UK National Screening Committee

Cervical Screening
Programme modifications looking at; interval/ surveillance, women over 64 and self-sampling

27 February 2019

Aim

1. To ask the UK National Screening Committee (UK NSC) to approve a series of modifications to the NHS Cervical Screening Programme. The modifications relate to:

- the intervals for primary screening and the surveillance pathway for women with HPV + / cytology – results
- the strategy for women aged 64 who are exiting the programme
- self sampling within the screening programme

Background

2. The UK NSC recommended the use of primary HPV screening in the cervical screening programme in November 2015. The review document informing this recommendation is attached for information.

Since that point the discussion focused on the national recommendations required on screening intervals for HPV negative women and the surveillance intervals for HPV positive / cytology negative women. The main discussion has focused on:

- whether to extend the screening interval for screen negative women
- a 12 month surveillance interval for HPV positive / cytology negative women and
- whether genotyping should be used to guide the colposcopy referral strategy in the surveillance pathway

In February 2018 the Committee received a report from the HPV pilot sites which suggested that there is little clinical advantage in using genotyping within a surveillance strategy. This was consistent with the results of the ARTISTIC model. The report from the pilot sites also highlighted concern about loss to follow up in women with HPV +/cytology – results if they are recalled for further testing rather than referred for colposcopy following the second surveillance round.

At the Committee's June 2018 meeting it was agreed that a model commissioned by the NHS Cervical Screening Programme should be used as the basis of the core consultation proposals relating to screening intervals and surveillance strategy in the four nations. The results of the model were broadly consistent with those of other models developed in this area. The proposed strategy was:

- an extended , five year, screening interval for HPV negative women irrespective of age
- a 12 month surveillance interval for HPV positive / cytology negative women and that
- women with persistent HPV infection and negative cytology should undergo two surveillance tests. If HPV positive at the second test they should be referred to colposcopy irrespective of cytology result

At the same meeting the strategy for women exiting the programme was also considered. The upper age limit of the screening programme is 64. It was noted that there was an absence of evidence to guide recommendations on women exiting the programme.

A literature search undertaken in October 2016 did not identify any primary studies exploring issues related to women exiting the programme when reaching the upper age limit for screening. Similarly no estimates of outcomes in this group were identified in a summary of modelling studies commissioned by the UK NSC evidence team.

The recommendations for women exiting the programme were proposed by the English Cervical Screening Programme Advisory Group. These were:

- HPV positive / cytology positive women should be managed in the same way as other age groups
- HPV positive / cytology negative women should be recalled at 12 months and, if still HPV positive, be referred for colposcopy. If colposcopy is:

  i. decisively negative this would prompt discharge from the programme
  ii. decisively positive this would prompt the offer of loop excision
  iii. indecisive this would prompt the offer of loop excision or recall a further 12 months later

- as there is an absence of evidence in this area the Programme should work with the relevant national professional or standard setting bodies to produce a clinical consensus statement to guide practice in this area.

In relation to self sampling within the screening programme the proposal was that:

- self sampling as a strategy to address non attendance for screening requires further study in well organised pilots and research projects
- other questions relating to the fit between this approach and the screening programme should also be the subject of research and piloting. For example this would apply to the use of self sampling as an approach to routine screening programme delivery.

Consultation

3. The UK NSC hosted a three month public consultation exercise which closed in January 2019. Comments were requested on the above proposals. Twenty one stakeholder organisations were contacted directly about the consultation these are listed at the end of this document. **Annex A**

Thirteen responses were received. The responses have been circulated as a zip file.

Responses

Screening intervals and surveillance intervals

Across the responses there was a broad consensus on the proposal for a five year primary screening interval and the proposal for two surveillance tests at 12 month intervals for women with HPV + / cytology – test results.

Views diverged on the management of women whose results remained HPV + / cytology – at the second surveillance test. It was acknowledged that there was a very limited evidence base relating to this point in the pathway and that the proposed strategy to offer colposcopy to all would be a conservative strategy. However there was also concern that the positive predictive value of colposcopy would be low and that cytology triage may be a realistic and equally safe approach. In addition there was interest in the use of genotyping and other markers to stratify risk at this point in the pathway.
Across the responses there was interest in monitoring and evaluating any strategies that were implemented to manage persistently HPV + / cytology – results.

Women aged 64 and over who are exiting the programme

The absence of evidence in this area was acknowledged across the responses and again there was broad consensus on the basics of the proposed strategy.

Again, views diverged on the management of women with HPV + / cytology – results at the final screening test. In this respect some stakeholders suggested that the number of surveillance test should be the same as in the younger age groups and different combinations of further surveillance, colposcopy and loop excision were suggested.

Given the lack of evidence, stakeholders generally found the proposal to develop a consensus guideline useful and, again, there was interest in monitoring and evaluating any implemented strategies.

Self sampling

There was broad consensus that further research and piloting was necessary before formally implementing self sampling within the screening programme.

Future developments

The responses raised a number of issues might be considered as part of the future development of the screening programme. These included:

- use of genotyping at the primary screening test and in the surveillance pathway
- use of novel markers to stratify risk
- revision of the upper age limit for screening
- revision of the screening intervals, for example six years for the under 50s and 10 years for the over 50s
- adjunctive colposcopy
- psychological impact HPV screening
- determinants of non-attendance

Some of these issues might feed into the programme's research agenda along with self sampling. Others might be addressed in the modelling work considering screening in the vaccinated population which is currently being initiated by the UK NSC evidence team.

Programme implementation and QA issues

The responses also raised a number of issues which are important to the delivery of the proposed changes but which are not strictly UK NSC issues. These included:

- planning to avoid logjams in service delivery
- ensuring an appropriately configured IT system is available
- communication strategy
- ensuring operational rules are in place regarding screening intervals in non attenders
- ensuring clear stopping rules are in place at the upper age limit, for example how to manage late attenders over the age of 64
- arrangements for audit and feedback
- monitoring performance of the test following implementation

Proposal

4. It is proposed that:

- an expanded, five year, screening interval for women who test HPV negative at their routine screen, irrespective of age should be implemented
- a 12 month surveillance interval for HPV positive / cytology negative women should also be implemented
- women who are HPV positive / cytology positive at their final screen should be managed in the same way as other age groups and those who are HPV positive / cytology negative women should be recalled at 12 months
- work should be undertaken to develop consensus on the acceptable options for managing women with HPV+ / cytology – test results in the surveillance pathway along

with a mechanism to evaluate the impact (for example clinical and logistic) of different strategies

- self sampling should not be implemented within the screening programme without further research and piloting which demonstrates its value
- UK NSC activity should be focused on the development of recommendations to guide screening in the vaccinated population

Action

5. The UK NSC is asked to approve above proposal.

Annex A

List of organisation contracted:

- The British Association for Cancer Research
- British Association for Cytopathology
- British Association of Surgical Oncology
- The British Society for Colposcopy and Cervical Pathology
- Cancer Research UK
- Faculty of Public Health
- Jo's Cervical Cancer Trust
- Macmillan
- Northern Ireland Cancer Network
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Nursing- Women's Health Forum
- Royal College of Pathologists
- Royal College of Physicians
- Royal College of Physicians and Surgeons of Glasgow
- Royal College of Physicians of Edinburgh
- Royal College of Radiologists
- Royal College of Surgeons
- Royal College of Surgeons of Edinburgh
- Society and College of Radiographers
- Cervical Screening Programme Advisory Group