

EXPLORING THE VALUE OF A RAPID, ON-DEMAND TEST FOR THE DETECTION OF HUMAN PAPILLOMAVIRUS

Background

In England, women are screened for cervical cancer in primary care as part of a national screening programme, with an annual coverage of 78% (HSCIC, 2013). Human papillomavirus (HPV) testing and triage is performed on samples with abnormal results, and there is also a primary HPV screening pilot being conducted (Szarewski,

Using a new, rapid, near-patient diagnostic test, there is the opportunity for HPV to be diagnosed both outside of the laboratory and within laboratories performing cytology and HPV testing. It may also have the potential to change clinical pathways for early detection of cervical cancer whilst improving patient experiences.

Objectives

- 1) To compile experts' views on opportunities, value, and challenges of implementing a rapid, on-demand,
- near-patient HPV test
 2) To explore opportunities for efficiency gains in the HPV screening and testing pathways, specifically in the case of rapid, near-patient diagnostic tests

- Conducted a literature review to understand cervical cancer pathways in England
- Performed 25 semi-structured interviews with laboratory, clinical, epidemiology, and policy experts from:
 - o London and non-London
 - Urban and rural o HPV triage and HPV pilot sites
- Informed interviewees that they would be acknowledged by name if they chose to be, but that their quotations would be anonymised to include only their role as identifier
 A snowball, convenience sample of respondents was chosen for the interviews
- Notes were analysed for themes

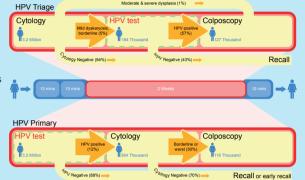
Results 1- Pathways

There are four main steps in the screening pathway from the patient and clinics' perspectives under both HPV triage and HPV primary screening, as the difference between these two screening paradigms are seen within the laboratory.



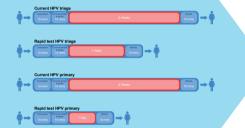
From the laboratory's perspective, the pathway for testing differs between HPV triage and HPV primary screening, as do the numbers of samples tested.

This is illustrated using published data from the English National Screening Programme and Kitchener et al., 2014.



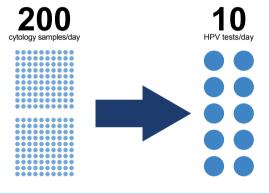
Under the current system of HPV triage, experts felt a rapid test could reduce the wait for results to one week from two, and provide a definitive result for patients a week earlier,

- 1) negative patients to exit the pathway more quickly, thereby reducing the anxiety of a pending result 2) positive patients to progress to follow up more quickly.
- Under primary HPV screening, a rapid test could mean that a woman receives her screening results on the same day compared to the current system where samples are sent to a laboratory for processing and could take up to two weeks to action results of both tests.



Current HPV tests are batched, and often sent to separate laboratories, where there can be issues with delays, errors, and length of time to result.

Experts reported that using a co-located, on-demand HPV test for triage following cytology could reduce the time to results by up to a week, compared to sending results to a central laboratory for HPV testing.



Results 2 - Advantages and Concerns

When we analysed experts' interviews, the following themes emerged.

<u>Advantages</u>

Deliver a faster result to women Decrease anxiety Might increase screening uptake Decrease time to negative results Decrease time and costs for sample transportation Improve care for rural patients and practices Decrease reporting errors

Concerns

Increased workload for practice staff
Will there be an impact on screening uptake? Commissioning/funding systems
Will the benefits be seen across the disease management pathway? Quality control issues

A selection of the quotations from the experts is presented below:

"I think a rapid test might encourage women to attend who don't usually go for screening" - Gynaecologist

"A good model might be for local primary care networks to have one clinic that processes the rapid tests, like a localised 'hub and spoke' model

 GP consultant "A point of care test for HPV [in primary HPV screening] may not be good for a service but could be good for patients"

— GP consultant

"We need to collect data on patient views about a rapid result and about the anxiety of waiting for a result" Commissioner

"How would we quality control a rapid testing platform in the community?" - Policy Maker

"My first thoughts are that it sounds good on paper, and might be good in certain situations, but it's likely to be more work and more expensive, so I'm not sure

- GP nurse

Discussion

- Rapid testing for HPV can fit into the screening pathway in several ways, and could yield many benefits. A rapid, near-patient test under primary HPV screening followed by cytology triage could radically change the testing paradigm
 - o Rapid tests → quicker results and reporting o Faster turnaround times → patient benefits
- Most women with a negative result could be notified the same day. Further opportunities were identified where rapid HPV testing results could play a novel role including its use in sexual health clinics, in conjunction with HPV vaccination and with self-taken swabs

Conclusions

Overall: Current opportunities for a rapid, on-demand HPV test include the numerous potential benefits to women and services both as part of a cervical screening programme and in other clinical situations. A faster test result under HPV triage or primary HPV screening allows clinicians to better manage their patients and improves patient quality of care. Additional research is needed to qualitatively and quantitatively assess the value of such a test.

- Examine and understand patients' views of a faster test result
 Broaden the scope: examine the perspective from whole health care system
- Assess the cost-effectiveness of introducing such a test Explore other pathways using the test and/or efficiencies
- Investigate potential for incorporating HPV testing into screening using self-collected samples

