UK National Screening Committee

Department of Health & Social Care

DECISION ANALYTIC MODEL AND COST EFFECTIVENESS EVALUATION OF FOR HUMAN PAPILLOMAVIRUS (HPV)

The offer of a choice between Human papillomavirus (HPV) self-sampling and clinician-taken sampling in the Cervical Screening Programme: cost effectiveness modelling

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1. Background

1.1. The health problem

In the UK, cervical cancer is the 14th most common cancer in females. There are approximately 3,200 (9.6 per 100,000) new cases of cervical cancer every year, accounting for 2% of all new cancer cases in females (2016-2018). (1) In England, around 51% of women diagnosed with cervical cancer survive their disease for 10 years or more (2013-2017).(1)

1.2. Screening Programme

Cervical cancer screening, which has been implemented for at least five decades, aims to detect precancerous lesions that can be treated before cancer develops. (2, 3)

Up until recently, cervical screening was based on cytology. However, there has been well-established evidence that infection with human papillomavirus (HPV, a sexually transmitted virus) is a necessary cause of cervical cancer. (4) Although most types of HPV are benign and clear up with no intervention, (5) a small proportion of 'high-risk' types of HPV infection persist and can lead to cervical cancer. (5,6) High-risk HPV is found in 99.7% of cervical cancers. HPV types 16 and 18 are particularly high-risk and contribute to around 70% of all cervical cancers. (7) A report in 2017 estimated that 3.2% of women in the general population have cervical HPV-16/18, increasing to 29.6% in women with low-grade cervical lesions, 58.6% in women with high-grade cervical lesions, and 79% in women with invasive cervical cancers. (8,9)

Given the instrumental role of the HPV high-risk strains in the aetiology of cervical cancer, along with the introduction of the HPV vaccination programme in 2008, there was a strong rationale for the implementation of primary HPV screening in the UK, reserving cytology testing for HPV positive women only. The UK NSC recommended

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the use of the test for HPV as a primary screening test in 2017. (10) Following this recommendation, a national programme of primary HPV screening was fully implemented in Wales (2018), England (2019) and Scotland (2020). Northern Ireland is aiming for implementation in 2022/2023.

Primary HPV screening is when the first test carried out on the sample looks for the high-risk HPV virus first. If high-risk HPV is detected, a cytology test is used as a triage to check for any abnormal cells. Please refer to the cervical screening care pathway for more information on the screening pathway.

1.3. HPV self-sampling

The move to primary HPV screening in the UK provides an opportunity to change the method of sample collection and allows women and other people with a cervix1 to self-collect a vaginal or urine sample at home via a self-sampling device.

Coverage in the UK cervical screening programme has been below the acceptable standard for many years, with a number of those invited choosing not to attend. As such, the offer of a self-sampling kit has the potential to increase the uptake of cervical screening and therefore could have a positive impact in reducing the incidence of cervical cancer.

The UK NSC currently does not recommend HPV self-sampling in the CSP. In 2017, the UK NSC commissioned an external review of HPV self-sampling to find out about the potential of HPV self-sampling to improve the performance of the CSP.(11) The review identified several evidence gaps.

In 2019, the UK NSC requested an in-service evaluation (ISE) of HPV self-sampling to address the evidence gaps from the 2017 review. The aim of the ISE is to provide the UK NSC with good quality, robust evidence on the clinical effectiveness, feasibility, acceptability, and cost-effectiveness in the use of HPV self-sampling in the CSP. Evidence from the ISE will support a definitive recommendation by the UK NSC to the four UK nations.

2. The requirement

2.1. Decision problem, key questions, and objectives

The HPV self-sampling ISE will offer a portion of women* eligible for cervical screening in England the choice between a clinician taken sample and a self-sample for HPV.

The UK NSC is looking to appoint a competent supplier to undertake a piece of cost-effectiveness modelling to understand the conditions under which harms will outweigh benefits for the offer of HPV self-sampling in the UK. This is particularly important given that testing for HPV on a vaginal/urine self-sample could be slightly less sensitive than a clinician taken cervical sample. Therefore, modelling is required to understand how the self-sampling offer under different uptake scenarios could impact on the number of screen-detected HPV and treated cervical lesion.

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This work will provide some guidance about how much less sensitive the self-sample can be before the number of women with CIN2 will fall and the offer not be safely made to all women (just the non-attenders for example).

There is suggestion that the test is a little less sensitive so it is essential to understand this so there is a need to understand whether the offer should be adjusted to maintain a safe service

The key objectives:

- To support a high-quality and evidence-based ISE, cost-effectiveness modelling is required to understand the conditions under which benefits will outweigh harms at a reasonable cost for the offer of HPV self-sampling in the UK. There is little and uncertain evidence for this in the UK context at present.
- To provide evidence on the conditions under which benefits outweigh harms for self-sampling in the cervical screening programme in terms of clinical outcomes and cost-effectiveness. Findings will inform an optimal delivery and/or monitoring strategy for the HPV self-sampling in-service evaluation estimated to start in Autumn 2024-Winter 2025.
- To provide a model assessing the impact of;
    - different self-sampling test sensitivities,
    - screening strategies (mail to all, opt-in etc.),
    - participant characteristics (vaccination status, age etc.) and
    - behaviours (screening uptake, switching etc.) on the detection and treatment

2.3. Resource

The projects require social and or behavioural science researchers with knowledge and understanding of cancer screening. In addition, knowledge, understanding and previous experience of working in the field of cervical cancer and HPV self-sampling would be preferable.

2.5. Project outputs

Deliverables will likely include the following:

- Model Specifications: Development of a model to determine the conditions under which the introduction of self-sampling in the cervical screening programme provides the most benefits in terms of clinical outcomes for women and cost-effectiveness for the programme.

- Cost effectiveness model: Running of model and analysis of cost-effectiveness.

- Model Technical Report: Interim report(s) by Spring 2025, to feed into the ISE design process.

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- Model: Final report(s) in Spring 2026 clearly outlining model type, analytical approach, assumptions, uncertainties, results, and discussion, including implications to policy.

- It is expected that the final paper is published in a peer-reviewed journal to highlight the high-quality and robust work required.

- Transfer of the model's outputs to the UK NSC

2.6. Timescales

After award of contract, detailed protocols for the research should be discussed with the UK NSC secretariat.

Key milestones	Estimated dates	Notes
Starting	Summer 2024	This may be delay depending on internal approvals
First draft of model	Summer 2025	
Workshops		To be decided in discussions between the Supplier and the UK NSC evidence team
Technical report		
Presentation of the model to the UK NSC reference groups and UK NSC		
Final model and technical report	Autumn 2026	
Manuscript	Winter 2026	
Publications	Winter 2026	

3. Project management

Regular online meetings between the Supplier's project team and the UK NSC project team will be scheduled throughout the duration of the contract. The frequency of these meetings will be decided by the Authority in collaboration with the Supplier.

The project will be monitored against the project plan submitted by the appointed Supplier.

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4. Contract Term

The contract will be for a period of 18 months with the option to extend for a further period or periods of up to 6 months.

5. Budget and Payment Schedule

The overall contract value is capped at £300,000 (excluding VAT). The Supplier will provide a project plan outlining key milestones and associated deadlines. Payment will be contingent upon the successful completion of key deliverables specified in the Supplier's project plan during that respective period. Payment for the contract value will be made in 2 equal instalments. The first instalment will be disbursed in arrears on the 3rd month following contract signature. The second instalment after the cost model has been developed and final instalment will be remitted upon project completion.

References

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10. The UK National Screening Committee. Cervical Cancer. [Available from: Cervical cancer - UK National Screening Committee (UK NSC) - GOV.UK (view-health-screening-recommendations.service.gov.uk)]

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