

## The difficulty with audit of high grade cervical cytology in the absence of a national screening programme.

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## **The Difficulty with Audit of High Grade Cervical Cytology in the Absence of a National Screening Programme**

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### **Abstract**

Audit is an essential requirement of a cervical screening programme to ensure that laboratories are practising to agreed standards, and to ensure high quality patient care. The aim of this study was to assess the ability to audit high-grade cytology smear reports in a large cervical cytology laboratory in Ireland, where a nationally organised screening programme does not exist. Seven hundred and five questionnaires were forwarded to smear takers requesting follow-up data regarding high grade smear results from 2003. Seventy-four percent of the questionnaires were returned containing insufficient data, with a "don't know result" rate of >50%. This attempt at detailed audit took place 5 years ago. Annual internal audit continues to the best of the laboratory's ability but the situation, in terms of a centralised database in the context of a national screening programme, remains unchanged. A National Cervical Cytology Screening Programme is essential to centralise patient data, to allow for improved patient care, patient follow-up and audit.

### **Introduction**

This report presents an attempt at audit of all high-grade cervical cytology cases reported in one institution for the year 01/01/2003 – 31/12/2003. The objective of this audit was to retrieve follow-up data in the form of colposcopy results and LLETZ histology reports on high-grade abnormal cervical cytology reports including those reported as "dyskaryosis, difficult to grade", (DIFR), for the year 2003, with the aim of: (1) Assessing the ability of a cytology department to audit a cytology service in the absence of a National Cervical Screening Programme. (2) Ensuring that the RCSI cytology screening programme is practicing to agreed standards. (3) Bringing attention to false positive high-grade cytology reports, if they exist.

### **Methods**

All data on high-grade cytology smear reports from the year commencing 01/01/2003 to end 31/12/2003 was retrieved. The data included: Patient name & Date of Birth, Laboratory number, Name of smear taker, Cytology

report. A letter was formulated and forwarded to smear takers, principally General Practitioners or other primary care practitioners, highlighting the purpose of the audit and the importance of correct and specific information. A detachable form detailing the required data was included with the letter. The information was requested in the form of the questionnaire. The data was returned by fax or post and analysed.

#### *Definitions*

A false positive result: A cervical smear incorrectly reported as showing a high-grade abnormality, which did not exist. A cervical smear was deemed a false positive if a thorough colposcopic review and LLETZ biopsy of the cervix were negative and a review of the cervical smear was negative.

A high grade cytology abnormality: Cervical intraepithelial neoplasia II (CIN II), Cervical intraepithelial neoplasia III (CIN III), Cervical glandular intraepithelial neoplasia (CGIN), Adenocarcinoma in situ (AIS)

DIFR: This designation is used when clusters of abnormal cells are seen which cannot be given an unequivocal report of high-grade dyskaryosis but where such a diagnosis cannot be excluded.

### **Results**

The total number of cases of high grade / DIFR smears for 2003 was 705.

The total number of questionnaires returned was 504 (71.5%).

The results are presented in Table I. They show that, where replies to audit letters were received, the result of colposcopy was not known in 28.77% of cases. Furthermore, the results indicate that among the respondents, the result of a LLETZ biopsy was not known in 46.83% of cases. If one includes the 201 cases in which no reply was received to the questionnaire, the figures rise to 43.4% (result of colposcopy not known) and 61.9% (result of LLETZ not known) respectively.

### **Discussion**

This report set out to establish the feasibility of auditing a cervical screening service over a one year period in a country that does not yet have a national cervical screening programme.

Audit is an essential requirement for cervical screening<sup>1-3</sup>. It is important to ensure that the facilities required for audit are available. Audit of cervical screening laboratories is important so that the laboratory can assess its performance against international standards. It is used to calculate positive predictive values of smears and to identify false positive and false negative rates. To perform such an audit it is essential for the laboratory to review results of LLETZ biopsies in cases of high-grade CIN abnormalities.

Currently in Ireland these results can only be obtained from information supplied by the smear taker. This is because colposcopies, LLETZ biopsies and histopathological analysis of LLETZ biopsies are carried out at a large number of colposcopy clinics throughout the country. As there is no formal

feedback from the colposcopy clinics or the histopathology laboratories to the cytology laboratories it is not possible for the cytology laboratories to obtain this information unless they write to individual smear takers. Cervical screening laboratories working in the context of a National Screening Programme have a centralised database where all of this information is collated and stored. Such a database is essential for audit in a cervical screening programme, for example as is seen in the United Kingdom, where annual audit allows for detailed quality assurance procedures to take place. This is in line with European guidelines and is accepted practice worldwide<sup>3,4</sup>.

In this report, letters requesting the results of colposcopy and LLETZ biopsies of the cervix were sent to smear takers of patients who had a high grade abnormality on their cytology smear. Seventy one percent of smear takers responded to the audit letter. Even when a response was received, the smear taker did not have the result of the colposcopy in 28.77% of cases and did not have the LLETZ histology result in 46.83% of cases. Including the number of cases for whom no response was received, these figures rise to 43.4% and 61.9%.

The lack of information available to smear takers regarding colposcopy and LLETZ biopsy results not only hinders accurate audit but also compromises patient follow-up and management decisions. In addition, the lack of information available to cervical cytology laboratories prevents calculation of positive and negative predictive values and assessment of performance against international standards.

| Table 1 a-d Data regarding response rates (1a) and detail of information received (1b-1d). |                 |                 |             |               |              |                 |
|--|-----------------|-----------------|-------------|---------------|--------------|-----------------|
| Table 1a : Audit Letter Requests   |                 |                 |             |               |              |                 |
|  | CINII           | CINIII          | CGIN        | DIFR          | AIS          | Total           |
| Audit Letter Requests Sent   | 236             | 420             | 6           | 40            | 3            | 705             |
| Audit Letter Replies Received  | 175<br>(74%)    | 298<br>(71%)    | 5<br>(83%)  | 25<br>(62.5%) | 1<br>(33.3%) | 504<br>(71.49%) |
| Table 1b :Respondents Colposcopy Performance   |                 |                 |             |               |              |                 |
| Reply from Smear Takers  | N. 175 *        | N. 298 *        | N. 5 *      | N. 25 *       | N. 1 *       | N. 504          |
| Reply Colposcopy Performed   | 163<br>(93.14%) | 278<br>(93.29%) | 5<br>(100%) | 22<br>(88%)   | 1<br>(100%)  | 469<br>(93.05%) |
| Reply Colposcopy Not Performed   | 4<br>(2.29%)    | 4<br>(1.34%)    | 0           | 0             | 0            | 8<br>(1.59%)    |
| Reply Don't know if Colposcopy was Performed   | 8<br>(4.57%)    | 16<br>(5.37%)   | 0           | 3<br>(12%)    | 0            | 27<br>(5.36%)   |
| Table 1c: Respondents Colposcopy Results   |                 |                 |             |               |              |                 |
| Reply from Smear Takers  | N. 175 *        | N. 298 *        | N. 5 *      | N. 25 *       | N. 1 *       | N. 504          |
| Colposcopy Result Known to Smear Takers  | 133<br>(76%)    | 199<br>(66.78%) | 1<br>(20%)  | 17<br>(68%)   | 1<br>(100%)  | 351<br>(69.64%) |
| Colposcopy Result not Known to Smear Takers  | 38<br>(21.71%)  | 95<br>(31.88%)  | 4<br>(80%)  | 8<br>(32%)    | 0            | 145<br>(28.77%) |
| Reply Colposcopy Not Performed   | 4<br>(2.29%)    | 4<br>(1.34%)    | 0           | 0             | 0            | 8<br>(1.59%)    |
| Table 1d: Respondents LLETZ Performance-result   |                 |                 |             |               |              |                 |
| Reply from Smear Takers  | N. 175 *        | N. 298 *        | N. 5 *      | N. 25 *       | N. 1 *       | N. 504*         |
| Reply LLETZ Performed  | 88<br>(50.29%)  | 236<br>(79.19%) | 2<br>(40%)  | 19<br>(76%)   | 1<br>(100%)  | 346<br>(68.65%) |
| Reply LLETZ Not Performed  | 22<br>(12.57%)  | 7<br>(2.35%)    | 0           | 2<br>(8%)     | 0            | 31<br>(6.15%)   |
| Reply Don't Know if LLETZ Performed  | 65<br>(37.14%)  | 55<br>(18.46%)  | 3<br>(60%)  | 4<br>(16%)    | 0            | 127<br>(25.2%)  |
| Reply LLETZ Result Known   | 56<br>(32%)     | 165<br>(55.37%) | 2<br>(40%)  | 13<br>(52%)   | 1<br>(100%)  | 237<br>(47.02%) |
| Reply LLETZ Result not Known   | 97<br>(55.43%)  | 126<br>(42.28%) | 3<br>(60%)  | 10<br>(40%)   | 0            | 236<br>(46.83%) |

There is an urgent requirement for investment in a national cervical screening programme in Ireland with a national database which maintains results of cervical smears, colposcopy and LLETZ histology and which operates a proper recall system and ensures adequate patient management and follow-up.

This report identifies the inability to carry out a complete audit of high-grade cervical abnormalities in the Irish setting. It also demonstrates the difficulty that smear takers have in following up patients with high-grade abnormalities. This detailed audit took place 5 years ago. Annual internal audit continues to the best of the laboratory's ability but the situation, in terms of a centralised database in the context of a national screening programme, remains unchanged. An urgent requirement for investment in a national screening programme in Ireland with a central database containing cytology, colposcopy and histopathology results is necessary for proper audit of high grade cervical abnormalities in line with European guidelines and international best practice.

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## **Other References**

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