Title: Concise Reporting of Benign Endometrial Biopsies is an Acceptable Alternative to Descriptive Reporting

Running title: Concise reporting for benign endometrial biopsies

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Summary

In the UK, endometrial biopsy reports traditionally consist of a morphological description followed by a conclusion. Recently published consensus guidelines for reporting benign endometrial biopsies advocate the use of standardised terminology. In this project we aimed to assess the acceptability and benefits of this simplified 'diagnosis only' format for reporting non-neoplastic endometrial biopsies. Two consultants reported consecutive endometrial biopsies using one of three possible formats: i) diagnosis only, ii) diagnosis plus an accompanying comment, and iii) the traditional descriptive format. Service users were asked to provide feedback on this approach via an anonymised online survey. The reproducibility of this system was assessed on a set of 53 endometrial biopsies amongst consultants and senior histopathology trainees. Of 370 consecutive benign endometrial biopsies, 245 (66%) were reported as diagnosis only, 101 (27%) as diagnosis plus a brief comment, and 24 (7%) as diagnosis following a morphological description. Of the 43 survey respondents (28 gynaecologists, 11 pathologists and 4 clinical nurse specialists), 40 (93%) preferred a diagnosis only, with 3 (7%) being against/uncertain about a diagnosis only report. Amongst 3 histopathology consultants and 4 senior trainees there was majority agreement on the reporting format in 53/53 (100%) and 52/53 (98%) biopsies. In summary, we found that reporting benign specimens within standardized, well-understood diagnostic categories is an acceptable alternative to traditional descriptive reporting, with the latter reserved for the minority of cases that do not fit into specific categories. This revised approach has the potential to improve reporting uniformity and reproducibility.

INTRODUCTION

Endometrial biopsies form a major portion of the workload in many histopathology departments. Most endometrial biopsies are taken from patients with abnormal or post-menopausal bleeding, the intention being to exclude hyperplasia and malignancy. Presently, much reporting follows the traditional structure of microscopic description followed by a conclusion, however in the context of growing staff shortages and increasing case numbers there is a drive to adopt more efficient practices. In our department, pathologists value the traditional approach to reporting, but would be receptive to adopting alternative methods of reporting if this improved efficiency, was acceptable to users, and did not adversely impact patient care in any way. Providing a morphological description for benign entities can be time consuming, does not necessarily add clinical value and may potentially engender confusion amongst service users as the terminologies applied by individual reporters are variable. The use of standardised terminology with the help of clearly defined categories, whose biological and clinical implications are well understood, offers distinct advantages for teaching and reporting. In addition this promotes quality assurance as diagnostic agreement can be monitored more accurately.[1]

In 2018, a gynaecological pathology special interest group from the Canadian Association of Pathologists – Association Canadienne des Pathologistes (CAP-ACP) published a set of guidelines for structured reporting of non-neoplastic endometrial biopsies[2]. A list of diagnostic entities was compiled through literature review and consensus, together with explanatory notes on the usage and implications of each category. The proposed terminology was implemented amongst 5 pathologists in their routine practice. It was found that 96% of all cases could be assigned to one of the diagnostic categories, without the need for a descriptive report. The group recommended the validation and use of this terminology and of concise/synoptic reporting on the grounds that this was found to be easy to use by pathologists. It also held potential for quality assurance and research thorough facilitating data analysis, in the same way as proforma reporting for cancers. This was also held to be of potential benefit to patients by promoting greater reproducibility in diagnosis and management if standardised diagnostic categories are clearly defined and adhered to, and their biological and clinical implications are understood by clinicians.

This study sought to validate the CAP-ACP guidelines and to explore the suitability and benefits of a simplified ‘diagnosis only’ format of reporting non-neoplastic endometrial biopsies.

MATERIALS AND METHODS

Case selection and reporting

‘Consensus guidelines for endometrial biopsy reporting of benign/ non-neoplastic diagnostic categories’[2] were adapted for local use by one of the pathologists (NS, table 1). The adaptations were as follows:

- Sampling categories were listed as utilised locally.
- An explanatory note (A) was added to explain the use of these categories.

- The category of ‘polypoid secretory endometrium’ was added; secretory phase endometrium is well documented to often show a polypoid hysteroscopic appearance[3]; including the term ‘polypoid’ to secretory changes acknowledges to the clinician that the tissue fragments have a polypoid contour, that sampling of a polyp has not been missed, and also that this is not an endometrial polyp with superimposed secretory changes (in our department, out of 107 consecutive samples with clinical/specimen details stated as ‘endometrial polyp’ and sufficient tissue for diagnosis, 11 (10%) showed secretory endometrium only; a further 12 (11%) showed a variety of non-physiologic changes with no endometrial polyp; unpublished intradepartmental audit). This term therefore encompasses a physiologic state that can result in a hysteroscopic impression of an endometrial polyp/polyps, and precludes stating any of this in the report.
- The category of ‘oral contraception’ was added to the list of changes consistent with exogenous hormones
- Products of conception and related categories were excluded as these emanate from a totally different clinical scenario, with different diagnostic and clinical implications. Furthermore the reporting of these categories is carried out in accordance with local protocols for sensitive tissue disposal and due regard to Human Tissue Authority guidance.[4]
- Categories of critical reporting were placed under a separate heading: the inclusion of tissue suggesting uterine rupture and unsuspected malignancy were placed in this category.

Consecutive benign endometrial biopsies reported by one of two pathologists (NS and NT) over a three-month period using these guidelines were analysed and the final histopathology reports were divided into three categories:

1. Diagnosis only
2. Diagnosis with a brief free text comment
3. Microscopic description and conclusion

Biopsies with features of atypical hyperplasia or malignancy were excluded.

Survey

Members of the multidisciplinary team (including consultant and senior trainee gynaecologists, consultant and senior trainee pathologists, nurses and clinical nurse specialists) were invited to complete an anonymous online survey comprising 3 questions that was designed to assess the acceptability of a diagnosis only report and to invite individual feedback. Pathologists were invited to determine acceptability in the use of this reporting system to sign out cases. The invitee pathologists included general and specialist gynaecological pathologists. The trainee pathologists were those preparing for their exit examinations in pathology. Clinicians were invited to assess their acceptability of a brief report instead of a traditional format. The clinical invitees included those working in a tertiary referral Centre as well as those from district hospitals. The trainee gynaecologists were those of sufficient seniority to act on pathology reports without consultant supervision. The survey questions and drop-down options, where provided, are listed in Table 2, together with results.

Reproducibility Analysis

53 consecutive endometrial biopsies showing benign histology were selected from the 370 biopsies that were reported using these guidelines. Two consultant pathologists and four senior trainees were provided with an H&E slide, the patient age and the clinical details (as listed on the pathology request form). For each case participants were asked to record whether they would report it as diagnosis only, diagnosis with a comment or using a descriptive report. For the first category they were asked to select their diagnosis from a pre-populated list (as shown in Table 1). For the latter two categories they were also asked to provide a brief comment or description.

RESULTS

Use of Guidelines

370 endometrial biopsies were assessed using the adapted guidelines (Table 1).

It was the opinion of the two consultant pathologists reporting these cases that 245 (66%) biopsies could be reported using 'diagnosis only' format, 101 (27%) required the addition of a short comment and 24 (7%) needed a more thorough descriptive report.

The cases that most commonly required additional comment were those where correlation was made with the clinical information provided, where the pathologist wished to pose a question to the recipient clinician, or where reference was made to the inclusion of non-endometrial tissue within the sample. Those that necessitated a more detailed descriptive report were cases from patients with previous and/or residual hyperplasia, currently on hormone treatment and undergoing follow up.

A single report elicited a query. This was a sample reported as inadequate in which the clinician emailed to ask if the appearances could represent pyometra; this query had not been raised in the clinical details.

Survey Results

Survey results are presented in Table 2.

43 members of the multidisciplinary team: 20 consultant gynaecologists, 8 trainee gynaecologists, 8 consultant pathologists, 3 trainee pathologists and 4 nurses/clinical nurse specialists responded to the survey, from a total of 100 email recipients.

40 (93%) participants favoured diagnosis only reporting of benign endometrial biopsies and only 3 (7%) - 2 gynaecologists and one pathologist - were opposed to or uncertain about the absence of a morphological description.

Reproducibility Results

53 biopsies were assessed for reproducibility of a) report structure ('diagnosis only', 'diagnosis plus comment', or 'microscopic description and conclusion') and, b) final diagnosis. Four senior histopathology trainees with over 3.5 years' experience in

histopathology, and 2 consultants with a special interest in gynaecological pathology participated in this portion of the study; the report assigned by the original consultant was included as the third consultant observation. In 43/53 cases, all four participating trainee pathologists agreed on the assigned report category while three out of four agreed on 9 of the 10 remaining. Therefore, the trainees achieved majority agreement on reporting format in 52/53 (98%) cases. In 46/53 cases, all three participating consultant pathologists agreed on the assigned report category, while two out of three agreed on the remaining 7. Therefore, the consultants achieved majority agreement on reporting format in 53/53 (100%) cases.

In 15/53 biopsies there was disagreement amongst consultant pathologists in the final report. The commonest reason for this was a difference of opinion along the spectrum of oestrogenic changes: normal versus disordered proliferation (n=6), or disordered proliferation versus hyperplasia without atypia (n=3). The second commonest reason was inadequate versus scanty (n=2). The remaining discrepancies were a single case each of benign polyp versus atrophy, inactive versus weakly proliferative endometrium, benign polyp versus hyperplasia without atypia, and presence of residual hyperplasia without atypia in progesterone treated endometrium with previous non-atypical hyperplasia.

DISCUSSION

This study validates the results from the Canadian consensus and evidence-based guidelines which showed that 95.8% endometrial biopsies can be reported using a template approach for diagnosis. We found that reporting standard benign specimens within standardized, well-understood diagnostic categories is an acceptable alternative to descriptive reporting with potential for improving uniformity and reproducibility. Descriptive reports are invaluable for the minority of cases which do not fit into specific categories due to the complexity of microscopic findings, or the need to raise specific clinico-pathological issues.

In order to standardise reporting, The Royal College of Pathologists in the United Kingdom publishes guidelines for cancer specimens that contain core dataset items that must be included in a pathology report.[5] The application of universal terminology aids and simplifies critical patient management decisions at multidisciplinary team meeting. However, this standardised method of reporting does not extend to non-neoplastic specimens, which constitute the vast majority of biopsies received. Amongst these benign biopsies there are very few actionable diagnostic categories with specific treatment implications. Defining these specific categories would be beneficial to pathologists and clinicians alike.

Within gynaecologic pathology in the UK and possibly elsewhere, endometrial biopsies in particular are typically reported as free text and lack consistency in terms of the diagnostic terminology applied. A retrospective review of surgical pathology cases showed that benign endometrial biopsies suffer from the greatest degree of interobserver variation and misdiagnosis.[6] A high percentage of these disagreements were seen as significant errors which had the potential to impact

patient management, however this review predates the WHO 2014 classification of endometrial hyperplasia and there are no recent studies on clinically relevant reproducibility in benign endometrial biopsies using current diagnostic terminology. There are several reports showing considerable variability in reporting inadequate/insufficient endometrial biopsies and quantitative criteria for adequacy have not yet been established.[7-9] Moreover, there exist multiple variations of similar diagnostic terminologies which ultimately lead to identical clinical management.[7] These characteristics make descriptive pathology reports more tedious to understand and prone to misinterpretation by clinicians, both of which may adversely affect patient care.

Standardised reporting terminologies have multifaceted advantages, the most significant of which is sending a clear message to the clinicians and patients. Furthermore, they provide the advantage of reducing the time taken to sign out individual reports, in comparison to the measures already in place in our department, which include the use of pre-formatted templates, canned reports using short codes, speech recognition and digital dictation which are available to all consultants. This system was found preferable to the two participating consultant pathologists as it minimised word processing effort and administrative work. A clear message in turn enables the clinician to act on the results sooner. Choosing from a list of clearly defined diagnostic categories promotes decisive reporting. Standardisation of terminology also facilitates quality assurance and aids future research. Going forward this format of reporting would be more amenable to incorporating into digital pathology, and promote overall improvement in efficiency.

These templates are also beneficial in training young pathologists who will undoubtedly find these easier to use and incorporate into their practice. The trainer can in turn concentrate on teaching how to make clinically relevant and accurate diagnoses instead of the minutiae of report writing. This helps generate additional time to discuss more problematic cases and produce better quality text reports where these are deemed essential. Reasons often given in support of descriptive reporting are to comply with the RCPath examination system, which currently requires a traditional description and conclusion format, and to facilitate review in cases receiving a second opinion, including medicolegal review. As far as the examinations are concerned, the assessment would be more objective and would be hugely facilitated if a brief and clear diagnosis, with or without differential diagnoses is assessed, rather than a description. Furthermore, an accurate description would not result in an exam pass mark, or support a misdiagnosis in any situation, if the diagnosis is incorrect.

We concede that a template format cannot be unanimously applied to all biopsies. Some cases will require additional information for correlation with clinical information, or an additional explanation. These cases may be reported with an additional comment. There will also be specific scenarios, the most common being cases of surveillance biopsies in patients undergoing progestin treatment for previous endometrial hyperplasia without atypia where it may be necessary to provide a more detailed description. However, we saw that 93% of our non-neoplastic endometrial biopsy samples could be reported using either a standardised diagnostic category or

a ‘diagnosis only’ template with addition of a short text comment. In the present study, as in the Canadian study being validated, the application of this approach was only evaluated in benign endometrial biopsies.

The additional reproducibility aspect of this study demonstrates good agreement amongst trainee and consultant histopathologists in assigning specific diagnostic categories to routine non-neoplastic endometrial biopsies. In addition, this highlights the areas in routine biopsies which suffer from the greatest lack of agreement: namely the threshold for adequacy, the difficulty in categorising cases within the spectrum of unopposed oestrogenic stimulation or in shedding endometrium, and distinguishing dysfunctional changes from architectural changes acceptable within benign endometrial polyps. While there exists a wealth of literature on reproducibility in the diagnosis of atypical endometrial hyperplasia and endometrial carcinoma, the paucity of published research on inter-observer variation in diagnosis of benign endometrial biopsies is striking. This may reflect the fact that endometrial biopsies are largely performed to exclude sinister pathology, and that different benign diagnostic categories have limited, if any, active clinical management implications. Efforts should be made to define actionable diagnostic categories as well as to assess and improve diagnostic concordance in benign endometrial pathology, as this constitutes a vast proportion of the diagnostic gynaecological pathology workload in many laboratories. The use of clear diagnostic categories will assist in these efforts.

CONCLUSION

In conclusion we found that 93% of routine, non-neoplastic endometrial biopsies could be reported as diagnosis only, with or without a brief comment, and without the need for an accompanying microscopic description. This system of reporting is acceptable to users, with 93% of multidisciplinary team members stating their preference for a short report. There was high concordance amongst trainee and consultant pathologists for signing out cases in different diagnostic categories (diagnosis with or without comment versus microscopic description and conclusion). There is good diagnostic concordance in reporting non-neoplastic endometrial biopsies, with major areas of discrepancy being the assessment of adequacy and classification of cases that lie in the spectrum of unopposed oestrogenic stimulation. Concise diagnosis only reporting would be applicable to other specialties and sample types.

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Table 1. Diagnostic categories and guidelines for reporting of benign/non-neoplastic endometrial samples (adapted from Canadian Association of Pathologists[1])

1. Procedure	
Biopsy: Pipelle	
Biopsy: Targeted hysteroscopic	
Biopsy: Vabra	
Biopsy: Other/not stated	
Curettage	
Polypectomy	
Myomectomy (trans cervical resection)	
Endomyometrial resection (ablation)	
Other (specify):	
Not specified	
2. Diagnostic Categories	Explanatory Notes
Diagnosis	• List incorporates the most relevant diagnoses in routine practice, excluding atypical hyperplasia, malignancy or biopsies taken in the follow-up of these conditions when these are being conservatively managed • In presence of atypical hyperplasia/malignancy benign findings are secondary, however, reporting of these is recommended since they may correlate with history and/or clinical findings • Multiple entities from the list, if present, should be included • The list is not exhaustive and other benign changes may be encountered.
Non-diagnostic sample (no endometrial tissue present)	• Absence of endometrial tissue in the specimen should be explicitly stated in the diagnostic line • If the tissue present has potential diagnostic value, eg pus, (possible pyometra), or adipose tissue (possible perforation), or necrotic material (possible neoplasia), then this should be reported despite absence of endometrial tissue
Scant fragments of inactive endometrial surface epithelium and/or stroma (suboptimal for	• Recommended when endometrial tissue is present but scant and therefore suboptimal for assessment • Informs clinician, so that a repeat procedure can

histopathological assessment)	be planned if clinically appropriate
Inactive endometrium Atrophic endometrium Cystic atrophic endometrium	• Inactive endometrium refers to endometrium that does not show clear evidence of proliferative or secretory activity, as a result of site sampled, eg isthmic or polyp tissue, hormone therapy, premenarche or postmenopause • Atrophy specifically refers to postmenopausal endometrium • The presence of evidence of cystic change should be noted as this may correlate with endometrial thickening on ultrasound scan
Normal proliferative endometrium	• Normal physiological pattern
Weakly proliferative endometrium	• Weakly proliferative endometrium represents instances in which only occasional glandular and/or stromal mitoses are identified in an otherwise uniform endometrium with round to tubular, evenly spaced glands • This term is suggested to separate instances of weak proliferative activity in post-menopause, which require reporting and clinical correlation, from the normal (physiologic) proliferative phase endometrium; this may also be seen in the reproductive age group as a result of hormone imbalance
Disordered proliferative endometrium	• Disordered proliferative endometrium is secondary to unopposed oestrogen stimulation of the endometrium. Common scenarios include anovulation, obesity and exogenous hormone administration.
Normal secretory endometrium (Early/mid/late secretory)	• Normal physiological pattern • Determination of the "date" in the secretory cycle on a routine basis is not necessary but may be requested for documentation of normal progression of the luteal phase in the context of infertility; in these or all cases determination of the date, or at least stage of the secretory phase (early, mid or late) may be undertaken
Polypoid fragments of secretory	• This term describes the common scenario of secretory phase endometrium in a patient with a

endometrium	hysteroscopic impression of endometrial polyp(s) • The proposed term reflects the underlying mechanism (physiologic change instead of a true lesion) and provides correlation with the clinical impression • Since secretory endometrium does not represent a true anatomic lesion (polyp), the term "functional polyp" is not recommended • This category does not apply to lesions with diagnostic criteria for endometrial polyp (irregular glands, fibrotic stroma, and thick-walled vessels) and superimposed secretory change
Irregular secretory endometrium	• Irregular secretory endometrium applies to benign endometria with secretory change that does not fit within normal physiologic progression of the luteal phase • Includes weak or uneven secretory changes and stromal breakdown suggestive of a luteal phase defects • Presence of disordered proliferative endometrium with superimposed secretory changes should be specifically commented upon
Menstrual/shedding endometrium	• Menstrual sampling may include late secretory endometrium that does not yet show signs of shedding as well as proliferative endometrium, alongside fragments with features of shedding
Benign endometrium with diffuse stromal breakdown	• Benign endometrium with diffuse non-physiologic breakdown can be seen in the context of cessation of exogenous hormonal therapy or after a defect in normal follicle/corpus luteum progression • It is distinguished from menstrual phase endometrium by the lack of late secretory changes
Endometrial polyp(s)	• Diagnosis of a benign endometrial polyp should be based on well documented features such as glands, stroma, contour, etc
Endometrial hyperplasia without atypia	• The term ‘endometrial hyperplasia without atypia’ is recommended as per the current WHO classification

	• Sub-classification as simple or complex is no longer part of routine terminology.
Chronic endometritis	• The diagnosis of chronic endometritis should be considered when several to numerous plasma cells are readily identified within the endometrium and are accompanied by altered stroma (fibrotic or oedematous) and glandular metaplasia (mucinous or tubal) • In isolation, occasional plasma cells can be seen in other conditions (endometrial polyp, disordered proliferative endometrium, stromal breakdown) and are not sufficient for a clinically relevant diagnosis of endometritis • The use of special stains for plasma cells is not recommended.
Changes consistent with exogenous hormonal therapy: Progesterone	• Progestins (oral, Levonorgestrel-releasing intrauterine device) and progesterone-receptor modulators are associated with characteristic morphologic endometrial patterns which, when observed, should be reported as consistent with therapy-related change • Other medications such as oral contraceptives, unopposed estrogen preparations and aromatase inhibitors produce less specific changes (asynchronous patterns, disordered proliferative endometrium, inactive/atrophy); in these instances, changes observed can be attributed to exogenous therapy if such therapy is documented.
Changes consistent with exogenous hormonal therapy: Selective Progesterone receptor selective	
Changes consistent with exogenous hormonal therapy: Oral contraception	
Decidualised endometrium	• This finding may be physiological or the result of exogenous progestin therapy • In samples received in the context of miscarriage, the absence of placental or fetal tissues after appropriate sampling raises the possibility of ectopic gestation
Leiomyoma	• Diagnosis should be based on well documented histological features
Other (specify):	
3. Critical reporting	• Findings that associated with potential medical complications that require urgent management

	• If the diagnosis or potential complication is not suspected clinically, *immediate communication* with the treating physicians is required
Benign serosal, bowel, adipose or other tissue suggesting uterine perforation	• Presence of serosal, bowel, adipose or other tissue suggesting uterine perforation at time of procedure • Review of recent clinical notes may be advised to determine if this possibility is suspected or confirmed
Unexpected diagnosis of malignancy	• An *unsuspected* diagnosis of malignancy should be considered urgent and result in prompt communication with the treating physician • Malignancy should be reported in accordance with protocols for diagnosis of cancer

Table 2: Survey questions, dropdown responses and results

Question	Responses	Result (number, %)
1. Which of the following best describes your role in the Trust?	Gynaecologist	20 (47%)
	Trainee gynaecologist	8 (19%)
	Pathologist	8 (19)
	Trainee pathologist	3 (7%)
	Nurse/clinical nurse specialist	4 (9%)
2. Are you happy for endometrial sampling reports to be issued as DIAGNOSIS ONLY, i.e. not as a microscopic description followed by a conclusion? (Please note this excludes samples showing atypical hyperplasia, malignancy or features suspicious for these diagnoses.)	Yes	40 (93%)
	No	1 (2%)
	Uncertain	2 (5%)
3. If you answered 'No' or 'Uncertain' to Question 2 please state your reason(s) below:	Free text	3 responses received[a]

[a2]Concerns regarding clarity of report.

[a2]Further clarity is provided when further information is given

[a3]I agree the majority of endometrial biopsies can be placed into one of the categories with a one line diagnosis. The biopsies in which I like to add a more descriptive report are - 1. difficult to date (maybe because of exogenous hormone effect or limited sampling) 2. small scanty fragments which might/ might not be representative (would describe what has been sampled). I think the microscopic report can add info in these biopsies including about how much/ what tissue has been sampled as sometimes this is different from the macro - don't know if the clinicians find this helpful? Happy to report endometrial biopsies as diagnosis only if this is the consensus.