DIGITAL CYTOLOGY

A transformative solution for cervical screening in the UK

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Executive Summary

- The UK's cervical screening programme faces significant challenges, including a shrinking workforce, increasing backlogs, and the risk of service deterioration.
- Digital cytology presents a compelling solution, empowering laboratories to help eradicate cervical cancer, improve workflow and enhance patient care, thus helping to mitigate the workforce crisis.
- Digital cytology is in routine use in Europe, Australia and New Zealand and has most recently been approved by the U.S. Food and Drug Administration (FDA). Despite strong evidence demonstrating the benefits of digital cytology, adoption within the UK has been slow and met with barriers related to funding, implementation, and communication with key decision-makers.
- This policy paper outlines the benefits of digital cytology, challenges to its widespread adoption, and proposes recommendations to accelerate its implementation within the National Screening Program.

Introduction

The United Kingdom's cervical screening program, while successful in reducing cervical cancer rates, faces imminent challenges (Public Health England, 2019). A shrinking and aging workforce, particularly among experienced pathologists and biomedical scientists, coupled with low uptake of specialised training, threatens the programme's ability to maintain efficiency and turnaround times (Royal College of Pathologists, 2018). According to 2018 workforce surveys, there is a 25% shortage of histopathologists, with only 3% of NHS histopathology departments able to meet demand for services (Royal College of Pathologists, 2018, 2018).

Additionally, attendance for cervical screening is in decline, with around 1.2 million women between 25 and 64 not attending in England alone (NHS Digital, 2023). There are many psychological, cultural and literacy barriers to attendance, as well as growing issues with access to testing. The fragmented governance and commissioning environment is exacerbating these issues and preventing progress (Jo's Cervical Cancer Trust, 2020).

To address these critical issues, the Institute of Biomedical Science (IBMS) and Hologic convened a roundtable discussion focused on the potential of digital cytology to transform cervical screening. This technology allows for remote reporting of samples, easier sharing of slides, and potential use of computer algorithms to assist.

Published data from laboratories in Europe using this technology routinely demonstrate significant benefits in clinical performance and streamlined workflows, including reducing slide reading time (Vodovnik, 2016). Digital histopathology is already in widespread diagnostic use across the UK, with recent approval for reporting biopsies from other cancer screening programmes (University of Warwick, 2024).

Digital cytology not only offers workflow improvements but also has the potential to address health inequalities in cervical screening. By enabling remote reporting and easier sharing of slides, it could improve access to expert diagnosis for underserved populations and areas with limited local expertise (Cancer Research UK, 2020; National Cancer Registration and Analysis Service, 2021).

This policy paper builds upon the IBMS/Hologic roundtable, outlining the compelling case for adopting digital cytology within the UK's cervical screening programme. The document explores the multi-faceted benefits of this technology, addresses implementation challenges, and proposes recommendations to accelerate regulatory approval and widespread integration.

What is Digital Cytology?

Digital cytology advances the traditional process of examining cell samples for cervical screening. Unlike conventional methods where slides are manually examined under a microscope, digital cytology leverages technology to enhance the screening process (Zarella et al., 2019). Here's a breakdown of how it works:

- **Slide Preparation**: Cell samples are collected in the same way as traditional cervical screening (smear tests). However, instead of being examined under a microscope, the slide is digitised.

- **High-Resolution Scanning**: A specialised scanner creates high-resolution images of the entire slide - Whole Slide Image (WSI). This allows for a comprehensive view of the sample and enables easy storage and sharing of images.
- **Advanced Analysis**: Sophisticated algorithms and software analyse these images, aiding pathologists and cytologists in identifying diagnostically relevant cells that could indicate pre-cancerous changes or cervical cancer. This step has the potential to incorporate artificial intelligence (AI) in the future, further enhancing the accuracy and efficiency of the screening process (Ikenberg et al., 2023).

Key Point: Digital cytology does not replace the expertise of pathologists and cytologists. It's a powerful tool that channels the experience and skills of this key staff group, leading to more efficient and accurate cervical screening for patients.

Benefits of Digital Cytology

Digital cytology offers a range of advantages that can significantly improve the cervical screening process, benefiting both patients and healthcare providers. The following points highlight the key benefits.

- **Patient Benefits:**

Digital cytology offers transformative benefits for patients undergoing cervical screening, promising:

  - **Faster Turnaround Times:** Digital cytology has been shown to reduce turnaround times significantly, potentially leading to significantly faster diagnoses and treatment initiation. This reduces patient anxiety and supports the timely management of pre-cancerous or cancerous conditions. A comparative study on 400 cases found that digital diagnostic time can be shorter than traditional microscopy in the routine diagnostic setting, with adequate and stable network speeds, fully integrated laboratory information

management systems (LIMS), and double displays as default parameters (Vodovnik, 2016).

- **Time Saving:** Digital cytology enables sharing of cases in real time with each slide being able to be reviewed across a network, this results in not only zero transportation costs, no lost or broken slides but also allows remote review and reporting by clinical teams. Digital Cytology can be used to address regional backlogs and flatten regional variation in turnaround times.
- **Future-Proofing:** Robust networking features allow laboratories to collaborate and share workloads. This ensures continuity of service even with localised pressures on the workforce, protecting patients' rights to timely and reliable screening results. Furthermore, the digital platform provides a foundation for future integration of artificial intelligence (AI) technologies, which could potentially enhance screening accuracy and efficiency (Ikenberg et al., 2023).
- **Improved Accuracy:** Digital cytology systems have demonstrated comparable or improved accuracy compared to traditional methods. The ability to easily share images for second opinions and the potential for AI-assisted screening could lead to more accurate diagnoses, reducing the likelihood of false positives or negatives (Ikenberg et al., 2023).

These benefits would demonstrate the commitment to patient-centred innovation within cervical screening, aiming to improve outcomes and experiences throughout the screening process. By leveraging digital technology, the cervical screening programme can potentially increase its effectiveness in detecting and preventing cervical cancer, ultimately contributing to better public health outcomes (NHS England, 2019).

- **Workforce Benefits:**

Digital cytology could hold the key to addressing the workforce challenges facing cervical screening programmes, offering solutions to issues such as staff shortages and an ageing workforce (Royal College of Pathologists, 2018). It offers the potential to:

- **Attract New Talent**: Digital tools make the field more appealing to younger biomedical scientists and pathologists, offsetting the effects of an ageing

workforce. The integration of cutting-edge technology can help position cytology as a modern and innovative career choice.

- **Improve Efficiency**: Digital systems streamline reporting processes, automate tasks, and reduce the overall workload strain on cytologists and pathologists. This frees up time for complex cases and improves job satisfaction.
- **Enhance Training and Assessment**: Digital tools offer innovative and engaging training platforms, facilitating both initial training and skill updates. This enhances competency and supports professional development within the field.
- **Boost Retention and Resilience**: By reducing workload, promoting flexibility, and offering opportunities for remote working, digital cytology helps retain experienced staff and makes the field more resilient to workforce fluctuations (Zarella et al., 2019). The Royal College of Pathologists highlights that digital pathology facilitates remote working, which can help address staffing issues by allowing home reporting and avoiding the need for physical presence for second opinions. This flexibility supports the retention of pathologists and the resilience of the workforce (RCPath, 2024).

Digital cytology offers a pathway towards a sustainable workforce within cervical screening, ensuring the continued provision of high-quality patient care. By addressing key workforce challenges, it supports the broader goals of the cervical screening programme to reduce cervical cancer incidence and mortality rates (NHS England, 2019).

- **Laboratory Benefits:**

Digital cytology provides significant advantages to cervical screening laboratories, enhancing their operational efficiency and overall effectiveness. The following points highlight the key laboratory benefits:

- **Increased Efficiency and Cost Savings**: Digitised workflows, algorithmic support, and automation can significantly improve efficiency within laboratories. This translates into long-term cost reductions and optimisation of resources.

- **Improved Resilience and Flexibility**: Digital cytology empowers laboratories to better manage workloads, share cases during staff shortages, and adapt to changing demands. This strengthens the overall resilience and responsiveness of the screening service. The ability to remotely access and review slides ensures continuity of service even during localised disruptions (Zarella et al., 2019).
- **Standardised Reporting**: Digital tools encourage consistency and interoperability by providing standardised reporting templates. This can help harmonise outcomes across different laboratories, provide clearer diagnostic audit trails and improve the quality of reporting at a programme-wide level. Standardisation also facilitates easier compliance with regulatory requirements and quality assurance protocols (Ikenberg et al., 2023).
- **Enhanced Networking and Collaboration**: A robust digital infrastructure enables laboratories to seamlessly connect, share expertise, and address backlogs collaboratively. This fosters a supportive network that elevates the quality of the screening programme.
- **Research opportunities**: there are significant opportunities for research to leverage the advantages of this technology including expanding into other subspecialties such as diagnostic cytology. Digital cytology platforms provide a rich source of data that can be used for research and development, potentially leading to new insights and innovations in the field (Zarella et al., 2019).
- **Improved Data Management and Security**: Digital cytology systems offer advanced data management capabilities, ensuring secure storage, easy retrieval, and efficient handling of large volumes of data. Enhanced data security measures protect patient information and ensure compliance with data protection regulations (NHS Digital, 2023).

These benefits underscore how digital cytology can transform laboratory operations, leading to a more efficient, reliable, and collaborative screening service.

Challenges to Adoption

- **Unclear Route for Adoption:**

One of the challenges associated with adopting digital cytology in the UK is the need for clearer, streamlined pathways to introduce innovations into national screening programmes. In the current system, companies developing these solutions face several obstacles:

- **Unclear Route**: There's no established process for submitting new technologies such as digital cytology for assessment and potential integration into the screening programme. This creates uncertainty and delays for companies, potentially discouraging further innovation.
- **Navigational Difficulties**: The current system lacks constructive guidance on evidence requirements, regulatory approvals, and the mechanisms for engaging with decision-makers. This makes it difficult for companies to understand and navigate the process effectively.
- **Need for Streamlined Guidance**: There's an urgent need for streamlined guidance and support to help companies understand the necessary steps, potential funding sources, and the key stakeholders involved. This will increase transparency and accelerate the adoption of beneficial technologies.

Key Message: The current system hinders the timely introduction of new technologies that can significantly benefit cervical screening programmes. Clearer pathways and guidance mechanisms are essential to foster a more receptive environment for innovation.

- **Lack of Communication from Screening Committees:**

A significant obstacle to digital cytology adoption is the limited communication from relevant screening committees and decision-making bodies. This challenge manifests in several ways:

- **Slow or Unresponsive Communication**: Companies and researchers experience delays or a lack of constructive responses when attempting to initiate discussions about new technologies. This creates uncertainty and undermines efforts to introduce much-needed innovations. The slow pace of

communication can lead to missed opportunities for timely implementation of potentially life-saving technologies.

- **Missed Opportunities for Collaboration**: Limited engagement from decision-makers hinders the potential for collaboration between technology providers, healthcare professionals, and the committees responsible for guiding the screening programme's direction. This lack of collaboration can result in solutions that are not fully aligned with the needs of the screening programme or the healthcare system as a whole.
- **Need for Increased Engagement**: A more responsive and proactive approach from screening committees is crucial. This includes inviting dialogue, providing timely feedback, and outlining the expectations for the potential integration of new technologies. Regular forums or workshops could be established to facilitate ongoing communication between committees, researchers, and industry partners.

Key Message: The lack of timely and constructive communication from screening committees creates a significant barrier to adopting transformative technologies like digital cytology. A collaborative approach built upon open communication and engagement is essential to drive innovation and ensure the future success of cervical screening.

- **Workforce Concerns:**

Cervical screening faces a looming workforce crisis, with a significant proportion of experienced pathologists and biomedical scientists nearing retirement. Data from the Royal College of Pathologists' 2018 Histopathology Workforce Survey provides a stark illustration of this challenge:

- **Aging Workforce:** 32% of histopathologists were aged 55 or over, with 25% expected to retire within the next five years. This trend further exacerbates the existing shortage of skilled professionals.
- **Staff Shortages:** The survey revealed a 25% shortfall in staff able to report results, with some regions experiencing even higher shortages. Only 3% of histopathology departments had enough staff to meet clinical demand.

- **Financial Impact:** Approximately £27 million a year was spent on locums and outsourcing work to cope with demand.
- **Workload Management:** 45% of departments had to send work away to cope with demand, and 50% used locums.

- **Impact of Aging Workforce**: The shrinking workforce places unsustainable pressure on remaining staff, leading to potential burnout and further attrition. This could compromise the quality and sustainability of the screening service (Royal College of Pathologists, 2018). The current age profile of cytologists across the UK is a risk to service delivery, potentially leading to backlogs and delayed diagnoses.

- **Retirement Projections:** If all staff aged 55 or more retired in the five years following the 2018 report, only 64% of that workforce would remain in Wales, 74% in England, 78% in Scotland, and 85% in Northern Ireland. This projection underscores the urgency of addressing the workforce crisis.

- **Digital Cytology as a Solution**: Adopting digital cytology is essential to address this crisis. Workload reduction, automation, and the potential for remote working make the field more adaptable and more attractive to new talent. This technology can help retain experienced staff and support training initiatives to ensure future workforce stability (Zarella et al., 2019; RCPath, 2024).

Key Message: Failure to address the workforce shortage jeopardises the long-term viability of the cervical screening program. Digital cytology offers a multifaceted solution to mitigate this crisis, safeguarding service delivery and patient care. By addressing efficiency, accuracy, and workforce challenges simultaneously, digital cytology presents a comprehensive approach to ensuring the sustainability of cervical screening services in the face of these pressing workforce issues.

Cost Concerns

While transferring to digital cytology offers significant long-term advantages for cervical screening, it's crucial to acknowledge the associated costs:

- **Initial Hardware and Software Costs**: Implementing digital cytology requires a significant upfront investment in scanners, digital pathology software, IT infrastructure upgrades, and pathologist workstations. These initial costs can be substantial and may pose a barrier to adoption for some laboratories.
- **Ongoing Maintenance and Training Costs**: Beyond the initial setup, there are ongoing costs associated with maintenance, software licenses, IT support, and continuous training for pathologists and cytology staff to adapt to digital workflows. These recurring expenses need to be factored into the overall budget.
- **Workforce Transition Costs**: While ultimately supporting workforce efficiency, transitioning to digital cytology may necessitate additional IT and informatics support staff, and temporary costs associated with retraining the existing workforce. This transition period can be resource-intensive and may require careful planning and management.
- **Potential Productivity Losses During Implementation**: As with any new technology deployment, a temporary dip in productivity may occur during the setup and training phases of digital cytology implementation. This initial disruption can impact service delivery and needs to be managed effectively to minimise its impact.

Key Message: The implementation of digital cytology involves significant upfront and ongoing costs, including hardware, software, training, and potential short-term productivity losses. However, these costs should be viewed as a strategic investment in the future of cervical screening. A comprehensive cost-benefit analysis, considering both immediate expenses and long-term savings through improved efficiency and accuracy, is crucial for informed decision-making. Balancing these costs against the potential for enhanced patient care, workforce sustainability, and overall system efficiency is essential when evaluating the adoption of digital cytology.

Addressing Cost Concerns

It's important to view these costs within the context of the long-term benefits to the cervical screening programme and the wider healthcare system. Here are strategies for addressing potential cost concerns:

- **Phased Implementation**: Rather than a sudden, nationwide overhaul, a phased approach across regions or laboratories would help spread out initial investments and allow for lessons learned to inform subsequent stages. This gradual rollout can help manage costs and reduce the risk of widespread disruption.
- **Pilot Programs**: Initial pilot programmes in select laboratories would provide valuable data on real-world costs and benefits, enabling more accurate budgeting and demonstrating ROI to secure long-term funding. Pilot programmes can also help identify potential challenges and solutions before broader implementation.
- **Partnerships and Collaboration**: Exploring funding partnerships between the NHS, technology providers, and research institutions could help defray costs and accelerate the adoption process. Collaborative efforts can use multiple sources of funding and expertise to support the transition to digital cytology.
- **Focus on Long-Term Savings**: Digital cytology has the potential for significant cost savings over time through improved efficiency, streamlined workflows, and optimisation of resources. By reducing manual workload and enhancing diagnostic accuracy, digital cytology can lead to long-term financial benefits for the healthcare system.
- **Government and Policy Support:** Advocating for government and policy support to secure funding and resources for digital cytology implementation can help address initial cost barriers. Policy initiatives that prioritise innovation in healthcare can provide the necessary financial backing and regulatory support.

Key Message: Despite the initial investment required, digital cytology has the potential to transform cervical screening in the UK. A strategic approach could lead to long term cost savings, workforce support and retention, and improved patient outcomes.

Next Steps

The UK's cervical screening programme faces a need for transformation. Digital cytology offers a compelling solution welcomed by the workforce, but its adoption requires decisive

action and commitment from key stakeholders. The following steps need to be taken to realise the full potential of this technology:

- **Evidence-Based Advocacy:** A robust, data-driven case highlighting the benefits of digital cytology must be presented to key decision-makers within screening committees. This should include:
    - UK-specific performance data demonstrating efficiency gains and accuracy improvements.
    - Quantified projections of workforce support and mitigation of staffing pressures.
    - Evidence from European implementations and Scotland's experience to support these projections.
- **Urgent Engagement:** Direct lobbying of screening committees is essential to create a sense of urgency to ensure, if proven, the technology is deployed rapidly to benefit patient care. Proactive dialogue should emphasise:
    - The critical challenges facing the programme, including workforce shortages and potential delays in patient care.
    - How digital cytology directly addresses these pain points and offers a clear path towards sustainability.
    - The potential consequences of inaction and the risks to the programme's long-term viability if these technologies are not adopted.

Key Message: Inaction risks compromising service outcomes and patient care. By embracing digital cytology, guided by robust evidence, we can revitalise the programme, protect patient well-being, and secure a sustainable future for cervical screening.

- **Engaging Commissioners:**

Securing the support of commissioners is vital for successful implementation. The messaging around digital cytology must resonate with their priorities:

- **Improved Service Delivery**: Demonstrate how digital cytology translates into measurable gains in efficiency, faster turnaround times, and greater accuracy.

These enhancements directly improve the quality, resilience and reliability of the cervical screening service.

- **Workforce Support**: Highlight the potential of digital cytology to attract new talent, retain experienced staff, and alleviate workload pressure. Emphasise that this directly addresses the pressing workforce crisis and ensures the programme's sustainability.
- **Enhanced Patient Care**: Underscore how the improved accuracy and efficiency offered by digital cytology translates into better patient outcomes. Faster diagnoses, early detection of cancer, and reduced false negatives are compelling benefits that align with commissioners' focus on patient wellbeing.

Key message: Digital cytology isn't merely a technological upgrade; it's a strategic investment in the future of cervical screening. By framing the technology's benefits in terms of improved outcomes, workforce support, and long-term sustainability, advocates can convince commissioners of its transformative value.

- **Robust Evidence-Gathering:**

A strong foundation of evidence is essential to convince stakeholders and drive change. Key actions in support of digital cytology adoption include:

- **Establishing UK Baselines**: Collect comprehensive data on current UK screening times and accuracy levels across all laboratories. This will provide a benchmark against which potential improvements with digital cytology can be measured.
- **Quantifying Potential Gains**: Draw on existing data from European implementations and Scotland's experience with an image-assisted system. Project the expected gains in efficiency, accuracy, and workforce support if digital cytology were adopted widely in the UK.
- **Demonstrating Clinical Benefits:** Compile and present clinical studies and pilot program results that highlight the improvements in diagnostic accuracy, reduced turnaround times, and enhanced patient outcomes associated with digital cytology.

- **Economic Analysis**: Conduct a detailed cost-benefit analysis to quantify the long-term savings from improved efficiency, reduced reliance on locums, and optimised resource utilisation. This analysis should include potential reductions in outsourcing costs and locum expenditures.
- **Updated Workforce Data:** While the 2018 Royal College of Pathologists' Histopathology Workforce Census provided valuable insights, it is now outdated. There is an urgent need for current workforce data to:
    - Assess if the workforce crisis has deepened since 2018.
    - Evaluate the current age distribution cytology staff within the cervical screening regions and projected retirement rates.
    - Determine the current extent of staff shortages and reliance on locums.
    - Understand the evolving impact on service delivery and patient care.

Key Message: By quantifying current challenges, demonstrating potential improvements, and supporting arguments with workforce projections, advocates create a compelling and irrefutable case for the adoption of digital cytology.

Conclusion

The UK's cervical screening programme stands at a pivotal moment. The workforce crisis presents a significant challenge to the programme's capacity to deliver timely and accurate results, ultimately impacting patient outcomes. The need for innovative solutions is critical.

Digital cytology offers a proven solution to mitigate these challenges, enhancing efficiency, improving accuracy, and revitalising the workforce. By addressing the £27 million annual expenditure on locums and outsourcing, digital cytology can help redirect resources more effectively. Failure to adopt this innovative technology risks compromising the quality of care for women across the UK.

This paper calls for a collaborative and concerted effort by all stakeholders, including commissioners, the UK National Screening Committee, healthcare providers, and technology companies. By working together, we can overcome obstacles, streamline regulatory

processes, and implement digital cytology seamlessly into cervical screening workflows. This commitment will not only safeguard the programme's future but also elevate the standard of care for women across the UK.

The time to act is now, before the projected retirement of a significant portion of our workforce further strains an already challenged system. We must embrace innovation, protect patient wellbeing and build a stronger, more resilient cervical screening programme for the generations to come.

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Appendix – Roundtable Attendees

With thanks to the attendees who contributed their expertise to the roundtable discussion. This summary provides an accurate representation of the discussion on the day but does not necessarily represent the organisational views of those in attendance.

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