The Royal College of Pathologists
Pathology: the science behind the cure

Best practice recommendations

Clinical responsibility for cytology services

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Author: Dr Paul Cross

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The Royal College of Pathologists
6 Alie Street
London E1 8QT
T: 020 7451 6700
F: 020 7451 6701
www.rcpath.org

Registered charity in England and Wales, no. 261035

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Foreword

Best practice recommendations (BPRs) published by the Royal College of Pathologists should assist pathologists in providing a high standard of care for patients. BPRs are systematically developed statements intended to assist the decisions and approach of practitioners and patients about appropriate actions for specific clinical circumstances. They are based on the best available evidence at the time the document was prepared. It may be necessary or even desirable to depart from the advice in the interests of specific patients and special circumstances. The clinical risk of departing from the BPR should be assessed and documented.

A formal revision cycle for all BPRs takes place every three years. The College will ask the authors of the BPR to consider whether or not the recommendations need to be revised. A full consultation process will be undertaken if major revisions are required. If minor revisions or changes are required, a short note of the proposed changes will be placed on the College website for two weeks for members' attention. If members do not object to the changes, a short notice of change will be incorporated into the document and the full revised version will replace the previous version on the College website.

This BPR has been reviewed by the Publishing team. It was placed on the College website for consultation with the membership from 22 May to 19 June 2019. All comments received from the membership have been addressed by the authors to the satisfaction of the Clinical Director of Publishing and Engagement.

This BPR was developed without external funding to the writing group. The College requires the authors of BPRs to provide a list of potential conflicts of interest. These are monitored by the College's Publishing team and are available on request. The authors of this document have declared that there are no conflicts of interest.

1. Introduction

The Royal College of Pathologists has previously issued guidance on clinical leadership and responsibility for cytology services – the most recent version was published in 2012.[1]

Since then, there have been significant changes and challenges in the field of cytology and the delivery of cytology services. These include:

- the increased role of cytology in direct patient management
- increased use of molecular and ancillary techniques
- issues related to staffing, training and education
- enhanced roles for biomedical scientists (BMSs)
- rising cytology workloads
- turnaround times
- pathology reconfigurations in cellular pathology services.

The impact on laboratory services of the very significant changes brought about by the implementation of primary human papillomavirus (HPV) testing in cervical screening programmes (CSPs) must not be underestimated. It is essential to ensure that there are sufficient suitably trained and skilled cytologists, including medical cytopathologists, for the future. It is within this context that this best practice recommendation (BPR) document has been reviewed.

The delivery of cytology services is normally part of an overall cellular pathology service. It is seldom truly a standalone service. This BPR relates to clinical responsibility and professional leadership for cytology, recognising that there may be other staff with management responsibilities for aspects of a cytology laboratory service. The BPR recognises the two main areas of cytology: cervical (screening) cytology and diagnostic (often termed ‘non-gynaecological’) cytology.

In this document, the term ‘cytopathologist’ is used to mean a medically qualified pathologist with appropriate training and qualifications (Fellowship Examination of the Royal College of Pathologists [FRCPath] and Certificate of Higher Cervical Cytology Training [CHCCT] if necessary, depending on training).

2. Recommendations

Definition of clinical lead

The clinical lead is the person who takes overall responsibility for the clinical quality and governance of a service. To an extent, the functions of quality and governance are a duty of everyone working within any aspect of a clinical service, but the clinical lead gives direction and takes responsibility for those functions in that area.

The clinical lead does not necessarily have a strict managerial or budgetary role, but on occasions may also have those roles.

Cervical cytology

The move to primary HPV testing in CSPs across the UK will result in a major change in cervical cytology laboratory configuration and staffing. The move to a far smaller number of laboratories offering high-risk HPV testing and triage cytology services in the CSPs will inevitably lead to a reduction in staff numbers and changes in staff grade/mix. The need to ensure the correct mix of professional, clinical and leadership skills is vital during such a period of change and in the future. There is also a need to train, retain and develop cervical cytology skills to ensure future delivery of the CSPs. It is accepted that this BPR may need to be reviewed once the new model of cervical screening delivery is fully established.

The clinical lead has governance responsibility for all results, or ensures that all results issued are done so in line with current guidance. This responsibility may be delegated on a day-to-day basis by the clinical lead to suitably trained staff who are following local implementation of national guidance.

The College is of the view that an individual with consultant-level skills and qualifications is fully capable of carrying out the clinical lead role in a cervical cytology laboratory. This may be a cytopathologist (FRCPath and CHCCT holder, if required, depending on training) or BMS with an advanced specialist diploma (ASD) in cervical cytology.[2] It should be a local decision as to who is best placed and has the best skills for the role. Appointment to the role must be made by an open and transparent process and the appointee must have local support in the role.

The clinical lead must have training, or access to training, in leadership skills. If they are not a medically qualified pathologist, then a medical lead – who is a qualified consultant cytopathologist reporting within the CSP – should also be identified to offer clinical advice and support to the clinical lead.

The College acknowledges that the delivery of the laboratory aspect of a CSP is a team effort, requiring a mix of skills, experience and knowledge. As part of the consultant-level reporting team, there must be active participation of at least two medically qualified consultant cytopathologists actively reporting cervical cytology in a CSP laboratory, irrespective of the number of consultant BMS staff (who hold an ASD in cervical cytology) who may also be reporting.

All those actively practising in the CSP at consultant level must be suitably trained and qualified and must comply with the quality requirements of the CSP (e.g. workloads, internal quality assurance, external quality assurance). It is beneficial to the screening laboratory to have active participation of consultant cytopathologists (with their medical training and histopathology background). This applies to single laboratories, managed networks and private laboratories. At

least one consultant-level cytologist must be available to offer reporting, clinical and leadership advice to all cervical cytology reporting staff on a daily basis and during normal laboratory working hours. This should regularly be one of the medical consultants.

Diagnostic cytology

The developing role of diagnostic cytology requires a separate identified clinical lead. The clinical lead for diagnostic cytology services, be they standalone or part of an overall cellular pathology service, must be a consultant cytopathologist who routinely reports diagnostic cytology.

They must take a lead role, as outlined earlier in this document, in the quality, governance, planning and delivery of the diagnostic cytology service, as well as responsibility for the issue of all diagnostic cytology reports, even though this may be delegated in certain areas on a day-to-day basis to medical or suitably qualified BMS staff following local implementation of national guidance.

The ASD qualification in diagnostic cytology is relatively new[3] and is not as well established as the ASD qualification and role in cervical cytology.[2] Holders of the ASD in diagnostic cytology can operate at consultant level in defined areas for reporting, but may not, as yet, have the breadth and depth of knowledge to embrace all components of the diagnostic cytology service[4] that is required for the role of clinical lead. However, the progressive acquisition of additional experience and enhanced skills by ASD holders may alter the situation. This recommendation will be reviewed as and when the guidance is next revised.

3. References

[1] The Royal College of Pathologists. *Clinical responsibility for cytology services*. 2012. Available at: www.rcpath.org/resourceLibrary/clinrespforcytol.html
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[3] Institute of Biomedical Science. *Advanced Qualifications: Non-Gynaecological Cytology*. Available at: www.ibms.org/education/advanced-qualifications/non-gynaecological-cytology
[4] British Association for Cytopathology. *Guidance outlining the role of biomedical scientists within the provision of non-gynaecological cytology services*. 2016. Available at: www.britishcytology.org.uk/go/news/archive~44