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## Guidance on the reporting of thyroid cytology specimens

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## 1. Background

This document is intended to help produce consistent and reproducible reporting and classification of thyroid cytology specimens in the UK. The importance of thyroid cytology in the diagnosis of thyroid nodules is highlighted in several guidelines.<sup>1</sup>

Thyroid cytology may be reported in prose only or in prose with an allocated category. The categories may be in words or numerical. Various categorical systems exist.<sup>2-4</sup> The system currently in most widespread use in the UK is the BTA/RCP Thy 1–Thy 5 categories 2007 terminology,<sup>3</sup> first produced in 2002. Recently, the National Cancer Institute (NCI) in the USA has proposed a system for thyroid cytology terminology arising from the NCI Thyroid FNA State of the Science Consensus Conference in 2007.<sup>5,6</sup>

The most important role of any reporting system is to provide clarity for patient management. It is also important to be able to audit outcomes to (a) refine and improve the reporting process, (b) give a relative risk of thyroid cancer for each cytological diagnosis, (c) begin the process of a national standardisation and (d) compare with other systems used internationally. Any system used must be easy to understand and apply in clinical practice, and should show good intra- and inter-observer reproducibility between the various categories.

This guidance is not intended to be a textbook of thyroid cytology, for which other texts are recommended.<sup>7-10</sup> Instead, it is intended to be a practical guide to thyroid cytology reporting in the UK, especially the use of terminology, based on available international evidence and our experience with reporting systems in other cytology areas, e.g. breast cytology. As with all guidance, it will require review during use, and amending when required, to remain relevant to up to date clinical practice.

## 2. Role of cytology in the management of patients with potential thyroid pathology

The importance of thyroid cytology in the management of patients with thyroid pathology is highlighted in several guidelines.<sup>3,11-14</sup> The workup of any patient requires full and appropriate clinical evaluation (including, depending on individual circumstances, biochemical, immunological [including thyroid autoantibodies], ultrasound, radioisotope and/or other imaging evaluation) before the decision to perform thyroid cytology is undertaken. It is essential that full clinical details are provided by the clinician/radiologist to give the reporting cytopathologist as much information as possible, including the degree of any ultrasound suspicion (if ultrasound has been used). The use of a proforma cytology request form may aid this.<sup>15</sup>

Thyroid cytology can provide a definite diagnosis of malignancy, with tumour type, enabling appropriate therapeutic surgery in one stage. It can triage the remaining patients into those who potentially require surgical as opposed to medical/endocrinological management. Since the incidence of thyroid malignancy is relatively low, and only 1 in 20 clinically identified nodules are malignant,<sup>16</sup> thyroid fine needle aspiration (FNA) can help reduce the rate of surgery for benign thyroid disease.

## 3. Taking thyroid cytology samples

This guidance will make a few specific points about thyroid cytology FNA,<sup>17-19</sup> but will not reiterate the standard guidance on the taking of cytology specimens.<sup>20,21</sup>

The success of thyroid FNA is known to be operator dependent. Although minimally invasive and safe, and usually performed on an outpatient basis, the optimal application of FNA

requires not only technical skill but also an awareness of the limitations of the procedure, the indications for its use, the factors that affect the adequacy of the FNA specimen, and the post-procedural management strategy. The results may be affected by the lesion characteristics, the accuracy of lesion and needle localization, the method of guidance, the number of aspirated samples, the needle gauge, the aspiration technique, and the presence or absence of on-site facilities for immediate cytological examination.

In most units the sample taker will be a surgeon/endocrinologist/oncologist/radiologist, rather than a cytopathologist, but this will vary from unit to unit, depending on resources and local preference and practice. To develop and maintain the necessary level of staff expertise in an institution, the number of staff who perform aspiration biopsies and the interpreting cytopathologists should be kept small. Each staff member who performs aspiration cytology must be subject to audit of their results. Staff members whose attempts at FNA repeatedly result in unsatisfactory specimens (suggested by experience of the working group to be greater than 15%) should be identified. For this purpose samples which are non-diagnostic (Thy1 – see below) should be separated from those samples which are non-diagnostic but from a cyst (Thy1c – see below) for audit purposes as the latter category should not be operator dependent. There should be discussion on this data, and this is probably best done within a multidisciplinary setting.

Ultrasound-guided FNA tends to have a higher adequacy rate than palpation-guided FNA.<sup>22–25</sup> Assessment of the sample for adequacy by a trained person (invariably with a cytology background) at the time it is taken can also reduce the rate of non-diagnostic samples.<sup>26, 27</sup>

More than one ‘pass’ of the lesion being aspirated yields a greater likelihood of a diagnostic sample, except when a cyst is fully drained. Samples produced from more than one pass should be identified as such.

Some centres may prefer to use alternative sampling techniques, such as samples taken with stylet needles,<sup>28</sup> core biopsies then spread for cytological evaluation or samples prepared with a ‘roll’ technique.<sup>29, 30</sup> These are specialised techniques which should not be used without sufficient local expertise. If such alternative techniques are used, this must be stated on the request form.

### **3.1. FNA training**

Currently, in the UK there is no formal training of pathologists in FNA technique. Links to an educational video on how to take an FNA are available on several websites e.g. [www.ukeps.com](http://www.ukeps.com), [www.papsociety.org](http://www.papsociety.org) and [www.pathlab.org](http://www.pathlab.org). This is currently the same video, and the accessibility and quality can vary from site to site (31).

## **4. Preparation and staining of thyroid cytology samples**

Thyroid FNA cytology specimens may comprise air-dried and alcohol-fixed direct spread samples, as well as aspirate washings and cyst fluid samples. Some units favour the placing of the entire specimen into a fluid medium. There is no direct evidence to date that any one approach yields better results than any other. The majority of units would appear to use a combination of Giemsa and Papanicolaou stains on direct smears, and Papanicolaou with or without haematoxylin and eosin stains on fluid-derived samples, depending on the method of preparation used. The approach used will depend on local resources and experience, but the staining used must be suitable for internal audit and, where applicable, enable review by the appropriate Cancer Network cytopathologist.<sup>11, 32, 33</sup> Such review can identify significant discrepancies in reporting that can affect patient management.<sup>34</sup>

The possible use of any thyroid cytology specimen for ancillary studies (e.g. immunocytochemistry, hormonal analysis, flow cytometry) may affect how a sample is taken, transported and handled. This requirement should be borne in mind and may require discussion between the sample taker and the laboratory prior to the sample being taken.

## 5. Thyroid cytology reporting

The primary aim of any cytology report is to describe and interpret the cytological appearances and convey this information in a clear, consistent and reproducible way to the clinician involved. The report then assists the clinical team in decisions as to any further clinical action. Standardised categorical systems for FNA reporting can make the results easier for aspirators to understand, and suggest therapeutic action.<sup>15</sup> The cytopathologist–aspirator communication can be enhanced in multidisciplinary meetings (MDMs) at which further clinical and/or radiological or pathological information may be available to inform the decision(s). The MDM is also an opportunity to discuss other aspects of the service as required.

Thyroid cytology categories are also required for coding, audit and comparison. To these ends, it is recommended that all thyroid cytology reports be clearly categorised using a numerical cytology category, as well as the full prose report and the appropriate SNOMED code (32,33). A modification of the British Thyroid Association (BTA)/Royal College of Physicians (RCP) Thy1–5 system<sup>3</sup> is therefore proposed, akin to the C1–5 system used in the NHS Breast Screening programme. Whilst it may be tempting to use these categories as a reporting shorthand, the categories by themselves do not convey the full cytological report, and should **not** be used alone without the cytological interpretation in discussions with clinicians.

The suggested numerical categories are listed and explained below.

### 5.1. Non-diagnostic for cytological diagnosis – Thy 1

The cellularity criterion (advocated by the BTA/RCP and Bethesda systems)<sup>3, 5, 6</sup> is agreed with, i.e. to be considered of adequate epithelial cellularity, samples from solid lesions should have at least six groups of thyroid follicular epithelial cells across all the submitted slides, each with at least 10 well-visualised epithelial cells.

The reason for a non-diagnostic sample should be clearly stated in the cytology report. This category will include samples which are non-diagnostic (i) most likely because of the operator/technique:

- Consist entirely of blood or are so heavily bloodstained that the epithelial cells or colloid cannot be visualised
- Are acellular, or have lower epithelial cellularity than the criterion above
- Are technically unable to be evaluated (e.g poorly spread, delayed air drying or fixation artefact, prominent crush artefact, cells trapped in fibrin)

and (ii) those that are most likely related to the lesion such as a cystic lesion:

- Cystic lesion fluid specimens which do not reach the epithelial cell adequacy criterion above and which contain mostly macrophages but without abundant colloid. Useful phrasing may be that ‘the sample is in keeping with fluid from a cyst but there are no epithelial cells or colloid to confirm cyst type’. Use the category **Thy1c**, where ‘c’ means ‘cystic lesion’. It is important for auditing results that any samples of insufficient epithelial cellularity that are cyst fluid can be separated from those which are non-diagnostic for the different reasons listed above. The assessment of thyroid cysts can be particularly problematic. There is a recognised risk of non-representative sampling, especially in cystic papillary thyroid carcinomas. It is important not to offer false reassurance on

suboptimal epithelial cellularity. Careful assessment is needed, possibly with MDM discussion.

## 5.2. Non-neoplastic – Thy 2

Samples in this category should achieve the epithelial cellularity adequacy criterion described above (samples from solid lesions should have at least six groups of thyroid follicular epithelial cells across all the submitted slides, each group containing at least 10 well-visualised thyroid epithelial cells).

This non-neoplastic category therefore includes:

- Normal thyroid tissue
- Thyroiditis
- Hyperplastic nodules
- Colloid nodules – these samples will contain abundant easily identifiable colloid with cytologically bland follicular epithelial cells reaching the cellular adequacy criteria outlined above, usually with the presence of macrophages
- Cystic lesion fluid samples which do have sufficient thyroid follicle cells to achieve the adequacy criterion, irrespective of any possible colloid and/or macrophage content
- Cystic lesion specimens which consist predominantly of colloid and macrophages, even if too few follicular epithelial cells are present to meet the adequacy criteria outlined above, can be considered to be ‘consistent with a colloid cyst’ in the appropriate clinical setting. Such samples could be reported along the following lines ‘the sample is in keeping with fluid from a cystic colloid nodule but there are no/too few epithelial cells for confirmation’. To allow audit, this particular category should be coded as **Thy2c** (‘c’ for ‘cyst’).
- Other non-neoplastic conditions

The specific diagnosis should be stated in the report when one can be made.

## 5.3. Neoplasm possible – Thy3

The majority of the lesions in this category are follicular neoplasms. Due to the limitations of FNA cytology, the nature of these lesions cannot be determined solely by FNA cytology and MDM discussion is needed to decide further management.

This category includes:

- Samples suggesting follicular neoplasms. These are likely to form the majority of the Thy3 category. The histological possibilities therefore include hyperplastic or other cellular but non-neoplastic nodules, as well as neoplasms, including follicular adenomas and follicular carcinomas. Follicular variants of papillary thyroid carcinoma without clear nuclear features of papillary thyroid cancer may fall into this category. These cannot be reliably distinguished on cytology alone. This group is to be classed as **Thy3f** (‘f’ for ‘follicular’). Samples consisting almost exclusively/exclusively of Hürthle cells are also included here.
- Samples which exhibit cytological atypia or other features which raise the possibility of neoplasia, but which are insufficient to enable confident placing into any other category. These should form only a small minority of Thy3 cases. This group is to be classed as **Thy3a** (‘a’ for ‘atypia’). Situations would include:
  - a) Samples in which there is architectural ‘atypia’, in the form of a mixed micro- and macrofollicular pattern (approximately equal proportions of each), where a definite distinction between a follicular neoplasm and hyperplastic nodule is difficult.
  - b) A specimen where only sparse colloid is evident and where a definite distinction between a follicular neoplasm and a hyperplastic nodule is difficult
  - c) Sparsely cellular samples containing predominantly microfollicles.

- d) Focal cytological changes which are most probably benign but where papillary carcinoma cannot be confidently excluded
- e) A compromised specimen (e.g. obscured by blood, or a poorly spread smear) where some cells appear to be mildly abnormal but are not obviously from a follicular neoplasm or suspicious of, or indicative of, malignancy
- f) Atypical 'cyst lining cells'

The cytological interpretation must be clearly stated in the reports, which may mean listing the likely differential diagnosis.

#### **5.4. Suspicious of malignancy – Thy4**

This category includes:

- Those samples which are suspicious of malignancy, but which do not allow confident diagnosis of malignancy. This will include specimens of low cellularity and mixed cell types (normal and atypical). The tumour type suspected should be clearly stated, and will often be papillary carcinoma. This category should not be used for samples that exhibit mild atypia, which should be categorised as Thy3a. Cases of definite malignancy, but where a specific diagnosis cannot be made (e.g. lymphoma vs anaplastic carcinoma), should be in the Thy5 category.

#### **5.5. Malignant – Thy5**

These samples are those that can be confidently diagnosed as malignant. The tumour type should be clearly stated, e.g.

- Papillary thyroid carcinoma
- Medullary thyroid carcinoma
- Anaplastic thyroid carcinoma
- Lymphoma
- Other malignancy, including potentially non-thyroid/metastatic malignancy.

Sometimes it may be possible to be confident of malignancy but not of tumour type. This should then be clearly stated and a differential diagnosis given, e.g. between anaplastic carcinoma and lymphoma, or anaplastic carcinoma and metastatic malignancy.

Obviously, the target is for 100% positive predictive value of all Thy5 cytology reports for malignancy on histology.

#### **5.6 Thyroid cytology coding**

All thyroid cytology reports should be fully coded using standard SNOMED codes<sup>32, 33</sup> and the suggested numerical categories Thy1–5 (see Table 3). It is emphasised that the categories by themselves do not convey the full cytological report and should not be used alone without the morphological cytological interpretation in written or verbal communications with clinicians.

### **6. Thyroid cytology audit**

It is essential, as with all cytology, that reporting categories and outcomes are audited. The proportion of cases reported as each category will vary with the local case-mix and aspirating protocols, so the most valid audit of accuracy is proven clinical outcomes, which will

predominantly be those cases where histology is available. Any cases which have histology performed should have the histology reported in line with RCPATH guidance,<sup>32, 33</sup> and those reports should be obtained for direct correlation with the cytology report. The likelihood of malignancy should be known locally for each cytology reporting category.<sup>5, 6, 24</sup>

The use of the reporting categories should be monitored to ensure their correct use, but also to allow any changes to this current thyroid cytology reporting guidance to be made on robust evidence (33a). Other aspects of the thyroid cytology service that may be audited will depend on local needs; examples may include quantity and accuracy of clinical information given on the request forms, use of reporting codes and SNOMED codes as compared to the text report, rate of insufficient samples per individual aspirators, proportion of benign/malignant nodules undergoing surgery. The use and discussion of audit data is probably best done within the MDT setting.

## **7. Diagnostic accuracy**

Recently published data regarding thyroid cancer detection for thyroid FNA<sup>34</sup> indicate a sensitivity for malignancy of between 65% and 98%, specificity of 76–100%, with a false-negative rate of 0–5%, a false-positive rate of 0–5.7%, and an overall accuracy of 69–97%.<sup>35, 36</sup> One of the problems with comparison of international data is how results are categorised and analysed. It is hoped that a greater international consensus in how this is done will aid in such comparisons (Table 1). That said, results such as those quoted should be achievable and sustainable with suitable training and audit (Table 2).

## **8. External quality assurance**

It is good practice for pathologists reporting in any area to take part in a suitable external quality assurance scheme. To date, no such scheme is known to exist for thyroid cytology. However, it is to be hoped that educational slide set circulation or a full EQA scheme will develop and that those reporting thyroid cytology will contribute and take part in such schemes.

**Table 1:** The RCPATH modified BTA nomenclature and comparison with the Bethesda System (modified from refs<sup>5,6</sup>) for Reporting Thyroid Cytopathology; Recommended Diagnostic Categories

RCPATH	Bethesda
<p><b>Non-diagnostic for cytological diagnosis (Thy1)</b></p> <p><b>Non-diagnostic for cytological diagnosis - Cystic lesion (Thy1c)</b></p>	<p><b>I. Non-diagnostic or unsatisfactory</b>            Virtually acellular specimen            Other (obscuring blood, clotting artefact, etc.)</p> <p>Cyst fluid only</p>
<p><b>Non-neoplastic (Thy2)</b></p> <p><b>Non-neoplastic, cystic lesion (Thy2c)</b></p>	<p><b>II. Benign</b>            Consistent with a benign follicular nodule (includes adenomatoid nodule, colloid nodule, etc)            Consistent with lymphocytic (Hashimoto) thyroiditis in the proper clinical context            Consistent with granulomatous (subacute) thyroiditis            Other</p>
<p><b>Neoplasm possible – atypia/non-diagnostic(Thy3a)</b></p>	<p><b>III. Atypia of undetermined significance or follicular lesion of undetermined significance</b></p>
<p><b>Neoplasm possible, suggesting follicular neoplasm (Thy3f)</b></p>	<p><b>IV. Follicular neoplasm or suspicious for a follicular neoplasm</b>            Specify if Hürthle cell (oncocytic) type</p>
<p><b>Suspicious of malignancy (Thy4)</b></p>	<p><b>V. Suspicious for malignancy</b>            Suspicious for papillary carcinoma            Suspicious for medullary carcinoma            Suspicious for metastatic carcinoma            Suspicious for lymphoma            Other</p>
<p><b>Malignant (Thy5)</b></p>	<p><b>VI. Malignant</b>            Papillary thyroid carcinoma            Poorly differentiated carcinoma            Medullary thyroid carcinoma            Undifferentiated (anaplastic) carcinoma            Squamous cell carcinoma            Carcinoma with mixed features (specify)            Metastatic carcinoma            Non-Hodgkin lymphoma            Other</p>

**Table 2:** The RCPATH/Bethesda System for Reporting Thyroid Cytopathology equivalents (modified from<sup>5,6</sup>)with implied risk of malignancy.

<b>Diagnostic category</b>	<b>Risk of malignancy (%)</b> <sup>37, 38</sup>
Non-diagnostic for cytological diagnosis (Thy1/Thy1c)/Unsatisfactory	0–10
Non-neoplastic (Thy2/Thy2c)/Benign	0–3
Neoplasm possible – atypia/non-diagnostic (Thy 3a)/Atypia of undetermined significance or follicular lesion of undetermined significance	5–15
Neoplasm possible - suggesting follicular neoplasm (Thy 3f)/Follicular neoplasm or suspicious for a follicular neoplasm	15–30
Suspicious of malignancy(Thy4)	60–75
Malignant(Thy5)	97–100

**Table 3** Proposed SNOMED Codes for Thyroid Cytology

Site – Thyroid	T96000
Procedure	P1149
<b>Result</b>	
Thy1	M09000
Thy1c	M09010
Thy2	M09450
Thy2c	M33790
Thy3f	M69701
Thy3a	M69700
Thy4	M69760
Thy5	M80013

## 9. Clinical action

The recommendations for clinical action as advocated by the BTA/RCP (3) are endorsed in general but it is considered preferable *not* to include these general recommendations in cytology reports as not all relevant clinical and/or radiological information may be available to the cytopathologist at the time of reporting. Any patient management decisions must rest on a multidisciplinary assessment of the patient. It is expected that any thyroid cytology cases categorised as Thy3, Thy4 or Thy5 will be reviewed by a cyto/histopathologist core member of the thyroid MDM and discussed in the MDM setting as should any other cases even if classed on cytology as Thy1 or Thy2 categories in which there is any concern, so that the correct individualised patient management plan can be made.

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