becoming cancerous, thus there was the possibility that a screening programme would in fact do more harm than good, with many people being treated for oral cancer whose lesions would not have caused any harm in the first place.

6.3 The committee discussed that the progression of lesions becoming cancerous was reasonably high and that further work is needed to address oral cancer. The committee agreed that further public education was needed on this area.

All responses to the consultation agreed that screening should not be recommended

6.4 The UK NSC concluded that a population screening programme for oral cancer should not be recommended as;

- a reliable screening test to detect potentially malignant lesions which could progress to cancer has not been identified
- it is unclear which individuals detected through screening should be offered treatment

Criteria	UK NSC Comments
The Condition	
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 phase.	There is an absence of a suitable biomarker therefore the identification of potential malignant lesions to progress to become cancerous cannot be identified reliability.
The Test	
There should be a simple, safe, precise and validated screening test.	A reliable screening test to detect potentially malignant lesions which could progress to cancer has not been identified.
The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.	

Screening for Prostate Cancer

7 Dr Mackie presented this item to the committee accepting that prostate cancer is an important health problem in the UK with over 40,000 new cases diagnosed every year.

7.1 In 2010, the UK NSC recommended not to offer a screening programme for prostate cancer as there was no clear evidence that the benefit of screening for prostate cancer outweighed the harms. The UK NSC then reaffirmed this decision in 2012 providing that at

both reviews the test for prostate cancer, prostate specific antigen (PSA) is a poor test and cannot accurately identify a large proportion of men who in fact have prostate cancer.

7.2 The committee reviewed the documents alongside the consultation comments and agreed that prostate cancer was a major health problem with severe health implications. The committee upheld that the PSA test remained inappropriate for the use within a screening programme as it was neither sensitive nor specific.

7.3 Dr Mackie updated the committee of the major randomised trial European Randomised Study of Screening for Prostate Cancer (ERSPC) which demonstrates a reduction of mortality from prostate cancer by at least 21%. Despite this significant reduction the committee agreed that the evidence is not yet sufficient to justify the introduction of a national screening programme using PSA as the primary screen test as the harms associated with the test still outweighs the benefits. Members discussed the potential harmful treatments in prostate cancer and agreed that the harm of screening currently outweighs the benefit. The committee noted that research is underway which may help shift the balance of harms and benefits relating to PSA testing. The Prostate testing for cancer and Treatment (ProtecT Trial) and Comparison Arm for ProtecT trial (CAP) are both expected to report in 2016. These studies will help to address the effectiveness of a population based PSA screening recommendation to reduce mortality. The committee agreed that prostate cancer needed to be kept under close review as the PROMIS trail was also due to report in 2016. The risk management document was also being revised.

In consultation a range of views were submitted. Where a direct opinion was expressed none disagreed with the recommendation.

7.4 The UK NSC agreed that a population screening programme for prostate cancer should not be offered as;

- although prostate cancer is a major health problem, the PSA test is still a poor test for prostate cancer and a more specific and sensitive test is needed
- PSA is unable to distinguish between clinically significant and non-significant cancers
- while there are other tests in development (particularly looking at combining risks) the current evidence does not support a population based screening programme

Criteria	UK NSC Comments

The Condition	
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 phase.	The natural history of prostate cancer is poorly understood.
The Test	
There should be a simple, safe, precise and validated screening test.	PSA is a poor test and cannot distinguish between clinically significant cancers (requiring treatment) and non-significant cancers
The distribution of test values in the target population should be known and a suitable cut-off level defined and agreed.	
The Intervention	
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.	The effectiveness of treatment for men with early localised prostate cancer remains uncertain. Current UK guidelines for treatment are outlined in the NICE clinical guideline 175
There should be agreed evidence based policies covering which individuals should be offered treatment and the appropriate treatment to be offered.	
Clinical management of the condition and patient outcomes should be optimised in all health care providers prior to the participation in a screening programme	
The Screening Programme	
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.	There is currently no conclusive evidence to support a PSA based screening programme
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 the criteria should have regard to evidence from cost benefit and/or cost effectiveness analyses and have regard to the effective use of available resources.	
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.	The PCRMP has produced information that are publicly available to assist primary care teams in providing information to asymptomatic men about the benefits and harms of PSA testing

Cervical Cancer – Human Papillomavirus

8 Dr Mackie said that the NHS Cervical Screening Programme currently offers screening to detect any abnormalities in the cervix by liquid based cytology. It is now known that high risk strains of Human Papillomavirus (HPV) have been found in 99% of cervical cancers. Recent pilots undertaken in the NHS Cervical Screening Programme have indicated that a move to use HPV as a primary screen would provide a more sensitive and specific test as well as being cost effective and cost saving.

8.2 The committee were supportive of the modification to the screening programme however were aware that a conversion to using HPV would take several years to fully implement. Members of the committee raised concerns with the current IT infrastructure in England as well possible workforce implications. Dr Mackie replied that there is planning work underway to get as smooth a transition as possible. In discussion there was some concern that the reduction in cytology will require fewer staff. Any announcement to roll out HPV primary screening may lead to premature flight from the programme by cytologists. Dr Mackie said work was in hand with the NHS-E to mitigate this risk informed by a workload model undertaken by the School of Health and Related Research (ScHARR) to look at how to mitigate this risk.

Members noted that much of the expected saving will accrue to extension of screening intervals. The Chair said that change to intervals would need to be based on evidence and should be brought back to the UKNSC in due course.

Most responses to the public consultation supported the proposal although some responses from laboratories expressed concern about the potential impact on cytology.

8.3 The UK NSC reviewed the evidence and recommends that the cervical cancer screening programme should adopt HPV as a primary screen test as it is a more accurate screening test.

Bowel Screening –Faecal Immunochemical Test

9 Dr Mackie introduced this item and informed the committee that it has previously discussed the benefit of possibly using faecal immunochemical test (FIT) as the primary screen for bowel cancer at the June NSC meeting.

9.1 The results of the pilot indicated that FIT is both easier to use, more sensitive and is more acceptable to the screened population noting an increase in uptake of around 10%. Members of the committee expressed their content to approve such a modification to the programme with the support of the economic modelling which specifies that FIT is highly cost effective and cost saving depending upon the cut off value. The committee discussed cut off values and raised possible issues with implementation which revolved around staffing and capacity. Dr Mackie highlighted to the committee that although all cut off points could be cost saving, it is imperative that the proposed cut off is set so as not to overwhelm endoscopy capacity. Dr Mackie confirmed that an implementation group is working on addressing and balancing capacity pressure based upon cut off points that mirror the current specificity of the FOBt.

All responses to a public consultation were supportive of the proposal with most pressing for a change as soon as possible although it was acknowledged that endoscopy capacity was currently a limiting factor in setting the FIT sensitivity as high as technically possible.

9.2 The UK NSC recommends that FIT should be adopted within the NHS Bowel Screening Programme as the primary test for bowel cancer as it is more sensitive and specific, acceptable to the screening cohort and is easier to use.

The Committee further agreed that as colonoscopy capacity grows or as screening uptake increases, it should review and recommend alteration of the cut offs to increase the number of cancers detected.

UK Age Trial

10 Professor Sue Moss provided the committee with an update on the results of the breast screening at 40. The committee thanked Professor Moss for the update which noted a reduction early increase in mortality for breast screening in the first 10 years (40-50) but not thereafter. The committee discussed the findings and considered that there was insufficient evidence to consider screening women under 50. The committee welcomed the need for additional data to help understand the long term effects of screening.

Diabetic Eye Screening

10.1 Mrs Anne Stevenson provided the committee with an overview of this item outlining that diabetic retinopathy is a common complication of diabetes that if left untreated could cause blindness. Early detection of sight threatening diabetic retinopathy and treatment can half the risk of blindness. Since the introduction of the NHS Diabetic Eye Screening Programme (DES) diabetic retinopathy is no longer the leading cause of blindness in the working age group in England.

10.2 The UK NSC has previously discussed the possibility of extending screening intervals from annually to every two years for those with low risk retinopathy at the November 2014 meeting and consequently in June which led to a public consultation to extend screening.

10.3 Mrs Stevenson outlined the ongoing work the four nations group have overseen to address the queries the committee raised over; grading, IT and pathways.

10.4 The committee concurred with the support received from the consultation to extend screening intervals for low risk diabetic patients as being both clinically and cost effective. The committee agreed that a move from one to two year screening for patients of low diabetic retinopathy would be more beneficial to the screened individual as well as enable the programme to support the rise of diabetes in the UK. The committee acknowledged the work undertaken by DH analysts that stated such a move to screening intervals would be cost effective.

10.5 Although in support of the move to two year screen, the committee did express concern on how such a change should be implemented and discussed the issues surrounding general eye screening led by optometrists. Mrs Stevenson responded affirming that a stratification method would be adopted and acknowledged the concerns highlighted by Diabetes UK. Several members of the committee raised how within their profession they were acutely aware how many diabetic patients were not engaging with DES. The

committee discussed how the programme could best engage and ensure that patient with diabetes are screened for diabetic retinopathy rather than attending an eye screening examination. The committee discussed the possibility of making diabetic retinopathy screening part of the diabetic care pathway.

10.6 The UK NSC summarised the findings and agreed that for people with diabetes at low risk of sight loss, the interval between screening tests should change from one year to two years. The current one year interval should remain unchanged for the remaining people at high risk of sight loss.

Fetal Maternal Child Health

11 Dr Hilary Angwin summarised to the committee the work of the Fetal Maternal Child Health group, highlighting that the terms of reference for this group was being revised to ensure alignment with the UK NSC. Once a final version has been agreed it will be brought to the UK NSC for approval. Dr Angwin then summarised the upcoming conditions which the FMCH will be discussing at their upcoming meeting in the New Year.

Screening for NIPT

11.1 Ms Sally Cartwright presented this item to the committee which discussed offering non-invasive prenatal testing (NIPT) also known as Cell Free Fetal DNA (cfDNA) to pregnant women in England who have a risk equal or greater than 1 in 150 of having a baby with either Down's, Edward's or Patau's syndrome.

11.2 At its last meeting in June, the UK NSC considered the evidence which showed that NIPT, when used as an additional test in the current screening pathway, is more accurate than the current combined test when detecting Down's, Edwards' and Patau's syndromes. This means that fewer women will then go on to have invasive prenatal-diagnosis (IPD), leading to fewer miscarriages.

11.3 Ms Cartwright said that both the systematic review and the NHS Reliable Accurate Prenatal non-Invasive Diagnosis (RAPID) study, which evaluated the use of NIPT as a contingent test, concluded that this implementation strategy will have minimal impact on the expenditure on the screening programme compared to alternatives. However, the review did highlight a number of uncertainties in implementing NIPT in the screening programme. In particular, the additional use of NIPT after the combined test will delay the timing of a potential subsequent invasive test (results can take up to two weeks). Some women may therefore choose to go straight to invasive testing. This may impact on the expected outcomes and anticipated reduction in the number of diagnostic tests. The choices women will make at different stages of the pathway are unclear.

11.4 Initial modelling suggests that implementing NIPT after the current first trimester combined screening test will result in similar numbers of babies with Down's syndrome being detected. This would result in a reduction in the number of IPD tests from 7,910 to 1,434 and therefore a reduction in IPD-related miscarriage of unaffected pregnancies from 46 to 3 per year. Based on the modelling commissioned by the UK NSC this is estimated to be approximately cost neutral.

11.5 Ms Cartwright said that further modelling would help support the estimation that moving to NIPT would be cost effective. It is expected that women with high risk pregnancies would still choose to move straight to invasive testing, but the choices women would make are not yet fully known. Initial modelling suggests that there could then be a reduction in the number of IPD tests from 7,910 to 3,718 leading to a subsequent reduction in the number of IPD related miscarriages from 46 to 17 per year.

11.6 While the test is accurate it is not perfect and there are some uncertainties in its performance, for example, the evidence is less clear about the tests ability to provide accurate risk information for Edward's and Patau's. It is also less effective in twin pregnancies.

Consultation

11.7 Ms Cartwright said that 30 stakeholders responded to the consultation. Responses varied. Many responses were positive, and many raised questions relating to the pathway options, test performance, laboratory specifications, and costings. For those that were not supportive, a programme with termination as a possible outcome is unacceptable.

11.8 The Nuffield Council is holding a workshop in January to consider and advise on the ethical issues raised in consultation. Roll out and evaluation will be informed by recommendations from the workshop.

11.9 The Committee reviewed the comments made and discussed reflex testing acknowledging that it would both dramatically reduce false positives and is already in use in other screening activities. However the committee agreed that reflex testing would not be practical in this instance because so much blood would need to be stored. In addition Ms Fisher informed the committee that concerns had been expressed about pre-test information if the reflex pathway were to be implemented. The committee agreed that test performance and pathways will not be known unless cfDNA is implemented. The discussion highlighted that maintaining the 1 in 150 threshold will allow the screening pathway to minimise any disruption to FASP. The committee agreed that the Nuffield workshop will help address the queries on the practicality of NIPT and discussed Pathway A as the preferred pathway.

The UK NSC agreed a pragmatic approach to the roll out NIPT with evaluation, which will allow detailed consideration of the issues raised in both the review and consultation.

Screening for Congenital Adrenal Hyperplasia (CAH)

12 Mr Marshall presented this item to the Committee and outlined that this rare inherited condition can cause serious complications to babies shortly after birth and throughout their life. The condition relates to an infant being unable to manage the body's water and salt balance.

12.1 The Committee noted that this condition was last reviewed in 2012 and recommended not to screen for CAH as there was uncertainties around the test.

12.2 The review of CAH looked at three clinical key questions to help determine whether a change to the current recommendation was necessary.

12.3 The committee noted that the review focused on incidence of CAH in the UK population, the evidence on the accuracy of the test and whether the test is suitable test for a population screening programme. The Committee accepted that the proposed test would provide an increase number of false positive results which would lead to many infants being treated unnecessarily.

12.4 The Committee noted that only one response to the consultation was received and this supported the current recommendation.

12.5 The UK NSC agreed that screening for CAH should not be recommended because the following criteria were not met:

- there is not a suitable screening test

Criteria	UK NSC Comments
The Test	
Should be simple, safe, precise and validated screening test.	There is no suitable screening test and the positive predictive value remains a concern.

Screening for Mucopolysaccharidosis I (MPS I)

13 Mr Marshall informed the committee that this was the first evidence review for MPS I and was initiated following discussion with the MPS society. The condition relates to a rare genetic disorder which can lead to organ damage.

13.1 The scope of the review focused on addressing the epidemiology and natural history of the condition as well as the test and treatment of the condition.

13.2 The committee recognised that the review found there to be a limited volume of evidence which restricted the ability to help draw clear conclusions in key areas. In relation to the test the committee were informed of three studies reporting on key test performance outcomes however these tests were unable to report on key measures looked at in a screening programme such as sensitivity, specificity and predictive values. No studies relating to treatment pathway was identified. Furthermore there was a lack of studies comparing treatment of pre-symptomatic with symptomatic detected cases.

Only one response to the consultation was received and this supported the recommendation.

13.3 Mr Marshall informed the committee that a paper submitted outside the research timeframe, had been excluded from the review. The paper would not have altered the conclusion of the review. The Committee agreed that accepting papers outside of the timeframe could set a precedent and impact on the rolling review process. In addition, it was clear that the Committee would review screening recommendations in the light of significant new peer reviewed evidence.

13.4 The UK NSC agreed to not screen for MPS I as the condition did not meet the following criteria;

- the UK incidence was unknown
- an ethical, safe, simple and robust test is not available
- an effective treatment is not available, and
- it was uncertain whether treating newborns in the period before symptom onset would improve outcomes

Criteria	UK NSC Comments
The Test	
Should be simple, safe, precise and validated screening test.	There is no optimum test for use within a population screening programme

Screening for Neuroblastoma

14 Mr Marshall presented this item to the committee which reviewed the most common form of cancer in children under the age of 5. Neuroblastoma affects around 100

children a year in the UK. The tumour can appear and disappear without treatment and without displaying any signs as well as appearing and developing aggressively.

14.1 The condition was reviewed in 2005. The committee reviewed the evidence again and supported the clinical view that it is difficult to distinguish between tumours that are regressive and progressive. Tumours detected through screening may not always have presented clinically therefore many children would undergo unnecessary treatment and caused anxiety that may not have caused any harm.

There were no responses to the public consultation

14.2 The UK NSC recommended not to screen for Neuroblastoma as the following criteria was not met;

- there is no high quality evidence from randomised controlled trails or non randomised controlled studies that neuroblastoma screening (at any age) reduces mortality from the disease
- concern that screening could lead to over-diagnosis of children whose condition would otherwise have regressed spontaneously without treatment had they not been screen detected

Criteria	UK NSC Comments
The Condition	
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.	There is no reliable way of differentiating between children detected through screening who would be likely to progress and so would require treatment from those who may never have presented clinically. No trials have been published that have disease characteristics or markers.
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.	Absence of any RCTs

UK Annual Stakeholder Conference

15 Mr Johnstone Waddell updated the committee on the Annual Stakeholder Conference scheduled for the 9th December at the Kia, Oval. The event is aimed at providing stakeholders with an insight on how the UK NSC make recommendations, processes it follows and engagements with researchers. Three recent recommendations will be presented to the committee which include; Atrial Fibrillation, Newborn Blood spot and Preterm Labour/ Bacterial Vaginosis. Two research presentations will also be provided by Dr Sian Taylor Phillips and Dr Chris Hyde. All members were welcome to attend

Action: Mr Johnstone Waddell to provide an update on the event at the February UK NSC meeting

Web Portal

16 All UK NSC pages have since transferred over to gov.uk. Mr Johnstone Waddell informed the committee that the Screening blog has fast become an important tool to help share screening related information and as a result receives above average hits when compared to other gov.uk blogs. Members of the committee were informed that guest blogs would be welcomed.

Action; Secretariat to circulate the gov.uk link

Action: Members to consider submitting a blog

17 Updates

NIHR NETSCC Update (for information)

No updates

SIGN Update (for information)

The Committee noted the updates

AOB

None noted

Date of the next meeting

Friday 12th February 2016- London

UK National Screening Committee

UK NATIONAL SCREENING COMMITTEE REGSITER OF INTEREST

Ms Jane Fisher
ARC has received unrestricted donations from biotechnical companies that provide NIPT and a breakdown of donation has been provided to the UK NSC. ARC is a non directive organisation which advocates individual choice. They do not promote any products or services. Money donated is put towards sustaining the service provided.
Professor Alastair Gray
Has been involved in the cost effectiveness work in both the Bowel and Cervical screening programme.