NHS

Cancer Screening Programmes

DH Department of Health

NHS Cervical Screening Programme

Implementing HPV triage for women with mild or borderline cervical screening test results and HPV test of cure

Advice to the NHS

July 2011

DH INFORMATION READER BOX

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Description	The Operating Framework for the NHS in England 2011/12 states that commissioners should work with their local services and NHS Cancer Screening Programmes to implement HPV testing as triage for women with mild or borderline results, leading to a more patient centred service and major cost savings.
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1. Introduction

1.1 *Improving Outcomes: A Strategy for Cancer* said that the Government will roll out Human Papilloma Virus (HPV) testing across England as triage for women with mild or borderline cervical screening test results and as a test of cure for treated women. The Operating Framework for the NHS in England 2011/12 states that commissioners should work with their local services and NHS Cancer Screening Programmes to implement HPV testing as triage for women with mild or borderline results, leading to a more patient centred service and major cost savings.

1.2 IO:SC noted that HPV testing as triage (sorting) for women with mild or borderline cervical screening test results has been piloted and shown to be effective. Women with mild or borderline results are tested for HPV and if negative are returned to the routine screening programme. Women who are HPV positive are referred to colposcopy. HPV testing can also be used to test whether women who have had cervical abnormalities treated have been cured and this has been shown to be effective. This is known as "test of cure".

1.3 This document aims to give practical, evidence based advice on implementing HPV triage and test of cure across the NHS Cervical Screening Programme. *It is suggested that SHAs work in close collaboration with their PCTs, primary care services, pathology services and screening services to develop plans to deliver HPV triage and test of cure*.

Background

1.4 Human Papilloma Virus (HPV) is a group of over 100 viruses, some of which are sexually transmitted and are known to be a necessary cause of cervical cancer. In most people, the virus is cleared naturally by the immune system, but it persists in some women conferring a higher risk of Cervical Intraepithelial Neoplasia (CIN) and cervical cancer. Most women (and men) contract the sexually transmitted virus at some point in their lives. Transient HPV infection is common, especially in women aged under 35 years. There is no reliable treatment to clear the virus.

1.5 The most common high risk types for cervical cancer and CIN are types 16 and 18, with 31 and 33 also being common. Non-oncogenic types, such as 6 and 11, cause visible genital warts. Other types cause the common verruca and some appear to have no effect. The prevalence of different types varies to some extent in different parts of the world. High risk HPV DNA has been found in 99% of cervical cancers.

HPV triage

1.6 HPV triage is a way of using HPV testing to sort women with borderline cervical nuclear changes or mild dyskaryosis into an appropriate management regimen. Only15 to 20% of women with such cervical changes have a significant abnormality (CIN) that needs treatment. Currently these women are invited back for another cervical screening test in six months time, and if this is also borderline again in a further six months time. If the third test is still borderline, a year or more later, the woman is referred to colposcopy.

1.7 High risk HPV testing in this group is effective in identifying which women may need treatment, and significantly reducing the time of the screening pathway. Women who test positive for high risk HPV are referred to colposcopy immediately, whilst women who are high risk HPV negative can be safely returned to routine recall.

HPV test of cure

1.8 Currently women who have been treated for CIN are subsequently screened annually for 10 years. Research has shown that women who have a normal, borderline or mild cervical screening test result six months after being treated for CIN, and who also test negative for high risk HPV, have a very low risk of residual disease.[1]

1.9 In HPV test of cure, six month post treatment samples that are negative, borderline or mild on cytology are tested for high risk HPV. Women who are HPV negative will be returned to the routine screening programme, avoiding the need for 10 year annual assessment. Women who have high grade cytology or are high risk HPV positive at six months after treatment are referred back to colposcopy.

Sentinel sites

1.10 In 2001, HPV/LBC pilot studies of the feasibility of introducing HPV triage in the English screening programme were started. Three sites in England converted to using liquid based cytology (LBC) and HPV triage for women with borderline or mild dyskaryosis. The results of this study suggested that while introducing HPV triage decreased the number of repeat cytology tests and reduced the time taken to return women to routine recall, it also resulted in a large increase in referrals to colposcopy. It was concluded that adding HPV triage to LBC screening was feasible, acceptable to women and cost effective both in terms of quality and of life years saved[2].

[1] Kitchener et al. HPV testing as an adjunct to cytology in the follow up of women treated for cervical intraepithelial neoplasia. BJOG 2008;115:1001-1007.

[2] Moss et al. Evaluation of HPV/LBC Cervical Screening Pilot Studies. First report to the Department of Health (Revised October 2004).
http://www.cancerscreening.nhs.uk/cervical/evaluation-hpv-2006feb.pdf

1.11 Following the evaluation of the original pilots studies, six 'Sentinel sites' were established to follow an agreed refined protocol for the use of HPV triage for women with borderline or mild dyskaryosis, and HPV testing as a test of cure for women with treated CIN. The sites included two of the original pilot sites, Bristol and Norwich, together with four additional sites; Liverpool, Manchester, Northwick Park and Sheffield. Together these six sites represent approximately 10% of the English Screening Programme. All women aged 25-64 with routine cytology reported as borderline or mild dyskaryosis were eligible for inclusion in the study. Women who tested negative for HPV were returned to routine recall at three or five years depending on their age. Women who tested positive were referred for a colposcopic examination.

1.12 The evaluation of the sentinel sites concluded that:

i) Triage would allow approximately a third of all women with borderline and mildly dyskaryotic results to be returned immediately to routine recall, thus reducing the burden on cytology services

ii) HPV testing on women with negative cytology as a test of cure had a low positive predictive value (PPV) for high grade CIN, but allows the majority of women who are negative for HPV to be returned directly to routine recall, bypassing the long management process normally associated with follow up after treatment

iii) Taking into consideration the loss to follow-up with repeat cytology, risk of progression with delayed follow-up and women's preferences, HPV triage is likely to be a highly cost-effective option compared with repeat cytology. As set out in the IO:SC Impact Assessment, switching to these approaches is likely to attract additional up-front costs in comparison to the current programme, but central funding is in place for 2011/12 (and expected to be for 2012/13) to help cover this. By the third year of roll out, if both HPV triage and test of cure are implemented, the Impact Assessment modelling suggests that these initial costs will be offset by quality and productivity gains of around £16 million a year from 2013/14, with this additional benefit continuing to accrue

iv) Modelling of HPV test of cure would generate cost saving compared with current cytology management due to a reduction in cytology workload and is also slightly more effective at averting cases of CIN3+. Therefore, this is a highly cost-effective policy option

1.13 A peer reviewed paper based on the evaluation is currently in press for publication in the autumn. We will publish the full evaluation alongside this.

Next steps

1.14 NHS Cancer Screening Programmes have produced *HPV Triage and Test of Cure: Implementation Guidance*, which complements this advice and is available at: www.csp.nhs.uk. The intention is that, subject to meeting certain criteria (see 2 below), local cervical screening programmes will implement HPV triage in 2011/12 and HPV test of cure in 2012/13. Implementing both improvements in the same year would risk the quality and safety of the current programme, and put an unnecessary burden on colposcopy services.

2. HPV triage – criteria for national roll-out

2.1 In order to ensure the quality and safety of local programmes in implementing HPV triage and HPV test of cure, the Department of Health and NHS Cancer Screening Programmes have agreed the following criteria.

2.2 Local screening programmes would ideally achieve the following criteria:

i) Size of laboratory - each laboratory should ideally be reporting a minimum of 35,000 samples per annum when implementation starts, or have local plans in place to report a minimum 35,000 as this is likely to optimise the cost savings of HPV triage and test of cure[3]

ii) Sufficient sustainable colposcopy capacity to deal with the increased workload[4]

iii) Achieving the operating standard of 98% of women receiving their cervical screening test result within 14 days[5]

iv) Achieving quality levels on HPV testing and taking part in External Quality Assurance (EQA) for the HPV test

v) Have in place a training programme for local professionals

vi) Developing an identifiable cervical screening network which comprises call/recall offices, colposcopy clinics and laboratories, and appointing a pathway manager for the network

vii) Sign off from the Regional Quality Assurance team and the Primary Care Trust (PCT), PCT Cluster or emerging Clinical Commissioning Groups

viii) Ability to start delivery within financial year 2011/12

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[3] School for health and Related Research (ScHARR): Option appraisal: Assessment of a seven-day turn-around for the reporting of cervical smear results (2006)
https://www.csp.nhs.uk/webdocuments.aspx?page=publications&doctype=Publications&Menu=publications

[4] Moss et al. Effect of testing for human papillomavirus as a triage during screening for cervical cancer: observational before and after study. BMJ 2006;332(7533):83-5
http://www.region8ipp.com/Docs/Articles/83.pdf

[5] Department of Health. Improving Outcomes: A Strategy for Cancer (January 2011)
http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_123394.pdf

3. Practical details

Funding

3.1 NHS Cancer Screening Programmes will retain and manage the funds for implementing HPV triage and test of cure in 2011/12 and 2012/13.

3.2 Based on the experience of the sentinel sites, in the first year £100,000 of funding will be allocated per 50,000 samples of women aged 25 and over. This covers all implementation costs, including: laboratory costs; test kits; training; and increased colposcopy and histology

3.3 The investment over 2011/12 and 2012/13 is expected to yield significant net savings of up to £16 million per annum thereafter[6].

3.4 Funding in 2011/12 and 2012/13 will follow activity. In reported women aged 25 and over, this will mean £2 per sample in year one and £1 per sample in year two. This is because the peak of colposcopy arrives in the first year when the two (old and new) protocols are both sending women to colposcopy and all the training must be done. In the second year the excess cost is HPV testing all "test of cure" women and some additional colposcopy. By year three savings accrue.

3.5 Eligible samples from KC61 data will come from GP and community clinics, hospital services and GUM clinics. Samples from women aged under 25 and non-NHS samples will not be eligible for funding.

National actions

3.6 In addition to this advice and the implementation guide, NHS Cancer Screening Programmes will develop a support pack for primary care and national patient materials (eg letters, leaflets).

3.7 NHS Cancer Screening Programmes will also issue revised guidelines on the operational requirements of the programme, plus revised editions of *Benchmarks for Reporting and Criteria for Evaluating Cervical Cytopathology*; *Colposcopy and Programme Management: Guidelines for the NHS Cervical Screening Programme*; and *Histopathology reporting in cervical screening*.

3.8 In addition, NHS Supply Chain are putting in place a Framework Agreement for purchasing HPV testing kits. The sentinel sites used the Qiagen HC2 kit, but four more have now been developed by: Roche; Abbott; GenProbe; and Hologic. These are being evaluated

[6] Impact Assessment of *Improving Outcomes: A Strategy for Cancer* (January 2011)

for potential use. This evaluation and a Framework Agreement will be available in September 2011.

Local actions

3.9 Local cervical screening services need to develop a proposal to implement HPV triage in 2011/12 based on the criteria set out in Section 2 above, and submit it as detailed in Section 5 below.

3.10 Other local actions will include:

i) Selecting a suitable HPV testing kit from the Framework Agreement (post September 2011)
ii) Identifying a network, the pathways and a pathway manager
iii) Ensuring sustainable sufficient colposcopy capacity, which may include support from the independent sector if required
iv) Re-write local protocols and amend laboratory systems to incorporate new result/action codes, synchronising them with the call/recall agency
v) Setting up call/recall systems to send appropriate invitation and result letters to women. This may mean different letters for different groups of women if HPV triage is not to be implemented across all areas simultaneously
vi) Educate primary care/sample takers
vii) Adopt national template letters

4. Other cervical screening actions in Improving Outcomes: A Strategy for Cancer

4.1 In implementing HPV triage and test of cure, local screening services will wish to take into account the other cervical screening actions outlined in the Cancer Reform Strategy. These are:

- The Operating Framework for the NHS in England 2011/12 states that commissioners should ensure that cervical screening results continue to be received within 14 days. As recommended by the Advisory Committee on Cervical Screening (ACCS), the threshold for achieving this has been set at 98%.

5. Support from NHS Cancer Screening Programmes

5.1 In the first instance, proposals to implement HPV triage in 2011/12 should be sent to:

Professor Julietta Patnick
Director
NHS Cancer Screening Programmes
Fulwood House
Old Fulwood Road
Sheffield S10 3TH

e-mail: Julietta.Patnick@cancerscreening.nhs.uk

6. Further details and support

6.1 Further support and advice can be obtained directly from NHS Cancer Screening Programmes, or from Regional QA Directors – see Annex A.

Annex A

Regional Quality Assurance Directors

Region	QA Director	Contact
East Mid	Dr D Slater	david.slater@sth.nhs.uk The Royal Hallamshire Hospital Department of Histopathology Floor E Glossop Road Sheffield S10 2JF
EoE	Dr Jem Rashbass	Jem.Rashbass@esqa.nhs.uk East of England Breast & Cervical QA Reference Centre Compass House Vision Park Chivers Way Histon Cambridge CB4 9AD
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NE & Yorks and Humber	Dr Keith Faulkner	keith.faulkner@nhs.net QA Reference Centre Unit 9, 9 Kingfisher Way Silverlink Business Park Wallsend Tyne & Wear NE28 9ND
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