British Association for Cytopathology response to the National Screening Committee consultation on proposed changes on delivery of cervical screening with adoption of HPV primary screening

The BAC has produced this response after consultation with its membership via an email request for comments and also after a discussion held at its Annual Scientific meeting.

The NSC consultation has referred to three specific documents as evidence of a case to convert the cervical screening programme from cytology first with reflex HPV testing when appropriate to one of HPV screening followed by reflex cytology on positive HPV tested samples. This consultation is not unexpected as all those working in the CSPs within the UK have been anticipating such a possible change since the introduction of HPV testing within the programmes, if not for many years longer. Some of the data justifying such a conversion is based on conventional, non-liquid based cytology studies. It is well accepted that the UK based CSP are amongst the most effective, if not the most effective, in the world, and any potential change to CSP delivery must be at least the same, and not be inferior to the current service.

The documents referred to by the NSC refer extensively to the primary HPV pilot sites, which have been testing the HPV primary approach since 2013. As such, the available evidence from these pilots is limited, and does show variation between the sites and between the technologies used. Whilst the adoption of an HPV first cervical screening approach is being adopted in some other countries, the UK based experience is of necessity limited to the pilot sites. The BAC would ideally welcome more up to date data from these sites in the public domain before any decision is made, but is also acutely aware of the need for a speedy decision on this.

The pilot sites having commenced in April 2013 have yet to cover one screening round and hence follow up/outcome data is limited to HPV positive cases. Data is limited on the outcomes of HPV *negative* women who will have to wait 3-5 years depending on age for their next sample. All the available data and the NSC documents themselves make note of an HPV negative rate amongst women with CIN and cervical squamous cancer, and more so with cases of HG CGIN and adenocarcinoma. No screening programme is perfect and the NSC must weigh up the potential sensitivity and specificity of the different types of approach in reaching its decision. Although HPV testing is more sensitive than cytological screening, it is not perfect and has a false negative rate for high-grade CIN and cancer estimated in various publications as between 4 and 18%. Depending on what age HPV primary screening is introduced at (20 vs 25 vs other) the potential in previously unscreened women in whom false negative HPV tests will occur might turn out to be important. This must also been seen in the context of an increasing rate of CIN 2 and 3 in the younger age groups, and rising cancer rates also in this age group. Amending the first age of screening from 25 to 20 should also be taken into consideration given this, and falling coverage rates in the age range. Consideration of co-testing for the first rounds of screening would reduce the cytology workload by approximately 70% compared with 85% for HPV screening, and may allow for a phased introduction of primary HPV whilst allowing laboratories to manage staffing and training issues better, as well as service reconfiguration issues.

The current position nationally is one of laboratories and laboratory staff being fully aware that a move to primary HPV screening is possible. The lack of a decision to implement or not is having a massive effect on the abilities of laboratories to retain and recruit staff let alone deliver the current cytology based screening programme. A rapid decision on the move, or not, to primary HPV screening is essential to allow for laboratories to plan for service configuration and staffing needs, and for individual staff at all grades to consider their future.

It will not be possible or feasible to retain or retrain all the current laboratory staff within the CSP and this is understood by the laboratory based staff. Many have valuable skills that can be used within cellular pathology such as in histology or non-diagnostic cytology or related to the molecular requirements of HPV testing. However, to consider that any such changes could be quickly and easily done is nonsensical. A decision from the NSC to convert even if the timescale is 3-5 years would allow for planning that currently cannot occur. Staff within the CSP have many valuable skills in cytology and many already undertake reporting or other duties within pathology laboratories. Enough staff with these skills and experience must be retained for service provision outside of those required for any future CSP delivery, but also for future staff development and training.

The configuration of the laboratory aspect of a future CSP if primary HPV is adopted would be vastly different. If the number of laboratories as outlined in the consultation documents is used as a possible future configuration, it would suggest that major and meaningful discussions will be required between providers and commissioners. If the numbers outlined for laboratory workloads is correct, and the ones outlined are speculative, then staffing levels at all levels would be radically different. This has immediate repercussions on staffing levels/training for the future and hence also on cytology training school requirements. It would also have a significant impact on future manpower planning, both scientific and medical. The current guidance about individual reporting workloads will need revisiting.

The documents highlight that an effective IT system is essential for the CSP to function. The current Exeter system is already well known to require major overhaul and whilst it has been able to work in the HPV primary pilots this is only with many local patches and much human intervention. On a national scale this is not feasible. An integrated system, such as the one used in the Bowel screening programme in England or the SCCRs system in Scotland would be ideal, and indeed the latter might be a system that could deliver this in the English setting. To commence any move to primary HPV testing without suitable IT could be potentially disastrous for the effectiveness and reputation of the CSPs, but also to women who may receive inappropriate advice or follow up.

Consideration must also be given to the extra workload, even if for a few years, of the increased colposcopy workload, and of the extra cervical pathology workloads from cervical biopsies and treatments. Both services are already stretched, and any increase in workload must be anticipated and resourced. The effect on histology services does require, given recent national reporting issues, a better national approach to cervical pathology reporting, and highlights the needs for systems to ensure consistent and accurate reporting in line with national standards and quality parameters.

Any potential changes must also be very much brought to the attention of commissioners, many of whom will be unaware of the implications of such a change. Their engagement and education is essential for the commissioning of appropriate services that are correctly resourced. Consideration should be given to national commissioning for the CSP services, given the vast reduction in cytology workload, and the likely massive laboratory reconfiguration that will ensue. Any commissioning must also include issues such as MDT provision, given what will be an even greater separation of cytology services from both histology and colposcopy services.

If the NSC should decide to adopt the recommendation to move to primary HPV screening it is essential that this recommendation is given with timescales that are clear and feasible for the current CSP services, especially the laboratories, to adopt and reconfigure. It should also give specific advice on which laboratory platforms are best suited to this primary HPV screening role based on best current evidence, and not allow a plethora of different approaches and platforms and what could potentially lead to a postcode lottery of pickups and referrals which may be more technology specific than based on population differences.

The NSC must also be fully convinced that if this change to primary HPV testing is adopted, there will be very little, if no, chance to revert to a primary cytology based screening programme given the huge staff changes and losses that will have occurred.

The protocols that would need adoption for use in a primary HPV screening programme will need to be clear and unambiguous. Variation based on local or personnel wishes or whims must not be allowed to develop.

In summary the BAC accepts that the adoption of primary HPV testing is most likely, and whilst more data would be desirable before a final decision is made, a speedy decision either way is required to help stem further degradation of the current service. A decision, to adopt or not, is essential either way to help manage the current position of uncertainty that is allowing in some areas the provision of the cytology based screening programme to disintegrate due to an inability to plan. Significant staffing changes would result from the adoption of this policy, and any implementation strategy must look to maximise the skills and experience of this workforce within the NHS both for current and future diagnostic services, even if not directly related to CSP provision.

Mr Allan Wilson
President of the British Association for Cytopathology
On behalf of the BAC
28th October 2015