

Best practice recommendations

Histopathology and cytopathology of limited or no clinical value

October 2019

Authors: Dr Rachael Liebmann, Dr Murali Varma.

Unique document number	G177
Document name	Best practice recommendations: Histopathology and cytopathology of limited or no clinical value
Version number	3
Produced by	Dr Rachael Liebmann and Dr Murali Varma with the Cellular Pathology Specialty Advisory Committee (SAC), chaired by Dr Michael Osborn.
Date active	October 2019
Date for review	October 2022
Comments	In accordance with the College's pre-publication policy, this document was on the Royal College of Pathologists' website for consultation from 21 March to 18 April 2019. Responses and authors' comments are available at: www.rcpath.org/profession/publications/documents-in-development.html Dr Lorna Williamson Clinical Director of Publishing and Engagement

The Royal College of Pathologists

6 Alie Street
London E1 8QT
T: 020 7451 6700
F: 020 7451 6701
www.rcpath.org

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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 21 March 2019 to 18 April 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

In January 2001, an article entitled 'A recovery plan for histopathology' was published in the *Bulletin* of the Royal College of Pathologists.¹ This article emanated from a meeting of consultant histopathologists in September 2000, in response to growing concerns about cellular pathology consultant staffing. The article was published as a draft, with the express purpose of encouraging comment and debate through wide consultation with the College membership.

The salient points were:

- the relationship between the College and cellular pathologists
- recruitment and training
- workforce and workloads
- flexible working
- service configuration.

Under the heading 'Workforce and workloads', the report stated that the College should 'initiate a series of evidence-based multidisciplinary evaluations of investigations of doubtful clinical utility to identify those that make little or no contribution to patient care and welfare. Some diagnoses made traditionally by histopathology may be made with higher sensitivity and specificity by other methods, thus relieving histopathologists of some of their burden.'

That statement formed the remit of the Working Group for the first version of this best practice recommendation (BPR; then known as guidance).²

2. Methods

The first version of this BPR was published in August 2002 after a period of consultation as a draft.

The second version was reviewed and published in accordance with the College publications policy in December 2015. In addition to the BPR's original goals, the second version examined areas not covered by the first version. In addition, it included data generated as a response to the original report (for example, audits, published work and abstracts).

This third version has been produced after articles in the *Bulletin* drew attention to the need among Fellows for an up-to-date document of this type, as many of the original drivers mentioned in the introduction are still very relevant and are reinforced by the recent Choosing Wisely principles.

3. Recommendations

General points

The authors re-emphasise the following general principles. Following this section, there are recommendations for specific systems.

- It must be stressed that these guidelines should be discussed and agreed at a local level with clinical colleagues. Implementation will vary depending on local circumstances, such as the degree of training, staffing and research interests.
- It should be appreciated that unnecessary biopsies have an impact beyond cellular pathology laboratories; for example, these specimens have to be transported to the laboratory, the reports read and filed, and appropriate letters about them written to GPs by clinicians.
- Cellular pathologists should critically review the length and complexity of their reports. A brief comparison of breast cancer reports from a number of neighbouring trusts revealed huge variation. Some reports covered less than a single page and others many pages, yet all contained similar data as outlined in the College's datasets for breast cancer. As well as being time-consuming to dictate, type and authorise, long and complex descriptive reports make clinical decision-making more difficult and increase the potential for misunderstanding.
- The use of standard 'canned' reports is strongly encouraged. This will save both secretarial and consultant time.
- College datasets and tissue pathways for cancers and other specimens are welcomed and play a key role in standardising reporting. Published evidence shows that the use of templates improves the quality of information in pathology reports.^{3,4,5} A national initiative to enable the easy introduction of datasets into departmental laboratory information management systems (LIMS) is being sought by the College.
- There are a number of idiosyncrasies leading to increased workloads that occur in almost every laboratory. Publicising these facts might help in their eradication. Historical panels of special stains and immunohistochemical panels should be examined critically and care taken to avoid redundancy.
- The major factors causing a huge increase in workload are those associated with increased clinical demand and a rise in the number of relevant prognostic factors. This has led to increased work on difficult cases, as well as an absolute increase in requests and reducing numbers of practising pathologists.
- Cellular pathologists are often asked for an opinion on a specimen that may not necessarily need extensive histopathology. For some specimens, a gross inspection with a single histopathology section to act as a record, and for audit purposes, may well suffice. However, specimen photography of slices could also provide more complete records of macroscopic normality than a random section that needs histological examination and reporting.

Thorough macroscopic examination by thin slicing of properly fixed specimens is more important than random histological sampling. Only about 0.2% of a specimen is examined under microscope even if the specimen is all embedded. Specimen blocking should be aimed at answering specific questions; the number of routine background blocks should be

limited. In most instances, a single block of macroscopically normal tissue for potential genetic testing would be sufficient.

The aim of histopathological examination is to stratify patients by identifying features that affect prognosis, so extensive histological sampling of specimens with no clinical suspicion of malignancy should be discouraged.

- There should be an aim to reduce the clinically irrelevant macroscopic description, particularly specimen measurements. In some instances, weight may be a simpler and more reproducible measure of specimen size. The key to macroscopic examination is to identify focal abnormalities: recording 'no focal lesion' is more valuable than specimen dimensions, which are frequently estimated rather than measured and then need to be dictated and typed.
- Some operations are therapeutic in nature and specimens from such procedures do not need extensive histology (for example, thyroidectomy for Graves, breast reduction specimens). Thin slicing after proper fixation and careful macroscopic examination is more important than random blocks.
- Some clinicians appear to feel that an examination is not complete without a biopsy, a good example being a normal upper gastrointestinal (GI) endoscopy. A change in this clinical behaviour pattern will only be achieved by good audit evidence and local discussion within clinical teams. Major changes in the method of diagnosing *Helicobacter pylori* have resulted in fewer gastric biopsies for this purpose.
- When drawing up guidelines, it would be helpful if clinical societies and organisations consult with cellular pathology colleagues with, ideally, one being on the team making the recommendations.
- The value of each test should be maximised by the correct submission of samples; for example, three sputum specimens should be sent on three separate occasions, rather than together at one time.
- Extended roles for biomedical scientists (BMSs) can be very effective in releasing consultant and trainee time. All available conjoint board examinations should be considered for the development of BMSs and departmental efficiency. These extended roles now include qualifications for specimen dissection, including all major cancer resections, independent reporting for diagnostic and cervical cytology and BMS histopathology independent reporting in the high-volume areas of gastrointestinal, gynaecological and dermatopathology. The introduction of these extended roles enables consultants to focus their activity on the most complex cases, to which their skills add the most value. Macroscopic description by BMSs and advanced practitioners is supported by the College, but there must be regular review and updating so that block numbers do not escalate in protocol-driven practice. At macroscopy, as in the rest of histopathology, judgement must be exercised.^{6,7}
- All changes to established protocols for referring cases to the laboratory need to be reviewed as part of laboratory and personal annual review processes.

Cytology systems

Cervical cytology

Due to a change in the age range for cervical screening and the introduction of liquid-based cytology, there has been a reduction in screening cervical cytology samples as a first-line investigation.^{8,9} Cervical cytology should not be used as a diagnostic test due to the known false negative rates and colposcopy +/- biopsy is therefore the appropriate investigation.

Respiratory cytology

Sputum samples should be requested in the main by respiratory physicians and only for patients unfit for bronchoscopy.^{10,11,12,13,14,15} A 60% reduction in sputum samples was reported following discussions with clinical colleagues about this BPR in 2015.^{16,17}

The British Thoracic Society's guidelines recommend biopsy, brushings and washings at bronchoscopy.¹⁸ The authors feel that, if a tumour is visible, biopsy and brushings should suffice. Washings are unnecessary when the tumour is visible.

Cytology should not be used to diagnose *Pneumocystis carinii*. A sample for microbiology is more appropriate, as a result is available within 24 hours of using specific immunofluorescence.

Urine cytology

A single cytospin slide is sufficient for diagnosis.¹⁹

Negative urines are often reported by BMS staff.¹⁷

An unpublished audit from Edinburgh looked at 2,256 cases and concluded that urine cytology should not be used in the follow-up of low-grade transitional cell carcinomas (TCC) due to poor sensitivity, and should not be used in patients before, or during, intravesical therapy. The authors also noted the extreme rarity of TCC in patients under the age of 50 years and that no patient with a biopsy-proven TCC presented clinically with microscopic haematuria.²⁰ The use of urine cytology as a reflex protocol-driven investigation following a positive dipstick test is not justified. The Paris classification for urine cytology emphasises that urine cytology is primarily for identification of high-grade urothelial neoplasia. 'Atypia, cannot exclude low-grade urothelial neoplasia' should be reported as 'negative for high-grade urothelial neoplasia'.²¹

The NHS Cancer Registry Office suspended all further work on the National Bladder Cytology Recall Scheme with effect from 1 June 2003.²² Screening urines should therefore not be encountered.

The practice of sending urine cytology from urodynamic clinics in patients without evidence of haematuria is inappropriate.

Pleural fluid

Only a single sample should be assessed when draining effusions related to cardiac failure, unless there is other good evidence of malignancy. Once a patient's pleural fluid has been reported as positive for malignancy, subsequent pleural taps performed for symptomatic relief should not be sent for cytology but should be discarded.

Ascitic fluid

For peritoneal washings and ovarian cyst fluid, see section on gynaecological pathology.

General fine-needle aspiration (FNA) comments

A maximum of four well-prepared slides should be submitted for examination.

Breast

FNAs should only be undertaken and reported by those skilled in each area.²³

Breast cyst fluid should only be examined if bloodstained or if there is a residual lump after aspiration.

For those using direct smears from FNAs, a maximum of four well-prepared slides is recommended, as previously stated.

Salivary gland and thyroid

FNA cytology of thyroid nodules and salivary gland lesions has an established role in the initial assessment of patients and in deciding which patients require surgery. However, this is a specialised field and both aspiration and interpretation of the material obtained is best restricted to centres and individuals with specialist expertise.²⁴

Cerebrospinal fluid (CSF)

Cytological examination should only be performed on cases with a suspicion of malignancy²⁵ or aseptic meningitis. The possibility of multiple sclerosis is not an indication for CSF cytology.

Gastrointestinal pathology systems

This is the area that can result in a significant reduction in workload, if this BPR is followed after dialogue with clinical colleagues. At consultation for the first version of this BPR, many pathologists responded that a management BPR such as this should be addressed not only to pathologists but also to endoscopists.

Following the publication of the first version of this BPR, reductions of 18–38% of total biopsy numbers were reported, with larger percentages seen for gastric biopsies.^{26,27,28,29} Audits have shown that no serious pathology would have been missed by this policy.³⁰ A simple rule of thumb is that biopsies from the upper GI tract should only be taken from endoscopic lesions and not from endoscopically normal mucosa. While some pathologists have stated that an upper GI endoscopy is incomplete without a biopsy (especially for the diagnosis of gastritis and 'carditis'),³¹ most gastrointestinal pathologists are unconvinced by this argument. There is no good evidence base to state that such biopsies are useful in the management of individual patients and the authors fear that the recommendation is more for research than for the provision of useful clinical information. The same applies to most colonoscopies, with the notable exception of an examination for chronic diarrhoea when biopsies of endoscopically normal large bowel are needed for detection of the various forms of microscopic colitis.

Oesophagus³²

There is no justification for a biopsy from a normal oesophagus.

Biopsies from patients with reflux oesophagitis are unhelpful; endoscopy is better at assessing reflux than histopathology. However, if there is considerable ulceration, biopsy may be justified to exclude malignancy. In the presence of specific symptoms it may be reasonable to take steps to exclude eosinophilic oesophagitis.

Diagnostic and surveillance biopsies for Barrett's oesophagus are reasonable, not least due to the increasing prevalence of the disease and its complicating adenocarcinoma.

So-called ultra-short segment Barrett's oesophagus (cardia intestinal metaplasia), with or without carditis, is a highly prevalent condition and its management is not yet determined. We believe that this condition should not be sought as it infers a normal junction, and there are currently no recommendations on the appropriate management of this condition or its neoplastic risk. However, as with all recommendations in this document, the decision to undertake biopsies of an endoscopically normal oesophagogastric junction must rest with the local medical community.

Oesophageal biopsy to demonstrate mainly *Candida* is much less sensitive than oesophageal brushing. Oesophageal brushing is often sent particularly for clinically suspected cases of *Candida*. Recent audit shows oesophageal brushing to be sensitive in 90% of cases and biopsy to be sensitive only in 12% of cases of suspected *Candida*.

Stomach³³

There is no evidence that biopsy of the normal stomach gives any useful clinical information that is likely to alter management in the routine setting. It is emphasised that there is always a need to biopsy abnormal areas of the stomach.

Biopsies should not be done purely to identify *H pylori*. There are equally good alternative, much cheaper tests.^{34,35,36,37,38}

There is little evidence that histopathological grading of 'gastritis', with or without intestinal metaplasia, gives any useful information for the subsequent management and follow-up of individual patients. Indeed, there are two time-honoured, admittedly retrospective, studies that indicate that the demonstration of intestinal metaplasia, particularly of incomplete type, is not of any use, in the clinical setting, for identifying those patients likely to suffer subsequent gastric cancer.^{39,40} While there is an important role for gastric biopsies in research, we believe that 'routine' biopsies of the endoscopically normal stomach cannot be justified because there is no evidence base that the information gleaned alters patient management.

We agree that there is little or no correlation between endoscopic appearances and the presence or absence of gastritis.^{41,42} Nevertheless, we reiterate our view that biopsies are unlikely to change management on the basis of such a lack of correlation and there is no evidence that they do.

Once again, we emphasise that any policy on biopsy for the diagnosis of any form of gastritis must be a local one, after discussion with all interested parties. For instance, advocates of routine gastric biopsy have indicated that the evidence of a severe atrophic gastritis, in *H pylori*-associated disease, is predictive of gastric cancer risk. We would not deny the evidence for this,⁴³ but would question whether such data justify the routine biopsy of all stomachs at endoscopy and whether the demonstration of such a phenotype changes management in any way (assuming the *H pylori* gastritis is appropriately treated).

Duodenum and small bowel

Biopsy of the second part of the duodenum (D2) or beyond remains the gold standard for the diagnosis of coeliac disease as serological tests are neither 100% specific nor sensitive. There are national and international recommendations indicating that four 'good-sized' biopsies are taken from D2 or beyond as the histopathological changes of coeliac disease can be strikingly focal.

Colonoscopic biopsies

A colonoscopic examination, with a normal appearance, should only prompt biopsies in the correct clinical setting. That is, persistent watery diarrhoea without blood, usually in a middle-aged or older (often female) patient, with the express intention of confirming or refuting a diagnosis of microscopic colitis.

When biopsied, a maximum of five or six biopsies are recommended and, in the correct clinical setting, there is a case for dividing them into two or three from the right side (caecum to distal transverse colon) and two or three from the left, so that only two slides need be examined.⁴⁴ This is because collagenous colitis, in particular, is more likely to be demonstrated in right colonic and transverse colonic biopsies.⁴⁵

Ileal biopsies purely to demonstrate that the colonoscopist has reached the terminal ileum are not justified (a photograph will suffice for audit and training purposes). Ileal biopsies for the demonstration of chronic inflammatory bowel disease and other inflammatory conditions are merited.⁴⁶

Random rectal biopsies with a clinical history of rectal bleeding are not justified.

Resection margins

For colorectal cancer cases there is no indication to take sections of the resection margins from a tumour case if the tumour is more than 3 cm from the margin in question. Resection margins need not be examined in resections for Crohn's disease as there is no evidence that a positive margin is predictive for recurrent disease, although macroscopic active ulcerating disease at a margin may influence subsequent therapy.

Gynaecological pathology systems

Social termination of pregnancy

Specimens should not be sent to the laboratory if foetal parts are visible. For social terminations there is no indication to undertake histology if there are no abnormal clinical findings.

Endometrium

Endometrial sampling should not routinely be performed in women with abnormal bleeding under the age of 40 years. Some gynaecologists do not biopsy the endometrium even in women over this age if the transvaginal ultrasound shows a thin endometrium with no focal lesions, and a normal hysteroscopy.

Normal uterus for abnormal bleeding

It is rare for a significant abnormality to be found on histopathology if the gross examination is negative.⁴⁷ A larger audit on this subject is recommended.

Uterus for prolapse

If there are no focal lesions, one block from the cervix and one from the endo/myometrium is all that is required.⁴⁸ Focal lesions should be examined as per protocols.

Hysterectomies after previous cervical intraepithelial neoplasia (CIN)

All the cervix should be sampled if examined soon after diagnosis of CIN. However, when there has been a series of interim negative smears, more limited sampling is appropriate.⁴⁹

Ovarian cyst fluid

It is not necessary to send ovarian cyst fluid with oophorectomy specimens as no lining cells are present in up to 76% of cases and the diagnosis would be based on the histological rather than cytological examination. In some infertility or other investigations the examination of ovarian cyst fluid may be helpful. Rarely, solid ovarian lesions may be investigated by FNA.

Peritoneal washings

These should not be sent for cytology during gynaecological surgery for benign disease.⁵⁰ However, when there is doubt whether an ovarian mass is benign or malignant, washings must be sent for cytological examination. These samples should be reported in conjunction with the resection specimen. Peritoneal washings are required for FIGO staging in cancer cases.

Omental sampling

Based on a ten-year experience of 692 cases, it is recommended that one block is needed if the ovary and omentum are either both benign or both malignant on gross inspection.⁵¹ If the ovary is malignant or borderline on gross inspection or histological examination and the omentum appears normal, and in post neo-adjuvant cases, thorough sampling is needed.

Urological pathology systems

Channel transurethral resection of the prostate (TURP) for treatment of retention in patients with known advanced prostate cancer requires minimal histological sampling.⁵² The rationale for systematic sampling of TURP specimens from patients with no clinical suspicion of malignancy is questionable. Sampling protocols designed to identify almost all incidental cancers in specimens from patients with no clinical suspicion of malignancy could be said to amount to histological screening for cancer. Hence, we suggest that such protocols should be reviewed.

Orchidectomy for the treatment of prostate cancer requires only limited sampling if there is no focal lesion.

Foreskin from a young patient with no macroscopic evidence of abnormality requires macroscopic description only.⁵³

General systems

Breast reductions for cosmetic purposes

These can generate a considerable amount of work. A section from macroscopically abnormal areas is always justified; however, the value of random histopathology is limited. A retrospective audit on 1,289 patients showed that, when two random blocks were taken from each breast, 'important diagnoses' were made in 2.1% of cases.⁵⁴ The question remains as to how many blocks are reasonable. Increased numbers of sections are reasonable in symmetrisation specimens when

breast cancer has already been found in the contralateral breast, as these patients are at increased risk.

Mastectomy specimens after primary chemotherapy

These can involve taking many blocks to look for residual tumour. Marking of tumours before chemotherapy will aid location of residual tumour and reduce the number of blocks that need to be taken.

Breast implant capsules

The description of breast implant-related anaplastic large cell lymphoma has resulted in the need to sample these explanted capsules thoroughly and submit for immunohistochemistry where clinically indicated.^{55,56}

Skin biopsies

Many plastic surgeons in secondary care units triage specimens that they send for histopathology. This applies in particular to multiple small (3 mm or less) skin tags. This can be supported. Excisions of non-pigmented benign keratoses and resolved lesions by plastic surgery teams often yield no discrete pathology and minimum numbers (one) of block suffices. No laboratory or consultant time should be wasted by the reporting pathologist chasing a non-existent lesion through levels or extra sections.

In primary care, there is widespread good practice clinical consensus that GPs undertaking minor surgery and GPs with a specialist interest in dermatology should submit all tissue removed for histopathological examination. This requirement is often part of local protocols to accredit service provision to ensure that any case of skin pre-cancer or cancer is not missed, as endorsed by the National Institute for Health and Clinical Excellence (NICE) in its *Improving outcomes for people with skin tumours including melanoma* guidelines.⁵⁷ In view of the low risk, however, it would appear reasonable that multiple small (3 mm or less) skin tags are submitted in one specimen container.

Reporting of excision margins on benign lesions should be limited to those with clinical relevance for potential recurrence and/or as specifically requested by a local clinician or agreed in local protocols. With adequate macroscopic examination and submission of transverse sections, routine submission of the 'tips' or ends is not supported by evidence.^{58,59}

In the performance of Mohs surgery under frozen section control, routine paraffin H&E examination is not required if there is a regular audit of the frozen sections.

Orthopaedic and soft tissue

Femoral heads and other articular surfaces removed for known osteoarthritis or inflammatory arthritis need not be submitted for histopathology unless there is a specific clinical question, such as: 'Is there evidence of pre-existing osteonecrosis, sepsis or a radiological abnormality suggestive of a coincidental metabolic bone disease or tumour?' In contrast, tissue removed at surgery for revision of a prosthesis does require examination, to differentiate between mechanical loosening and infection.

In patients with femoral neck fractures, femoral heads should only be examined where there is a suspicion radiologically of a pathological fracture or there is relevant past history of malignancy.

All soft tissue lumps and bumps (for example, ganglia and Morton's neuromas) do need to be examined because of the risk of missing small juxta-articular synovial sarcomas, epithelioid sarcomas and the like.

Amputation specimens for non-tumorous reasons such as ischaemia should not be sent to the laboratory for examination.

Re-excision of melanomas

There is evidence in the UK literature to show that gross inspection, with a single slide from the centre of the previous biopsy site, is all that is needed if the original lesion was fully excised and in the absence of macroscopic disease.^{60,61,62,63}

Gallbladders and appendices

These should be examined, as significant pathology may be present with normal gross morphology, despite one study suggesting that routine gallbladder histopathology is not indicated.⁶⁴

Placenta⁶⁵

There is no justification for examination of the placenta following a normal birth. In general, only those placentae associated with maternal conditions such as pre-eclampsia or with abnormal live births (prematurity, growth retardation, malformation, etc.) should be examined. There are few indications for placental examination in the case of twin births where both twins have been delivered and are thriving. Certainly monochorionicity is not a particularly rewarding histological diagnosis and genetic analysis would be preferable if there is real clinical indication. Clinical suspicion of chorioamnionitis is also not an indication for placental examination since microbiological diagnosis is likely to be more helpful to treatment decisions. It is reasonable to suggest that placental examination in the case of abnormal live births ideally should be undertaken by a pathologist with a special interest.

Nasal polyps

It is rare to find significant pathology in nasal polyps that are not worrying on clinical grounds or gross inspection, therefore most should not be submitted for histopathology.⁶⁶ If nasal polyps are sent to the laboratory then we recommend only minimal sampling.

Tonsils

These should not be submitted for histopathology unless there is a clinical suspicion of malignancy.

Discussion

It is clear that the areas identified in these recommendations have resulted in some decrease in work for which there is limited or no clinical value. The topics should be discussed with clinical colleagues in a multidisciplinary manner.

4. Conclusion

The authors have produced this third edition in order to maintain a level of College best practice recommendations in this important area and to prompt discussion with local colleagues to help with workload management. The issues roughly divide into the following four:

- specimens being sent for histopathology without any obvious clinical reason, for example, ischaemic limbs, placentas from normal pregnancies, and pleural fluid and ascites from patients with known disseminated cancer
- changing clinical practice, for example, gastric biopsies for *H Pylori*, identification of *Pneumocystis carinii*
- misuse of the service by users, for example, inappropriate sputum and urine cytology, and overuse of the 'urgent' designation for cases with no clinical urgency
- inefficient service provision, for example, unnecessarily long-winded reports, lack of involvement of BMS for extended roles.

It is stressed that any decision regarding limiting clinicians' access to cellular pathology must be discussed and recorded at local multidisciplinary team and management meetings. It should be remembered that clinical requestors are frequently nursing and other healthcare professionals working to protocols that have not been designed with the involvement of a pathology consultant. With frequent discussion, consultants and their teams should be entirely happy to comply with demand management.

Undoubtedly, the value of certain cellular pathology tests will change over time and with further evidence. This area should be interpreted as 'fluid' and reflecting the views of the authors in 2019. It should not be seen as a permanent record.

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