Cancer Screening: Call for Evidence

Response from the Royal College of Pathologists

This consultation response from the Royal College of Pathologists (RCPath) has been compiled with contribution from sub specialty advisors on Cellular Pathology; relevant College Specialty Advisory Committee Chairs and College members.

Whatever the actual mode of screening delivery, the need for a trained and competent workforce to undertake all aspects of screening must be developed and maintained, along with suitable infrastructure (especially IT) to enable it to operate effectively.

Problems and solutions
1. Immediate/recent issues
• Breast
• An increasing complexity and increased workload in breast screening pathology, for example as a result of age extension, as well as changes in approach to the management of benign lesions of uncertain malignant potential (B3s) by vacuum-assisted excision, has not been balanced by recognition of this in terms of breast pathology workforce. Novel approaches, such as advanced practitioners, digital pathology and AI are under-supported and under-explored. • Similarly, resulting changes required for data collection (e.g. the need to be able to categorise vacuum-excisions as a separate type of specimen) have been hampered by the breast screening computer system's age and inflexibility with only work-arounds proving possible. • The complexity of governance, between NHS England, Public Health England, and Quality Assurance and Programme aspects of the latter, have delayed ongoing work. As examples: the annual pathology audit providing feedback to individual pathologists regarding their performance has not been undertaken since analysis of the 2013 to 2016 data; it has to date been impossible to update pathology guidance for the screening programme – which is now done through the RCPath; there is a reduction in joint working between multidisciplinary groups (CPGs) since the changes in governance structure (e.g. the surgical and radiological CPG meeting minutes seemingly cannot be made available to the pathology group so we are unable to advise). • While pathology departments all have different IT systems, none link with breast screening systems, so there remains significant duplication of manual data entry and potential for error. • The digital pathology option for pathology diagnosis has, to date, been blocked yet screening governance systems, to the extent that some pathology departments are reporting all histopathology, other than screening samples, digitally. The digital approach will assist in workforce issues by facilitating transfer of material to where pathologists may be available, as well as second opinion reviews etc. Subsequent investigation of the use of artificial intelligence has the potential to reduce inefficiencies further.
• Cervical
Historically cervical cancer screening relies on the examination of cells on a glass slide under a microscope, with certain types of abnormality having a second test for the virus (HPV) which causes virtually all cervical cancers.

By the end of this year, the first step will be to look for the virus infection. The cells will only be examined down the microscope if the test for the HPV virus is positive. This change, supported by all professional bodies, including the College, means that the number of laboratories in England will be reduced from 49 to 9.

Because of a dissociation between standard setting and commissioning and service reality, there was a lack of workforce planning and development that has caused grave concern. This lack of integrated planning has had profound service implications.

This reorganisation is causing many issues for laboratories in retaining and recruiting staff, with many experienced staff looking for new roles or a change of career. This is causing major problems in delivering the expected results to women within the NHS target of 14 days. Many laboratories have significant backlogs of samples. This is putting severe strain on laboratory staff who are trying hard to meet the NHS target and maintain quality standards while dealing with backlogs of thousands of slides and falling staff levels.

We fully support current efforts to increase the number of women attending, but we are acutely aware that this coincides with laboratories being under extreme pressure. Cytology staff have a long history of delivering a high quality service. They will always offer a professional service, but increased workloads, often of the order of 30% or more with these campaigns, means that many will be unable to report the samples within the 14 days' target. In many places, reporting will take many weeks and potentially a month or longer.

Our cytopathology members tell us:
The Cervical Screening Programme (CSP) has worked well since its inception, and has reduced the incidence of cervical cancer over many years. The delivery model has changed from cytology only, to cytology first with reflex HPV testing, to now the introduction of HPV first and reflex cytology. These changes have been on the background of many scientific, clinical and NHS changes. Whilst the programme has worked well, it has suffered from many well publicised and often very high profile problems. It has a highly motivated, skilled and trained laboratory workforce. These staff should not be lost and their skills can be utilised within pathology or elsewhere in the NHS with retraining if required.

- Bowel

FIT is a type of faecal occult blood test for bowel cancer screening which uses antibodies that specifically recognise human haemoglobin (Hb). It is used to detect, and can quantify, the amount of human blood in a single stool sample and is carried out in clinical biochemistry departments. FIT has been shown to have higher participation rates by the population and the switch is expected to increase screening uptake by around seven to eight percentage points in England. Whilst we welcome higher uptake in testing and the benefits for earlier diagnosis, this will increase pathology demand, both as a result of increased initial testing and because positive results lead to further testing.

2. Governance of Cancer Screening

Members tell us that there is fragmentation and constant change in governance and accountability. They have questioned whether delivery and quality assurance of screening programmes could go back to NHS rather than Public Health England as it is too bureaucratic. They think there are too many organisations with different opinions amongst commissioners.

Members suggested a single commissioning system for screening and diagnostics with an architecture in place to reduce the constant change.

It is possible that lessons could be learnt from the devolved nations e.g. the roll out of faecal immunochemical testing (FIT) in Scotland and cervical screening in Wales.

Our cytopathology members tell us
Problem: the move to introduce HPV Primary screening has highlighted major problems with the Public Health England and NHS England relationship. The ability for them to work well together and include sound professional input and advice has not worked well. Communication has been generally poor at many levels, and the credibility of both has been seriously challenged on occasions. Confidence in the process has varied. At local level commissioners have invariably done their best with little or often poor advice. The National Screening Committee (NSC) plays a major role in defining all screening programmes, and whilst this has been much improved, it may warrant clarifying in certain aspects. In general, all guidance needs a speedier route from development to implementation.

Solution: the interaction of the advisory and commissioning arms of the NHS needs to be far more effective and able to incorporate professional advice. Whether these functions should be integrated, or their remits altered, may be necessary. One body would be more streamlined, and able to cover both functions. Involvement and communication must be better. Quality Assurance which is integral to the Cervical Screening Programme (CSP) and has helped raise the quality of it, must be maintained. It needs a clear mandate, communication route and its approach must be both evidence based and consistent. At the NSC level, its remit as to what is a population based screening programme, what counts as major vs minor changes in a screening programme, and how this is done, may need re-evaluating and defining. This is a national screening programme, but delivery is left in the hands of local commissioners/providers, which can lead to significant differences in the ability to run the service.

3. Uptake/coverage in general and in vulnerable and minority groups

Members tell us that there is a need to reduce inequalities, especially in lower socio-economic status groups or high risk groups e.g. homeless women. There are transport issues, issues of poverty and larger elderly populations face particular problems in rural areas.

Better use of social media and technology is recommended. For example a video of what a screening test entails, text reminders for appointments, appropriate language.

Communication should be in easy to understand/plain English with simple explanations of what is actually involved. This would help demystify the procedures.

Members suggested improved methods for booking appointments e.g. better awareness of availability of out of hour's services: allowing open access; using QR codes so appointments can be booked anywhere/anytime and allowing people to have appointments when they suit them. Members recommended making screening less burdensome, and would support screening in work locations.

It could be useful to engage women from hard to reach groups during pregnancy when they have lots of contact with healthcare professionals. New approaches are needed for certain Black, Asian and Minority Ethnic communities e.g., bespoke invitations, in people's first language, approaches from within the community.

Our cytopathology members tell us
Problem: coverage is low and falling. It is essential to improve it to maintain an effective population based screening programme. Different approaches to screening delivery, e.g.

self-sampling, may help. Different social, ethnic and religious groups have different perceptions and understanding of what cervical cancer and screening is for, and advice from those in and who understand these groups is required to help ensure that any population based programme is able to reach all aspects of UK society.

Solution: campaigns and positive media can help to improve coverage and uptake. Any such campaigns must be coordinated with the ability of the rest of the programme to ensure effective and timely delivery. Recent campaigns have resulted in a poor experience for women and low morale in the laboratories screening the samples. The introduction of self-sampling, either for specific groups or generally, should be rapidly piloted if not formally introduced as soon as can be. Use of targeted campaigns to groups in society can be effective. The use of social media and the ability to be able to deliver results electronically to women (email/text etc.) must be greater to engage with women.

Better choice of where a woman can go for her cervical screening test is needed. The vast majority are only offered through their GP with limited slots and times which does not fit in with today's lifestyle.

Look at offering women more choices such as hub clinics, community clinics etc. Explore the possibilities of 'pop-up' clinics in shopping centres, supermarkets and gyms. Consider the possibility of mobile screening clinics.

Our members from the Clinical Biochemistry Specialty Advisory Committee tell us that, similar to other screening programmes there are issues with sample collection in bowel cancer screening and the nature of investigations which result. The change to FIT testing improves the diagnostic test but does not change the acceptability of it or resultant investigations. Less than 60% uptake in UK.

4. IT issues

Investment in IT is needed to ensure it is fit for purpose. IT infrastructure, hardware (to replace the nearly 30% of Laboratory Information Management Systems (LIMs) that are virtually obsolete), connectivity to link systems, and, for histopathology and haematology, digital imaging will be key to making services more stable and efficient. There have been some good examples of single LIMS roll outs in Wales that have made patients' test results more accessible, and able to be reported across the country. Similarly, some regions have good systems that link many hospitals and indeed some acute and primary care systems. These models need to be widely adopted. LIMS are vital to effectively manage samples, and associated data and automate workflows.

Our cytopathology members tell us
Problem: The current system (Open Exeter system) for providing clinicians with access to patient data has been used since 1988, and it is a tribute to it that it is still in place, despite being identified as not fit for purpose in 2011. It links with National Health Application and Infrastructure Services and lab systems. As identified in the recent National Audit Office report it is too old, with many manual workarounds. Members have told us that the recent stripping of Capita of its screening function due to publicised issues in screening and the apparent development of a bespoke screening system may address this.

Solution: the Cervical Screening Programme (CSP), along with all other mass population screening programmes, needs a modern, functional and flexible screening IT system. It must be able to deliver the needs of the programme now, and be able to develop into what will be required in the future. It must include HPV vaccination data, screening history, and clinical outcomes (colposcopy and histology). It must be an integrated system, able to link easily with all required systems, and serve the functional needs of those within the CSP

nationally. It must be able to easily deliver information for the screening process, but also data for monitoring the effectiveness of the programme at as many levels as is possible. It must be accessible for all involved within the CSP and not restricted to area.

Our members from the Clinical Biochemistry Specialty Advisory Committee tell us that for bowel screening we need to ensure secure links to report results in a timely way and which allows secondary care to view results.

5. Workforce issues

Our workforce census, *Meeting pathology demand*, showed that only 3% of NHS histopathology departments have enough staff to meet clinical demand. The census focused on the histopathology workforce – the specialty vital to cancer management from initial diagnosis to guiding patients' treatment.

The cost of staff shortages across histopathology departments is high for both patients and for our health services. For patients, it means worrying delays in diagnosis and treatment.

For NHS hospitals, it means spending more resources on locum doctors to fill staffing gaps, or outsourcing services. We estimate this costs £27m each year across the UK health service – money that could be better invested in staff and new diagnostic equipment.

There is a growing demand for pathology services, both in the number and complexity of tests performed. This is caused by developments in testing such as the introduction of the faecal immunochemical test (FIT), which will increase clinical biochemistry and histopathology workload and new targeted therapies needing genetic or molecular tests on samples. With an ageing population and a rise in obesity, leading to increased cancer rates, pressure on already-stretched pathology services will also increase.

Our cytopathology members tell us
Problem: no national review of what is required to deliver cervical screening has ever been taken, with all delivery left to local providers. This is at all levels, and often staff hear of decisions second hand or via the media. This applies to all staff in the Cervical Screening Programme (CSP).

Solution: the move to HPV Primary and the reduced laboratory profiles should allow for a realistic national laboratory screening workforce plan. This would include training, ongoing education and retention/recruitment policy, some of which is already in place. It should also include looking at alternative roles for staff as and when indicated to ensure that the skills of the workforce are not lost and are retained and used as best as they can be. The impact on the delivery of training via the current cytology training schools will need assessing to ensure continued access to high quality training in the future. These schools deliver a wide range of training, but with only 9 labs likely the number of schools and their funding needs re-evaluating.

6. Equipment Issues

Our cytopathology members tell us
Problem: in general the Cervical Screening Programme (CSP) is well supported with the equipment necessary to carry out its laboratory function. There are a number of pieces of guidance re the approved equipment and its use however the process can be slow and laborious with layers of bureaucracy. Equipment in its broadest sense must include all

relevant aspects such as direct analytical equipment, but also IT, Microsoft Office software etc.

Solution: the CSP must maintain its appropriate, relevant and evidence based guidance to ensure patient safety but we need to develop a system that is quicker to react to new tests which may benefit women in the CSP. The need for compliance, as with all guidance, must be integral to any contracting and form part of the ongoing QA process. If data indicates certain platforms are more effective (in whatever assessment is used to measure this) then a definite steer as to what can and should be used must be taken.

7. Potential for risk-based screening?

Our cytopathology members tell us
Problem: currently all women receive the same screening pathway, irrespective of actual or potential risk. Whilst different HPV subtypes are tested for, management does not currently rest on this. Other bio markers, such as methylation status, are being investigated. The HPV vaccinated cohort are now entering the screening programme in significant numbers, and this may affect screening delivery.

Solution: the CSP must base its pathway based on best available proven scientific evidence. If the use of HPV subtypes, or any other bio marker, can offer a better approach to the clinical management and hence triage women who are at higher risk from those with a lesser risk, this needs to be incorporated. This may alter direct clinical referral and follow up. As such, all other parts of the programme must be able to adapt to such changes easily. The vaccinated cohort effect may allow for a different programme all together with time.

Our members from the Clinical Biochemistry Specialty Advisory Committee tell us
With respect to bowel cancer screening there are no well-defined high risk (or low risk) groups at present so no scope for risk based screening (outside the established age categories) at present.

8. Digital pathology

Digital pathology (whole slide imaging) is a technology that allows glass histopathology slides to be reviewed digitally on a computer screen, rather than with a microscope. As a result, it is a technology that will transform pathology services in the NHS and beyond.

Digital pathology can help with many aspects of screening pathology including education, audit, and maintaining standards by training and continuing professional development.

Many screening programs use digital pathology based EQA scheme Breast EQA https://nccbp.nottingham.ac.uk/index.shtml and Bowel Cancer EQA http://www.virtualpathology.leeds.ac.uk/eqa/specialist/nbcs) to support quality and standards in screening.

There is increasing potential to use digital pathology for primary diagnosis, i.e. Making a diagnosis on the digital image.

This has several useful applications, such as in pathology networks to share work across regions, to encourage pathologist recruitment/ retention in the NHS, and to provide support for services in NHS Trusts who do not have enough pathologists and are unable to maintain turnaround times.

The College position is that digital pathology is still new technology in which experience is limited, so a cautious approach to adoption is warranted.

However we believe that the technology can be used safely for primary diagnosis if the Royal College Validation Guidelines are followed.

These guidelines allow pathologists to gain experience in digital pathology while deferring to the microscope when there is uncertainty. See https://www.rcpath.org/resourceLibrary/best-practice-recommendations-for-implementing-digital-pathology-pdf.html .

The guidelines have been used in several sites to deploy digital pathology for primary diagnosis and the work to date suggests that pathologists can develop proficiency with digital images similar to the microscope – see Histopathology 72, 662-671 http://www.virtualpathology.leeds.ac.uk/research/publications/pub_docs/dt/201819%20Digital%20Pathology%20for%20the%20Primary%20Diagnosis.pdf for one example

However we understand that Public Health England (PHE) are currently prohibiting the use of digital pathology in screening programs.

The College would welcome a dialog with PHE about the use of digital pathology in screening, including collecting both experimental and real world evidence in addition to the evidence already provided (SEE APPENDIX)

9. Scope for Artificial Intelligence in screening

- AI is a very powerful technology with the potential to greatly improve healthcare including pathology diagnosis.
- AI has the potential to introduce efficiencies into pathology services by freeing highly trained pathologists from more routine and repetitive work – for example by searching lymph nodes for cancer, a task which takes human pathologists a lot of time and effort.
- The development of AI in pathology has to be a collaboration between pathologists and computer scientists.
- The use of AI would also need a qualified pathologist to interpret, combine, and intervene when the computer needs assistance. The best use of AI often involves a “human in the loop” to guide the machine, and interpret the outputs.
- AI has great potential to assist in pathology based diagnostics but ultimately it is a machine tool that a trained pathologist will use to make their job faster and more accurate.
- The integration of extra data and information requires a human expert. Computational pathology can step in for some of the repetitive tasks, but at the same time, it is likely to add even more information from a different angle for the pathologist to integrate into the whole picture.
- AI is applicable across different pathology specialties but will have very different types of application in blood sciences, microbiology and cellular pathology.
- Getting the patient perspective – there is a need for more engagement with patients about the potential use of AI in their healthcare. Work by the Academy of Medical Sciences suggests that patients strongly support the use of AI in healthcare provided it improves quality and frees up time for doctors to spend with patients.

In digital pathology imaging, AI is particularly suited to repetitive tasks and classification of simple diagnostic categories, exactly the sort of specimens that are generated In the area of cancer screening.

As a result, artificial intelligence is likely to of benefit to screening programmes, for example in excluding normal tissue or identifying / classifying lesions

A national screening programme is a strong environment in which to develop, evaluate and roll out AI based tools for diagnosis. The NHS should aim to be a leader in this area, and research to develop AI tools for digital pathology in screening should be encouraged.

One issue in cervical screening is that, because the need for cervical smear interpretation will likely drop in future, commercial interest in funding AI solutions in this area is likely to be lower.

Our cytopathology members tell us
Problem: the interpretation of cytology slides has been dependent on human skill since the Cervical Screening Programme (CSP) was introduced, and will continue to be so. Whilst there are some technologies that can aid this they are in general expensive but still depend on human input and interpretation. True computer interpretation of cytology is a long way off, but could arguably occur.

Solution: the use of AI may not be cost effective given the falling cytology workloads in the Cervical Screening Programme. It may have a role if staffing levels fall to critical levels, but the cost effectiveness of this would need assessing. Alternative strategies to cytology, such as molecular markers may mean that the role of cytology may decease or even be redundant within the CSP. However, cytology interpretation will be required for the foreseeable future. In colposcopy there may be scope for use of AI to help improve assessment of the cervix, e.g. Z scan and other systems.

Our members from the Clinical Biochemistry Specialty Advisory Committee tell us
For bowel cancer, current tests are automated. There may be scope for resultant investigations like colonoscopy / CT colonoscopy to use AI.

10. Forward Look – How should screening look like in 2028?

Our cytopathology members tell us
The impact of the vaccinated programme and developments in potential molecular markers, ought to have a major impact on the Cervical Screening Programme (CSP). Whilst 2028 may be too early, one could easily envisage a CSP where screening is done on cervical samples (taken by women themselves potentially) which are evaluated for disease/risk by HPV status alone or in combination with other markers. In this scenario, the role of cytology may well be small if in fact used at all. The use of non-cervical samples may also be able to be developed, using blood and/or urine samples but again this is a way off as yet. Whatever the actual mode of delivery, the need for a trained and competent workforce to undertake all aspects of the CSP must be developed and maintained, along with suitable infrastructure (especially IT) to enable it to operate effectively.

Our members from the Clinical Biochemistry Specialty Advisory Committee tell us
For bowel screening, the main issue is to increase uptake of the test and move all of UK to FIT testing at present. In the future we may be doing faecal DNA tests or using imaging like CT colonoscopy?

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