

# Annual Scientific Meeting ICC Belfast 4-6<sup>th</sup> May 2022

# **Book of Abstracts**

### Table of Content

Section 1 – Poster Presentations	3 - 123
Section 2 – Oral Presentations	124 - 131
Section 3 – Poster Numbers	132 - 138

# CLINICAL AUDIT: COMPLIANCE WITH BHIVA-RECOMMENDED HIV TESTING AT NEW DIAGNOSIS OF CERVICAL CANCER IN A LARGE UK CANCER CENTRE

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#### **Introduction / Background:**

HIV infection, and the associated immunosuppression, reduce ability to clear concurrent HPV – and hence represents a recognised risk factor for developing cervical dysplasia and cancer. Current British HIV Association (BHIVA) Testing Guideline states '…people presenting with HIV indicator conditions - including cervical dysplasia and cervical cancer - should be offered HIV testing; with repeat offer at subsequent visit if declined…'. Patients with such indicator conditions are believed to have an undiagnosed seroprevalence of >0.1%; contributing to the some 9000 people living with HIV unaware in the UK.

#### Aims / Methodology:

Evaluate compliance with BHIVA guidance through reviewing rates of HIV testing at the time of diagnosis of cervical cancer in a large UK gynaecological-oncology centre. All patients newly diagnosed with cervical cancer within the University Hospitals of Derby and Burton NHS Foundation (UHDB) Trust over a 2 year period (2019-2020) were identified via the UHDB tumour registry. All cervical tumour types, grades and stages were included. Electronic-care records were reviewed and data collected on HIV screening undertaken within the 6 month interval from diagnosis.

#### **Results:**

104 patients were identified and data accessible for n=99. Of records reviewed, 2 patients (1.9%) underwent HIV testing within the 6 months from receiving a new cervical cancer diagnosis. Both results were negative.

Whilst accepting a weakness of our study may be the inability to capture those patients offered, but declining, HIV testing – our data does demonstrate massive under-utilisation of HIV screening in this context. We would anticipate encountering similar findings in the setting of cervical dysplasia. Poor compliance with national guidance likely reflects lack of clinician awareness of BHIVA recommendations. Direct incorporation of such into key colposcopy and cervical cancer guidelines more familiar to gynaecologists would perhaps serve to better promote this as standard practice – optimising outcomes for this at-risk population.

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## CONSERVATIVE MANAGEMENT OF CIN2 IN YOUNG WOMEN BELOW 35 YEARS: A RETROSPECTIVE STUDY

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#### **Introduction / Background**

Cervical dysplasia is common amongst women of reproductive age group. Treatment of CIN1 and CIN3 is well defined, the former being managed conservatively while women with CIN3 undergo excisional treatment. The treatment of CIN2 is variable. Excisional treatment modalities have been associated with increased obstetric complications like mid trimester loss and preterm labour. Studies show that 40-75% of CIN2 regress spontaneously so conservative management may be suitable for young women. Current guidelines suggest to consider conservative management up to thirty years. It however requires careful selection of cases, patient consent, multidisciplinary team discussion (MDT) and strict adherence to follow up with cytology, histology and colposcopy.

#### Aims / Methodology

- 1. Assess regression rate of CIN 2 managed conservatively.
- 1. Identify any preventable risk factors like smoking.
- 2. Audit on documentation of Multidisciplinary Team Discussions (MDT) after each visit.

Retrospective observational study. Twenty-two women with biopsy proven diagnosis of CIN2, at a district general hospital, were followed up for two years from 2019 to 2021.

#### **Results**

Median age was 28 years (23-35years). 85% were nulliparous. Two were lost to follow up and two women opted out of conservative management after one year. Sixteen (88.8%) regressed to CIN 1. Six patients (37.55%) were HPV negative at the end of the two years follow up. One patient (5.5%) progressed to CIN3 and one patient (5.5%) remained unchanged with CIN 2. No risk factors were identified within the study group. MDT discussion was documented at every visit.

#### Conclusion

CIN 2 has a high spontaneous regression rate. Conservative management can be offered to young women up to the age of thirty-five with careful follow up as an alternative to excisional management. This can avoid the obstetric complications associated with the latter.

# DIAGNOSTIC APPROACH AND LAPAROSCOPIC TREATMENT OF EARLY-STAGE INVASIVE CERVICAL ADENOCARCINOMA: A CASE REPORT

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#### **Introduction / Background**

The Laparoscopic Approach to Cervical Cancer (LACC) trial has reported a significant oncologic inferiority of minimally invasive radical hysterectomy compared to the open approach in women with early-stage cervical cancer. However, combined laparoscopic-vaginal technique with a transvaginal closure of vaginal cuff prior to laparoscopic radical hysterectomy can provide oncologic outcomes comparable to those of open radical hysterectomy.

#### Aims / Methodology

We report the case of a 46-year-old woman referred to our department due to ASC-H diagnosis on Pap test and we present the diagnostic approach and course of treatment of the patient.

#### **Results**

A 46-year-old woman with no significant past medical history (except for allergic asthma) was referred to our department with ASC-H diagnosis on Papanicolaou test. Initially, cervical punch biopsies were taken, revealing HPV-related cervical adenocarcinoma in situ. A LEEP procedure was subsequently performed and the histological examination of the excised cone was indicative of well-differentiated, focally invasive adenocarcinoma of cervix, with a stromal invasion of 5.5mm, leading to the diagnosis of invasive cervical adenocarcinoma FIGO stage IB1. For further assessment, cancer biomarkers were measured and an abdominal and pelvic CT scan was scheduled, which shown a small amount of fluid in the pouch of Douglas but no ovarian pathology or enlargement of pelvic lymph nodes. Considering our treatment plan, we opted for a two-step surgical procedure; the patient initially underwent a laparoscopic systematic pelvic lymphadenectomy, during which 17 lymph nodes were excised and confirmed as non-metastatic after pathological examination. Finally, a laparoscopic radical hysterectomy with transvaginal closure of vaginal cuff was successfully performed and the surgical specimen was confirmed to be negative for malignancy. The patient had an uneventful postoperative recovery and was discharged on 2nd postoperative day. At one-year follow-up, the patient remained disease-free, with no evidence of recurrence.

#### A CASE REPORT OF GLANDULAR CELL TUMOR OF THE VULVA

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#### Introduction:

Glandular cell tumors (GCT) of the vulva is one of the rare benign gynecological tumor that affects approximately 10% of women globally. It's believed to arise from the Schwann cells and is usually described as a solitary painless slow growing mass on the affected area. In women, its been noted to occur in women over 50 years of age and the common areas affected include the ovaries, uterus, cervix, vagina and mons pubis. They are generally benign but on rare occasions, they could be malignant.

#### Aims / Methodology

#### Case:

We had a 65 year old Irish lady Para 2 was referred by her GP with left posterior introits lump which she noticed couple of months prior to presentation. She described it as painless but had gradually increased in size.

Her medical history included hypercholesterinemia and her medications included HRT and Statins. Surgical history included Appendectomy, Total abdominal hysterectomy and Bilateral Salpingo-ophorectomy for Menorrhagia.

She eventually had an examination under anesthesia and subsequent excision of a 5x4cm hard mobile mass which was initially thought to be a sebaceous cyst but was sent for histopathology. Histopathology report:

#### **Results**

#### Micro:-

Tissue fragment from the vulva showed not well circumscribed relatively cellular tumor nodule with masses and nest of rounded polygonal large cells with small dense nuclei and abundant Eosinophilic cytoplasm showed coarse granules. There was no evidence of necrosis. No mitotic figures were seen. The tumor cells are strongly positive for S100, CD56 and weakly positive for CD68 and calectin. Also weakly positive for PAS/DPAS.

**Macro-** Tissue fragments both firm and oval shaped nodule. The larger is 22x15x15mm. the smaller is 4mm largest in diameter.

**Conclusion**: The lesion is regarded as benign based on the Fanburg-Smith and Nesser Ahmed-Kowalski Criteria.

She was later discharged as no follow up was required after an MDT review.

## PATIENT SURVEY – QUALITATIVE ANALYSIS OF ACCEPTABILITY OF OUTPATIENT TREATMENT

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#### **Background**

Treatment of high grade Cervical Intraepithelial Neoplasia (CIN) is highly effective with high cure rate of 95% and comprise of two modalities – excisional method such as Large Loop Excision of Transformation Zone (LLETZ) and ablative method such as Thermal Ablation (TA). LLETZ is more popular and more often performed procedure in the rest of UK and hence there is information available on patient acceptability and anxiety levels around such treatment. However, there is paucity of such data around TA and our study aims to collect this information.

#### Aim

To assess patient perception and acceptability of outpatient treatment of high grade CIN by LLETZ and TA.

#### Method

A questionnaire was devised by two clinicians using Likert scale for assessment (score of 1 to 5). The questionnaire was then validated by piloting the study in 15 patients following Ethics approval. Subsequent to validation, our main study is underway with an aim to survey 10% of our annual treatments. Prior to treatment, the survey is explained to the women and written consent obtained to participate in the study. Demographics of the women such as age, parity, details of colposcopy visit, treatment are collected from the colposcopy card. Following treatment, there is a brief interview of the woman (conducted by a member of the staff who has not performed the procedure) to collect information as outlined in the survey form. Both objective (on Likert scale) and subjective information will be collected to enable data analysis later. Four to six weeks postprocedure, the women will be contacted to ascertain if they had to seek medical help for bleeding or infection and the amount of treatment needed. Also, women will be asked about time taken to resume sexual intercourse.

#### Result

We have outcomes from the pilot study. 1/10 women who underwent TA reported pain and 1/10 reported discomfort when compared to 1/5 women who underwent LLETZ and 4/5 reporting discomfort. The questionnaire had 3 components – preprocedure anxiety levels, immediate postprocedure assessment followed by 4 weeks postprocedure phone call survey and we aim to present the qualitative analysis of these three segments.

#### **Conclusion**

There is renewed interest in ablative methods of treatment of high grade CIN and our study fills the gap in the literature about patient acceptability of TA. With high success rates of treatment, as well as high patient acceptability, TA needs to be considered on par with LLETZ as long as criteria for ablative methods are fulfilled.

#### **COLPOSCOPY AUDIT ON TREATMENT WAITING TIMES**

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#### **Introduction / Background**

- 1. SQAS recommendation at the cervical screening QA visit to MKUH in March 2020.
- >90% women requiring treatment should have this performed within four weeks after the receipt of a biopsy result

#### Aims / Methodology

- To ensure that the MKUH colposcopy service is meeting national targets
- Where not meeting targets, to identify reasons for delay and make appropriate recommendation
- Retrospective audit
- Data collected using Cyres and infoflex (colposcopy IT systems)- from July 2020- October 2020

#### **Results**

- Total number of treatments- 55
- Number of see and treats- 11 (Excluded from audit)
- No biopsy at initial appointment-1 (excluded from audit)
- Number of treatments performed within 4 weeks of receiving a biopsy result- 25/43
- Number of appointments for treatment offered within 4 weeks of a biopsy result- 43
- 25/43 (58%)- Had treatment within the timeframe
- However, 43/43 (100%)- were offered appointments within 4 weeks
- 37/43 (86%)- seen in colposcopy clinic within 4 weeks of receiving a biopsy result, 6/43 rescheduled their appointments by choice
- We did well on appointing everyone to a colposcopy clinic within recommended timeframe (100%)
- Only 58% women had treatment within the 4 weeks
- We undertook this audit- to look reasons for not achieving the national target
- No problem with administrative support as 100% women were being allocated to a colposcopy clinic within 4 weeks for a LLETZ
- The outliers were either complex clinical scenarios where a second opinion, discussion at MDT or GA LLETZ were required or patients chose to defer their treatments
- None of these outliers could have been brought within the national target range for treatment
- Intention to treat was within 4 weeks, any delay was caused, predominantly, by patient related factors
- Look at reducing the time frame for a GA LLETZ after the colposcopy appointment (the aim would have been to perform an out-patient LLETZ at this appointment)
- The new policy of getting a second opinion before listing a patient for GA LLETZ may have a
  positive impact on this audit.
- Re-audit is recommended in 6 months

# EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV WOMEN OVER 40: SUB-ANALYSIS OF THE PALOMA CLINICAL TRIAL & PAPILOBS REAL-LIFE STUDY

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#### **Introduction / Background**

HPV clearance and resolution of cervical HPV-dependent lesions become difficult in peri and postmenopausal women.

#### Aims / Methodology

The objective of this sub-analysis was to evaluate the effect of the Papilocare®, a multi-ingredient Coriolus versicolor-based vaginal gel in repairing the high-risk (HR) HPV-dependent low-grade cervical lesions in women over 40 years old.

Paloma study (NCT04002154) was a multicenter, randomized, open-label, parallel-group, watchful waiting approach-controlled clinical trial. Unvaccinated HPV-positive women aged between 30-65 with cytology of ASCUS/LSIL and concordant colposcopy image were randomized into: A) Papilocare® 1 cannula/day (1 month) + 1 cannula/alternate days (5 months); B) Papilocare® 1 cannula/day (3 months) + 1 cannula/alternate days (3 months); C) Control group: watchful waiting approach. Papilobs study (NCT04199260), was an observational, multicenter, prospective, one-cohort study. HPV-positive women aged > 25yo with cytology of ASCUS/LSIL and concordant colposcopy were included. Patients were treated with Papilocare® 1 cannula/day (1 month) + 1 cannula/alternate days (5 months). Percentages of HR-HPV patients with normal cytology and concordant colposcopy after treatment in over 40yo subpopulation are presented

#### **Results**

A total of 30 and 68 HR-HPV patients were evaluated in Paloma and Papilobs studies, respectively. In the Paloma trial, normal cytology and concordant colposcopy was observed in 90% vs 33% patients in A+B Papilocare® and control groups, respectively, (p=0.003, Fisher test). In the Papilobs study, normal cytology and concordant colposcopy was achieved in 73.5% of patients. Conclusions: After a 6-month treatment period, Papilocare® showed a clinically robust and statistically significant efficacy in repairing cervical HR-HPV lesions in women over 40yo with HR-HPV vs watchful waiting approach. This efficacy was corroborated in real-life conditions.

# EFFICACY OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HIGH-RISK HPV INFECTED PATIENTS: RESULTS OF 6 DIFFERENT STUDIES

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#### **Introduction / Background**

Real life data are relevant to evaluate the effectiveness of a medical device/drug, providing additional practical information to the clinical trials one. Consistency in the data observed in both designs provide strength and credibility to the results, even more if they come from independent studies.

#### Aims / Methodology

Evaluate the consistency of the efficacy data of a multi-ingredient Coriolus versicolor-based vaginal gel, Papilocare®, on HR-HPV clearance in both observational studies and in a randomized clinical trial.

Results from 4 independent observational studies (6 month-treatment period with Papilocare®) were compared to results from a randomized, open, parallel, controlled trial (Paloma: NCT04002154) and an observational, multicenter, prospective, one-cohort study (PapilOBS: NCT04199260).

- 1. Vigo study: Prospective one-cohort. Secondary endpoint (SE), HPV clearance in 25 patients infected by HPV 16 and/or 18.
- Coruña study: Retrospective one-cohort. Primary Endopint (PE), HPV clearance assessed in 57 medical patients' records.
- Hospitalet study: Retrospective one-cohort. PE, Composite efficacy variable (patients with normal cytology and/or HPV clearance) in 91 HR-HPV patients.
- Roma study: Retrospective controlled. PE, HR-HPV clearance in 183 patients.
- Paloma trial: SE, HR-HPV clearance in 65 patients.
- PapilOBS study: SE, HR-HPV clearance in 176 patients

#### **Results**

48% of patients cleared HR-HPV in Vigo study. 58% of reduction was observed in the number of HR-HPV patients (Coruña) and 72.5% negativized cytology and/or cleared HR-HPV (Hospitalet). 67% HR-HPV clearance was observed (treated group) vs 37.2% (control group), in the Roma study. In the Paloma trial, HR-HPV clearance reached 63% (treated group) vs 40% (control group). 57.4% HR-HPV clearance was observed in the PapilOBS study.

Papilocare® has shown significant consistent rates of efficacy with a weighted average of 62,3% of HR-HPV clearance at 6 months in 6 different studies involving 597 patients. These findings reinforce its clinically significative beneficial effect for HR-HPV patients already observed in clinical practice over the world.

## BORDERLINE CHANGES IN ENDO-CERVICAL CELLS: WHERE ARE WE? A COMPLETED AUDIT CYCLE

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#### **Methodology:**

We conducted a retrospective re-audit to complete audit cycle on management of borderline changes in endocervical cells in assessing histology outcome from January2020 till December2021. Initial audit was performed from January2018 till December 2018.

Colposcopy examination was performed on all the patients within two weeks as per guidance. In 2018, 15 patients identified, 7/15 showed CIN2 &CIN3, 5 were CIN1 and 3 had normal biopsy. In 2020, seven patients, 3/7CIN2, 2/7 CIN1 and 2 showed squamous metaplasia on biopsy. In 2021, ten patients, biopsy showed 5/10 normal, 4 CIN1 and one inadequate. 7/10 were conservatively managed, two had LLETZ and one is waiting for hysterectomy.

#### **Results:**

Over three years, 96% (31/32) had satisfactory colposcopy.

Every patient underwent single or multiple biopsies despite the absence or presence of abnormalities at colposcopy(100%).

All cases were discussed in MDT for management and follow up plans(100%).

In 2018, 11/15 patients underwent complete excision (LLETZ,73.3%). 6/11 had CIN2 and CIN3 disease.

In 2020, 6/7(85.7%) patients had LLETZ treatment except one which showed Koilocytosis & Squamous metaplasia and negative P16. 3/6(50%) LLETZ showed koilocytosis, two had CIN1 and one CIN2.

In 2021, 2/10(20%) underwent excision, one showed no CIN, second 56years old woman had unsatisfactory colposcopy and LLETZ confirmed high grade CGIN, referred to tertiary care. 4/17(23.5%) patients had no treatment in 2018 whereas 1/7(14%) and 7/10(70%) managed conservatively in 2020and 2021 respectively.

#### **Conclusion:**

- · Due to lack of evidence and limited guidance on the management of borderline nuclear changes in endocervical cells, all patients should undergo colposcopy examination, biopsy, and MDT discussion.
- $\cdot$  A repeat smear, colposcopy assessment and biopsy should be performed in 6-12 months if managed conservatively.
- . This re-audit has shown less number LLETZ needed to be performed as a result of the histology outcome found in the first audit.

## CHALLENGES WITH CIN 2 CONSERVATIVE MANAGEMENT DURING COVID-19 PERIOD

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#### **Introduction / Background**

Research shows CIN 2 lesions regress in young patients. However, patients with CINII should be closely monitored in colposcopy at 6 monthly intervals and offered treatment if not resolved by 24 months. Many units, nationally and locally in London, including GSTT were managing CINII conservatively.

#### Aims / Methodology

To ensure safe management over COVID 19 period in view of local and national screening challenges in the pathway.

Patients with CINII were identified from August 2018 to July 2019 be reviewing the colposcopy database Viewpoint, Cyres and local EPR. An excel spreadsheet was used for analysis.

#### **Results**

Total number of patients with CINII n=128

Conservatively managed n= 43 (34%)

Offered treatment at first instance n= 85 (66%)

With complete regression within 2 years n= 20 (47%)

With partial regression within 2 years n= 7 (16%)

With no sign of regression n= 16 (37%)

With no regression identified as needing follow up n= 12

With follow up appropriately booked n= 5 (42%)

Without follow up n= 7 (58%)

Patients discharged (without offering treatment) because of non-attendance n= 3 (60%)

#### **Conclusions**

COVID -19 pandemic affected the care of some patients manged conservatively with CINII. This was attributed to cervical screening delays, pause, sickness, deployment, staff leaving the trust, working from home followed by a backlog of patients requiring appointments. It is highlighted the importance of robust failsafe and audit. All patients affected have been contacted and safely managed. The development of an information leaflet for CINII management as well as failsafe follow up of patients who do not attend are recommended.

## AUDIT OF LLETZ PROCEDURES IN A HEALTH TRUST IN NORTHERN IRELAND AGAINST NATIONAL STANDARDS

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#### **Introduction / Background**

The NHSCCP document 20 provides a national set of standards for colposcopy services throughout the UK. This audit compares standards relating to LLETZ procedures with practice in a health care trust in Northern Ireland.

#### Aims / Methodology

A flow study of patients with abnormal screening smears through the Colposcopy Service in the South Eastern Trust from first referral to TOC during January to February 2020 was conducted to provide baseline data to inform quality improvement. Data from all patients who had a therapeutic LLETZ within this sample was audited against the NHSCCP document 20 standards, 2.5, 2.7, 2,7 and 3.3.

#### **Results**

Of the 98 patients referred into the service 33 went on to have a LLETZ procedure.

20/33 had a See and Treat LLETZ, 65% of specimens had CIN 2 or greater present.

Of the patients who returned to have a LLETZ 31% (n=4) where treated within 4 weeks and 69 % (n=9) within 8 weeks (delays due to Covid 19).

45% (n=15) patients had a LLETZ specimen removed as a single sample.

The type of transformation zone was not recorded in the clinical notes, where the colposcopy examination was described as satisfactory and TZ visualised, 96.96% (n=32) of patients had a LLETZ that was >7mm depth which would satisfy standards for Type I and type II transformation zones. Where the Transformation Zone was not seen (5/33) i.e type III transformation zone, only 1 patient underwent LLETZ excision to the recommended depth of >15mm

100% of LLETZ procedures had an adequate pathology report as outlined in the document 20 standards.

In conclusion, this audit shows that the South trust Colposcopy service is complying with document 20 standards in the area of histology report. However there are areas of improvement needed in compliance with document 20 2.5, 2.6 and 2.7 standards.

## AN AUDIT ON EXCISIONAL TECHNIQUE FOR CIN IN NOTTINGHAM UNIVERSITY HOSPITALS NHS TRUST

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#### **Introduction / Background**

This is a quality assurance audit assessing loop excisional technique for the treatment of CIN. The timeline for this audit is 1<sup>st</sup> January, 2020 to 31<sup>st</sup> December, 2020.

The standards are, as stated in the NHS Cervical Screening Programme, Document 20.

- 1. In excision technique, at least 80% of cases should have the specimen removed as a single sample.
- 1. For ectocervical lesions, excisional techniques should remove tissue to a depth of more than 7mm in equal to or more than 95% of cases.

#### Aims / Methodology

A retrospective review of all cases were done. Data was collected from the hospital database. The number of LLETZ procedures, number excised in 1 piece, depth of specimen and data for individual colposcopists were all collected and analysed. The cases where depth of specimen was less than 7 mm were further analysed to: a) find any cause for such low depth and b) if the specimen margins were clear of CIN inspite of depth <7mm

#### Results

590 cases of loop excision were done in this timespan. 95% of these were removed in 1 piece. But only 505 specimen i.e.86% had more than 7mm in depth.

Thus in 85 cases, specimen depth was less than 7mm. Amongst these, 10 cases had valid reasons for it (namely, high BMI, flushed cervix with vault or previous LLETZ procedures)

But more interestingly only 11 out of these 85 cases had endocervical margins involved with CIN. Hence, in conclusion it can be said that practise needs to improve in terms of specimen depth. Also type of transformation zone needs to be documented in each case so that correct specimen depth required can be identified.

However, if the vast majority of cases with specimen depth <7mm had clear endocervical margins (87%), should our practice, perhaps be individualised?

# EVALUATION OF THE CLINICAL PERFORMANCE OF HPV ONCOPREDICT® QT ASSAY WITHIN THE VALGENT-2 FRAMEWORK

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#### **Background**

Human papilloma virus (HPV) assays used within a cervical cancer screening setting should be clinically validated according to international accuracy criteria. HPV OncoPredict® QT is multiplex real-time PCR with full genotyping capability targeting DNA of the E6/E7 genes of 12 high risk (HR) HPV types. The assay allows quantification of the viral load of each targeted genotype separately. Quality controls for sample adequacy, efficiency of nucleic acid extraction and PCR inhibition are included in the testing.

#### **Methods**

Clinical accuracy of HPV OncoPredict® QT was assessed using the VALGENT-2 panel. Study population included 1,300 cervical liquid based cytology (LBC) samples from women aged 20-60 attending the Scottish cervical cancer screening: 1000 consecutive samples from routine screening enriched with 300 cytological abnormal samples. Denominator for sensitivity was defined by women with cervical intraepithelial neoplasia scoring grade 2 or worse (CIN2+) and CIN grade 3 or worse (CIN3+) confirmed by histology. Denominator for specificity included women with two consecutive negative cytology. Non-inferiority test was applied to assess accuracy relative to the standard comparator test (GP5+/6+- PCR-EIA).

#### **Results**

HPV OncoPredict® QT showed high clinical sensitivity of 94.7% (95% CI, 93.2 - 96.3%) for CIN2+ and clinical sensitivity of 93.6% (95% CI, 91.9 – 95.3%) for the detection of CIN1 or less. The relative sensitivity and specificity for CIN2+ of HPV OncoPredict® QT vs GP5+/6+-PCR-EIA were 1.01 (95% CI, 0.99-1.03) and 1.03 (95% CI, 1.0-1.06), respectively. The p-values for non-inferiority were all  $\leq$ 0.001. Test performances did not change when restricted to women aged 30 years or older. OncoPredict® QT fulfils the international clinical accuracy criteria for HPV tests that can be used in primary cervical cancer screening.

#### **Acknowledgments**

HPV OncoPredict® assay was developed as part of a European Commission funded Horizon 2020 SME Instrument Phase 2 Project (Grant agreement ID: 806551).

## AN ANALYSIS OF COLPOSCOPY REFERRALS AND OUTCOMES IN THE OVER 60S WITHIN THE NORTHERN TRUST

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#### **Introduction / Background**

The postmenopausal patient necessitating colposcopic examination poses various diagnostic challenges to the colposcopist. This is an important cohort of patients to manage as they approach exit criteria from the screening programme, especially as approximately 10% of new cervical cancer diagnosis are made in those over 75 years.

We looked at patients over the age of 60 years attending for Colposcopy over a 15 month period during the COVID 19 pandemic.

This was a reaudit within our department to identify if referral trends and management strategies had remained similar for a previous episode outside of the pandemic.

#### Aims / Methodology

We identified patients attending colposcopy clinics within the NHSCT who were aged 60 years and over using the regional excelicare database system from March 2020 until end June 2021.

#### Results

We identified 37 patients attending colposcopy. The average age was 64.5 years, the range being 60 – 69 years. 35% of patients had attended colposcopy before. Of the cytological referrals received, 24% were for repeated inadequate smears. 24 out of the 37 cases were for Borderline nuclear abnormalities, 1 mild dyskaryosis and 3 moderate dyskaryosis. HPV 16 accounted for 14% of the samples qualifying for HPV status. At colposcopy, the majority of patients were reassured with a normal examination but 13 of the cases had a biopsy – 8 LLETZ and 5 punch biopsies. Of these, 4 cases had high grade changes.

At 6 month follow up, the majority of patients were discharged but 5 patients still had low grade changes on cytology with follow up pending.

Our results show that inadequate cytology referrals form the burden of workload in this cohort. Future development to reduce this could include smear taker education / refresher courses or the use of vaginal oestrogen pessary to reduce the likelihood of inadequate cytology.

# AUDIT OF OUTCOME OF GLANDULAR SMEARS OF ENDOCERVICAL ORIGIN AND EFFECTIVENESS OF LOOP EXCISION (LLETZ WITH TOP HAT) IN THE TREATMENT OF HIGH GRADE GLANDULAR NEOPLASIA

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#### **Introduction / Background**

Glandular smears of possible endocervical origin constitute a subcategory of smears that need specific pathway for management. A more accurate assessment is likely to be obtained by combining: cytological review, colposcopic appearances, and histological biopsy of any abnormality seen. Coposcopic features and directed punch biopsies are less likely to be of value in excluding disease.

#### Aims / Methodology

We audited :a) All Glandular Neoplasia Smears of endocervical origin within a 5 year period between June 2013- May 2018. b) CGIN identified on histopathology on cervical biopsy (punch or excisional LLETZ) were also identified and backtracked to their presenting cytology and clinical presentation. c) Cervical adenocarcinoma diagnosed in the same 5 years windows were also identified and traced back to their smear history.

The aim is to review the adherence to clinical standards and review the outcome of abnormal glandular smears of endocervical origin.

#### Results

Histopathological final Diagnosis of all Glandular Neoplasia of endocervical origin smears showed: i)Cervical Adenocarcinoma: 31.4%, ii)CGIN: 29.4%, iii)CGIN+ CIN2+:17.6%, iv)CIN2+: 9.8 %, v)Normal histopathology with only HPV changes: 9.8%

Outcome of Management: i) LLETZ with top hat excisional biopsy at outpatient setting was associated with 56% complete excision of CGIN.ii)TOC (Cytological cure): of complete excision of HG CGIN at LLETZ up to 95%, iii) Where Adenocarcinoma was identified without a glandular smear referral: 45% had normal smears before.

# A FIVE REVIEW OF CERVICAL GLANDULAR INTRAEPITHELIAL DISEASE (CGIN)

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#### **Introduction / Background**

The diagnosis, evaluation and treatment of CGIN present challenges to both the cytopathologist and clinician, due to their rarity, lack of characteristic colposcopic findings and usually inaccessible endocervical location. Women diagnosed with CGIN remain at risk of further pre-malignant and malignant disease and require rigorous post-treatment follow-up. We reviewed the management of women with CGIN in our colposcopy unit at BWCH.

#### Aims / Methodology

A retrospective study was conducted of women diagnosed with CGIN between 01/01/2016-31/12/2020.

A primary excisional procedure is the main treatment for initial management of all cases of high-grade atypical glandular cytology, with further management decisions based on a thorough histological assessment, including margin status. For women with suspected CGIN or early invasive adenocarcinoma, the extent of the cervical excision can be individualised.

In contrast to CIN, about 10% of cases of CIGN may show skip lesions higher in the endocervical canal. CGIN is co-existent with squamous CIN in as many as 50% of cases. All cases of CGIN are discussed in colposcopy MDT to guide further management. There is a high association between H-CGIN and invasive disease. In the management of such alleged precursors, it is important to ensure adequate free margins.

#### **Results**

Total women were 65 with an average age of 36, 65% were multiparous. 32% smoked. 62% women were referred with? Glandular neoplasia of endocervical type. 61% women were seen within 2 weeks. All women had a primary loop as initial investigation/treatment with just under a quarter (23%) requiring a second LOOP. CGIN or higher glandular cell abnormalities were diagnosed on histology of first LOOP in 75% cases. 19% of women had invasions present and were treated at the cancer centre. CGIN was not present on histology of first and second LOOP in 13% and 35% of women respectively. Associated CIN was present in 58% of cases. Incomplete margin status was found in 75% of cases. Margin status was complete in 88% on second LOOP. 55% were followed up at our colposcopy unit. 15% were discharged to GP for follow up. 9% women did not attend for follow up.

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# AFFECT OF IMIQUIMOD ON VAGINAL INTRAEPITHELIAL NEOPLASIA (VAIN)

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#### Introduction/Background

Vaginal intraepithelial neoplasia (VaIN) is a rare pre-malignant lesion affecting 0.2-0.3 women per100,000 <sup>2,3</sup>. Potential risk factors for VaIN development include infection by one of the high risk HPV types, smoking, immunosuppression, prior pelvic irradiation and in utero DES exposure <sup>4-6.</sup> Early detection and prevention of cancer are relatively difficult as VaIN in majority of cases lacks symptoms. The management of high-grade intraepithelial neoplasia should be tailored according to the patients' characteristics.

#### Aims / Methodology

To identify that Imiquimod can potentially be the best management of VaIN depending on patients' characteristics. A retrospective review of patients of high grade VAIN from 2000- 2019. 64 cases were found, data was entered on excel spread sheet and following results were obtained.

#### **Results**

Total women were 64.Average age was 48.5 years.58% were primiparous and 42% were nulliparous. 53% had no significant medical history. 87% were not on any medications. 75% were smokers. 58% had associated high grade CIN. 4 patients had previous radiation to the pelvic area. 18 patients had hysterectomies. All of these cases were high grades, confirmed on biopsy. From 2000-2012 high grade VAIN were treated with WLE, Laser, partial vaginectomy, TAH with removal of vaginal cuff. From 2013 we started to use Imiquimod successfully in our VAIN cases.

#### **Conclusion**

According to our review 5% Imiquimod is an effective and safe non-invasive alternative treatment for VaIN with high cure rate and low recurrence rate.

5% Imiquimod appears to be a promising, alternative, non-invasive treatment option.

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# LARGE LOOP EXCISION OF THE TRANSFORMATION ZONE, A SINGLE CENTRES RESULTS, AND RATES OF RECURRENCE OVER A TWO YEAR FOLLOWUP PERIOD

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#### Aim:

A 2 year review of outcomes of cervical biopsy and/or LLETZ performed following positive CST HPV (16/18 or other) and CST cytological findings.

#### Methods:

Results of patient who had cervical biopsy, and/or LLETZ performed at Fremantle Hospital between March 2019-2021 were reviewed. A total of 153 women, between the ages of 23-75 were included in the current study. Of these 131 patients had cervical biopsy and 151 had LLETZ performed.

#### **Results**

Frequency analysis of initial CST cytological findings with biopsy results, showed that 93% of CST cytological findings and 92% of Biopsy results were reported as positive for either HSIL, LSIL or AIS. Of these, 85% of Biopsy results were classified HSIL. In comparison 72% of LLETZ were positive, with 66% classified as HSIL. In addition, 2 cases of microinvasive carcinoma and one focal carcinoma in situ were also detected (the former not detected on biopsy). Permutation tests comparing CST cytological findings with biopsy histopathological results showed a significant association,  $p = 2.2 \times 10^{-16}$ . However, no significant association was found between CST cytology and LLETZ histopathology results, p = 0.27; and Biopsy histopathology and LLETZ histopathology results, p = 0.37. Regarding repeat CST at 12 months, 46 patients had available results with 65% being negative. Permutation tests comparing LLETZ histopathology findings and repeat CST cytology results did not show a significant association, p = 0.27. Finally 4% of patients included in the original cohort had LLETZ repeated at 24 months, with permutation tests showing no significant association between CST at 12 months and LLETZ at 24 months.

#### **Conclusion:**

Rates of detection of and follow-up appear appropriate based on local guidelines, however overcall and disease regression contribute to lower rates of positive LLETZ than the preceding biopsy results would suggest. Similar results have been found by larger cohort studies, and further analysis into methods of reporting and patient selection may be necessary.

#### **Introduction**

In the year 2020, 933 women were diagnosed with cervical cancer in Australia, with 238 women dying that year from said cancer. This constitutes 1.1% of female cancer related deaths in Australia. Cervical cancer mortality has fallen significantly over the past 2 decades, since the initiation of cervical screening in 1991.<sup>1-3</sup>

Regarding current standards of care, following virus identification, cytological diagnosis, colposcopy, and biopsies are often performed to establish severity of disease and indication for progression to treatment. For those with precancerous lesions detected on biopsy, Large Loop Excision of the Transformation Zone (LLETZ) or Loop Electrosurgical Excision (LEEP) are the preferred treatment techniques in Australia. Histopathological analysis proceeds.<sup>3,4</sup>

As noted within NICE guidelines, colposcopy is subject to user variability. However current practice utilises colposcopy to assess for regions of cervical abnormality and thus guide biopsy of these regions.<sup>4</sup> Historically studies have showed variation between the results of biopsy histopathology

and LLETZ histopathology, with the former returning false negatives, potentially missing cancer diagnosis. <sup>4-8</sup> It has also been suggested by a number of studies that there is overcall bias within initial screening to avoid instances where high grade or malignant change is overlooked. <sup>6-10</sup>

Regarding the efficacy of LLETZ, though it is a standard of care, studies have shown a high rate of marginal involvement in the sampling process. Whilst the preferred means of treatment, cautery makes histopathological assessment of margins difficult. However, at 1 year follow-up there are very low rates of recurrence despite an absence of definitively clear margins. 6-16

The following audit is designed to analyse the process from selection for LLETZ to follow-up thereafter. Initially the association between positive CST, cytology, Biopsy and LLETZ and histopathology will be analysed. The proportion of patients with biopsy performed prior to proceeding to LLETZ in comparison to LLETZ alone will be analysed. Finally, the effectiveness of LLETZ as a treatment, percentage cured in addition to numbers of those requiring repeat LLETZ will be analysed. Incidental findings of cancer on histopathology, the frequency and management will also be investigated.

#### Method

Patients were selected who attended Fremantle Hospital for LLETZ between March 2019 and March2021. Totalling 153 female patients aged between 23-75. Two patients were excluding having never had a LLETZ performed, despite booking. Data regarding patients biopsy results, LLETZ histopathology, follow-up CST, and additional LLETZ procedures was collated from histopathological records, operation reports and outpatient letters available on the I. Clinical® system. Frequency analysis was then conducted on patients age, biopsy and LLETZ diagnosis using STATA 16®. Initial multinomial logistic regression and Chi Squared analysis were conducted with STATA 16® – however, this was replaced with permutation tests using R® completed on the following; between CST histopathology, cytology results and biopsy results; biopsy and LLETZ; LLETZ results, 12 month follow-up CST results, and repeat LLETZ at 24 months.

#### **Results**

Initial frequency analysis were conducted. CST HPV analysis, showed 35% if cases had either HPV 16 or HPV 18, a further 11% had HPV 16 and other, 2 % had HPV 18 and other. HPV other affected 50% in isolation, finally 5% of cases did not have HPV identified. Of the above cases, all had CST cytology performed, the results of which showed 47% of cases has LSIL, and 36% had HSIL, 1% were normal, 7 % had possible LSIL and 1 % and atypical cells of undetermined significance. Finally 1% of cases has possible AIS or confirmed AIS; 6% of cases had missing data. Again a total of 148 cases being analysed.

CST HPV	Freq.	Percent	Cum.
0	7	4.73	4.73
16/18	51	34.46	39.19
16/HPV other	12	8.11	47.30
18/HPV other	3	2.03	49.32
HPV other	75	50.68	100.00
Total	148	100.00	

CST Cytology	Freq.	Percent	Cum.
0	9	6.08	6.08
pLSIL/pAIS/AIS	2	1.35	7.43
HSIL	53	35.81	43.24
LSIL	69	46.62	89.86
atypical cells	2	1.35	91.22
normal	2	1.35	92.57
pLSIL	11	7.43	100.00
Total	148	100.00	

Frequency analysis of biopsy histology showed that 86% of biopsy results returned positive for HSIL whilst 4% were identified as LSIL. Negative biopsy results were identified in 8% of cases and 3% were identified at ACIS. LLETZ histology showed 67% with HSIL, 6 % with LSIL and 28% negative results.

Biopsy Histology	Freq.	Percent	Cum.
ACIS	4	3.03	3.03
HSIL	113	85.61	88.64
LSIL	5	3.79	92.42
negative	10	7.58	100.00
Total	132	100.00	

LLETZ histology	Freq.	Percent	Cum.
CIN 1/3	1	0.66	0.66
HSIL	99	65.56	66.23
LSIL	9	5.96	72.19
negative	42	27.81	100.00
Total	151	100.00	

Only a small proportion of patients were followed up with 46 having repeat CST at 12 months and 16 having repeat LLETZ at 24 months.

Modelling the association between CST and HPV with the permutation test gave a p value of 0.33 (X2= 16.8, DF = 15), thus there is no significant association between HPV infection and cytological change. Modelling the association between CST cytological findings and histopathological findings on biopsy, produced a p value p =2.2 x  $10^{-16}$  (X² =136.98, DF =15,), a significant association. Permutation calculations for Biopsy histopathology and LLETZ histopathology were not significant (X2 = 79.62, df = 117) with a p value = 0.37. Results from permutation test for association between LLETZ histopathology and CST cytology were not significant p= 0.27 (X2= 116.53, df = 108) Results of permutation test comparing LLETZ histopathology and follow-up CST at 12 months, p =0.27 (X2= 116.53, df = 108)

) gives a thus there is no significant association. Finally when permutation tests were calculated using LLETZ histopathology in association with follow-up LLETZ at 24months, no significant association was seen (p = 0.466,  $X^2 = 5.623$ , DF =6)

Followup CST results	CIN 1/3	LLETZ his HSIL	tology LSIL	negative	Total	Followup CST results	Repe 12 months		at 24 month not perfo		Total
16/18 HPV other negative	0 1 0	6 5 16	0 0 2	1 3 12	7 9 30	16/18 HPV other negative	1 0 0	0 0 4	0 3 7	1 0 0	2 3 11
Total	1	27	2	16	46	Total	1	4	10	1	16

Only two patients within the current study were excluded from LLETZ (procced to cone biopsy) based on biopsy findings, in both these instances that patients were identified to have of AIS or atypical cells of indeterminate significant on both CST and Biopsy results. A further two patients who had possible AIS on Cytology and Biopsy proceed to have LLETZ, only one of which had focal carcinoma in situ detected. Finally 2 patients had HSIL on cytology and biopsy histopathology, which were later identified as microinvasive carcinoma detected on LLETZ.

#### **DISCUSSION**

Analysis of the above results reinforces existing guidelines; which emphasis variability in screening tests and highlight the importance of LLETZ in patients of concern. Interestingly there were higher rates of positive biopsy results than positive LLETZ results. It follows that, no significant association exists between biopsy and LLETZ histopathological findings, or LLETZ and CST cytological findings.

Despite this, a significant associations exist between CST cytology and biopsy histopathology results. It was observed that of these whilst 95% of patients had HPV 16/18 or other detected on CST, only 84% had cytological findings indicative of LSIL or HSIL change. A further 8% did however have possible LSIL, and 2% had atypical cells of either undetermined significance, suspicious of malignancy. The significant association between CST cytology and biopsy histopathology but not LLETS histopathology is understandable given the frequency statistics of the latter, with only 6%

negative results for CST cytology, and 8% for biopsy histopathology. In contrast LLETZ histopathology reported at 28% negative rate.

This variability in result outcomes is consistent with findings reported in current literature. Studies have shown that biopsy historically both underestimates the severity of disease; but also, may misidentify regions of atypia and malignancy. Thus, current NICE guidelines specify that in instances where high grade disease is suspected by not proven, biopsy is not recommended. Listing "inter- and intra-observer variability" a key point of discrepancy and thus concern. Interestingly the merits of colposcopy directed biopsy in reducing unnecessary LLETZ have been reported by a handful of studies. However, the current cohort, in fact, reports higher rates of HSIL on biopsy than in LLETZ histopathology. Furthermore, regarding overreporting, current literature suggests that 7.9-25% of patients return with negative resections following positive biopsy. Current data reports 28% returned negative results, with only 8% of biopsies identified as negative.

The discrepancy between cytology and LLETZ histopathology, is reportedly common. With several studies identifying a non-significant association. This has been attributed overcall, both present in CST cytology and biopsy results. Throughout other cohorts rates of negative LLETZ are  $^{\sim}$  20%, then reported in the current study  $^{\sim}$  28%. It has been identified within other cohorts that those with LSIL on initial cytology were more likely to exhibit variation in LLETZ outcomes, as they are often negative. With 55% of cytology being either pLSIL or LSIL on initial CST, these findings are consistent and reflective of the overcall bias within other cohorts. Despite this known tendency in reporting, it is retained that patient with suspected high grade change should not be biopsied to determine severity of disease, but rather clinicians should procced directly to LLETZ.  $^{4,5}$ 

Only two patients within the current study were excluded from LLETZ based on biopsy findings, in both these instances that patients were identified to have of AIS or atypical cells of indeterminate significant on both CST and Biopsy results. A further two patients who had possible AIS on Cytology and Biopsy proceed to have LLETZ, only one of which had focal carcinoma in situ detected. Finally, two patients had HSIL detected of cytology, and biopsy who later had microinvasive carcinoma detected. Again, this is in keeping with current literature, where there is variable reporting on detection of cancer on biopsy results, leading the conclusion that in instances where high grade lesion is suspected, biopsy is not recommended to determine the necessity of LLETZ.

Regarding reoccurrence, there was no significant association between positive CST cytology repeated at 12 months, and previous LLETZ procedure. Furthermore, there was no significant association between repeat LLETZ at 24 months and previous LLETZ and CST at 12 months, however for the latter, on 12 patients could included. Whilst the permutation tests utilised have adequate power for this analysis, a more concerning feature is that a large proportion of women have not had CST follow-up arranged through current hospital systems and thus no results are available for analysis. However, it is noted that for these, no re-referral to gynaecological services had been made, suggesting either loss to follow-up or normal results. This is predicated on the assumption that there is adequate liaison between hospital clinics and GP practices. Of those who had documented 12 month CST results, 33% had HPV either 16/18 or other detected, with 65% being negative. Of those that had repeat LLETZ, one was performed at 6 months, one at 12 and four at 24 months. Of the four performed, all were negative. Given data collection from 2019- 2021, only a small proportion of patients have reached 24months post initial surgery at the time of data collection. Recurrence rates and residual lesions, appear in 2-6% of cases in the current literature. Within the current study rates of HPV recurrence at 34%, however this is difficult to interpret as only 30% of patients proceed to have repeat CST at 12 months. Again for repeat LLETZ at 24months, only 10% of cases could be included as the majority of patients within the study are yet to reach 24months post. Of the 16 able to be analysed 38% had repeat LLETZ. With only 2 have abnormal findings.

#### **Limitations**

As mentioned previously, one of the significant limitations of the current study is that only 46 patients of 153 had repeat CST, and 6 had repeat LLETZ at the time of data collection. Due to the nature of the data available, categorical, this limits possible statistical analysis. With multinomial logistic regression requiring large numbers of data to have stability, the analysis of LLETZ at 24 months had large confidence intervals, disproportion to data and thus is indicative of improper use of analysis.

#### Conclusion

There is a significant association between CST cytological findings and positive biopsy results. These findings are not consistent with LLETZ histopathology finings, and thus no significant association exists between Biopsy and LLETZ histopathology findings. This is likely due to high numbers of negative LLETZ. There was no significant association between LLETZ and repeat positive CST, or repeat LLETZ at 24 months, with low numbers of patients being referred back or retained in outpatient gynaecology clinic. A total of 5 patients had either AIS or microinvasive carcinoma in situ detected, three were referred directly to cone biopsy and only 2 proceeded to have LLETZ. All were determined abnormal prior to LLETZ being performed.

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## POST TREATMENT TEST OF CURE (TOC): DOES EXCISION DEPTH REALLY MATTER?

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#### **Background**

Large loop excision of the transformation zone (LLETZ) is one of the surgical techniques used to treat cervical intraepithelial neoplasia (CIN). National guidelines advise that, depending on the type of transformation zone, ≥7mm of tissue should be excised in up to 95% of cases1. This is based on histological evidence of the depth of crypt involvement in CIN 2,3, for which no further research has been done to identify whether the advised depth can be reduced.

#### **Aims**

This audit aims to identify whether there is a difference in test of cure (TOC) rates for patients who have had <7mm of cervical tissue excised during treatment, compared with those who have had ≥7mm excised.

#### Methods

Excisional treatment for CIN was performed on 231 patients seen at a district general hospital between 1st April 2020 and 31st March 2021. TOC results 6 months post treatment were collected from the NHAIS Open Exeter System. The presence of human papillomavirus (HPV) with or without a cytological abnormality constituted a failed TOC. 30 patients did not have a suitable TOC result (either lost to follow up, pregnancy, cervical smear appointment awaited or inadequate sample) and were excluded from the analysis. The statistical significance of the hypothesis was determined using the chi-squared test.Results

201 patients were included in the analysis, of which 41 patients (20.4%) had <7mm of cervical tissue excised during treatment, and 160 patients (79.6%) had  $\geq$ 7mm excised. In 34 patients (82.9%) with a negative TOC, the depth excision was <7mm. 136 patients (85%) had a negative TOC with  $\geq$ 7mm depth excision. This data demonstrates that the TOC result is not significantly related to the depth of tissue excised, X2 (1, N=201) = 0.108, p<0.05.

#### Conclusion

Removing <7mm of cervical tissue during excisional treatment of CIN does not increase the likelihood of a failed TOC when compared to removing ≥7mm and therefore it may be sufficient to remove less than what is currently advised.

#### Recommendations

Further analysis is required using a larger dataset to support our findings and to explore the effect of confounding factors.

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# RETROSPECTIVE STUDY: COLPOSCOPY REFERRALS FOLLOWING CHANGE FROM CYTOLOGY TO PRIMARY HPV SCREENING, NHS LOTHIAN

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\*\*NHS Lothian, Edinburgh, United Kingdom

#### **Introduction / Background**

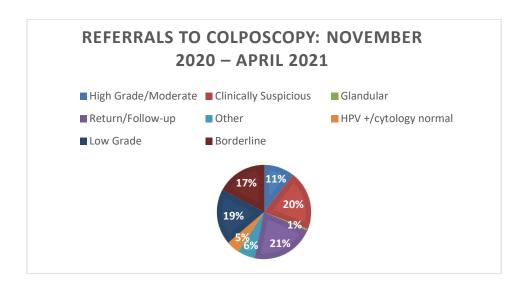
- 1. Primary HPV screening replaced primary cytology screening for Cervical Screening in Scotland March 2020.
- Alongside this patient pathway referrals to Colposcopy Clinics have changed. This includes all hr-HPV positive patients, all borderline squamous and all low grade squamous cytology.

This retrospective data analysis shows the initial impact on the Colposcopy Service with this change in referral pathway (specifically borderline and low grade squamous cytology).

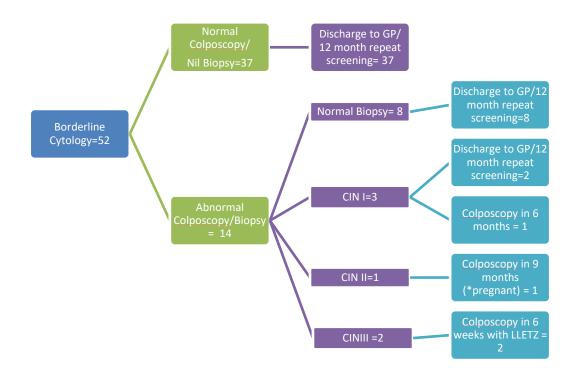
#### Aims / Methodology

- Data collection from November 2020 April 2021 (inclusive)
- Total patients (seen/attended colposcopy clinic): 309
- Data were collected for each patient, including: referral indication, colposcopic findings, biopsy and pathology, treatments and follow-up.

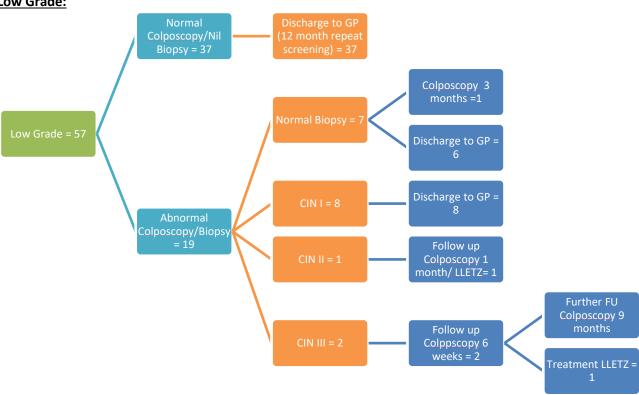
#### **Results:**



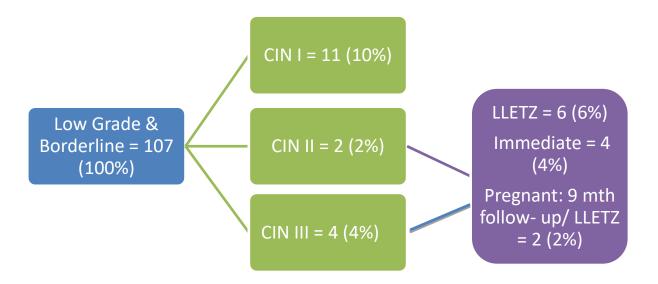
#### **Borderline Results:**



#### **Low Grade:**



#### Totals:



#### **Conclusions**:

- Since March 2020 referral system: all borderline and low grade cytology referred to colposcopy
  - Together accounted for 36% all referrals in this study
- 6% of all borderline and low grade cytology referred required intervention/LLETZ
- Incidental learning point/Area for improvement. Patients awaiting pathology result from cervical biopsy should be counselled regarding delay in treatment in context of pregnancy.

# SINGLE-INSTITUTION RETROSPECTIVE REVIEW OF HISTOPATHOLOGY OUTCOMES REFERRED WITH BORDERLINE CHANGE IN ENDOCERVICAL CELL SMEARS

Miss Racheal Johnson<sup>1</sup>, <u>Mr Hany Nagib<sup>1</sup></u>

<sup>1</sup>St James University Hospital, Leeds, United Kingdom

#### **Introduction / Background**

The updated colposcopy guidelines in 2020 upgraded borderline change in endocervical cells from a 6-week wait to a 2-week wait referral to colposcopy. Our institution hypotheses that the histopathology outcomes do yield a significant amount of high-grade CIN or invasion making a 'see and treat' policy inappropriate.

#### Aims / Methodology

Retrospective tertiary centre data analysis of of 20 patients with borderline change in endocervical cells referred from 01/04/2020 to 31/03/2021. 1 patient was excluded as she moved out of area after her smear.

Primary outcomes included histopathology of cervical biopsy or LLETZ. Secondary data collected included age, smoking status, contraception, and results of test of cure smear.

#### Results

Our patients were aged between 25-49 (median age 36 years old), 2 patients were documented as smokers and 8 patients were taking hormonal contraception. A total of 11 patients had directed biopsies, of which 3 went on to have a LLETZ. A total of 8 patients underwent a 'see and treat' LLETZ. Histopathology confirmed 10 patients (52.7%) had normal or HPV effect and 3 patients (15.7%) had CIN 1, accumulating a 68.4% rate of normal/HPV/CIN 1. In this cohort 6 patients were subjected to a LLETZ, demonstrating an overtreatment rate of 46%. A further 2 patients (10.5%) had CIN 2 (1 of which had CIN 3 on biopsy) and 2 patients (10.5%) had CGIN (1 low-grade CGIN). Our results identified 1 (5.3%) patient with invasive adenocarcinoma, she was 49 years old. These results demonstrate a low rate of significant high-grade pathology and high rate of overtreatment. It is therefore inappropriate to manage these patients as 'see and treat'. Patients of older age should be managed with caution.

# RETROSPECTIVE LOCAL AUDIT REVIEW OF PATIENTS WITH CONSERVATIVE MANAGEMENT OF CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN2)

<u>**Dr Tuan Kamaruddin<sup>1</sup>**</u>, Miss Anita Juliana<sup>1</sup>

<sup>1</sup>Nottingham University Hospital NHS Trust, Nottingham, United Kingdom

#### **Introduction/Background**

The cervical screening programme in the UK aims for early detection of pre-invasive lesion, also known as cervical intraepithelial neoplasia (CIN). CIN stages starts from low grade CIN1, a stage well documented to spontaneously regress, accelerated with lifestyle modifications and influenced by certain risk factors such as age. Whereas, CIN3 has strong possibility of cancer progression, hence benefit of treatment is more favoured. However, with CIN2, more evidence is supporting conservative management, as the rate of spontaneous regression (with close monitoring) can occur. Understandably, due to the risk of disease progression with CIN2, 24 months surveillance is recommended. Although most trust are treating CIN2 as CIN3, some trusts including Nottingham University Hospital NHS Trust are looking into reviewing if conservative management of CIN2 is a sizeable approach.

#### Aim/Methodology

To audit the standard of current local practice in Conservative Management of CIN2 at each stages of 6-monthly surveillance.

Retrospective data collection of new patients reviewed in colposcopy in the trust, following diagnosis of CIN2 between August 2019 to December 2020. Data are collected by the number of patients with disease progression, persistent disease or regression of disease, at each 6-monthly surveillance period, up to 24 months.

#### Results

138 eligible patients were identified and 40(29%) patients went for conservative management of CIN2 (surveillance) whilst 93(67%) patients went for loop treatment (LLETZ). At 6-months surveillance, 3 patients had disease regression. Meanwhile, 29(72.5%) patients had further surveillance and 3(7.5%) patients ended up with LLETZ. At 12-months, 6(15%) patients were discharged but up to 10(25%) patients continued surveillance. 3(7.5%) patients ended up with LLETZ and out of these, one had invasive carcinoma. At 18-months, 1(2.5%) patient ended up with LLETZ. Concurrently, 1(2.5%) patient was discharged, whilst 1(2.5%) patient continued surveillance. At 24-months, the only patient who was still followed up eventually had disease regression.

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## IMPROVEMENT OF PERFORMANCE INDICATORS FOR COLPOSCOPY OVER 3 YEARS

Mrs Kamakshi Karri<sup>1</sup>, Dr Ying Liaw, Dr Indira Buduru

#### Aim

To evaluate local colposcopy service against the national standards and demonstrate the performance via a dashboard.

#### Methodology

Data is obtained from the colposcopy database and the electronic patient record (Fusion) of hospital. Data is collected every quarterly each year and collated into an average for the year. Performance is viewed against the national standards via a dashboard incorporating the required standards.

#### **Results**

Performance is assessed by the lead colposcopist and shared with other colposcopists in the team on a quarterly basis, showing both the individual and team performance via a dashboard. The performance is also regularly discussed in the operational team meeting. A total of 7 performance indicators are used to demonstrate the performance of the local colposcopy service from April 2019 to Dec 2022 -(Table 1).

Table 1: Dashboard showing the results of performance indicators for colposcopy measured against national standards.

	Average	Average	Quarter 1	Quarter 2	Quarter 3	Target
E9 Treatment with local	2019/20 82.8%	2020/21 88%	2021/22 96%	2021/22 84%	2021/22 91%	≥85%
anaesthesia	02.070	0070	3070	0470	31/0	203/0
E12 Proportion of	70%	75%	76%	73%	88%	≥95%
treated women with						
depth >7mm						
E13 Proportion of	83.7%	83%	88%	77%	74%	≥80%
treated women						
removed as a single						
loop						
H3 Proportion of	95%	94%	98%	93%	96%	≥90%
adequate biopsy						
H7.1 Prediction of HG	64%	73%	97%	93%	90%	≥65%
histology						
H9 Proportion of	4 cases in	nil	nil	nil	nil	≥90%
women treated at first	all					
visit after referral for LG	quarters					
dyskaryosis with HGCIN	together					
or CGIN>						
E8 Treated women with	0%	0%	0%	0%		<5%
CIN or cancer within 12						
months						

#### **Conclusions**

<sup>&</sup>lt;sup>1</sup>Walsall Health Care NHS Trust, Walsall, United Kingdom

Our study has observed a significant improvement in the treatment with local anaesthesia. The proportion of treated women with depth >7mm has also improved remarkably but has yet to meet the standard. The standards for prediction of high-grade histology and proportion of adequate biopsy have been consistently achieved. The percentage of recurrence of CIN or cancer within 12 months has remained <5% throughout the last 3 years. The performance for proportion of treated women removed as a single loop has fallen below the target over the years, highlighting the area for improvement. None of the women have been treated as first visit after being referred for low grade dyskaryosis reducing the overtreatments with absence of high grade cervical intraepithelial neoplasia. Overall, the dashboard is very helpful as it provides an at-a-glance overview of the performance and allows an effective comparison of latest performance with previous quarters and years.

#### Recommendations

To maintain the standards that are being achieved and improve performance for areas that have yet to meet the required standards. To continue sharing the individual practices and team performance through dashboard which allows the colposcopists to reflect on individual practice and make improvement as a team.

## AN ANALYSIS OF THE TREATMENT OF WOMEN WITH A TYPE 3 TRANSFORMATION ZONE

<u>Miss Wioletta Kapadia</u><sup>1</sup>, Miss Linda Tan<sup>1</sup>, Mr Haytham Khalil<sup>1</sup>, Miss Jatinder Kaur<sup>1</sup> <sup>1</sup>London North West University Healthcare NHS Trust, London, United Kingdom

#### **Introduction / Background**

A type 3 transformation zone (TZ) in relation to colposcopy is defined as a where the upper limits of the transformation zone cannot be assessed.

This makes colposcopic examination in the presence of abnormal cervical cytology problematic. We wanted to assess the cases of women presenting to the colposcopy department with type 3 TZ who underwent treatment in the form of large loop excision of the transformation zone (LLETZ).

#### Aims / Methodology

We assessed if the depth of excision was adequate in our department. Further to this we wanted to assess the impact on test of cure at 6 months.

#### Method

We used data collected from our colposcopy system (compuscope) for the preceeding twelve months.

We collected demographic data and data relating to referral smear and treatment.

#### **Results**

Eleven cases were identified, these cases had high grade cytology and underwent LLETZ. The average age was 41 years, (range 27-57).

Six had a colposcopic opinion that was unsatisfactory, most of these cases were in women over 50 years of age.

Histology was confirmed as high grade disease in 73% of cases.

Recorded depth of excision specimen was the recommended 15mm in just one case. The average depth of excision in this group was just 8mm.

Test of cure cytology taken at six months was negative in 82% (n=9).

#### Conclusion

As expected with type 3 transformation zone the colposcopy is commonly unsatisfactory. The lack of high grade histology in a quarter of cases can be explained by the small depth of excision. Suggested improvements in the treatment of this small group would be to actively excise a greater depth of tissue, this would lead to higher rates of positive histology, higher rates of negative cytology at six months and a potential lower likelihood of recurrence.

## IMPACT OF ZEDSCAN ADJUNCT TECHNOLOGY IN COLPOSCOPY PRACTICE: SERVICE EVALUATION A YEAR AFTER EFFECTIVE IMPLEMENTATION

<u>Miss Uma Krishnamoorthy</u><sup>1</sup>, Dr Divya Jayaram<sup>1</sup>, Dr Mayurika Sinha<sup>1</sup>, SN Tammy Waddington<sup>1</sup>, SN Faye Pemmett<sup>1</sup>

<sup>1</sup>East Lancashire Hospitals NHS Trust, Blackburn, United Kingdom

#### **Introduction / Background**

Colposcopy is reliant on nonspecific visual indicators which are highly variable and subjective. Variation in performance for colposcopy is high with average sensitivity to distinguish between low and high grade CIN being around 55%. ZedScan offers an adjunct that helps exclude high grade disease, reduce biopsies and number of follow up visits. ZedScan was implemented fully in 2020 further to effective pilot in 2019 presented at BSCCP2021.

#### Aims / Methodology

To evaluate impact of ZedScan one year after full implementation on 4 key outcomes

- 1. Diagnosis/exclusion of high-grade disease at first visit
- 2. Impact on punch biopsy at first visit
- 3. Impact on follow up visits
- 4. Value added gains as a result of above

Retrospective evaluation over 6months(1/7/2021-31/12/2021)N=363. Full data set available for 313.

#### **Results**

Direct referral accounted for 254(81%) & Clinical indications in 59(19%).

73BNA23%,113Lowgrade36%, 61HRHPV+NegCytology20%, 7HighGrade2%

High-grade CIN at Colposcopy in46(15%) while ZedScan suggested high-grade in180(58%) and 150 had biopsies.

89/150 (59%) punch biopsies confirmed CIN.

41(27%)high-grade CIN. 30CIN2(20%),11CIN3 (7%) and 48CIN1(32%).

40%HPV(43),Inflammation(10).Normal in3(2%)& Inadequate in3(2%).

23/313(7.5%) overall had Nil high-grade disease on Colposcopy. 21(6.7%)of these had High-gradeCIN on ZedScan and histology.

#### Colposcopy without ZedScan would have missed 21high-grade CIN(6.7%)

ZedScan diagnosed 6CIN (10%) among 59clinical indications. (4CIN1,2CIN2/3) which would have been missed. 53/59(90%) were discharged after ZedScan+/- biopsy after 1<sup>st</sup>visit or 2<sup>nd</sup>after treatment.

73.5% overall discharged at first visit or +/- after treatment at second visit. MDT plans in 9.5%(30), follow up in 16.5%. 139 of 313(45%) discharged at first visit without a biopsy and a further 89(28.5%) after appropriate treatment of biopsy proven CIN due to adjunct enhancing colposcopist's confidence in excluding high-grade disease.

Use of ZedScan enhanced detection of high grade disease, reduced biopsy rates to 48% (up to 95% in past) and consistency with reduction in pressures on Histopathology and follow ups.

#### UPTAKE OF SCREENING BY INDIVIDUALS AFFECTED BY HIV

<u>Dr Kalpana Ragupathy</u><sup>1</sup>, Miss Shiv Ranjini Krishnan<sup>1</sup> <sup>1</sup>University Of Dundee, Dundee, United Kingdom

#### Introduction

UK-wide national cervical screening program recalls individuals every 5 years for a cervical smear test. However, the screening is more frequent in individuals who are HIV positive because of increased susceptibility to Cervical Intraepithelial Neoplasia (CIN). This cohort is therefore invited annually to partake in the screening program. An audit was conducted in 2021 to evaluate the compliance of these individuals.

#### <u>Aim</u>

To evaluate the compliance of HIV positive individuals to their annual cervical screening programme by reviewing their records over the last five years.

#### Method

We utilised the anonymised electronic medical records of HIV-positive participants (n=94) to assess the compliance of these individuals. We recorded information on the patient's HIV status, date, results and screening pathway.

#### Results

The ideal standard is having 100% of the participants being compliant to their annual cervical screening. However, the audit revealed only 79% (78.7%) of the participants having been in recent contact with the surveillance teams, with 21% (21.3%) of the cohort not been tested at all for over 2 years. Moreover, two groups on either ends of the age spectrum (20-29 and 63-65) were found to be less compliant than the rest of the cohort. Cervical cancer screening was clearly underutilised by a good percentage of the women in this study.

#### **Conclusion**

An exploration in to methods of identifying and encouraging defaulters to return to cervical cancer surveillance will be discussed and once the required intervention is in place, a reaudit will be conducted in 6 months' time to compare outcomes.

## DEPTH OF LLETZ- ARE WE SEEING THE SAME? A JOINT COLPOSCOPY AND HISTOPATHOLOGY AUDIT AT UNIVERSITY HOSPITALS OF LEICESTER

<u>Mrs Akshatha Kulkarni</u><sup>1</sup>, Mr Obehioye Enabor, Ms Catherine Moreman, Mrs Vishanthi Shesha <sup>1</sup>University Hospitals of Leicester, United Kingdom

#### **Introduction:**

LLETZ specimens excised with adequate depth is crucial for complete excision of cervical intraepithelial neoplasia (CIN) or cervical glandular intra-epithelial neoplasia (CGIN) and prevention of recurrence. Quantification in depth measurement is an integral part of colposcopy MDT discussions to reduce the number of repeat excisions in difficult clinical scenarios. By auditing the clinic depth of excision and comparing with the actual depth of excision as measured in the lab, we aim to improve the ability to acquire the desired depth of excision and the accuracy of interpreting the depth of excision.

#### Methodology

The aim of this audit was to identify any significant difference between LLETZ specimen depth in clinic and post formalin fixation. This was a prospective audit with the population being patients referred with abnormal cytology (moderate, severe, endo-cervical or glandular), CIN2 or persistent CIN1 on punch biopsy and diagnostic loop biopsy with CIN or CGIN on histology at University Hospitals of Leicester. Data was collected from colposcopy database and histopathology records over a 3 month period. LLETZ specimen depths measured at clinic and post formalin fixation in histopathology were recorded. Depths and slide measurements were in millimetres with the deepest margin from ostium being recorded.

#### **Results**

The mean LLETZ depth measurement in clinic was 11.517mm and the macroscopic measurement of post formalin fixation was 11.379mm. There was no significant difference between the two(p value 0.783). The above audit demonstrates that macroscopic measurement of depth correlates with the clinic depth. Thus selecting the appropriate loop and ensuring an adequate desired length ensures to not just treat the disease effectively but also minimize the potential risk of adverse obstetric morbidity. Additionally, recording the depth of specimen on the pathology request form has helped with improving the accuracy of the depth measurement by the lab team.

## AUDIT OF REFERRAL FOR SEVERE DYSKARYOSIS AND HOW EFFECTIVELY MANAGE THESE CASES IN COLPOSCOPY UNIT, LUTON AND DUNSTABLE HOSPITAL

<u>Dr Mya Kyar Phyu</u><sup>1</sup>, Ms Pushpakala Maharajan, Ms Claire Goodwin <sup>1</sup>Luton and Dunstable Hospital, Luton, United Kingdom

#### **Introduction / Background**

With the introduction of the NHS cervical screening program, the number of women dying from cervical cancer has halved and saves around 4500 lives in every year in England.

#### Aims / Methodology

This audit is to reduce the incidence of and mortality from cervical cancer progression from severe dyskaryosis and how it was effectively managed in the colposcopy unit at Luton and Dunstable hospital.

It is a retrospective study and all 43 cases with referral for severe dyskaryosis from 1<sup>st</sup> April, 2019 to 31<sup>st</sup> March, 2021 were analysed.

#### **Results**

Out of 43 patients, 36 patients (83.7%) chose treatment option with receiving complete excision in 28 patients. The histology report was as no CIN (5 patients), CIN1 (2 patients), CIN2 (7 patients), CIN3 (21 patients) and stage 1 B squamous cell carcinoma (1 patient).

From the treated patient group, 2 patients did not attend for test of cure, 28 patients (77.8%) had negative test of cure results, 6 patients (16.7%) had failed test of cure with CIN1 (1 patient) and CIN3 (5 patients). Among them, 4 patients were treated with 2<sup>nd</sup> loop excision, 2 patients with hysterectomy.

Among conservative management arm, 4 patients were treated later due to persistence or progression to CIN 3 whereas one has ongoing CIN 1 and is on regular follow up and two patients failed follow up.

CIN 3 is a direct precursor to cervical cancer and treatment is always recommended if confirmed on testing. Among our patients, we closely follow up for all patients and treated in time before it progressed to cancer. Overall, our colposcopy unit follows national guidance with good and efficient continuity of care in managing referral for severe dyskaryosis.

### COMPARING AND EXPLORING BARRIERS, ATTITUDES AND IMPACT OF COVID-19 PANDEMIC ON COLPOSCOPY SERVICES IN IRELAND AND UNITED KINGDOM

<u>Dr Nyan Chin Liew</u>, Dr Jun Ching Wong, Dr Consol Plans, Sheila O'Donnelle, Deborah English, Teresa Brown, Dr Mendinaro Imcha

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#### **Introduction/ Background**

Women may not attend colposcopy due to various reasons. Barriers and the women's attitude make them less likely to attend colposcopy and Covid-19 pandemic is seen as a new barrier in comparison to pre-existing barriers. Some avoid attending colposcopy due to fear of the virus.

#### Aims / Methodology

The aim to discern any patterns that could be addressed to reduce non-attendance rate during Covid-

19 pandemic by done by breaking down the barriers. Patients are given questionnaire consisting of 10 questions that were distributed in two centres, exploring the barriers, attitudes and impact of Covid-19 on colposcopy. The other aim is how to restart colposcopy safely post Covid-19 era as there is lack of comprehensive guidance on continuation of colposcopy in the midst of waxing and waning of infection. By adjusting to new strategies, management protocols and governance will restore patients' trusts in the new normal situation.

#### **Results**

Covid-19 pandemic has an unprecedented effect on healthcare and has put colposcopy to a complete

"stop" resulting in backlog of the waiting time for high-grade cases. It is too premature to know the true number of cases on delayed diagnosis of cervical cancer and long-term effect of women's mental

health. Virtual consultation can be used to keep the women engage in loop and be reassured during this heightened time of uncertainty. On-site vaccinations for partially or unvaccinated women attending colposcopy is seen as a potential for administering catch-up and scheduled vaccinations. This contribute to health care of an often disadvantaged group. Colposcopists must see opportunistic

vaccination as an important part of clinical duties. It is hope that this pandemic bring opportunities for development of new initiatives in delivering colposcopy services, patient flow and safety as it will be a disaster if mortality is increased as a result of delay in diagnosis of cervical cancer from pandemic.

### COLPOSCOPY OUTCOMES OF WOMEN WITH POSTCOITAL BLEEDING WITH NEGATIVE CYTOLOGY: THE VALUE OF POSTCOITAL BLEEDING CLINICS

<u>Miss Melis Altunel</u><sup>1</sup>, Dr Thida Oo<sup>1</sup>, Dr Mary George<sup>1</sup>
<sup>1</sup>University Hospital of North Tees, Stockton, United Kingdom

#### **Introduction / Background**

Post-coital bleeding is very common and causes anxiety due to concern of the possibility of high grade cervical intraepithelial neoplasia (CIN2/3) and cervical cancer as the underlying pathology. This prompts referral for colposcopy despite recent negative cytology. Post-coital bleeding clinics can be valuable in providing assessment for women with a history of post-coital bleeding and can reduce the burden on colposcopy and rapid access clinics.

#### Aims / Methodology

A retrospective study of all patients referred to North Tees Hospital post-coital bleeding clinics during a 12month period from January 2021 to December 2021 was conducted with the aim of determining the frequency of high-grade intraepithelial neoplasia and cervical cancer in this patient group.

Patients were identified through clinic database and data extracted from computer records. Subsequent cervical cytology and histology results were obtained through ICE system.

#### Results

A total of 204 patients were referred to our clinics during the study period with post-coital bleeding. The overall prevalence of cervical intraepithelial neoplasia was 15.6% and of high- grade cervical intraepithelial neoplasia was 0.98%. The cervical cancer rate was 0.49%.

141 out of 204 patients had negative cytology within 3 years of referral. Of these patients the incidence of CIN 1 was 14.1%. There were 2 patients with ECUS (1.42%). No high-grade abnormality or cervical cancer was detected in this patient group.

## AUDIT ON MANAGEMENT AND OUTCOME FOR PATIENTS REFERRED WITH CGIN BETWEEN JUNE 2018- JUNE 2020 AT EAST LANCASHIRE HOSPITAL TRUST

Mr Yeneit Liew<sup>1</sup>, Miss Mayurika Sinha<sup>1</sup>

<sup>1</sup>East Lancashire Hospital Trust, Manchester, United Kingdom

#### **Introduction / Background**

An audit on the management and outcome of patients referred to East Lancashire Hospital Trust directly with query cervical glandular intraepithelial neoplasia (CGIN) on smear between June 2018 and June 2020 was conducted.

#### Aims / Methodology

The data was collected retrospectively by reviewing patient notes and compuscope record. This cohort of patients were selected to assess the timing of their test of cure smear if indicated. The audit standards were based on NHS cervical screening programme guidance.

#### **Results**

There were 22 patients referred directly to our colposcopy service within this time frame. One patient was excluded from the audit as she did not attend the clinic appointment. Eighteen patients were below 50 years old and 3 patients were 50 and above. All patients who were less than 50 years old with type 1 transformation zone received treatment of excisional biopsy measuring  $\geq$  10mm (100%). Only 2 patients who are  $\geq$  50 year old had excisional biopsy and both of their biopsy were measured less than 20mm.

In term of histology findings, 52% (11/21) of them were high grade CGIN, 33% (7/21) were adenocarcinoma and 14% (3/21) of the biopsy did not show any CGIN.

18% (2/11) of the high grade CGIN patients had complete excision of disease at first attempt. 66% (6/9) of them required repeat excision to obtain negative margin. 2 patients opted for hysterectomy. Only 1 patient was managed conservatively with 10 years follow up smears for incomplete excision of CGIN.

10 patients were eligible for the 6months and 18months test of cure (TOC) pathway. 40% of them had both negative TOC smear and were discharged back to routine recall. 40% only had their 6month TOC smear. 20% of the patient missed their 6month TOC but had negative 18 month TOC smear.

#### PATIENT SATISFACTION ON COLPOSCOPY SERVICES: A MULTI-CENTRE AUDIT IN THE SOUTH EASTERN HEALTH AND SOCIAL CARE TRUST

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#### Objective

To assess the quality of information received by patients and their experiences of attending the Colposcopy Service in the South Eastern H&SC Trust.

#### **Methods**

48 consecutive patients attending colposcopy clinics were recruited over three weeks in January 2022. A self-devised survey was used; including data on demographics, questions regarding patients understanding of their cervical smear results, background knowledge regarding the role of HPV, and the quality of information received before clinic attendance. Patients' levels of anxiety and pain were determined by visual analogue scales.

#### **Results**

Total of 48 patients were audited. 62.5% (n=30) were review patients and 37.5 %(n=18) were new. 87.5 %( n=42) were aware of their smear result prior to clinic. 44% patients (n=21) were unaware of role of HPV virus. 90% patients (n=43) received colposcopy information leaflet before their clinic attendance. Within this group, 83% (n=40) were satisfied with the quality of leaflet information and 66.6% (n=32) felt that it had prepared them "very well" for the clinic.

One third of patients (33.3%, n=16) didn't respond to Colposcopy experience & Self-rating of level of satisfaction questionnaires. Of the remaining two thirds (n=32), 34.3% (n=11) had "moderate worry, physical agitation" prior to clinic and similar proportion of patients expressed "mild" (34.3%, n=11) and "moderate" (34.3%, n=11) pain during the procedure.

#### **Implications**

This audit highlighted the need for routine monitoring of service quality from the patients' perspective. Although patient satisfaction with the overall services provided in colposcopy clinic was generally at high level, the survey provided evidence of where specific service improvements were needed i.e., need to raise awareness about the role of HPV in cervical abnormalities. We acknowledge that the study involved a small sample size, but it has elaborated a significant aspect of women's health which can be further investigated by large scale quality improvement studies.

# CONSERVATIVE MANAGEMENT OF CERVICAL INTRAEPITHELIAL NEOPLASIA GRADE 2 (CIN2) IN WOMEN 30 YEARS OF AGE AND UNDER, RETROSPECTIVE AND PROSPECTIVE UPDATED COHORT STUDY IN TALLAGHT UNIVERSITY HOSPITAL

Dr Reem Magzoub<sup>1</sup>, Dr Gunther Von Bunau<sup>1</sup>

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#### **Background**

The management for CIN2 remains debatable as its clinical course is not well known. Active surveillance of CIN2, especially in women of reproductive age is feasible option and may be more acceptable, with favourable outcomes in term of significant regression and lower persistence rate for CIN2, as well as reproduction future.

#### **Aims**

To establish the safety of conservative management of CIN2, through assessing the rates of regression, persistence, and progression in the light of the new BSCCP guidelines (February 2020).

#### **Standards**

BSCCP guidelines (February 2020) on conservative management of CIN2

#### Method

- All eligible cases (110) for conservative management of CIN2 were retrieved from MediScan BSCCP Audit Report 2017.
- Inclusion criteria were adequate colposcopy examination, CIN2 involving ≤2 quarters of cervix, MDT review of histology, patient compliance and consent on regular 6 monthly follow up, patient have not completed her family and not immunocompromised, and patient understanding of the need to treat if no resolution within 24 months.
- SPSS was used for data analysis

#### **Results**

110 patients with mean age (SD) of 26.8 ± 1.7 yrs,

- Mean number of visits was 3.57±1.14.
- At 1st visit, colposcopy impression was normal or low grade in 72%, Conservative management offered to 83 patients (75.4%).
- Treatment was offered to 27 patients (24.6%) and their histology confirmed: 40.8% CIN1, 25.9% CIN2, 29.6% CIN3 and 3.7% 1B1SCC
- The total regression rate was 94.8%, 50% without treatment and 41.8% with treatment

#### **Conclusions**

Half of cases of CIN2 in the study cohort regress to negative cytology without treatment.

- Only 6% of the CIN2 cohort progress to CIN3 or persist within the study period.
- Active surveillance of CIN2 rather than immediate intervention is justified, in women of reproductive age (<30 years)

#### Recommendations

- There is significant time lag before cytology becomes negative, so early recourse to treatment based on cytology only should not be advised where cytology is satisfactory and reassuring.
- We recommend carrying out a re-audit in 24 months.

• A multicenter study investigating the conservative management of CIN2 in Ireland under the umbrella of the national cervical screening programme or BSCCP is recommended to identify clear patients' selection criteria and management strategies.

#### Re-audit

We recommend carrying out a re-audit in 24 months.

## CERVICAL SCREENING POST-HYSTERECTOMY- A RETROSPECTIVE REVIEW OF HPV AND CYTOLOGY TESTING ON VAGINAL VAULT SMEARS

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#### **Introduction / Background**

CervicalCheck, the National Cervical Screening Programme in Ireland transitioned from cytology-based screening to HPV-based screening in March 2020. High-grade cervical intraepithelial neoplasia, prior to or at the time of total hysterectomy, is a known risk factor for the development of secondary VAIN, with reported recurrence rates of 0.9–7.4%. The Cobas HPV test, used by CervicalCheck, is not indicated for use as a primary screening test on vaginal samples. We aimed to determine if vaginal HPV testing is useful to aid risk stratification post-hysterectomy as this evidence is not available.

#### Aims / Methodology

We conducted a retrospective audit of all vaginal samples co-tested with HPV and cytology at the Coombe Women and Infants University Hospital, over a 2-year period (Jan 2015-Dec 2017). Data was analysed to assess correlation between HPV result, cytology and histology follow-up where available.

#### **Results**

1,760 vaginal vault smears were reviewed at the CWIUH Laboratory over the two-year period. Of these, 1263 had cytology only, while 477 had both cytology and HPV test results available for analysis. Within this 477cases, there were 13 samples which were unsatisfactory for cytology analysis. There was moderate agreement between both tests (Cobas HPV test and cytology) of 81.9% (380/464) (Kappa 0.556). The highest discordance occurred in women with an HPV positive result and no abnormality on cytology (n=54), and women who had low grade cytology (ASCUS (n=10) LSIL (n=20)) and tested negative for HPV. Further follow-up cytology and histology data is being collated.

Following an internal validation exercise, including this audit, the CervicalCheck Clinical Advisory Group recommended primary HPV testing of vaginal vault samples in women post-hysterectomy. It is reassuring that no women were identified as having high grade lesions in the absence of HPV infection. Correlation with follow-up histology and cytology results will add to this dataset.

### MANAGING A SCREENING PROGRAMME IN A PANDEMIC: THE EXPERIENCE OF IRELAND'S CERVICAL SCREENING PROGRAMME

<u>Dr Caroline Mason Mohan</u><sup>1</sup>, Ms Grainne Gleeson<sup>2</sup>, Ms Fiona Ness<sup>1</sup>, Dr Noirin Russell<sup>2</sup>

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#### **Introduction / Background**

In 2018 CervicalCheck, the national cervical screening programme for Ireland, was affected by a crisis due to the non-disclosure of audit results to women who had experienced an interval cervical cancer. In the aftermath of that crisis, the National Screening Service and CervicalCheck have been working to improve trust and confidence in screening. Early implementation of a HPV primary screening programme on March 30<sup>th</sup> 2020 - the biggest change to CervicalCheck since it began in 2008 - was part of that trust building. In early March, with the work of switching from a cytology-based programme to an HPV one well advanced, the COVID-19 pandemic struck Ireland.

#### Aims / Methodology

The aim of this paper is to describe the impact of the COVID-19 pandemic on running a cervical screening programme and the decision-making required.

#### Results

It will outline the factors considered and the challenges encountered in the:

- 1. Pause on the day of the HPV programme launch
- 1. Managed restart
- 2. Subsequent challenges (rebound increase in samples; cyber attack)
- 3. Learning

It will discuss the complexity of the decision-making for the implementation and the management of the programme through the first wave of COVID-19; the risk-based framework that was adopted to implement the HPV programme safely and manage the pause and restart of the programme; the outcomes for the programme and the participants; and the learning from this experience. Two years on the HPV programme is in place and all participants due a screen between March 2020 and Dec 2021 have been sent an invitation. In 2021 the programme screened an additional 100,000 participants and has caught up on the initial backlog.

#### THE SUSPICIOUS CERVIX CLINIC- WHO AND WHAT ARE WE SEEING?

<u>**Dr Ciara McArdle<sup>1</sup>**</u>, Dr Myra Fitzpatrick

<sup>1</sup>National Maternity Hospital, Dublin 2, Ireland

#### **Introduction / Background**

Since the 2018 CervicalCheck controversy in Ireland, referrals to colposcopy for the clinically suspicious cervix have increased. Combined with the change to primary HPV screening, there has been growing demand for colposcopy services and longer wait times. The National Women and Infants Health Programme (NWIHP) and CervicalCheck have implemented new guidelines to refer patients with 'suspicious cervix', inter-menstrual bleeding (IMB) or post-coital bleeding (PCB) to a gynaecology service, rather than colposcopy. The National Maternity Hospital (NMH) set-up a cervical review clinic (CRC) in March 2021, led by a trained colposcopist, which accepted these referrals.

#### Aims / Methodology

To conduct a retrospective cohort study of women referred to the CRC from March-August 2021. Data collection was performed by electronic chart review.

#### Results

Over 6 months, 157 women were seen. Indications for referral were; suspicious cervix (62%), IMB (13.1%), PCB (15%) and polyp (9.9%). Mean waiting time was 32.3 days (SD:14.9). Mean age was 38.83 years (SD: 8.7). 90.4%(n=142) of women had an up-to date cervical screening test. In those with results, 83.47% (n= 101) were HPV negative and 14% (n= 17) were HPV positive. In those with HPV positive smears, cytology was normal in 64.7% (n=11) and abnormal in 35.3% (n=6). 25% (n=39) had no findings on examination. Those with findings, were almost all benign findings with cervical ectropion most identified (38%). 87.7% (n=136) were discharged to their GP. 9% (n=14) were referred for colposcopy. CIN was confirmed in four women and invasive cervical carcinoma in two women.

#### Conclusion

Women with a clinically suspicious cervix should be assessed in a rapid access clinic. A gynaecology clinic rather than colposcopy is an appropriate setting to review these women, as most have no pathology. Increased investment in services should be made to establish this resource nationally to ensure best management.

## AN AUDIT OF LLETZ PROCEDURES IN PATIENTS WHO ATTENDED THE COLPOSCOPY CLINIC WITH NORMAL CYTOLOGY BUT HIGH RISK HPV OVER A 3 YEAR PERIOD IN A TERTIARY REFERRAL CENTRE

Dr Bernadette Mcelhinney<sup>1</sup>, <u>Dr Hilary Goldsmith<sup>1</sup></u>, Dr Jennifer Pontre<sup>1</sup> \*\*Xemh, Perth, Perth, Australia

#### **Introduction / Background**

In the 1980's, researchers discovered that virtually all cancers were caused by the human papilloma virus (HPV). Although HPV acquisition is a risk factor for the development of cervical cancer, most HPV infections are cleared by cell mediated immunity. High grade squamous intraepithelial lesions (HSIL) occur at a rate of 8.5 per 1000 cervical cytology tests per year. This means that 21000 Australian women receive a report of HSIL each year. Twelve per cent of HSIL will progress into cancer, if left untreated.

Following the discovery of the relationship between persistent HPV infection and cervical cancer, the first HPV vaccination was developed in Australia and approved for use in 2006. With the knowledge that HPV acquisition was necessary for the development of cervical cancer, Australia launched its renewed National Cervical Screening Programme (NCSP) in 2017. The test screens primarily for highrisk HPV with partial genotyping and reflex liquid-based cytology (LBC.). Patients with HPV 16 or 18 on CST, irrespective of LBC, are referred to colposcopy. Patients with HPV 'other' are referred if LBC reports possible HSIL/HSIL or after three normal/LSIL LBCs with persistent HPV 'other'. If a high-grade lesion is suspected and confirmed histologically, excisional treatment is recommended.

#### Aims / Methodology

The study was designed to determine the number of patients referred to the colposcopy service with HR HPV and normal LBC, that had high grade cervical dyspasia detected by colposcopy. Other aspects of the colposcopy service were examined including the number of LLETZ specimens over a 36-month period that returned negative histology, the demographics of the patients undergoing LLETZ's, the time interval between diagnosis and treatment.

This study was a retrospective, observational chart review of all patients who underwent a LLETZ procedure at KEMH over a 36-month period (January 2018-December 2020). Data were summarised using mean, interquartile range (IQR) and range (R) for continuous characteristics and frequency distributions for historical data. Comparisons between women with confirmed HSIL vs. negative biopsy results were made using the Mann-Whitney test for continuous outcomes and the Chi-square test for categorical outcomes. SPSS version 27.0 statistical software was used for data analysis.

#### Results

In total, 477 LLETZ's were performed over the time period. Of those, 35 (7.3%) were in patients who attended colposcopy with normal cytology. If these patients had undergone conventional 'pap smear' screening, they would have not been screened again for another two years, at least. Two patients already had an invasive cervical cancer. Cervical cancer is most frequently diagnosed between the ages of 35 and 44 years. A quarter of Australian women giving birth are 35 years or over, hence the need for early diagnosis and conservative surgery to preserve reproductive potential.

Three LLETZ's were in patients who were negative for high-risk HPV; two patients had invasive disease. Two thirds of patients (68.9%) had a HSIL report on the referral CST. The average age of patients undergoing a LLETZ was 35 years (31-45; 24-70).

It is reassuring that the renewed NCSP is detecting 'at risk' patients and who would have been previously missed. Fortunately, these patients are being identified earlier and receiving timely treatment.

## AN ANALYSIS OF THE FLOW OF PATIENTS WITH AN ABNORMAL SCREENING SMEAR THROUGH A COLPOSCOPY SERVICE FROM REFERRAL TO TEST OF CLEARANCE

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<sup>1</sup>South Eastern Health and Social Care Trust, Dundonald, United Kingdom

#### **Introduction / Background**

The Colposcopy Service within the South Eastern Health and Social care Trust has encountered an increase in demand in referrals since the introduction of HPV testing for low grade smears with a concurrent reduction in the supply of clinics. This has impacted service performance in relation to waiting times.

#### Aims / Methodology

A flow analysis of patients with abnormal screening smears through the Colposcopy Service in the South Eastern Trust from first referral, during January to February 2020, through to TOC was conducted to provide baseline data to inform quality improvement and service redesign.

#### **Results**

98 referrals were analysed, the majority were (72) borderline or low grade, 10 moderate, 11 severe and 2 severe? invasion. The 72 low grade smears were subdivided into low grade with HPV other (61) and Low grade with HPV 16 and/or 18 (11). 3 patients DNA'd, all had low grade HPV other smears.

The level of high grade and CIN 3 disease increased with severity of smear as anticipated: 27.8% HG and 9.3% CIN3 in low grade HPV other. 36.3% HG and 27.35%CIN3 in low grade HPV 16 and/or 18. 50% HG and 20% CIN3 in moderate. 82% HG and 73% CIN 3 in severe. Of the two patients with query invasion, one had a squamous carcinoma and one CIN3 with SMILE.

Rates of disease clearance at TOC were lowest in low grade HPV other smears (41%) were over half of patients had conservative management over a longer time frame, and highest in those with severe smears (82%), who were treated with a LLETZ.

Waiting time targets where met in 100% of severe ?invasion patients, 82% of severe smears, 40 % of moderate smears, 8.2% of low grade HPV 16 and/or 18 and 3% of Low grade HPV other.

### THE IMPACT OF COVID-19 ON THE CERVICAL SCREENING PROGRAMME AND COLPOSCOPY SERVICES IN NORTHERN IRELAND

Dr Josh McMullan<sup>1</sup>, Dr Laura Rainey<sup>2</sup>, Dr David Morgan, <u>Dr Lorraine Johnston</u>

<sup>1</sup>Northern Health and Social Care Trust, United Kingdom, <sup>2</sup>Northern Ireland Medical and Dental Training Agency (NIMDTA), Belfast, United Kingdom

#### **Introduction / Background**

Screening programmes are an important aspect of illness prevention. In April 2020, in response to the COVID-19 pandemic, the Northern Irish (NI) government took the decision to pause all routine cervical screening invitations. Colposcopy services continued but capacity was reduced due to infection control measures. This has raised concerns of a potential delay in cervical cancer diagnosis and treatment.

A negative screening result is only indicative of a low risk of developing disease and relies on follow up screening to prevent progression of disease. This is in line with the World Health Organisation (WHO) and their strategy to eliminate cervical cancer as a public health problem. There is concern that this will be compromised and cause a backlog of patients when services are reintroduced.

#### Aims / Methodology

Data was collected from the largest geographical health and social care trust within NI. All patients who were invited to colposcopy following an abnormal cervical screening result from September to November 2019 were compared to those patients presenting from September to November 2020 during the peak of COVID-19. Data collected included demographics, presenting smear, time to report, method of biopsy and biopsy result.

#### **Results**

158 patients were included in 2019 and 87 in 2020 (45% reduction). There was a mean increase of 5 days to report the presenting smear in 2020. The most common presenting smear result was a borderline result for both years however more patients presented with severe dyskaryosis during 2020 (7% increase). A smaller time interval was seen in 2020 for colposcopy review and a mean reduction of 36 days for reporting the cervical biopsy result was seen during 2020 but no significant change in biopsy results were seen. There was a slight increase in cervical cancer during 2020 (2.3% vs 0.63%).

## URGENT - IS ACTION REQUIRED? : RETROSPECTIVE ANALYSIS OF URGENT PRIMARY CARE REFERRAL OUTCOMES DURING COVID19 PANDEMIC

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<sup>1</sup>St John's Hospital, Livingston, United Kingdom

#### **Introduction / Background**

Urgent suspected cancer and patients with clinically suspicious symptoms have target appointment times of 2 and 4 weeks respectively as per NHS Scotland Referral Guidelines. There has been growing pressure on clinic capacity due to HR-HPV primary screening along with rising clinical indication referrals. This has impacted the ability of units to meet expected appointment timeframes throughout the Covid19 pandemic, with waiting times up to double the set standard.

#### Aims / Methodology

To determine the outcomes of patients referred to NHS Lothian colposcopy services from primary care as urgent 'suspicious cervix' or urgent suspected cancer.

Retrospective analysis between 01 May and 31 July 2021 inclusive. Clinic lists were screened and relevant patient notes were read to confirm referral reason and time-frame. Colposcopy notes from these attendances were examined to determine findings and outcomes by clinicians. If tissue biopsies were obtained, pathology results were sought to determine results.

#### Results

185 patients offered appointments between ten gynaecological consultants and one consultant nurse colposcopist over a three-month period:

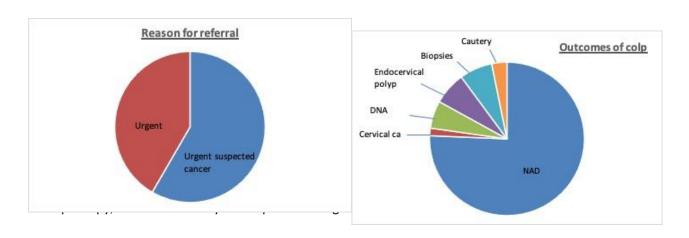
1. Suspected cancer: 108 (58%)

Urgent suspicious: 77 (42%)

•

#### **Outcomes:**

- 143/185 (77%) colposcopies normal and patients were discharged
- 3 cases were confirmed as cervical cancer (referred as suspected cancer)
- 11 patients did not attend
- 13 cervical biopsies performed
  - 1 biopsy was reported as CIN1
  - 12 reported no abnormality
- 13: benign endocervical polyps all confirmed by histology



education events. This will be an ongoing collaboration to reduce the pressures on an already stretched service recovering from the impact of the Covid19 pandemic.

### COMPLIANCE BETWEEN COLPOSCOPIC IMPRESSION OF HIGH GRADE DISEASE AND HISTOLOGICALLY PROVEN CIN

#### Dr Sumaira Arain<sup>1</sup>

<sup>1</sup>The Princess Alexandra Hospital NHS Trust, Harlow, United Kingdom

#### **Auditable standard**

Compliance between Colposcopic impression of High-grade disease and Histologically proven CIN

#### **Period of Audit**

4 months

#### **Data Collection**

Retrospective randomised collection of data using custom made proforma from patient's Hospital paper notes and Colposcopy software Infoflex and Open Exeter at a district general hospital with a busy colposcopy unit.

#### Observation

There was >65% compliance between Colposcopic impression of high-grade disease and histologically proven CIN. The outcome of the audit was dependent upon clinician's experience. The compliance was more in case of experienced clinicians.

#### Conclusion

To increase standardised compliance, the use of other imaging modalities like Zed Scan and Dysis would be useful.

#### TRENDS IN THE MANAGEMENT OF CIN2+ IN IRELAND

Dr Therese Mooney<sup>1</sup>, <u>**Dr John Price<sup>1</sup>**</u>, Mr Micheal Rourke<sup>1</sup>, Dr Noirin E Russell<sup>1</sup> *National Screening Service, Dublin, Ireland* 

#### Introduction/ Background

CervicalCheck, the national cervical screening programme commenced in September 2008 and offers free cervical screening to 1.3 million eligible people living in Ireland. The aim of the programme is to reduce the number of people who develop cervical cancer by providing population-based screening. Each year, approximately 16,000 to 19,000 patients are referred to colposcopy, of whom 12,000 receiving treatment for high grade CIN.

#### Aims/ Methods

This study reviews trends in the management of CIN2+ from 2008 – 2019. Data was retrieved from annual data extracts from the contracted colposcopy units.

#### **Results**

Excisional treatments have fallen over time from 89% of total treatments in 2008-2010 to 70% in 2018/2019 (p<0.001). Increased rates of ablative treatments are noted. During the same time period, the number of diagnostic biopsies being performed has risen from 55,000 in 2010 to 85,000 in 2019. Of note however is the unchanging rate of patients managed by cone biopsy, trachelectomy and hysterectomy which remains unchanged at approximately 1.0 - 1.5 %.

#### Discussion

Initially 'see and treat' was the preferred management however, as the programme has matured and attitudes to the management of CIN have become more conservative a trend toward 'select and treat' and an increased use of ablative techniques has become evident.

Despite an increasing sophistication in diagnosis and management there remains a core number of women who present diagnostic and management problems and require more invasive forms of treatment to obtain an optimal outcome. This leads to a potential problem as to who manages this group of patients as many colposcopists no longer perform major gynaecological procedures. It is important that streamlined care pathways are in place for this cohort of women.

### DOWNSTREAM EFFECTS OF THE CERVICALCHECK CRISIS ON WOMEN ACCESSING THE PROGRAMME

<u>Dr Therese Mooney</u><sup>1</sup>, Ms Lorraine Fahy<sup>1</sup>, Dr Caroline Mason Mohan<sup>1</sup>, Ms Grainne Gleeson<sup>1</sup>, Prof. Patricia Fitzpatrick<sup>1,2</sup>, Dr Noirin E Russell<sup>1</sup>

<sup>1</sup>National Screening Service, Dublin, Ireland, <sup>2</sup>School of Public Health, Physiotherapy and Population Science, University College Dublin, Ireland

#### **Introduction / Background**

In April 2018, the CervicalCheck clinical audit non-disclosure issue – where women who had been diagnosed with cancer were not informed or were badly informed about their clinical audit results – became an issue of national importance. In response to public concern, the Minister for Health offered a free, out-of-programme-cycle smear test to all women within the screening age-range. This created a surge in demand, with over 100,000 extra women attending screening.

#### Aims / Methodology

The aim of this study is to document the impact of this decision on the programme and the women. Metrics were derived from the CervicalCheck screening register, time periods; average of five years pre-crisis (01 Sept 2012-31 Aug 2017); year of the crisis 01 Sept 2017-31 Aug 2018 and post-crisis 01 Sept 2018-31 Aug 2019.

#### **Results**

Despite high levels of tests, programme coverage fell from 80.2% to 79.7% to 79.2%, indicating that the majority availing of the offer had attended previously. The unprecedented demand on laboratories impacted the number of women receiving results within four weeks, falling from 73% pre-crisis to <50% during and <7% post-crisis. Many women waited over six months for results, creating anxiety and resulting in a documented loss of trust and confidence in the programme. There was a significant increase in referrals to colposcopy - referral rate for abnormal smear test increased from 4.5% to 4.6% and 5.7% and clinical indications increased from 1.9% to 2.7% to 4.2%. This resulted in waiting times for colposcopy falling outside programme standards. Pre-crisis, >96% of women were offered a colposcopy appointment within eight weeks of referral; this remained at 96% during the crisis but fell to <60% post-crisis.

#### Conclusion

This study highlights the impact a change in eligibility criteria had on the cervical screening experience of women due to the absence of planning concurrent resource and downstream capacity increases.

## LLETH DEPTH - DOES THIS AFFECT THE PRESENCE OF THE TRANSFORMATION ZONE OR A PATIENT'S NEGATIVE 'TEST OF CURE' RATE

Mrs Catherine Muggeridge<sup>1</sup>, Mr David Gareth Beynon

The NHS Cervical Screening: Programme and Colposcopy management guidance stipulates that Colposcopy units, within the United Kingdom, should ensure that at least 95% of women treated in Colposcopy, have a depth of excision >7mm. According to the 'Annual Individual Colposcopy data 2020/21', Frimley Park achieve this in only 68% of cases. This audit looks to establish if this practice affects the rate of transformation zone present in the biopsy and the number of patients who are negative for HPV at 'test of cure'.

<sup>&</sup>lt;sup>1</sup>Frimley Health NHS Trust, United Kingdom

### AUDIT ON COLPOSCOPY SERVICES IN 2019 AT THE NOBLE'S HOSPITAL

#### Ms Nang Ohn<sup>1</sup>

<sup>1</sup>Noble's Hospital, Douglas, Isle of Man

#### **Objective**

To audit the abnormal cervical smears with borderline, low grade and high grade changes
To improve upon waiting time to the first clinic appointment, waiting time for the biopsy results and
the histological failure rates after treatment of high grade abnormal smears.

#### Method

Retrospective data collection of all the new patients with borderline, low grade and high grade abnormal cervical smears from the period 01/01/2019 to 31/12/2019. Data such as results of initial smear, date of referral to the colposcopy clinic, date of first clinic appointment, histology results and the date that patients were informed by lette, test of cure smear results after treatment of high grade dyskaryosis were collected.

#### **Standards**

According to the NHS cervical screening programme and colposcopy management guidance 2020, 99% of patients with borderline and low grade abnormal smears should be seen within 2 weeks of referral, 100% of patients should know the histology results within 8 weeks of biopsy taking and histological failure rate after treatment of high grade cervical intraepithelial neoplasia (CIN) at 6 months follow up should be <5%.

#### **Findings**

Among total 148 patients, 16% were borderline, 57% were low grade and 27% were high grade abnormal smears.

97% of borderline and high grade abnormal smears were seen within 6 weeks (standard not met). All the patients knew the histology results within 8 week time and the standard was met. Histological failure rate after treatment of high grade CIN was 1.75% (standard met).

#### **Conclusion**

Most data met the standard but the area needed to be improved was waiting time for the first clinic appointment of the patients with high grade dyskaryosis. It was recommended to run extra colposcopy clinics whenever necessary.

## ARE WE CAPTURING THEIR VACCINATION STATUS? AUDIT OF THE RECORDING OF HPV VACCINATION STATUS IN WOMEN AGED 25 TO 28 YEARS OLD ATTENDING OUR REGIONAL COLPOSCOPY SERVICES

#### Dr Catherine O'Regan, Dr Rosemary Harkin

<sup>1</sup>North East Regional Colposcopy Unit, Louth County Hospital. Co Louth, Rep of Ireland. HSE North East. RCSI Group, Dundalk, Ireland

#### **Introduction / Background**

In 2010 the HSE introduced the HPV vaccination schedule in secondary schools across Ireland and offered the HPV-4 to girls in 1st and 2nd year. A year later, in 2011, and for a total of three years, a catch-up vaccination program was introduced for girls exiting the school system in 6th year. These girls are currently aged between 25 and 28 years of age, and as such have entered the Irish National Cervical Check screening program.

HPV testing is now the mainstay of screening, however, as levels of neoplasia fall, the optimal time to start screening in the vaccinated population of Ireland still remains to be answered. Knowing the vaccination trends in our population is important for future research and a vital part of information we should be recording as it will inform future decisions on screening, management and treatment.

#### Aims / Methodology

To audit and assess the practice of recording the HPV vaccination status of the women attending our colposcopy services during their first visit in our electronic colposcopy chart, Mediscan. We reviewed the electronic charts of 39 women born between 1993 and 1996 who attended our colposcopy unit over a period of 2 months.

#### **Results and Conclusion**

Of the 39 women audited, only 8 (20 %) had their vaccination status recorded. Of these, 62% (n=5) were vaccinated. From this data we conclude that we are not recording the vaccination status of women who may have been offered the HPV vaccination. Making this a mandatory data box to fill would ensure better data collection.

We have also observed that many women do not recall if they were vaccinated or whether they completed both doses. Having access to this data on a national database would be helpful if compliant with GDPR.

# REVIEW OF THE HPV STATUS, REFERRAL CYTOLOGY, COLPOSCOPY FINDINGS, BIOPSY RESULTS, OUTCOMES AND SMOKING STATUS OF WOMEN, BORN BETWEEN 1993 AND 1996, WHO WOULD HAVE BEEN OFFERED THE HPV-4 VACCINE BETWEEN 2011 AND 2013

#### Dr Catherine O'Regan, Dr Rosemary Harkin

<sup>1</sup> North East Regional Colposcopy Unit, Louth County Hospital. Co Louth, Rep of Ireland. HSE North East. RCSI Group, Drogheda, Ireland

#### **Introduction / Background**

In 2011 a catch-up vaccination program for girls exiting the school system in the Republic of Ireland was introduced. These girls are currently aged between 25 and 28 years of age, and have entered the Irish National Cervical Check screening program. It is important to monitor population trends in vaccine uptake and how this translates into clinical findings.

#### Aims / Methodology

To review the referral cytology, colposcopy findings, biopsy results and outcomes of women that would have been offered the HPV-4 vaccine during the catch-up program between 2011 and 2013. The electronic charts of 41 women born between 1993 and 1996 who attended our colposcopy unit over 2 months were reviewed.

#### **Results and Conclusion**

38 charts were included for analysis, 3 charts were excluded as the referral was on clinical grounds. Of these, 97% (37) were HPV positive. The majority of cytology referrals were ASCUS (42%) and LSIL (26%). High grade and ASCUS-H accounted for 10% (n=4) of cases. 23% of all referrals were current smokers. Colposcopic impression was normal/viral 18% (n=7), low grade 63% (n=24), and high grade 21% (n=8) of cases . 33 punch biopsies were carried out. CIN 1 accounted for 54% (n=18) of cases, 77% (n=14) of these were booked for repeat HPV in 12 months, the remainder (n=4) had undergone repeat colposcopy (n=2) or were waiting to be seen (n=2). The biopsy results confirmed CIN 2 in 30% (n=10) of cases, and of these 60% (n=6) had cold coagulation, 10% (n=1) had a LLETZ, and 30% (n=3) were awaiting review. There was one CIN3 result, which had originally been referred with Severe High Grade cytology and was a smoker, and this person underwent LLETZ treatment. As more data on vaccination trends becomes available, it is essential to monitor clinical outcomes in

As more data on vaccination trends becomes available, it is essential to monitor clinical outcomes in this population.

#### **COLPOSCOPY DEFAULTERS AND THEIR OUTCOMES**

<u>**Dr Ruby Brown**</u>, Dr Sangeetha Palaparthy, Dr Uzma Minhas <sup>1</sup>NHS Lanarkshire, Wishaw, United Kingdom

#### Aim

To look at the defaulter rate in Colposcopy clinics in NHS Lanarkshire and outcomes in these cases.

#### Methodology

Colposcopy defaulters in NHS Lanarkshire from 18<sup>th</sup> August 2021 to 18<sup>th</sup> January 2022 obtained from Intranet Trakcare.

#### **Results**

Total patients booked for the colposcopy clinics in NHS Lanarkshire during this time was 1007 including both new referrals and follow ups. 154 patients were non – attenders, giving a defaulter rate of 15.3%.

65 (42.2%) were follow up cases of which 52 were follow ups for cervical pathologies and 13 were for other pathology. 40 patients were not included in the study as they were booked in the colposcopy clinic for other reasons.

The remaining 114 defaulters were distributed according to their geography. 37 patients (32.45%) were defaulters at Monklands, 74 (64.91%) at Wishaw and 43 (37.71%) were at Hairmyres. Of the 62 new referrals with cervical smear changes, patients were distributed according to the initial smear. 30 (46.87%) had Low grade / Borderline smear, 23 (37.09%) had high grade and 9 (14.51%) had unsatisfactory smears.

Distribution by age was looked at and 43 patients (69.35%) were <40 years, 13 (20.96%) were between 40 and 50 years and 6 (9.67%) were >50 years.

The final outcomes were looked at and we could not get any sample from 42 patients (67.74%) due to repeated non attendance. 6 (9.67%) were negative, HPV changes were seen in 2 patients (3.22%), CIN 1 in 2 cases (3.22%), CIN 2 in 2 cases (3.22%) and CIN 3 in 5 cases (8.1%). Smear result is still awaited in 2 cases (3.22%). There was one case of Squamous cell carcinoma of the cervix that was identified (Garde 2 Stage 3C1) who was seen after two non attendances.

### HAS COVID-19 AFFECTED THE QUALITY OF COLPOSCOPY PERFORMANCE IN ENGLAND?

Ms Philippa Pearmain¹, Mr Philip Sweeney¹

<sup>1</sup>NHS England, Birmingham, United Kingdom

#### **Introduction / Background**

The COVID-19 pandemic has been an exceptional challenge for everyone involved in the provision of health services. Throughout the pandemic, screening programmes have been prioritised and have continued to operate, albeit with fluctuating activity during 2020/21.

#### Aims / Methodology

The Screening Quality Assurance Service collates data on a routine annual basis from all colposcopy clinics to assess the quality of colposcopy in England. This analysis compares the performance of colposcopy clinics in 2020/21 with the previous year.

#### **Results**

The data show that for 2020/21 versus 2019/20:

- 1. new referrals reduced by 7.8% (15,002 referrals)
- 2.2% more women were referred to colposcopy through screening while the proportion of clinically indicated referrals fell by 3.3%
- the standard of offering at least 93% of women with a high grade screening result an appointment for colposcopy within 2 weeks was achieved (93.2%)
- waiting times for women referred with negative or low grade screening results increased significantly (72.5% versus 93.0% of clinics met the standard)
- 4% more women in 2020/21 received their biopsy results within 4 weeks of the sample being taken (standard >90%)

#### Conclusion

The majority of colposcopy services have coped exceptionally well with the challenges of the COVID-19 pandemic and all the staff involved should be congratulated for their commitment to keeping services operational and quality high during this challenging time. Whilst the data need to be interpreted cautiously, they show that the women most at risk of significant cervical disease were prioritised and managed promptly and that disease detection increased, reducing the potential for cervical cancer to develop. However, women referred with less severe screening results have waited significantly longer for their appointments. Patient attendance was better than expected and clinic cancellations were not widespread.

#### MANAGEMENT OF CIN2 IN AN ERA OF CHOICE

<u>Dr Sarah Petch</u><sup>1</sup>, Dr Elzhara Ibrahim<sup>1</sup>, Dr Susan Clinton<sup>1</sup>, Professor Graine Flannelly<sup>1</sup>

\*\*National Maternity Hospital, Dublin, Ireland

#### **Introduction / Background**

The management of women with CIN2 remains controversial, especially for younger women. Colposcopists must balance the risk of cancer with the risk of overtreatment. There is a risk of preterm birth in future pregnancy with multiple excisional treatments. Latest guidance defines criteria for conservative management, including that CIN 2 should occupy no more than 2 quadrants. Surveillance involves increased follow up appointments for up to two years with a risk of default.

#### Aims / Methodology

The aim of this audit was to review the management of CIN 2 in a service which sees 2500 new referrals a year. Our service offers excision and thermal ablation for suitable candidates. The selection should be based on BSCCP guidance.

This audit involved a retrospective chart review of women with proven CIN 2 on biopsy from October 2019 to June 2021. Data collected included the referral smear, previous smear history, smoking and HPV vaccinations status, colposcopy impression and management as well as test of cure smear results.

#### **Results**

Analysis is complete for 236 of 485 women. Abnormalities were documented in two quadrants or less in 138 women. Treatment was offered to 110 women with cold coagulation (56) or LLETZ (54). Twenty-five women had conservative management and 3 defaulted follow-up.

Changes were documented in three quadrants or more in 98 women, 36 had cold coagulation and 37 had a LLETZ. Twenty-one women in this group were offered conservative management. Four women defaulted follow up.

#### Discussion

This is an apparent preference for treatment rather than conservative management for women with CIN2 in our service. The fact that some women were offered conservative management with more than 2 quadrants involved highlights the need to ensure awareness of the BSCCP guidance in our unit.

### CHANGING ROLE OF A COLPOSCOPIST - POST TREATMENT RECALL FACILITATOR

Ms Fiona Cummings, Ms Jenna Paton<sup>1</sup>, **Dr Kalpana Ragupathy**<sup>1</sup>

\*\*NHS Tayside, Dundee, United Kingdom

#### **Introduction / Background**

Cervical Cytology screening was changed to Primary HPV screening in Scotland in September 2020. Recall pathways were also changed during this time and the primary responsibility for recall pathways delegated to colposcopists (previously, the recall was advised by cytologists). Whilst getting used to HPV screening, colposcopists were also deciding on selecting the most appropriate discharge pathway from colposcopy (6 in total: CIN conservative management, Cytology surveillance – high grade and low grade, Test of Cure, Primary HPV screening – routine and nonroutine) as well as the timing of the recall.

#### Aims / Methodology

The aim of this quality improvement project was to evaluate NHS Tayside colposcopy teams' accuracy in selecting the discharge pathway following a colposcopy appointment Colposcopy database was queried to retrieve details of women discharged between 1st September 2020 and 30th November 2020 (n=56, 3 months duration). Further details of the colposcopy visit was collected such as indication for colposcopy visit, colposcopy examination findings and procedure carried out in the clinic. The discharge pathways were then checked by two clinicians. Subsequent to the first study, recommendations were made, and another study done to check compliance.

#### Results

In the first study, 2/56 were on the incorrect pathway. Both were on the default pathway (primary HPV – non routine) and not updated following treatment in the hospital. We presented the findings in the loco-regional colposcopy meeting and went through the pathways again, highlighting that patients who are discharged following smears in the hospital will also need pathways changed on the SCCRS (Scottish cytology call recall service). The second study was done subsequently on a random selection of 30 women who were discharged from the colposcopy service. Again, there were two patients on the incorrect pathway. However, there was only one on the incorrect pathway due to clinician's error. The other patient was on the incorrect pathway due to the default settings when SCCRS was updated to be in line with HPV screening in 2020.

#### Conclusion

With introduction of primary HPV screening, role of a colposcopist has changed from being a facilitator of recall pathway to the primary decision maker. Our studies show that we are still in the learning phase and recall pathways have to be audited in a regular fashion until there is 100% compliance. Few interventions to help with the compliance include regular updates via locoregional meetings, deciding on pathways with a buddy and case-based discussions.

### 5 YEAR REVIEW OF THE MANAGEMENT OF CIN 2 AT WREXHAM MAELOR HOSPITAL WALES

<u>Dr Autanza Badcock-Scruton</u><sup>1</sup>, Dr Autanza Badcock-Scruton<sup>1</sup>

\*Betsi Cadwaladr University Health Board, Wrexham Mealor Hospital, Wales

#### **Background**

Treatment for CIN2 is usually excision with high success rates. In a high proportion of women with CIN2 the changes regress, therefore an option is to monitor and not treat immediately. A benefit of conservative treatment of CIN compared to LLEZT is retention of fertility, as LLEZT is associated with increased risk of pre-term labour and rupture of membranes. It is widely accepted that smoking status is a risk factor for the development of CIN.

#### **Material and methods**

A retrospective audit using data extracted from CANISC database. 286 patients diagnosed with CIN2 over 5 years between January 2015 to December 2019 at Wrexham Maelor Hospital were identified. Looked at 3 treatment types: cold coagulation, LLEZT and no treatment. Analysis was carried out on referral cytology, colposcopy opinion, smoking status, age distribution, use of progesterone based contraceptives and follow up cytology. Treatment outcomes were analysed and compared looking at HPV status and/or cytology at 6 month and 12 month if still positive cytology and HPV. Cytology was graded as high grade, low grade or borderline.

#### Results

286 patients with CIN2 were audited. Of these 135 had LLETZ, 86 cold coagulation, and 65 no treatment. Cure rate at 6 month follow up was 86% for LLEZT, 89.5% for cold coagulation and 49.2% for no treatment.

#### **Discussion**

Smoking and age did not seem to have a bearing persistent of disease in all treatment groups. Suggest selective use of conservative treatment with set treatment criteria.

### AN INTERVENTION TO REDUCE WOMEN REFERRED TO COLPOSCOPY IN IRELAND FOR REASON OF CLINICAL INDICATION

Dr Therese Mooney<sup>1</sup>, Professor Patricia Fitzpatrick<sup>1</sup>, Dr John Price<sup>1</sup>, Ms Grainne Gleeson<sup>1</sup>, Dr Mary Short<sup>1</sup>, **Dr Noirin Russell<sup>1</sup>** 

<sup>1</sup>Cervicalcheck, Cork, Ireland

#### **Introduction / Background**

CervicalCheck, the Irish National Cervical Screening Programme which screens 300,000 women annually, transitioned from cytology-based to HPV screening in March 2020. On average, 4.5% of screened women are referred for colposcopy. Sample takers can also refer directly to colposcopy for clinical reasons, including: clinically suspicious cervix; contact bleeding; post-coital bleeding; polyps. Prior to CervicalCheck issues in 2018, clinical referrals comprised 32% of the total. Following high-profile court cases regarding non-disclosure of audit results, women were offered an out of programme smear. Labs were overwhelmed, contributing to clinical referrals rising to 45% due to increased anxiety among women and GPs. This affected colposcopy clinics' ability to see women in a timely manner. As HPV screening is known to result in an initial doubling of referrals to colposcopy, a plan was needed to ensure sufficient colposcopy capacity for screened women. Establishment of an alternative care-path for symptomatic women was a key priority.

#### Aims / Methodology

The intervention included engaging with primary care smeartakers and gynaecology services via the National Women and Infants Health Programme (NWIHP). The programme organised Information webinars for smeartakers detailing the differences between screening and diagnostic tests while also posting this information on the website for women. A joint statement was released with NWIHP advising that holistic assessment of women with symptoms should include gynaecological assessment rather than colposcopy.

#### **Results**

From 1<sup>st</sup> January to 31<sup>st</sup> March 2021 clinical referrals made up 30% of total colposcopy referrals. This decreased to 20% from April to July and to 17% for the remainder of 2021.

This study demonstrates that providing information to empower women and education interventions for staff was successful in reducing numbers of women referred to colposcopy for clinical reasons. This allowed the programme to maximise colposcopy capacity for HPV screening and ensuring symptomatic women get full gynaecological assessment and optimal care.

### ASSESSMENT OF 'CLINICALLY SUSPICIOUS CERVIX' REFERRALS: AN AUDIT AND PROPOSED MANAGEMENT PATHWAY FOR COLPOSCOPY REVIEW IN A DGH

Dr Liam Beamer<sup>1</sup>, Ms Rosamund Sawyer<sup>2</sup>, Ms Deborah Doyle<sup>2</sup>

<sup>1</sup>Halth Education North West (Mersey), Liverpool, United Kingdom, <sup>2</sup>Mid-Cheshire Hospitals NHS Trust, Leighton Hospital, United Kingdom

#### **Introduction / Background**

Non-NHSCSP screening programme referrals constitute 27-32% of referrals to colposcopy clinics, of these referrals the 'clinically suspicious cervix' makes up a sizable proportion. The possible causes of atypical cervical appearance are plethora and range from variation on normal to advanced neoplasia and everything in between. For this reason, expert review in a timely manner is essential to ensure appropriate cancer pathway referrals but also reassurance or treatment of benign conditions in those that require.

#### Aims / Methodology

A retrospective audit of all colposcopy attendees with referrals for 'clinically suspicious cervix'. For each patient identified we reviewed the relevant primary care referral forms, case files and electronic colposcopy database Compuscope entries. We audited against locally established best practice guidance.

#### Results

- 1. 35 referrals to colposcopy with a 'clinically suspicious cervix' during audit period.
- 32 were 2 week wait referrals for suspected cancer, one urgent 4 week referral and 2 routine referrals from GP.
- 3 referrals via GOPD whilst 32 were streamed directly to Colposcopy.
- Time from referral to colposcopy was a median of 8 days. Only 4 referrals took longer than 14 days to be seen in colposcopy.
- Average age 39.7 years. Range 19-64. 3 patients were outside NHSCSP screening population.
- 27 women had a concomitant complaint whilst 8 were asymptomatic findings at routine procedures. The mean duration of symptoms was 4 months.
- Colposcopy was normal in 23, benign pathology in 4, LSIL in 4, HSIL in 2 patients.
- Investigations: histology performed in 9, cytology in 3.
- Histological Pathology: benign pathology in 7 patients, CIN in 1, Invasive disease in 1.
- 19 patients required only reassurance and a total of 28 were discharged on their first attendance at colposcopy.

A 'Clinically Suspicious Cervix' assessment algorithm for use in the outpatient and colposcopy clinics was produced to streamline management.

#### **AUDIT OF CERVICAL CANCER**

<u>Mr David Semple</u><sup>1</sup>, Dr Emma Formoy<sup>1</sup>, Dr Emily Knight<sup>1</sup>, Dr Liam Beamer<sup>1</sup>, Sister Jane Brookes<sup>1</sup>, Dr Jackie Elder<sup>1</sup>

#### **Introduction / Background**

The ultimate aim of the NHSCSP is to prevent cervical cancer and colposcopy is one component of the screening programme. Referrals to colposcopy come usually either as direct laboratory referrals or as clinical referrals. Approximately 800 colposcopy referrals are received annually at COCH.

#### Aims / Methodology

The electronic records of patients diagnosed with invasive cervical cancer were audited. These were identified via a local database of patients who were submitted to the national NHSCSP audit.

#### **Results**

Twenty two patients had a new diagnosis of cervical cancer between 1/1/2020 and 1/10/2021 with an age range of 27 - 80.

Thirteen patients were referred with smear abnormalities; five with severe dyskaryosis, five with a glandular smear, one with a borderline endocervical smear and two with cancer smears. The other nine patients were clinical referrals.

Fifteen patients had a squamous cell carcinoma while seven patients had an adenocarcinoma

Staging	Number
1a1	4
1a2	2
1b1	2
1b2	3
3c1	5
3c2	1
4a	3
4b	2

Twelve patients had either no or incomplete screening history. Three patients had been ceased from recall aged 62–65 but went onto develop cervical cancer.

All patients were discussed at local gynaecology-oncology MDT or central SMDT.

All patients were included in the national cervical cancer audit

Treatment	Number
High grade smear + colposcopy follow up	3
Knife Cone +/- Nodes	2
Simple hysterectomy	1

<sup>&</sup>lt;sup>1</sup>The Countess of Chester Hospital NHS Trust, Chester, United Kingdom

Radical hysterectomy	5
Clinical Oncology referral	9
Supportive / Palliative Care	2

It is imperative that the NHSCSP continues to focus on improving strategies to increase screening uptake in order to reduce the numbers of women diagnosed with cervical cancer who have either never been screened or missed screening.

As women live longer longer should screening continue beyond 65 as three patients (14%) in our audit were diagnosed with cervical cancer within 10 years of being ceased from recall?

# CONSERVATIVE MANAGEMENT OF CIN2 – DO OUTCOMES MATCH INTENTIONS? A RETROSPECTIVE AUDIT OF COMPLIANCE WITH PROTOCOLS AND REVIEW OF OUTCOMES AT A DISTRICT GENERAL HOSPITAL

Dr Liam Beamer<sup>1</sup>, Dr Emily Knight<sup>1</sup>, Dr Emma Formoy<sup>1</sup>, Sr Jane Brookes<sup>2</sup>, <u>Mr David Semple<sup>2</sup></u>

<sup>1</sup>HENW (Mersey), Liverpool, United Kingdom, <sup>2</sup>Countess of Chester Hospital NHS Foundation Trust, Chester, United Kingdom

#### Introduction:

High-Grade Squamous Intraepithelial Lesions (HSIL) encompass Cervical Intraepithelial Neoplasia 2 and 3 (CIN2/3). However, these two histological diagnoses reflect conditions with significantly different rates of regression and progression. The recognition of the more indolent progression and greater rate of regression with CIN2 has led to conservative management guidelines being adopted. These frequently include strict exclusion/inclusion criteria and regimented follow up protocols to ensure disease progression is not missed. The benefits of conservative management include reduced procedural and obstetric morbidity. Conservative management of CIN2 was introduced locally in 2018. We audited current compliance with local protocols and determined final treatment outcomes.

#### Results:

- 1. 58 patients with CIN2 managed conservatively over audit period.
- >95% compliance: requirements for prior MDT discussion, <35 years age criteria, nonsmoking status and exclusion of immunesuppression.
- <95% compliance: 2 site punch biopsy for diagnosis, small volume disease and 6 monthly follow up.</p>
- Outcomes: 40% proceeded to LLETZ, 40% regression to normal cytology, 20% remain under follow up.
- LLETZ: 37.5% of loops positive for CIN3, 50% positive for CIN2 and 12.5% positive for CIN1.
- Average 4.3 colposcopy clinic appointments per patient (excluding DNA appts).

#### **Conclusions:**

Compliance with guidance is sub-optimal, some short comings likely result from the impacts of COVID-19. Changes required include more robust 6 monthly follow ups and improved awareness of the need for multiple focal biopsies in patients potentially suitable for conservative management. Our results would suggest local rates of progression to CIN3 are in keeping with those quoted in the literature. Of those proceeding to treatment 87.5% had HSIL lesions suggesting no significant over treatment. However, we acknowledge 40% of patients proceeding to excision may represent a significant obstetric morbidity in the future and we wonder if destructive treatment of HSIL lesions may represent an alternative method for management.

### MANAGEMENT OF HIGH GRADE VIN AT THE COUNTESS OF CHESTER HOSPITAL

<u>Mr David Semple</u><sup>1</sup>, Dr Emily Knight<sup>1</sup>, Dr Liam Beamer<sup>1</sup>, Dr Emma Formoy<sup>1</sup>, Sister Jane Brookes<sup>1</sup>, Dr Jackie Elder<sup>1</sup>

#### **Introduction / Background**

The RCOG guidelines on vulval conditions (2011) and BGCS guidance on vulval cancers (2020) give recommendations on how high grade VIN2/3 should be managed but there are few auditable standards.

#### Aims / Methodology

A retrospective review of patients managed with high grade VIN, along with review of the most recent guidelines prompted us to set out our own standards. We have audited our compliance with them -

- All women with VIN3 should be offered wide local excision (96%)
- All women should be educated on vulval skin care and prescribed an emollient plus a soap substitute (43%)
- Topical steroids should be prescribed to manage symptoms and reduce risk of progression (80%)
- Vulvoscopy follow up should be 4 monthly for the first 1 year, 6 monthly for 2 years, then annually for a minimum of 5 years. If recurrence or new lesions occur, vulvoscopy frequency should be increased until the disease is stable. In those with recurrence or progression to vulval carcinoma, annual review should continue (66%)
- Patients with a history of multifocal disease are at increased risk of recurrence. Follow up should include vulvoscopy and colposcopy of the lower genital tract including the cervix (37%)
- Multifocal lesions should be considered for Aldara treatment (100%)

#### Results

40% went on to have further biopsies showing recurrence during their period of surveillance, of these, 8% progressed to vulval carcinoma. These rates are in keeping with the literature, though the type of VIN as well as margin status at initial excision is likely to cause this to vary.

Clearly we do not meet our own standards. However we acknowledge that many of these cases were diagnosed and managed prior to the recent 2020 BGCS guidelines. This audit provides areas for education and improvement in future practice.

<sup>&</sup>lt;sup>1</sup>The Countess of Chester Hospital NHS Trust, United Kingdom

## RETROSPECTIVE AUDIT ON OUTCOME OF CONSERVATIVELY MANAGED CIN2 IN OXFORD FROM 2009 UNTIL 2019

Miss Maria Isabella Sereni<sup>1</sup>, Ms Geraldine Spain<sup>1</sup>

<sup>1</sup>Oxford University Hospitals Foundation Trust, United Kingdom

#### **Introduction / Background**

CIN2 has been shown to regress spontaneously in a high percentage of patients (65%), with a low progression rate to CIN3 (13%). To investigate the lack of a systematic surveillance process for patients enrolled in conservative management for CIN2 in our Trust, an audit was performed.

#### Aims / Methodology

A retrospective audit investigating the outcome of all the women who underwent conservative management for biopsy-proven CIN2 between 2009-2019 at Oxford University Hospital Foundation Trust, obtained by review of paper and electronic patient records.

#### **Results**

A total of 197 women underwent conservative management between 2009-2019 in Oxford, with full data available for a total of 175 patients, aged 20-50. 41 out the 175 CIN2 patients were lost to follow up (23%).

The proven rate of regression was 117 of 134 (87%) patients who attended for follow-up. Amongst the 17 women who did not spontaneously regress, to date none has developed a cervical cancer. 9 were treated for persistent high-grade disease. 3 were pregnant at the time of diagnosis and remained on follow-up. 4 have stable disease on follow up. 1 has died from metastatic Pancreatic cancer during follow up.

#### Discussion

This audit demonstrated a very high rate of spontaneous regression of biopsy-proven CIN2 (83%) in our Trust in the decade 2009-2019. However, it also showed a concerning rate of patients lost to follow up (23%). Despite this being very likely related to the high population turnover in Oxford, with most of the lost-to-follow up patients having moved out of area, this data triggered a review of our conservative management guidelines.

Following this audit, a new system has been developed in Colposcopy to ensure a more robust follow up system, including keeping an up-to-date registry of all patients on conservative management for high grade lesions, which is periodically reviewed.

#### **COLPOSCOPY MDT AND OUTCOMES AUDIT**

#### Dr Nidhi Shandil Singh<sup>1</sup>

<sup>1</sup>Milton Keynes University Hospital, United Kingdom

#### **Introduction / Background**

- 1. Recommendation from SQAS visit- March 2020
- All cases as indicated in the NHSCSP guidelines need discussion at MDT
- Measurement of outcomes from the MDT
- NHSCSP guidelines used as standard to select cases for addition to the MDT

#### Aims / Methodology

- To ascertain that all cases that should have been discussed were discussed at the monthly colposcopy MDTs
- To ascertain that all recommendations made at the MDT were actioned appropriately and in a timely manner
- All women attending colposcopy clinic between April 2020- September 2020 were included
- Retrospective data collected using infoflex and Cyres
- All colposcopy MDTs audited from April 2020 to September 2020 to ascertain whether recommended action was carried out

#### **Results**

- MKUH runs monthly colposcopy MDTs
- Total number seen in colposcopy- 596 (218 +378, Q1+Q2)
- Total number referred from colposcopy to MDT- 59
- Total number discussed at MDT- 67
- Request for addition to MDT from cytology/histology- 8
- Recommendations for all 82 patients on the MDT from April –October 2020 were actioned appropriately
- Selection of MDT patients was in accordance with the NHSCSP guidance
- Patient were added to the MDT by colposcopy, histology and cytology as recommended by the NHSCSP
- Local MKUH MDT SOP, which mirrors the national guidance was also followed
- Failsafes were added to reduce the risk of missing cases from MDT
- Additional category- borderline endocervical abnormality now added to infoflex
- All borderline endocervical abnormalities are now added to the MDT at referral by the colposcopy administrator
- A flow chart for escalation of endocervical abnormalities has been developed
- All MDT recommendations were actioned with appointments booked as recommended by the MDT.
- To simplify data collection, an extra column- 'actions' has been added to our monthly colposcopy MDT templates since February 2020.
- The preceding month's MDT actions are discussed at the subsequent MDT meeting to
  ensure that recommendation has been actioned with the action date noted on the MDT
  proforma.
- Rolling re-audit every 6 months

#### **COLPOSCOPY FAILSAFE AND DNA AUDIT**

#### Dr Nidhi Shandil Singh<sup>1</sup>

<sup>1</sup>Milton Keynes University Hospital, United Kingdom

#### **Introduction / Background**

- 1. Recommendation following SQAS visit in March 2020
- Quality assurance to ensure that no women referred to colposcopy slip through the system
- Review reasons for repeated nonattendance in colposcopy clinics

#### Aims / Methodology

- To audit the failsafe process for the colposcopy service at MKUH
- To specifically look at patients who have not attended and measures put in please to follow this cohort of women
- Retrospective analysis between June2020- November 2020
- Infoflex any Cyres used to gather data
- · Excel data sheet (live document) to record and follow up DNAs used to inform results
- All patients were telephoned after their DNA to ascertain the reason and repeat appointments booked in colposcopy according to their convenience

#### Results

DNA breakdown by month (2020)

June- 22

July-15

August-12

September-14

October-11

Total colposcopy referrals from July to September 2020-378

DNA rates:

News- 5.36% (15/280)

Follow ups- 16.03% (38/237)

- Colposcopy DNA rate for new referrals- 5.36% (national target <10%)</li>
- Colposcopy DNA rate for follow-ups- 16.03% (national target <15%)</li>
- All DNAs were looked at individually
- Prospective rolling audit is maintained for all DNAs from June 2020
- Actions are taken in accordance with the SQAS COVID-19 recommendations
- All patients who DNA are accounted for
- Patient are telephoned after each non-attendance to ascertain the reason and rebook an appointment according to their convenience.
- A letter is written to the GP for every patient who DNAs
- Continue prospective rolling audit and analyse after every 3 months.
- Present and disseminate this at the quarterly colposcopy operational meetings
- Continue with phone calls to patients who DNA as this has been seen to promote attendance

## AUDIT ON TYPE OF ANALGESIA USED IN LLETZ/ PROPORTION OF DAY CASE LLETZ

#### Dr Nidhi Shandil Singh<sup>1</sup>

<sup>1</sup>Milton Keynes University Hospital, United Kingdom

#### **Introduction / Background**

- 1. The aim of NSH Cervical Screening Programme (NHSCSP) is to reduce the incidence and mortality from cervical cancer
- Since the introduction of NHSCSP, it has helped half the number of cervical cancer cases
- Colposcopy clinics play an essential role of NHSCSP
- Colposcopy should be organized as a quality assured service and data needed to meet the minimum dataset of British Society for Colposcopy and Cervical Pathology (BSCCP)
- One of the standards is proportion of women managed as outpatient with local analgesia
- Effective outpatient management in appropriately selected cases can reduce the number of hospital admission and is more cost effective

#### Aims / Methodology

- To evaluate the number of patients who had LLETZ under GA (day case)
- To evaluate the reason of referral for GA LLETZ
- To evaluate the proportion of outpatient procedure under LA
- Retrospective review of all LLETZ procedures performed between 1.4.2020 and 31.3.2021 in colposcopy clinic of Milton Keynes University hospital
- Data was collected from the hospital electronic data base system (Infoflex) and CYRES
- Data was recorded into Microsoft excel for analysis

#### **Results**

- Total 143 patients had LLETZ (2020-2021)
- 126 patients had outpatient procedure and 17 had day case procedure
- 88% were LA LLETZ in the colposcopy cinics
- 12% GA LLETZ as day cases in theatre
- Of the GA LLETZ- 65% were patient choice and 35% clinicians' recommendations
- Total 235 patients had LLETZ in the preceding year year (2019-2020)
- 200 (85%) patients had outpatient procedure and 35 (15%) had day case procedure
- The overall data from our colposcopy unit has met the national standard
- The most common reason for referral was patient anxiety and patient choice
- Where individual colposcopists have not met criteria- individual practice audit has been performed
- Two colposcopists do not perform GA procedures due to lack of accessibility to a theatre list
- Perform a repeat audit as a part of the annual QA requirement for 2021-2022

## AUDIT OF 'SEE & TREAT' CLINIC IN COLPOSCOPY UNIT OF A TEACHING HOSPITAL IN LONDON

Ms Jyoti Singh<sup>1</sup>, MS Samar Shoeir<sup>1</sup>, Ms. Maha Alkatib<sup>1</sup>

<sup>1</sup>Croydon University Hospital, London, United Kingdom

#### **Background**

An audit done in 2020, increased number of high grade referrals – not all referrals could be accommodated in time, and FDS targets were not being achieved.

Of the referrals, 69% turned out to be more than or equal to CIN 2.

Therefore, a 'see & treat 'clinic was started in April 2021

#### Aim

- 1. To comply with FDS criteria (28 days from referral to diagnosis)
- 1. To meet the national standard, (the histological finding to match the colposcopic and the referral smear findings in at least 90% of the cases)
- 2. To save time and resources

#### Standard

The proportion of individuals treated at the first visit who have evidence of CIN2, CIN3, or CGIN on histology, must be ≥90%.

#### Methods

- Retrospective data collected from hospital records, from the start of the clinic (mid-April 2021) to July 2021, for 50 patients.
- -All women with high grade moderate ( > 40 yrs) and severe smears ( any age) , or CGIN were triaged into the 'see and treat clinic.

#### Results

**95** % of the patients treated had colposcopy finding which corresponded to histological diagnosis (2 patients, > 45 yrs, for diagnostic LLETZ, excluded)

In the normal pathway, time taken from referral to treatment was **3 to 6 weeks** average – 31 days) In the 'see & treat pathway, this interval was 0 -13 days (6.7 days average)
Therefore waiting time cut down 4-5 times

#### Conclusion

See and treat clinic in our unit is a good initiative

- national standard of adopting 'see & treat' clinic met
- Significantly improved patient compliance. (only 2% DNA in see and treat clinic, compared to the 12.4% otherwise).
- Significantly reduced time from referral to treatment (from 31days to 6.7 days)
- 2<sup>nd</sup> appointment for the same patient not needed can now be given to other patients

#### **CONSERVATIVE MANAGEMENT OF CIN 2**

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#### **Objectives**

Cervical dysplasia commonly occurs in women of reproductive age. Treatment with a large loop excision of the transformation zone (LLETZ) is associated with mid-trimester loss and pre-term delivery. Average maternal age of first delivery in the UK was 28 years in 2016 now in 2019 is 30 years. Evidence suggests CIN 2 in women over 25 regresses in 40 to 74% within 2 years, less know in older women.

#### **Methods**

A retrospective study of 120 patients seen in 2019 who attended colposcopy and had a biopsy showing CIN 2. These patients should have all been though the colposcopy MDT and outcome recorded.

Patient mainly under 30 years of age with low or nil parity and non-smokers are generally recommended for conservative management. This is a re audit from 2016 to see if our guidance can change to include a different age range.

#### **Conclusion**

Findings to be presented at the conference.

## AUDIT REPORT: MANAGEMENT OF CERVICAL GLANDULAR INTRAEPITHELIAL NEOPLASIA (CGIN) IN THE ROTHERHAM NHS FOUNDATION TRUST -OVER 5 YEARS (2016-2021)

Dr Shireen Syed<sup>1</sup>, Mrs Radhika Gosakan<sup>1</sup>

#### <u>Introduction</u>

The natural history of Cervical Glandular Intraepithelial Neoplasia (CGIN) remains unclear. It is associated with high levels of invasive (40% to 43%) and pre-invasive (20% to 28%) disease. Approximately 50% have concomitant CIN. May be multifocal and skip lesions and there are no classic Colposcopic features. The definitive treatment is a cylindrical excision of the transformation zone (TZ) and a proportion of full thickness endocervical canal epithelium with a depth of 10 mm to 25 mm with clear undamaged margins to be available to the histopathologist.

#### **Aims & objectives**

To assess compliance with the NHSCSP guidelines including waiting times and follow up to improve practice in line with the updated guidelines.

#### Methodology

All women referred with the cytology reported as Glandular neoplasia of endocervical origin and Borderline endocervical cells, between March 2016 to April 2021 over a period of 5 years, Total women n=38; Glandular neoplasia (n=28); Borderline endocervical (n=8). The women were identified using the Colposcopy Database Masey. Initial biopsy results and subsequent smear results were checked via ICE and Open ICE.

#### **Results**

Majority of the women in this cohort were found to be less than 50 years of age (n=34) and only 2 women were in the older age group (60 and 62 years). All the 36 (100%) women were referred to colposcopy within 2 weeks (100%). 72% women had LLETZ at initial colposcopy and remaining had excision after initial punch biopsy. Single pass at excision was done in 85% of the women. The depth of LLETZ on initial or repeat LELTZ was >10 mm in 73% of the women. There were 28% (n=10) who had incomplete histology samples and 8 out of them are on annual cytology pathway for 9 years. A total of 34 patients (94%) cases discussed at MDT. The follow up for Test of Cure (TOC) cytology in 6 months was 67% and remaining attended later ranging from 7 to 14 months due to change of address or pregnancy.

#### **Conclusion**

The excision not offered at initial visit due to lack of expertise and to meet the 2 weeks wait. This practice is in the process of change since the audit. Colposcopic impression and women's choice may drive the choice of biopsy at initial colposcopy. This can be improved by better communication through letters and counselling at the initial appointment. The depth of excision biopsy with the loops size used was maximum 18 mm. New deeper loops have been procured for cylindrical excisions since the audit report. A reaudit is planned for assessing the impact of the recommendations from this audit report.

Key words: CGIN, Audit of Management of CGIN.

<sup>&</sup>lt;sup>1</sup>The Rotherham NHS Foundation Trust, United Kingdom

## AN AUDIT OF THE DEPTH OF LOOP EXCISION TO TREAT CIN AGAINST NATIONAL COLPOSCOPY STANDARDS; DIFFICULTIES IN MEETING THE SPECIFIED TARGETS

Dr Zebia Thomas<sup>1</sup>, Mr Nicholas Myerson<sup>1</sup>

#### <u>Introduction</u>

Large loop excision of the transformation zone (LLETZ) is the most common technique used to treat CIN (cervical intraepithelial neoplasia). National standards on depth of excision and specimen quality must be met as incomplete excision is linked to recurrence.

#### Aim

The aim of our audit was to assess the adequacy of depth of excision achieved at LLETZ. Our results were measured against the standards in NHS Cervical Screening Programme and the Colposcopy Management Guide 2020.

#### Methodology

A retrospective analysis 107 of consecutive LLETZ procedures for CIN/ HSIL from October 2020 to February 2021.

#### Results

90.7% specimens were removed as a single piece. Depth of excision was analysed for single piece specimens.

Cervix with type 1 TZ (transformation zone), 87.7% (43/49) had depth of excision > 7mm and 50% of them (21/43) had excision > 10mm. The women in this cohort were mainly of reproductive age. In those with excision > 7mm, the endocervical margins were involved in 16.2% but in < 7mm (6/49) only one had endocervical margin involvement.

Cervix with type 2 TZ, 77.3% (17/22) had depth of excision between 10-15mm and the rest had < 10mm. There was no involvement of the endocervical margin in this group.

Those with type 3 TZ recorded, 23% (6/26) had depth of excision from 15-25mm, the rest were < 15mm. In the latter group, 4 excisions (15.4%) involved the endocervical margin.

#### **Conclusion**

The depth of excision > 7mm in type 1 TZ is 87.7% (< 95%) but only 50% reach the depth specified in Document 20, however associated risk of preterm labour with depth of excision >10mm must be weighed.

Depth of excision for type 3 TZ was not achieved in 77%, use of a larger loop (20x20 mm) should be considered, and loop size documented for future quality assurance.

<sup>&</sup>lt;sup>1</sup>Bradford Teaching Hospital NHS Foundation Trust, United Kingdom

## AN AUDIT OF WOMEN PRESENTING TO THE COLPOSCOPY CLINIC WITH A HISTORY OF POSTCOITAL BLEEDING

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#### **Introduction / Background**

Post coital bleeding (PCB) is a cardinal symptom in women presenting with cervical cancer and consequently women presenting with this symptom are referred through the 2 week cancer wait pathway. There appears to be an increase in the number of women presenting with this symptom especially during this age of Covid despite the lack of increase in the number of cases of cervical cancer.

#### Aims / Methodology

This audit covers the year May 2018 to April 2019. 109 patients' notes, colposcopic findings and results were reviewed.

#### **Results**

One hundred and nine (109) women were referred to the Colposcopy Service at Whipps Cross with a history of PCB. The age range was from 20-57 years with most women being in the 25-50 years bracket. The referrals were triaged as urgent if >35 years old or more than 4 weeks' history of symptom and seen within 2 weeks. The remainder were seen within 6 weeks of referral. 93% were discharged after one visit with no significant pathology identified.

There was very little significant pathology found in any of these women. Only 4 (3.5%) had biospy confirmed abnormalities with no lesion graded more than HPV/CIN1. In the 2-week wait group, only 2 had abnormal cytology, 12 had normal cytology and the remainder had no recent cytology or a normal screening history.

Many of these women arrive at the clinic believing that they had cancer. Details of this cohort will be presented with the findings of no significant pathology. This audit would recommend that most women presenting with PCB in primary care can be reassured that colposcopy referral is to exclude pathology especially with a normal screening history.

# FLUCTUATIONS IN THE COLPOSCOPIC CLINIC WORKLOAD AND THE IMPACT FOR CERVICAL HISTO-PATHOLOGIC WORKLOAD 2018- 2021; OVERVIEW OF THE EFFECTS OF COVID-19 PANDEMIC AND EFFECTS OF NATIONAL HPV SCREENING CHANGES IN A SINGLE TRUST

Dr Apostolos Xynos<sup>1</sup>, **Dr Helen Doran**<sup>1</sup>

<sup>1</sup>James Cook University Hospital, Yarm, United Kingdom

#### **Background**

This is an overview of the impact of the 2020/21 COVID-19 pandemic as well as the recent changes in HPV screening testing from 2019 locally, -on our respective workloads.

#### Method

Data collection from January 2018-December 2021 was retrieved from WEB-ICE, HPV-ICE and NHAIS Open-Exeter IT-systems. The inclusion criteria were patients who were "New Direct Referral" from the cervical screening program and who attended their appointment.

Data collected included the number of patients who underwent a punch biopsy (single/multiple) or See & Treat LLETZ at their first visit. These workloads were compared for each annual data set, considering 2018 as our baseline.

#### Results

Table 1

Year	Number of 1 <sup>st</sup> visit	Number of punch biopsies	Number of See & Treat LLETZ	
	attendances	at 1 <sup>st</sup> visit	excisional biopsies	
		(single/multiple)		
2018	726	376	218	
2019	762	417	211	
	(5% increase(762/726))	(11% increase(417/376))	(3% drop (211/218).	
2020	660	370	150	
	(9% drop (660/726))	(2% drop) 370/376))	(31% drop (150/218))	
2021	988	593	144	
	(36% increase (988/726))	(58% increase (593/376))	(34% drop (144/218))	

The sub-analysis of this data by referral type (low grade/high grade) will be presented too.

#### Discussion

In 2020, the drop in new "Direct referrals" and hence histopathological workload coincided with the 2020 COVID-19 wave/lockdowns, which reduced cervical screening in the community. Similarly, the dramatic increases in 2021 likely reflect the catch-up in community screening, resulting in increased workload in 2021. This workload also likely reflects the effect of Primary HPV-screening from 2019, which was predicated to cause a transient increase in colposcopic referrals [1] We note there is a dramatic decrease in the number of See & Treat LLETZ operations in 2020 and 2021. This likely reflects the instigation of our CIN2 surveillance program which coincided with the launch of the new NHSCSP Guidance Feb 2020 [2] more widely supporting CIN2 surveillance. Furthermore, there is a notable increase in the proportion of punch biopsies in 2021. Subanalysis suggests that these are related to the increase in the proportion of low grade referrals, as anticipated [1].

In conclusion, our workloads have dramatically increased and interestingly the proportion of punch biopsies versus LLETZ has changed 2018-2021. This has affected our ability to maintain KC65 Colposcopy-clinic targets and Histo-pathology Turnaround time targets [3].

#### **References**

- 1. PHE NHS CSP Colposcopy and Programme Management NHSCSP Publication Document 20
- 2. PHE NHS CSP Feb 2020
- 3. PHE NHS CSP Histopathology Reporting Handbook Sep 2021

## COMPARING THE EFFECTIVENESS OF MONSEL'S SOLUTION AND DIATHERMY AS HAEMOSTATIC AGENTS FOR CERVICAL TREATMENT

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#### **Introduction / Background**

Excisional treatment of the cervix for cervical preinvasive and early invasive disease has been proved to increase the risks of adverse obstetric outcomes, including preterm labour. This risk is proportional to the depth of excision. Diathermy and Monsel's solution are both commonly used methods to achieve haemostasis after cervical excisions. However, diathermy has been shown to cause further cervical tissue destruction by up to an additional 0.5cm, whilst Monsel's solution, only 0.06cm. We aim to assess whether Monsel's solution is a safe alternative to diathermy as a haemostatic agent.

#### Aims / Methodology

A retrospective audit was performed of all excisional treatments performed between 01/07/20 and 31/12/21 at St Mary's Hospital, Imperial College Healthcare NHS Trust. Data was collected from Excelicare Colposcopy database, entered onto spreadsheet and analysed statistically.

#### Results

A total of 543 patients were identified. Haemostasis was achieved in 330 patients by diathermy, 207 by Monsel's solution and 6 required both methods. Overall, the number of patients who represented with post-procedure vaginal bleeding or offensive discharge was 39/543 (7.36%). There was a statistical difference between the overall complication rate: Monsel's group (n=5 (7.36%)), Diathermy group (n=34 (10.30%)), p=0.000608. The Monsel's group had statistically less representation with vaginal bleeding compared to the diathermy group (n=1 vs n=25, p=0.000194). However there was no difference in the number presenting with vaginal discharge (n=4 vs n=16, p=0.082).

#### **Conclusions**

According to our data, Monsel's not only appears to be a safe alternative haemostatic agent to diathermy, it appears to be associated with fewer complications, particularly vaginal bleeding. It may also decrease the tissue destruction associated with cervical treatment

## LANGERHANS' CELL HISTOCYTOSIS INVOLVING THE CERVIX AND MANDIBLE

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#### **Introduction / Background**

A 59-year-old lady who was under review by the gynaecology for chronic pelvic pain was found to have an abnormal cervix after an episode of post-coital and post-menopausal bleeding. Cervical biopsies were taken showing inflammation in the presence of HPV. Simultaneously, she was investigated for a 19-month history of unilateral conductive deafness, otalgia and ear discharge. MRI and biopsy of the mastoid confirmed the rare diagnosis of Langerhans' Cell Histocytosis (LCH). Subsequently, she underwent colposcopy and a LLETZ (large loop excision of the transformation zone). Immunohistochemical staining also confirmed the presence of LCH in the ectocervix and radial stromal margins. She was then referred to haematology oncology for treatment of her mastoid lesion with radiotherapy and high dose anti-inflammatories. Following MDT advice, it was decided to primarily continue treating the cervical LCH with anti-inflammatories and follow up with colposcopy once radiotherapy was complete.

#### Aims / Methodology

A literature review of online databases PubMed, Embase, Medline and Ovid was conducted using the terms 'Langerhans Cell Histocytocis' and 'cervix'. Four relevant articles were included describing cases of genital LCH.

#### **Results**

- A rare multi-organ diagnosis that can present similarly to cervical neoplasia
- Diagnosis is confirmed by histology
- Treatment is offered after MDT discussion with a good prognosis if complete removal is achieved.

## CASE REPORT - INVASIVE SQUAMOUS CELL CARCINOMA ARISING WITHIN A CERVICAL LEIOMYOMA

<u>Dr Ahmed Sheta<sup>1</sup></u>, Ms Smitha George<sup>1</sup>, Ms Sonia Chachan<sup>1</sup> <sup>1</sup>Stockport NHS Foundation Trust, Greater Manchester, United Kingdom

#### **Introduction / Background**

Invasive squamous cell carcinomas are very rare and not many cases have been reported.

#### Aims / Methodology

The patient presented with rapidly growing vaginal mass and menorrhagia. the endometrial biopsy you took shows strips of squamous epithelium with dysplastic changes which are of concern and there is evidence of moderate to severe dysplasia.

MRI scan of pelvis and abdomen was performed. Large prolapsing lesion associated with significant uterine descent to the level of the introitus. The prolapsed lesion is felt most likely to reflect a partially necrosed polyp or fibroid polyp. It is not possible to differentiate it from the posterior lip of the cervix and this may therefore be its point of origin. There were no specific features of malignancy identified - but since partial necrosis is likely to be present this was not considered to have been excluded. Interestingly the endometrial biopsy showed strips of squamous epithelium with dysplastic changes which were of concern and there was evidence of moderate to severe dysplasia. Left internal iliac node measures 8.1 mm in maximum short axis diameter and has a slightly round configuration. Its significance was unclear.

It was decided to undertake an examination under anaesthetic and removal of the prolapsing mass in the first instance for a more complete histological assessment. This will give us the opportunity to assess this in detail and to exclude any neoplastic process within the mass itself which may necessitate more radical treatment.

Hysteroscopy + cervical polypectomy + cervical loop done.

Histology revealed a cervical fibroid polyp with 4 cm A stage 1B2 poorly differentiated squamous cell carcinoma (FIGO) of the cervix, the interlacing fascicles consisted of bland smooth muscle cells in keeping with leiomyoma.

She has a PET CT positive right external iliac lymph node. It was then upstaged to FIGO Stage 3C1. She was advised radical chemoradiotherapy with a curative intent

#### **Results**

An invasive lesion within a benign looking leiomyoma may lead to delay in diagnosis and treatment of cervical cancer. In this case, the presence of squamous epithelium with severely dysplastic changes alerted the clinicians to alter the management strategy. It was decided to perform a polypectomy and loop excision of cervix rather than a routine hysterectomy.

Our experience with this case has lead us to conclude that it would be prudent to maintain a high index of suspicion in high risk women with fast growing cervical fibroids.

# A CASE OF ENDOMETRIAL ADENOCARCINOMA INCIDENTALLY DIAGNOSED ON ROUTINE CERVICAL SCREENING – A DYING INCIDENTAL DIAGNOSIS DUE TO THE CHANGE TO PRIMARY HUMAN PAPILLOMAVIRUS CERVICAL SCREENING?

<u>Dr Marie-Therese Grant</u><sup>1</sup>, Mr Michael Davis<sup>1</sup>, Margaret Morgan<sup>2</sup>

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#### Introduction

Endometrial cancer is the most common gynaecological malignancy and the fourth most common cancer in the UK amongst women. Despite this, there is no screening test available. The disease is however, occasionally diagnosed incidentally by the cervical screening programme as outlined in the case report summarised. However, since 2019, the cervical screening programme in England, Scotland & Wales has changed to primary human papillomavirus (HPV) testing, thus, only patients who are HPV positive will then have cytological analysis of their smear test. As a result, the opportunity to incidentally diagnose Endometrial cancer in HPV negative women will be lost.

#### **Case Report**

A 57 year old lady attended for her routine cervical screening test and was found to be HPV positive. Therefore, cytological analysis was performed which identified abnormal cells of likely endometrial origin. The patient was asymptomatic and a transvaginal pelvic ultrasound was unremarkable with a thin endometrium of 2.9mm. The patient was invited for colposcopy and the cervix was found to be normal. A pipelle biopsy was obtained and the pathology reported papillary serous carcinoma. The patient subsequently underwent a robotically-assisted hysterectomy, bilateral salpingo-oophorectomy, sentinel lymph node dissection and peritoneal washings. The final histopathology confirmed serous endometrial intraepithelial carcinoma with no residual invasive adenocarcinoma seen.

#### **Conclusion/Discussion**

Since going live with primary HPV screening, cervical screening London (CSL) has identified 14 cases of non-cervical cancers. Although this is a relatively small number, as >85% of all cervical screening samples are reported as HPV negative, it is likely that many other cases are no longer identified. On review of the literature, a systematic review of 45 studies reported 45% of patients with endometrial cancer have abnormal cervical screening cytology before their diagnosis. This was significantly higher among non-endometrioid histological subgroups versus endometrioid histologies.

## EQUIVALENCY STUDY OF CLINICIAN AND SELF-COLLECTED SAMPLES FOR CERVICAL CANCER SCREENING

<u>Dr Ola Ibrahim<sup>1,2</sup></u>, Dr Prerna Tewari<sup>1,2</sup>, Ms Eilis O'Toole<sup>3</sup>, Dr Tom D'Arcy<sup>4</sup>, Dr Gunther von Bunau<sup>5</sup>, Dr Grainne Flannelly<sup>6</sup>, Dr Britta Seivereth<sup>7</sup>, Ms Diana Thamke<sup>7</sup>, Dr Joseph Marano<sup>7</sup>, Professor John O'Leary<sup>1,2</sup>, Assistant Professor Cara Martin<sup>1,2</sup>

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#### **Background**

Human papillomavirus (HPV) testing is now being adopted as the primary screening method for the prevention of cervical cancer in many countries including Ireland. With this change, more options are now available for women including the potential for women to self-collect a cervico-vaginal sample which can be sent to the laboratory for HPV testing. While all previous studies comparing cobas® HPV test results using self-versus clinician-collected samples have demonstrated feasibility, none of these studies have used a workflow for testing self-collected samples which is easily scalable to enable testing on a national scale. This study is the first part of a multi-centre trial funded by Roche Molecular Diagnostics to determine if self-collected samples using a scalable pretesting process yields **cobas** 4800® HPV test results that are comparable to clinician-collected samples.

#### Methodology

In total, 340 women between the ages of 25 and 65 years presenting at the colposcopy smear clinics of three large colposcopy units in Ireland, for follow up on the Management of Uncertainty in Colposcopy HPV (MUCH) pathway were enrolled in the study. Once consented the participants self-collected a cervico-vaginal sample using the Evalyn Brush. The clinician then proceeded to collect a standard cervical sample in a PreservCyt vial. Both specimens collected were then sent to the molecular laboratory for HPV testing with the **cobas**® 4800 HPV Test. All data analysis was performed using SPSS version 26 and Microsoft Excel.

#### Results

Overall, 39 % of self-collected and 38 % of clinician collected samples were positive for HR HPV. The concordance between self-collected and clinician collected samples was good at 86.7% [95%CI: 82.6-89.9] and a kappa value of 0.72.

The data confirms that cervico-vaginal self-collected samples using the Evalyn Brush has a high concordance/equivalence with clinician -collected samples for use with the **cobas**® 4800 HPV Test.

#### **NEGATIVE LLETZ – AN ENIGMA OR A PRACTICAL REALITY?**

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<sup>1</sup>Northwick Park Hospital, Wembley, United Kingdom

Large Loop Excision of Transformation Zone (LLETZ) is one of the most common surgical therapeutic techniques used in treatment of High Grade Intraepithelial lesions. Most cone biopsies will confirm the presence of cervical intraepithelial disease, but in some cases there is simply no evidence despite the fact that the diagnostic biopsy was positive for CIN. There are a number of possible reasons for this, including: incorrect diagnostic biopsy or smear results, removal of the lesion as part of the diagnostic biopsy, insufficient LLETZ samples or regression of the lesion. The incidence of such negative cone biopsies in the literature is estimated between 10.6% and 34%.

An audit on negative cone biopsies was conducted between 1/1/2021 and 31/12/2021 in Northwick Park Hospital. 255 women underwent treatment for abnormal cervical abnormalities; 12% were in their reproductive age group and 3% were under 30. Negative cone biopsy was identified in 55 cases, 9% with severe dyskaryotic smear (86% CIN2+) and 7% moderate (44% CIN2+). Over half of these cases were discussed at our colposcopy MDT meetings, and negative cone biopsy was reconfirmed in all cases.

The incidence of negative cone biopsies was nearly twice as high in Women over 50. There was a slightly increased incidence of negative cone biopsy in samples with a depth of less than 7mm. There was a correlation between the results of diagnostic biopsy and cone biopsy; evidence of CIN on diagnostic biopsy was confirmed by cone biopsy in over 80% of cases. The type of anaesthesia or type of procedure did not influence the incidence of negative cone biopsy. So, is negative cone biopsy an Enigma or a Practical Reality? Should we be worried? We plan to continue this audit cycle by collecting data on Test of Cure to confirm whether negative really means negative.

## HIGH GRADE CYTOLOGY WITH NORMAL COLPOSCOPY AND THE OUTCOMES

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<sup>1</sup>Barking, Havering and Redbridge University Hospitals NHS Trust, Bromley, London, United Kingdom

#### **Objectives**

To review all high grade cytology smears showing moderate or severe dyskaryosis with normal and satisfactory colposcopies. Were these patients sent to MDT and what was the outcome if treatment was recommended?

#### Methods

Retrospective search through our MDT minutes from 2020 and 2021. All patients sent to MDT for smear review.

Treatment results of recommended and outcomes of those not for treatment.

All age ranges included and type 1-2 transformation zones.

The colposcopy multidisciplinary meeting's primary purpose is to plan the management of patients with discrepancies in either histology, cytology and/or Colposcopic findings. NHSCSP publication 20 recommends this as a good practice point.

One of the criteria for discussion should be all cases where high grade cytology has not been confirmed on colposcopy.

#### Conclusion

Findings to be presented at the conference.

## EXTENDED GENOTYPING FOR HPV HAS AN IMPORTANT ROLE AS A TRIAGE STRATEGY FOR HPV PRIMARY SCREENING

Ms Padmaja Naik<sup>1,2,3</sup>, Dr Helen Keegan<sup>1,2</sup>, Dr Christine White<sup>1,2</sup>, Dr Stephen Reynolds<sup>1,2</sup>, Ms Roisin O'Brien<sup>1</sup>, Ms Loretto Pilknigton<sup>2</sup>, Dr Sharon O'Toole<sup>2,3</sup>, Dr Prerna Tewari<sup>2,3</sup>, Professor John J \*O'Leary<sup>1,2,3</sup>, Dr Cara M \*Martin<sup>2,3</sup>

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#### **Introduction / Background**

HPV (human papillomavirus)-based cervical cancer screening is more effective than cytology and many countries have switched to HPV-based primary cervical screening. While HPV primary screening is more sensitive than cytology, HPV assays have a lower specificity and therefore appropriate triage of HPV positive women is crucial.

#### Aims / Methodology

CERVIVA (www.cerviva.ie), have undertaken a longitudinal observational HPV Primary Screening Study, embedded within the Irish cervical screening programme (CervicalCheck), to investigate alternative approaches for triage of HPV positive women. HPV genotyping is the one of the triage options being evaluated. Cervical cytology samples from >11,000 women undergoing routine cervical screening were tested for HPV DNA (cobas 4800 HPV test). HPV positive women (n=1,864) were further assessed using the BD Onclarity HPV Test. The BD Onclarity HPV test, targets HPV E6/E7 DNA and offers extended genotyping of 14 high-risk HPVs as either individual (16, 18, 31, 45, 51 and 52) or as grouped genotypes (P1: HPV33/58, P2: HPV56/59/66, P3: HPV35/39/68). The performance of genotyping singly and in combination was determined for detection of CIN2+.

#### **Results**

In total 80.6% (1502/1864) of cobas HPV positive specimens tested were positive using the BD Onclarity HPV assay. Within this group, the prevalence of HPV genotypes was as follows: HPV16 (27.1%), P2 group (HPV 56/59/66) (26.6%), P3 group (HPV 35/39/68) (19.3%), HPV31 (16.0%), P1 group (HPV33/58) (13.7%), HPV52 (12.7%), HPV51 (10.7%), HPV18 (8.5%) and HPV45 (8.1%). To date baseline histology on 444 cases of which, 216 are CIN2+ is included. More than 50% of CIN2+ cases were associated with non-HPV16 genotypes. The specificity for HPV16 genotype positive cases was 59.3%, HPV18 genotype positive cases was 92%, while the specificity of non-HPV16/18 genotypes ranged from 67.6-90.1%.

Extended genotyping may be a useful tool to aid in triage of HPV positive cases.

#### THE EFFECT OF A LLETZ PROCEDURE ON PAP STAIN CYTOLOGY, HR-HPV GENOTYPING AND P16/KI-67 DUAL STAIN TEST RESULTS IN A DIVERSE COHORT OF PATIENTS

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#### Background

The p16/Ki-67 dual stain test (DST) detects mutual expression of p16 and Ki-67 in the same cell, which is considered a marker for HR-HPV induced cell cycle deregulation. Patients treated for CIN2+ stay at risk of persistent/recurrent disease or even invasive cancer in later life.

HR-HPV testing provides improved sensitivity and similar specificity to PAP cytology for post-treatment surveillance. No study has investigated the effect of a LLETZ procedure on DST results in the same cohort of patients, nor has the value for post-treatment surveillance been assessed.

#### Methods

During the first part of this cohort study, 110 patients were recruited prior to a LLETZ procedure. Participants were invited to attend a 6-months follow-up visit. At this timepoint, a new cervical cytology sample was obtained for PAP staining, HR-HPV genotyping and dual staining.

#### **Results**

A total of 83 datasets were available for comparison. The mean duration of follow up was 187.91 days (95% CI 182.91- 192.93), mean age was 41.4 years (95% CI 39.25-43.46).

Overall dual stain positivity was 70.9% and 30.1% prior and 6-months after the LLETZ procedure (p<0.001, McNemar test). HR-HPV testing (dichotomous outcome) and abnormal PAP cytology (dichotomous outcome at an ASCUS or worse threshold) showed a similar significant reduction (84.5 vs 42.2% and 72.7 vs 28.9% respectively, p<0.001, McNemar test). The Chi-Square test showed high dependency among all three assays (HR-HPV & DST - HR-HPV & PAP staining - DST & PAP staining, all highly significant, p values < 0.001).

#### **Conclusion**

A LLETZ results in significant decrease in HR-HPV positivity, abnormal cytology results and DST positivity rates in a diverse cohort of patients. Results of all three assays showed high dependency. Whether the DST provides additional value in post-treatment surveillance in the long term, needs to investigated in a larger prospective observational cohort study.

## URINE HIGH RISK HUMAN PAPILLOMAVIRUS TESTING AS AN ALTERNATIVE PRIMARY CERVICAL SCREENING STRATEGY – THE ACES STUDY

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#### **Background**

Testing urine for high risk human papillomavirus (hr-HPV) may be an attractive option for non-attenders of routine cervical screening. The accuracy of urine hr-HPV testing varies with different collection protocols. We hypothesised that Colli-Pee has better sensitivity for CIN2+ detection than standard pot-collected urine through reliable first-void collection, standardisation of volume collected, and immediate preservative-fixation. The aim of the Alternative CErvical Screening (ACES) Colposcopy study was to compare the sensitivity of matched urine and cervical hr-HPV testing for CIN2+ detection using two urine collection devices.

#### Methods

Colposcopy attendees in Manchester (UK) with abnormal cervical screening results were randomised (1:1) to Colli-Pee® 10mls with preservative or standard pot for urine collection. Urine was self-collected and matched cervical samples taken immediately prior to colposcopy; hr-HPV testing used Roche Cobas 8800. Colposcopic opinion and/or histology informed clinical diagnosis. A power calculation indicated that 480 participants (with 120 CIN2+/group) would have 89.8% power to establish a sensitivity of urine for CIN2+ detection >80%.

#### **Results**

324 participants were included in this interim analysis (Colli-Pee n=162, pot n=162; full data end March 2022). The groups were balanced in age (median 35.6 vs 35.8 years), ethnicity (77% vs 81% White) and referral screening results (n=74 vs n=73 high grade; n=68 vs n=71 low grade/borderline; and n=17 vs 17 persistent hr-HPV+/cytology-negative) in Colli-Pee and standard pot arms, respectively. Cervical hr-HPV was 96.6% sensitive (95%CI 92.2-98.9%) for CIN2+ detection (n=141/146). Urine hr-HPV sensitivity for CIN2+ was higher using Colli-pee (95.5%, 95%CI 87.5-99.1%, n=63/67) than when collected using the standard pot (75.0%, 95%CI 64.1-84.1%, n=60/80, p<0.001).

#### **Conclusion**

Hr-HPV tested Colli-Pee-collected urine shows similar sensitivity for CIN2+ detection compared to routine cervical screening. Further work in the general cervical screening population will establish its specificity and its potential to improve cervical screening uptake in current non-attenders.

## HR-HPV TESTING IN SELF-TAKEN VAGINAL SAMPLES IN WOMEN WHO DEFAULT FROM CERVICAL SCREENING: LESSONS FROM NHS DUMFRIES AND GALLOWAY

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#### **Background**

Self-sampling as an alternative to clinician-taken cervical smears is a means to engage women in cervical screening. We present an interim analysis of a population-based study where individuals defaulting from routine screening in one of the territorial health boards in Scotland (Dumfries and Galloway; D and G), were offered a self-sampling kit

#### **Methods**

Individuals within NHS D&G aged 25-64 who had never attended screening, or had defaulted for an invitation >= 6 months were mailed a vaginal self-sampling kit and invited to consent & participate. Samples were tested for HPV centrally using the assay used for routine cervical screening Scotland. HR-HPV positive women were invited to colposcopy with biopsies taken if clinically indicated. Uptake, colposcopy attendance rate and HPV prevalence was determined.

#### **Results**

4168 invitations were disseminated with 843 {20.3%; (95%CI- 19.1-21.5)} returned. Return rate of self-samples was highest in 55-65 year olds 24.0% (95% CI- 22.0-26.1) and lowest in 25-35 year olds 15.8% (95%CI- 13.0-19.0). 15 (1.8%) samples were unsuitable for testing and 34 were technically invalid (4.0%). HPV prevalence was 12.2% (95% CI- 10.1-14.6) - highest in 25-35 year olds 25.3% (95% CI- 17.1-35.0) and lowest in 55-65 year olds 7.9% (95%CI- 5.4-10.9). Of those invited to colposcopy, 87.4% (90/103) attended.

#### Conclusion

A contemporary depiction of the nature and level of uptake of self-samples in the defaulter population will be key for future planning and service developments based on self-sampling within screening. A 20% return rate is in line with international observations and compliance to follow up in positive women was high. HPV prevalence was similar to that observed in the routine screening population. Analysis is ongoing and will include the assessment of future screening engagement as well as performance of HPV testing in self-samples for CIN2 detection.

## EFFECT OF THE 9-VALENT HUMAN PAPILLOMAVIRUS (9VHPV) VACCINE IN A SUBGROUP OF FEMALE CLINICAL TRIAL PARTICIPANTS WHO UNDERWENT CERVICAL SURGERY

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#### **Introduction / Background**

In a subgroup of female clinical trial participants who underwent cervical surgery (loop electrosurgical excision procedure or conization) after vaccination, we performed a post-hoc analysis on the development of disease related to the 9vHPV vaccine types after cervical surgery.

#### Aims / Methodology

Three international, randomized, double-blind studies were conducted in women aged 16-26 years; a pivotal efficacy study evaluated the 9vHPV vaccine (n=7106) vs qHPV vaccine (n=7109) (NCT00543543) and two efficacy studies evaluated qHPV vaccine (n=8810) vs placebo (n=8812) (FUTURE I [NCT00092521] and FUTURE II [NCT00092534]).

Among the subgroup of clinical trial participants who underwent cervical surgery and had ≥6 months' follow-up post-surgery, the incidence of HPV6/11/16/18-related condyloma, cervical (CIN), vulvar (VIN), and vaginal intraepithelial neoplasia (VaIN) in 9vHPV vaccine recipients was compared with incidence in placebo recipients from the FUTURE I/II studies; incidence of HPV31/33/45/52/58-related disease was compared with qHPV vaccine recipients from the 9vHPV vaccine study.

#### **Results**

The post-cervical surgery subgroups included 295 9vHPV vaccine recipients, 493 placebo recipients, and 313 qHPV vaccine recipients (from NCT00543543) who underwent cervical surgery and had  $\geq$ 6 months' follow-up post-surgery.

Prior 9vHPV vaccination was associated with reduction of incidence of HPV6/11/16/18-related condyloma, CIN, VIN, and VaIN at≥6 months post-surgery by 95.4% (95% confidence interval [CI]: 74.7, 99.8) vs placebo (incidence: 1.3 vs 29.0 per 1000 person-years, respectively) and a reduction of the incidence of HPV31/33/45/52/58-related disease by 86.3% (95% CI: 47.5, 97.8) vs qHPV vaccine (incidence: 2.7 vs 19.4 per 1000 person-years, respectively). Although not statistically significant due to the small number of observed cases, the incidence of high-grade CIN, VIN, and VaIN among 9vHPV vaccine recipients tended to be lower compared with the rates in the relevant comparator groups. Among women who underwent cervical surgery, prior vaccination with 9vHPV vaccine was associated with reduced incidence of disease.

# DESIGN OF A PHASE III IMMUNOGENICITY AND SAFETY STUDY EVALUATING TWO-DOSE REGIMENS OF 9-VALENT HUMAN PAPILLOMAVIRUS (9VHPV) VACCINE WITH EXTENDED DOSING INTERVALS

<u>Ms Maria Giwa</u><sup>1</sup>, Dr Alain Luxembourg<sup>1</sup>, Dr Hedy Teppler<sup>1</sup>, Dr Oliver Bautista<sup>1</sup>, Dr Thomas Group<sup>1</sup>, Sheryl Flores<sup>1</sup>, Jennifer McCauley<sup>1</sup>

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#### **Introduction / Background**

HPV vaccines are widely licensed as 2-dose regimens for young adolescents, with doses administered 6 - 12 months apart. However, immunogenicity of longer intervals between doses is not well characterized. This international, multi-center, open-label study evaluates safety and immunogenicity of 2-dose regimens of 9vHPV vaccine with intervals of 1-5 years between doses in boys/girls vs a standard 3-dose regimen in young women.

#### Aims / Methodology

Participants (*N* = 753) were enrolled into six cohorts; Cohort 0: boys/girls aged 10–15 years who received one 9vHPV vaccine dose ≥1 year before enrolment without completing the series received one study dose of 9vHPV vaccine at day 1; Cohorts 1–4: HPV vaccination-naïve boys/girls aged 9–14 years received two doses (day 1 and month 12, 24, 36, or 60); Cohort 5: HPV vaccination-naïve women aged 16–26 years received three doses (day 1, months 2 and 6). Primary analyses were based on serological responses one month after final vaccine dose.

#### Results

Over 99% of girls receiving 2 or 3 doses seroconverted for the 9 HPV vaccine types at 1 month post last dose. Anti-HPV geometric mean titers (GMTs) were highest at 1 month post last dose, decreased sharply during the subsequent 12 months, and then decreased more slowly. GMTs at 1 month post last dose in girls receiving 2 or 3 doses were similar or greater than GMTs in young women receiving 3 doses. This trend was still observed through 24-30 months post last dose. A single dose of vaccine resulted in partial seroconversion (41% to 98% at 6 months after a single dose, depending on the HPV type, vs 97% to 100% at 6 months after completion of the 0,6 regimen) and lower GMTs than after 2 or 3 doses (6- to 14-fold lower than after the 0,6 regimen at 6 months post last dose).

## REDUCTION IN CERVICAL SCREENING UPTAKE IN PREGNANT WOMEN DURING COVID-19

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#### **Introduction / Background**

Cervical screening aims to reduce the incidence and mortality of cervical cancer. To achieve this aim, **80%** of the population should be screened. Women aged 25-49 should be screened every 3 years, and those aged 50-64 every 5 years.

Nationally in 2021, 69.9% of the population aged 25-49 were screened.

Locally, in the boroughs of Lambeth and Southwark, **60.3**% of this age group were screened in 2021 compared to **64.5**% in 2019.

#### Aims / Methodology

To compare if factors such as COVID and pregnancy are impacting screening in 2021-22, compared to figures obtained in 2019.

To investigate changes around HPV screening and vaccine uptake.

100 post-natal women were surveyed at St Thomas' between December 2021-January 2022.

#### Results

The sample size was **100** versus **53** (2019).

The mean age was **34** versus **33** (2019).

52% were asked about smear history at booking, versus 71% (2019).

18% of women surveyed had an abnormal smear versus 16% (2019).

64% of women were compliant with screening, versus 67% (2019).

**50%** of women who had missed a smear reported pregnancy as the main reason, **6%** reported pregnancy and COVID-19, while **6%** reported pregnancy and other factors. Only **1** participant reported COVID-19 as the sole reason for missing a cervical smear.

44% felt that pregnancy had affected their cervical screening.

16% felt that COVID-19 had affected their screening in some way.

**80%** were unaware of the addition of HPV screening versus **94%** in 2019. **22%** had received the vaccine in 2022.

#### Conclusion

This data suggests that patients have become less compliant with cervical screening with the main reported reason for missed smears as pregnancy. COVID-19 has had some impact on smear compliance.

#### Recommendation

Roadshows and newsletters will be helpful to improve compliance. In the future, self-testing may increase compliance.

## PERFORMANCE OF AN EPIGENETIC BIOMARKER-BASED TEST FOR CERVICAL CANCER SCREENING IN A NIGERIAN POPULATION OF WOMEN (PECCAN) – STUDY DESIGN

<u>Miss Ojone Illah</u><sup>1</sup>, Professor Martin Widschwendter, Ms Adeola Olaitan <sup>1</sup>University College London Hospitals, United Kingdom

#### **Introduction / Background**

Much of the burden of cervical cancer lies in Africa where a paucity of preventative screening measures has resulted in persistently high disease prevalence compared to the Western world. Compounding this are much higher rates of HIV infection in African nations compared to Western countries. Promising recent research shows high diagnostic accuracy of epigenetic biomarker-based tests in detecting premalignant and malignant cervical disease, however, the majority of this research has not included women in low-to-middle income countries (LMIC). Given the ongoing burden of cervical cancer in many African nations, it is worthwhile to study the applicability of these tests to the African population. Hence, we present our proposal to study the diagnostic capabilities of an epigenetic biomarker-based test to screen for cervical pathology in a Nigerian female population.

#### Aims / Methodology

The aim of this study is to assess the feasibility and diagnostic accuracy of epigenetic biomarker-based testing in a Nigerian population of women, as a cervical screening tool. In Nigeria's Lagos, Ibadan and Jos teaching hospitals, we will recruit two study groups — women with normal cervical cytology and women with high grade cervical cytology. Both groups of women will undergo self-collected testing for epigenetic biomarkers for cervical disease, results from which will be compared against the gold standard histological diagnosis from colposcopy and cervical biopsy.

#### **Results**

We hypothesise that epigenetic biomarker-based testing as a means of screening for cervical disease in Nigerian women will yield high diagnostic capability. In comparison to other existing screening methods, this may offer the right balance when considering resource intensity, cost effectiveness and diagnostic accuracy, while still offering the option of self-collected samples which is culturally important in many LMICs.

### IMPROVING CARE FOR WOMEN LIVING WITH HIV IN COLPOSCOPY CLINIC

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#### **Introduction / Background**

To achieve the UK government's commitment to eliminating HIV transmission by 2030, individuals living with undiagnosed HIV infection need to be identified and treated.

Cervical intraepithelial neoplasia (CIN) is an indicator condition for HIV, yet routine HIV testing is not offered at colposcopy services in the UK.

Two patients diagnosed with HIV in Swindon in 2020 were found to have attended colposcopy prior to their HIV diagnosis. Both were diagnosed with HIV at a late stage of infection.

HIV testing at colposcopy has the potential to reduce late HIV diagnoses and their associated health risks, as well as improve colposcopy outcomes for adults living with HIV.

#### Aims / Methodology

At the Great Western Hospital (GWH) Swindon, we carried out a cross speciality (sexual health and gynaecology) quality improvement project to explore how best to improve care for women living with HIV the colposcopy service.

This included a retrospective case note review of all women diagnosed with HIV in the last 15 years, and cross checking against Open Exeter and colposcopy database and records.

#### **Results**

Only 43% of women living with HIV were having annual cervical screening. 5% of women living with HIV under care of sexual health had been seen in colposcopy with CIN prior to their HIV diagnosis. Currently GWH colposcopy does not offer HIV testing or routinely recommend an HIV test on diagnosis of CIN.

We have developed a pathway to inform the laboratory of HIV positive women, to ensure they are on the correct yearly screening recall. We have developed a patient information leaflet suggesting patients diagnosed with CIN attend either their GP or the sexual health service for an HIV test. We have implemented a new agreed cross specialty referral pathway for colposcopy referral at time of HIV diagnosis.

## PCNA IN CERVICAL INTRAEPITHELIAL NEOPLASIA AND CERVICAL CANCER: AN INTERACTION NETWORK ANALYSIS OF DIFFERENTIALLY EXPRESSED GENES

<u>Miss Apostolia Galani</u>, Dr Konstantinos Kechagias<sup>1</sup>, Mr Panagiotis Giannos<sup>1</sup>, Dr Sarah Bowden<sup>1</sup>, Dr Neha Tabassum<sup>1</sup>, Dr Maria Paraskevaidi<sup>1</sup>, Dr Maria Kyrgiou<sup>1</sup>

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#### **Background/Objectives**

The investigation of differentially expressed genes (DEGs) and their interactome could provide valuable insights for the development of markers to optimize cervical intraepithelial neoplasia (CIN) screening and treatment. This study investigated patients with cervical disease to identify gene markers whose dysregulated expression and protein interaction interface were linked with CIN and cervical cancer (CC).

#### Methods

Literature search of microarray datasets containing cervical epithelial samples was conducted in Gene Expression Omnibus and Pubmed/Medline from inception until March 2021. Retrieved DEGs were used to construct two protein-protein interaction (PPI) networks. Module DEGs that overlapped between CIN and CC samples, were ranked based on 11 topological algorithms. The highest-ranked hub gene was retrieved and its correlation with prognosis, tissue expression and tumor purity in patients with CC, was evaluated. Screening of the literature yielded 9 microarray datasets (GSE7803, GSE27678, GSE63514, GSE6791, GSE9750, GSE29570, GSE39001, GSE63678, GSE67522).

#### **Results**

Two PPI networks from CIN and CC samples were constructed and consisted of 1704 and 3748 DEGs along 21393 and 79828 interactions, respectively. Two gene clusters were retrieved in the CIN network and three in the CC network. Multi-algorithmic topological analysis revealed PCNA as the highest ranked hub gene between the two networks, both in terms of expression and interactions. Further analysis revealed that while PCNA was overexpressed in CC tissues, it was correlated with favorable prognosis (log-rank P=0.022, HR=0.58) and tumor purity (P=9.86 × 10-4, partial rho=0.197) in CC patients. This study identified that cervical PCNA exhibited multi-algorithmic topological significance among DEGs from CIN and CC samples.

#### **Conclusions**

The disease burden of CC has significantly decreased in recent years in developed countries, however the financial costs of screening, the limited capacity of cytological-based diagnosis and the competing risk of reproductive consequences following treatment, remain a challenge. Our study identified that cervical PCNA exhibited multi-algorithmic topological significance among DEGs from CIN and CC samples. Overall, PCNA may serve as a potential gene marker of CIN progression. Experimental validation is necessary to examine the screening, diagnostic and prognostic value of PCNA in patients with CIN and CC.

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#### PATIENT SATISFACTION SURVEY IN COLPOSCOPY DEPARTMENT

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#### **Introduction / Background**

To evaluate the service provided within the colposcopy clinics which is a part of our on-going service monitoring and Quality assurance.

#### Aims / Methodology

The questionnaire was based on the BSCCP standards/guidance agreed by the Clinical effectiveness unit at Barking, Havering and Redbridge University Hospitals NHS Trust (BHRUT).

All women attended the Colposcopy clinics in November 2021 for one month were invited to participate in the survey.

The questionnaire included information about procedure what to expect and if it was useful, waiting times (especially during pandemic), facilities, Covid testings/self-isolation, their experience, staff attitude and their overall experience. The final result would be presented at the conference

#### **Results**

Gaining feedback and opinions of the department is an important part running a Colposcopy unit. At present we are dealing with covid restrictions and feel this will be a vital practice.

Colposcopy department at BHRUT is providing services according to the national standards.

## WHAT INFLUENCES CERVICAL SCREENING UPTAKE IN OLDER WOMEN AND HOW CAN SCREENING PROGRAMMES TRANSLATE THIS KNOWLEDGE INTO BEHAVIOUR CHANGING STRATEGIES?

Dr David Joyce<sup>1,2,7</sup>, Dr Bernadine O'Donovan<sup>1,7</sup>, Dr Therese Mooney<sup>3</sup>, Dr B Rimmer<sup>4</sup>, Prof Patricia Fitzpatrick<sup>3</sup>, Dr Grainne Flannelly<sup>5</sup>, Dr Noirin Russell<sup>3,6</sup>, Professor Linda Sharp<sup>4</sup>, Dr Mairead O'Connor<sup>6</sup>, Prof John O'Leary<sup>1,2</sup>, **Dr Cara Martin<sup>1,2</sup>** 

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#### **Introduction / Background**

Cervical screening uptake among older women (>=50 years) has been consistently below the minimum standard of 80% over the last five years in Ireland, with lowest coverage among women aged 55 years and over. This research seeks to explore factors that influence women's decisions to participate in cervical screening and help develop behaviour change solutions.

#### Aims / Methodology

The methodology follows the COM-B model of behaviour utilising the theoretical domain framework (TDF) to identify effective behaviour change strategies. The research comprises 3 phases: 1) qualitative interviews to identify influences on screening behaviour; 2) a population-based quantitative study using results from phase 1 to determine associations between influences and behaviours and 3) behavioural analysis, triangulating findings from phases 1 and 2 to create a theoretical model of factors that influence cervical screening decisions and develop solutions.

#### Results

Phase 1 is completed. 48 women were interviewed - 31 aged 50 or older with 17 aged below 50; 34 had adequate screening histories, 14 had inadequate screening histories. All participants found smear tests unpleasant. Most reported competent smear takers helped reduce anxiety. Women with inadequate screening histories viewed HPV self-sampling kits positively. Many older women reported negative attitudes to screening, linked to age-related difficulties. Older women reported the positive role of HCPs (e.g., GPs) as screening advocates.

Following an inductive thematic analysis and subsequent deductive mapping of themes to the TDF, 7 themes were identified: Knowledge of cervical cancer and screening; Coping with smear tests; Competing motivational processes; Cognitive resources, Environmental influences, Role of social support and Perceptual and practical influences. This analysis was used to develop the population-based survey for phase 2, which is underway.

Phase 1 provides insight into screening participation and provides a theoretical underpinning for phases 2 and 3 which will aid development of theoretically informed interventions to increase uptake.

## CIN RATES IN VACCINATED VERSUS NON-VACCINATED PATIENTS REFERRED TO COLPOSCOPY AFTER A FIRST ABNORMAL SMEAR

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#### **Introduction / Background**

The national HPV vaccination programme has been introduced in the UK with a bivalent vaccine (Cervarix) in Sep 2008, to all girls aged 12-13 (school year 8), with a catch-up programme for girls ages 13 to under 18. The first cohort of routinely vaccinated girls have become eligible for cervical screening in England in Sep 2020. The impact of the national programme in the UK has not yet been assessed by large clinical studies. Prediction models estimated a reduction in CIN rates by 97% in girls vaccinated at 12-13.

#### Aims / Methodology

Aim

This study aimed to assess CIN rates in vaccinated versus non-vaccinated patients referred to our Colposcopy department after a first abnormal smear.

#### Methodology

This is a retrospective cohort study. Data was obtained from Colposcopy records. We included consecutive patients aged 24-26yo, attending a Colposcopy appointment between 14.01.2019 and 15.11.2021, who had been referred after a first abnormal smear.

We excluded patients with incomplete records (i.e. vaccination status not known) as well as patients who had an inadequate cervical biopsy.

#### **Results**

We identified a total of 163 patients. Out of these, 108 (66%) had received the HPV vaccine, while 55 (34%) were not vaccinated. The CIN rates in each group were as follows:

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Vaccination								
status	Colposcopy/ Histology findings							
	Normal Colposcopy, no							
	biopsy required	No CIN	CIN1	CIN2	CIN3			
Not								
vaccinated	11 (20%)	18 (33%)	17 (31%)	2 (4%)	7 (13%)			
Vaccinated	24 (22%)	35(32%)	27 (25%)	9 (8%)	13 (12%)			

Our study shows that CIN3 rates are similar in the vaccinated versus the non-vaccinated patients who were referred to Colposcopy with an abnormal first smear. These findings warrant further investigation, via a prospective study in the first instance.

## MODELING THE ADOLESCENT DOSE DEFICIT OF HPV VACCINATIONS DURING THE COVID-19 PANDEMIC IN THE UNITED KINGDOM

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#### **Introduction / Background**

The COVID-19 pandemic led to significant disruption in health care including reduced administration of routinely recommended HPV vaccines among adolescents in the UK. Despite recovery efforts, the time and effort required to reach pre-pandemic levels of coverage is unclear. We used a prediction model to estimate this gap.

#### Aims / Methodology

Reductions in HPV doses administered to UK boys and girls between 12-14 years of age during the COVID-19 pandemic were quantified using NHS HPV vaccine coverage estimates between 2018/19-2020/21 school years. Using 2018/2019 as a reference year, a previously published model was utilized to estimate the cumulative deficit in HPV doses during the pandemic. The model also estimated time-to-catch-up and catch-up rates needed to recover from the deficit.

#### **Results**

The annual coverage of at least one/two dose vaccination in adolescents 12-14 years of age was 89%/83.9%, 80%/57% and 74%/NA in 2018/19, 2019/20 and 2020/21, respectively. The cumulative deficit at start of catch-up period was projected to be 25%/61% for at least one/two dose respectively. The projected deficit for at least one dose is expected to be cleared between 2024 and 2026, assuming annual catch-up rates of 10% and 5%, respectively. The projected deficit for two doses is expected to be cleared between 2025 and 2028, assuming annual catch-up rates of 20% and 10% respectively.

#### **Conclusion**

Administration rates of routine HPV vaccines decreased significantly among UK adolescents during COVID-19 pandemic. The recovery to pre-pandemic coverage level and catch-up of missed doses will require a sustained increase in vaccination and potentially necessitating additional follow up over multiple years.

## HIGH-THROUGHPUT METABOLOMICS IN SCREENING, TRIAGE, DIAGNOSIS AND TREATMENT OF CERVICAL DISEASE

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#### **Introduction / Background**

Given the high prevalence of HPV, reflex cytology is used in hrHPV positive women to select those that need to be referred to colposcopy. However, reflex cytology only performs moderately, is prone to human error and unlikely to be of value in self-collected samples(1). Given the high prevalence of passenger HPV infections with no carcinogenic potential and the mediocre performance of existing triage tests, novel technologies that offer rapid and simultaneous HPV testing, as well as automated triaging of women at high risk of high-grade precancer, are highly sought after.

Screen-positive women referred to colposcopy often require multiple punch biopsies for diagnosis prior to local excision of precancer at a separate visit, as the diagnostic accuracy is poor. Excision of precancer with clear margins is important as the risk of high-grade recurrence drops to 3.7% as opposed to 17.1% in the case of positive margins(2).

Innovative technologies are needed to offer bedside diagnosis at one-stop clinics minimising the risk of non-compliance, repeat visits and over-treatment. Preliminary data generated by using metabolomics-based technologies, such as the Rapid Evaporative Ionisation Mass Spectrometry (REIMS), suggests that the technology can detect the presence of hrHPV infection or abnormal cytology in cell pellets(3) and detect cervical cancer and precancer in tissue samples(4).

#### Methods

LBC and tissue samples were collected from women attending the colposcopy/gynaecology clinics at Imperial College NHS Healthcare Trust. After REMS analysis, the diagnostic accuracy parameters were measured to investigate whether the technology could discriminate between women with or without a hrHPV infection and detect the presence of CIN2+ using cell pellets. We further assessed whether REIMS could detect precancerous changes in tissue.

#### **Results**

REIMS in the cell pellets achieved 94% sensitivity and 83% specificity (AUC: 91.6%) after comparing women with and without hrHPV infections (n=130) using a validated hrHPV assay as the gold standard(3). The technique also discriminated CIN2+ from normal with 91% sensitivity and 73% specificity (AUC: 86.7%). We have also tested the technology's feasibility in tissue biopsies taken during colposcopy, showing good discrimination between normal and CIN.

#### **Conclusion**

REIMS has the potential to offer a single, automated highly-accurate screening and triage test that will enhance *disease prevention* at reduced cost for the health services. The expansion of laser-REIMS in colposcopy could further enhance *diagnostics and 'precision' treatment*.

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#### REAL WORLD DATA SHOWS ELECTRICAL IMPEDANCE SPECTROSCOPY (ZEDSCAN) INCREASES DETECTION OF HG-CIN IN MULTIPLE HEALTHCARE SETTINGS

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#### **Objective**

To evaluate the performance of EIS (ZedScan) with colposcopy in the detection of high grade CIN (HG-CIN) in different health care settings.

#### Method

Pooled analysis of data from 26 colposcopy centres in 9 countries. All women underwent colposcopy and ZedScan examination. Data was recorded prospectively via a proforma. Indications for referral to colposcopy were according to national guidelines. Pathology was reported according to national guidelines.

#### **Results**

5257 women were examined by 82 colposcopists, median 93 women per centre (range 41-2684), 3 users per centre (range 1-8). Referral indications were; 19.3% high grade cytology, 50.4% low grade, 30.4% clinical or HPV positive / cytology negative. The prevalence of HG-CIN was 26.5%; 79.1% high grade referrals, 16.7% low grade, 9.4% clinical or HPV positive / cytology negative. The use of ZedScan detected an extra 269 (22.7%) cases of high grade CIN (7.5% in high grade referrals, 57.9% low grade, 52% clinical or HPV positive / cytology negative. The sensitivity of colposcopy for CIN2+ was 74.1% compared with 91.6% for colposcopy with ZedScan (Chi² p<0.0001). The PPV for a ZedScan directed biopsy varied according to referral cytology and colposcopic impression (19.5% to 85.7%)

489 underwent treatment at first visit. When ZedScan suggested treatment 95.1% had HG-CIN/HG-CGIN or cervical cancer.

The results remained consistent across multiple sub-analyses including the exclusion of the largest centre.

#### **Conclusions**

The addition of ZedScan increases detection of HG-CIN with the PPV for a ZedScan directed biopsy consistent with PPV and APV data from the NHSCSP. Result were similar in multiple healthcare settings demonstrating the applicability of the device. With more women being referred to colposcopy at low risk of HG-CIN due to HPV vaccination and primary HPV screening, this study confirms the value of a real time adjunctive technology.

## SEXUALLY TRANSMITTED INFECTIONS (STIs), HPV INFECTION AND CERVICAL CYTOLOGY: A MOLECULAR EPIDEMIOLOGY STUDY BASED ON 2268 CASES

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#### **Introduction / Background**

HPV prevalence and hrHPV persistence consequences have been extensively investigated in the last decades; nevertheless, the possible association of other sexually transmitted pathogens with HPV cervical infection has not yet been fully elucidated.

#### Aims / Methodology

This study aims to investigate the possible association of sexually transmitted infections (STIs) with cervical cytology and HPV genotyping results in a Greek population.

Liquid based cytology and molecular detection for both HPV and STIs was performed in cervical samples from 2268 women visiting outpatient Gynecology Departments for routine cervical screening between October 2015 and June 2017.

#### **Results**

Mean age of women was  $37.0\pm11.7$  years. Among cases with valid STIs detection result, 722 (33.30%) tested positive, with a mean age of  $34.23\pm10.87$  years, whereas, those tested negative had a lower mean age  $38.34\pm11.83$  years (p<0.05). Out of the total positive STIs cases, *Chlamydia trachomatis* was found in 59 (8.2%), *Mycoplasma hominis* in 156 (21.6%), *Mycoplasma genitalium* in 14 (1.9%) and *Ureaplasma spp* in 555 (76.9%); in 73 samples (10.1%) had two infections; no sample had three or more infections. HPV was detected in 357 out of 1385 samples (25.8%) with valid HPV typing result. The mean age of HPV positive women was  $32.0\pm8.4$  years, whereas it was higher for the HPV negative (N=1028) cases:  $34.4\pm9.2$  (p<0.05). Out of the with a valid result both for STIs and HPV detection (1361), women with a HPV positive sample were more likely to harbor an STI (OR: 2.69, 95% CI 2.10-3.46, p<0.05). STI positivity presented significant heterogeneity between NILM and LSIL cases, with 28.88% of NILM and 46.33% of LSIL cases harboring an STI (p<0.05).

#### **Conclusions**

In a population with a high prevalence for STIs, an association was established between pathogen detection and HPV infection or abnormal cytology; this finding calls for further investigation.

## SELF-SAMPLING FOR CERVICAL SCREENING OFFERED AT THE POINT OF INVITATION: A CROSS-SECTIONAL STUDY OF PREFERENCES IN ENGLAND

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### **Introduction / Background**

HPV vaginal self-sampling is increasingly being used to engage cervical screening non-participants. However, there is no published UK literature on anticipated preferences for self-sampling if it were offered as an alternative choice to clinician-based screening at the point of invitation for cervical screening.

### Aims / Methodology

This study aimed to ascertain the proportion of invitees who would choose self-sampling over clinician screening and reasons for participants' preferences. An online questionnaire was completed by screening-eligible participants in England (n=3,672). Logistic regressions explored the association between demographic characteristics and screening preferences, stratified by previous screening attendance.

#### Results

Overall, more participants intended to choose self-sampling (51%) than clinician screening (36%), with 11% being unsure and 2% preferring no screening. Most irregular and never attenders of screening chose self-sampling (71% and 70% respectively), but a high proportion of regular attenders also selected this option (41%). In regular attenders, self-sampling was preferred more frequently by the highest occupational grade, older and non-heterosexual women, and those with experience of blood self-tests. In irregular attenders, older women and those with experience of blood self-tests were more likely to choose self-sampling. In never attenders, self-sampling was less popular in ethnic minority groups. Reasons for selecting self-sampling included ease (84%), comfort (81%), privacy (79%), convenience (76%), and reduced embarrassment (70%). Those preferring clinician screening did so because they would be more confident in the test being done correctly (88%), have greater trust in the results (88%), and preferred the screening status quo (72%).

### **Conclusions**

Our findings suggest that around half of women in England may choose self-sampling if they are offered a choice at screening invitation, but a substantial proportion would still prefer clinician screening. Screening providers need to plan for many regular attenders switching to self-sampling if this is offered at the point of invitation.

# INCREASING ACCESS TO CERVICAL SCREENING IN THE MUSLIM MIGRANT COMMUNITY, BY UNDERSTANDING THE BARRIERS TO ENGAGEMENT AND ASSESSING ACCEPTABILITY OF SELF-TESTING AND POINT-OF-CARE ASSAYS

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### **Introduction / Background**

PHE figures again show that the UK is falling below its cervical screening target of >80% in 2021. There's an urgent need to explore novel strategies to overcome the barriers to cervical screening and HPV vaccination, and understand how to implement a roll-out of HPV DNA self-sampling in communities which face the most challenges.

Socioeconomic deprivation often results in healthcare inequity, and women in the most deprived groups and minority ethnic backgrounds are least likely to attend screening. Evidence shows that cervical cancer incidence in England is 65% higher in the most deprived quintile compared with the least deprived.

Common barriers to accessing screening include fears around discomfort, embarrassment, and desire for a female healthcare practitioner. The question remains however, whether self-sampling presents a solution, and is acceptable to communities of women least represented in the CSP.

### Aims / Methodology

St. George's serves an ethnically diverse population and this study builds on existing international data on patient and stakeholder acceptability of self-sampling, cervical screening and HPV vaccination, but specifically in the migrant Muslim population of Southwest London. Studies have shown that self-sampling may be up to 97% acceptable and may double engagement with the CSP, but has not been specifically analysed in this under-represented community.

We are undertaking a qualitative in-depth interview study of women from this community and stakeholders in our local area. After coding and analysis, we will feedback the results to the local community, and to policymakers to influence and optimise the pioneering of self-screening.

This data will contribute to a larger study investigating the development of a point-of-care HPV DNA test

which aims to improve access to cervical screening in low and middle-income countries.

### **Results**

We are currently collecting data for the qualitative interview study and expect to have begun analysis and discussion by the end of May and will have original results to share at the conference.

### IS SEE AND TREAT AN OPTION FOR ALL COLPOSCOPY CLINICS?

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### **Introduction / Background**

The cervical screening programme suggests treatment for high grade dyskaryosis. The guidelines suggest that either punch biopsies are taken with a view to women returning for treatment or they undergo excision treatment at first colposcopy, "see and treat". In our unit, in London, we currently have no policy for see and treat.

### Aims / Methodology

To assess the feasibility of implementing a see and treat policy in our colposcopy department.

### Method

Using the data collected from our colposcopy programme (compuscope) we were able to assess the women who underwent treatment (LLETZ) for high grade lesions in the preceding 12 months. We analysed referral cytology, colposcopic opinion and treatment details including depth of excisions and test of cure cytology at six month follow up.

### Results

84 women were seen in the colposcopy department with high grade referral cytology. At colposcopy 10 (12%) were recorded as having low grade or normal features, however most of this group underwent punch biopsy that then meant they were treated with LLETZ. Histology confirming high grade disease following treatment was present in 58 women (69%). 31% of women referred with high grade smears did not have histology confirming high grade cervical disease.

### Conclusion

Two thirds of women referred with high grade disease who underwent excision treatment had histology confirming high grade disease.

Regarding the 31% of women with histology that was low grade, it would be simple to assume that this represents women who were over-treated. However once depth of excision, skip lesions and other factors such as diathermy artefact are taken into account this number is reduced significantly. Is the department ready to introduce See and Treat? From the data analysed this is plausible and the obvious next steps would be, reinforced education, introduction of a local guideline and analysis at six and 12 months.

### CASE REPORT OF SUSPECTED CERVICAL CANCER IN PREGNANCY

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### **Background**

There has been a dramatic reduction of invasive cancer in the UK as a result of the screening programme. The incidence in pregnancy is estimated at 1-10 per 10,000 pregnancies. it is recommended to refer any suspected cervix during pregnancy for a colposcopy examination. It is not recommended to take cervical smears during pregnancy as decidual cells can be mistaken with atypia but the diagnosis must be performed with direct biopsy from the lesion.

### Case summary

A 18 years lady presented at the Gynaecology assessment Unit and complaining of vaginal bleeding at 6, 9, 12 and 13 weeks of pregnancy. She is a non-smoker, with no HPV vaccination or previous smears and had multiple sexual partners. Following speculum examination, she was diagnosed with a Threatened miscarriage with a closed cervix. Subsequent scans showed single viable pregnancy. The Patient presented to her GP with another episode of vaginal bleeding and examination showed a cervical mass and an urgent referral was made to colposcopy clinic at 14 weeks gestation. Colposcopy examination revealed an abnormal-looking raised irregular mass covering three quadrants of the cervix with dense aceto white and iodine negative, suspected invasive changes. Colposcopy and wedge biopsy of the cervix under a spinal anesthetic has showed significant warty changes and abnormal vasculature. Histology reported verrucous carcinoma but GynaeOncology MDT suggested condylomatous growth. Following referral, to the preterm clinic, she had fortnightly cervical length scans without any signs of funneling or shortening, and cyclogest pessary till 34 weeks. The patient spontaneously labored at 38 weeks had a normal vaginal delivery and is waiting for colposcopy and cervical biopsy 3 months postpartum.

### Conclusion

It is difficult to diagnose cancer cervix during pregnancy. Repeated presentation with vaginal bleeding should raise red flags. Management of suspected cervical mass in pregnancy should be managed in MDT approach to tailor patient wishes and expectations.

## INVASIVE CERVICAL CANCER AUDIT: WHAT LESSONS CAN WE LEARN LOCALLY AND WHERE WOULD WE STAND WITH REGARD TO DUTY OF CANDOUR?

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### Aims / Methodology

**Objective:** To identify lessons learned locally from the invasive cervical cancer audit. To estimate the impact that the application of "Duty of Candour' may have upon our future service provision.

Design: Retrospective cohort study with interval analysis.

Setting: Large university teaching hospital in Sheffield, UK.

**Population or Sample:** All women diagnosed with cervical cancer at STH NHS Foundation Trust between 1<sup>st</sup> April 2007 to 31<sup>st</sup> December 2019.

**Methods:** Prospective data collection with retrospective categorisation by screening history and invasive cervical cancer audit outcomes as satisfactory, satisfactory with learning points, and unsatisfactory.

Statistical analysis was performed using Chi Squared test and paired t test.

#### **Main Outcome Measures:**

Outcome by screening history and outcome by final invasive audit categorisation.

### **Results**

**Results:** Cervical cancer was diagnosed in 344 women. Seventy-eight (23%) had no record of prior cervical cytology, 108 (31%) had delayed attendance to the screening programme, 102 (30%) were detected by routine screening, and 56 (16%) were screening programme compliant. Satisfactory management was undertaken in 301 (87.5%) cases; 26 cases (7.5%) were satisfactory with learning points, and 17 cases (5%) were considered as unsatisfactory.

### **Conclusions:**

Seventeen cases were applicable to the 'Duty of Candour' process equating to 1.3 cases per year incurring minimal impact upon future service provision.

Invasive audit categorisation however is subject to bias with the potential for considerable intra- and inter-observer variation, the authors recommend that a further study is conducted to investigate both consistency and reproducibility of the invasive cervical cancer audit categorisation.

## THE CELLULAR AND MOLECULAR CYTOPATHOLOGY TRAINING SCHOOL (CMCTS) AT COOMBE WOMEN AND INFANTS UNIVERSITY HOSPITAL, DUBLIN

<u>Dr Helen Keegan<sup>1,2</sup></u>, Ms. Nadine Oldfield<sup>1</sup>, Ms Alison Malkin<sup>3</sup>, Ms Kate Thompson<sup>1</sup>, Dr Victoria Malone<sup>1</sup>, Dr Marguerite Carter<sup>1</sup>, Ms Padmaja Naik<sup>1,2,4</sup>, Dr CM Martin<sup>1,2,4</sup>, Ms Martina Ring<sup>1</sup>, Dr David Nuttall<sup>5</sup>, Dr NE Russell<sup>5</sup>, Professor JJ O'Leary<sup>1,2,4</sup>

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### **Introduction / Background**

The Cellular and Molecular Cytopathology Training School (CMCTS) provides training events in Cervical Cytopathology, Histopathology and Molecular Pathology in the area of cervical cancer and cervical screening. The CMCTS is supported by CervicalCheck and the Irish Faculty of Pathology.

### Aims / Methodology

The annual activity reports of the CMCTS and CPD event registers from April 2017- January 2022 were reviewed and activity type and the disciplines of attendees were recorded.

#### Results

The CMCTS provides training to Specialist Registrars in Pathology, Biomedical Scientists, Colposcopy Specialists in Training, Colposcopy Specialist Nurses and Pathologists. The CMCTS provides this through a variety of individual sessions, microscopy workshops, lectures, guest lectures, departmental CPD and student placements. The CMCTS also provides research supervision in its state-of-the art Molecular Pathology Laboratory to BSc, MD, MSc and PhD students of Trinity College Dublin and TU Dublin in the areas of cervical screening and molecular epidemiology through the Irish Cervical Screening Research Consortium's research programmes (CERVIVA). In March 2020, the School launched a collaborative QQI Level 9 CPD Certificate Programme with the School of Biological and Health Sciences, TU Dublin, supported by CervicalCheck, aimed at upskilling cervical cytologists in Molecular Cytopathology. This course is the first of its kind nationally and provides the cytologist with the knowledge and understanding of molecular advances in cervical cytopathology. To date, over 190 people have been trained in the CMCTS since April 2017.

### **Conclusion**

The CMCTS provides a framework for the dissemination of health services research knowledge and insights gained through CERVIVA, directly to health service professionals involved in cervical screening. The CMCTS has an important role to play in the development of scientific capacity and expertise for the Irish cervical screening programme (CervicalCheck), particularly in the context of the new National Cervical Screening Laboratory.

## CREATING A DIGITAL PATHOLOGY TEACHING RESOURCE FOR CERVICAL HISTOPATHOLOGY TRAINING: A DEMONSTRATOR PROJECT

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### **Introduction / Background**

The aim of this study was to create a digital pathology teaching resource that could be used for online training in cervical histopathology and to demonstrate ease of use and acceptability with end users. The resource was aimed at colposcopy specialists and specialist nurses who are required to complete cervical histopathology training sessions as part of their training logbook for qualification.

### Aims / Methodology

A range of cases showing cervical pathologies (normal, CIN1, CIN2, CIN3, VAIN, cGIN, CIS, ICC) were chosen by a Consultant Histopathologist from the slide repository at the Histology Laboratory at CWIUH. In total 68 individual slides were scanned using the Zeiss Axio Scanner Zen 2.6 and the Blue Edition Software. Of these, 51 were stained with haematoxylin and eosin and 17 with various immunohistochemical staining including p16, Ki-67, CD34, CD31, and p53. Once scanned, patient identifiers were remove from the digitised image using a programme from Zeiss to remove slide labels. A webinar consisting of supporting lecture content, digitized glass slides accessed in real-time using the Zeiss Software and a live microscopy session was created and delivered. Trainees were invited to feed back on the webinar via SoGoSurvey and a time-in-motion study of the scanning process was conducted.

#### Results

A standard operating procedure for scanning at 20X was created. The average file size of each image was 30MB and the average time taken to create each image was 14.4 mins. A total of 13 scanned images were chosen for the webinar. The webinar was delivered in April 2021 to 6 trainees during a time when face-to-face teaching was not possible due to Covid-19 restrictions. All survey respondents were satisfied with the webinar as a teaching resource.

### **Conclusion**

Digital pathology is particularly useful for the delivery of remote teaching sessions in cervical histopathology and may be a way forward particularly in view of the ongoing health crisis.

## BEYOND THE CERVIX: UNDERSTANDING THE PSYCHOSEXUAL IMPACT OF CERVICAL SCREENING, COLPOSCOPY AND TREATMENT

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### **Introduction / Background**

A 56-year-old healthy, non-smoking female was referred to colposcopy with an abnormal smear showing cytological atypia of endocervical glandular epithelium and presence of HPV infection. Her most recent smear in 2011 had been unsatisfactory and the patient had not attended follow up since. At colposcopy, a cervical biopsy was taken which revealed CIN1. On further consultation as to the reason for non-attendance for routine screening earlier, it became apparent that there was a psychosexual element to this patient's history. She had been unable to have sexual intercourse with her long-term partner since the unsatisfactory smear over ten years ago, citing low libido to her GP. During her review, she disclosed that her inability to maintain any form of physical or sexual relationship with her partner was due in part to severe discomfort experienced during the initial smear that had not been addressed, as well as health anxiety surrounding her understanding of HPV transmission and risk of pre-invasive disease.

### Aims / Methodology

Women can present with sexual problems that are contextualised as a physical entity, although their psychological reaction to them may be unrecognised. Here we sought to understand the combination of physical and psychological implications of past cervical healthcare, to be able to help the patient engage in services.

### **Results**

Despite the finding of low-grade disease, the patient was adamant she wanted treatment to reduce likelihood of need for future attendance, and after MDT review, opted to proceed with cervical treatment (LLETZ). The histology revealed CIN1 with complete excision. Supporting this patient to acknowledge and address the impact of her previous clinical interactions on her sexual life with the support of psychosexual counselling, has enabled her to resume a sexual relationship with her partner. As a colposcopist, being mindful of psychosexual presentations alongside cervical pathology can promote patient health and wellbeing.

### DEVELOPMENT OF A LGBT+ QUICK REFERENCE GUIDE FOR SAMPLE TAKERS

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### **Introduction / Background**

CervicalCheck, the Irish national cervical screening programme commenced in September 2008 and offers free cervical screening to 1.3 million eligible people living in Ireland. The aim of the programme is to reduce the number of people who develop cervical cancer by providing population-based screening. Overall population coverage has ranged from 75-80% since the programme began.

### Aims / Methodology

The programme is committed to ensuring equitable access across marginalised groups. In 2021, a study was performed to examine the knowledge, attitudes, participation and experiences of lesbian and bisexual women, trans-men, non-binary and intersex people with a cervix in cervical screening. Approximately 450 people who identify as LGBT+ took part in the study which was carried out using an online survey, focus groups and stakeholder interviews.

### Results

The study found that the LGBT+ community face a number of barriers to participating in cervical screening including:

- 1. heteronormative assumptions being made by health care professionals
  - being asked heterosexual questions
  - fear of the test procedure
  - embarrassment
  - bad experience of cervical screening in the past

Over 62% of respondents do not state their gender/sexual identity when participating in cervical screening. While many reported positive experiences, only 66.5% said they attend cervical screening regularly. Six percent of survey participants have never had a test despite receiving an invitation.

The LGBT+ community expressed a need to feel welcomed, safe and free to be out. It is important for the programme to be LGBT+ friendly and understand the specific healthcare needs of this community. A clinical environment where sample takers have practical tools and resources increases inclusivity for LGBT+ people. Sample takers need to be able to identify those eligible for cervical screening and be familiar with LGBT+ supports. Gender neutral language and a clearer understanding of the barriers to screening will improve participation and communication with this population.

### CORRELATION OF LOOP DEPTH AND TEST OF CURE RESULTS IN COLPOSCOPY

### Dr Nidhi Shandil Singh<sup>1</sup>

<sup>1</sup>Milton Keynes University Hospital, United Kingdom

### **Introduction / Background**

- 1. Smear results- Low grade/ High grade
- Biopsy results- CIN1/2/3
- What is LLETZ- How deep should it be
  - NHSCSP recommendation
- More than 90%- No cytological abnormality after LLETZ

### Aims / Methodology

- · QA recommendation
- Overall standard for adequate depth not met
- To assess the test of cure results particularly with non-compliance with the depth of loop standard
- Retrospective data collection
- Electronic records- 1/4/2020- 31/03/2021
- Total cases- 143
- Intact loop (1)- 80% or more
- Depth of loop excision 7mm or more (95% or more)
- No dyskaryosis on smear 8 months post-treatment- 90% or more

### **Results**

52% had a loop depth of more than 7mms, standard was 95%

48% had a loop depth of less than 7 mms

85% samples were removed as 1-piece, intact loop, standard was >80%

Standard for intact loop >80%

Two colposcopists not meeting standard

Colposcopist 1 at 75%

Colposcopist 2 at 73%

Test of cure results were negative in 92% of treated patients irrespective of the depth, standard was >90%

Abnormal smears were: Low grade- 6

Borderline- 3 Moderate- 2

Out of these, 1 patient had a loop depth of 8-10 mms, 4 had a loop depth of 5-7 mms, and 6 had a loop depth of < 5mms

### **Conclusions and recommendations**

Some but not all of the NHSCSP recommendations were being met, however test of cure results were encouraging despite the loop depth

Depth of loop- (more than 7mm)- 52% (95%)

Intact loop- 85% (80%)

No dyskaryosis on smear 6 months post-treatment- 92% (90%)

Re-audit in 12 months

Audit of individual performance where targets not being met to be performed annually

### THE RISK ASSOCIATED WITH SURGICAL PLUME IN COLPOSCOPY

### Mr Steve Veck<sup>1</sup>

<sup>1</sup>SURGIVEX, Garvagh, United Kingdom

LLETZ has been performed as part of colposcopy procedures, for many years. From the humble beginnings to the purpose-built colposcopy suites/departments of today.

However, other than improved medical devices for performing LLETZ, not much has changed in terms of making the procedure safer, especially with regards to surgical plume.

Examples exist of inappropriate devices being used for removing surgical plume from the vaginal introitus. These include liquid suction units, low power evacuation devices, indeed sometimes no plume removal at all.

Surgical Plume contains both Chemical and Bacteriological, organic and inorganic matter. Most will know of the added risks associated with HPV specifically p16 and p18. There are over 40+ chemicals which exist within surgical plume, some of these as single chemicals, are banned in Europe, they include Benzene, Toluene, Cyanide, Carbon Monoxide and Formaldehyde to name a few Benzene is a known carcinogen and can even diffuse across the placenta during pregnancy, giving rise to a fetotoxic placenta. Toluene is a neurotoxin which may cause developmental and functional deficits.

There are several publications that show, categorically that HPV can by a mutagenic process enter the host, eg the Colposcopist and potentially staff within the vicinity.

Given the potential high risk, we seek to provide a detailed explanation of what the risks are, why they exist, how they can be eliminated. The outcome is to improve operator, staff and patient safety.

### ONCOLOGICAL AND REPRODUCTIVE OUTCOMES AFTER TREATMENT FOR CIN: A SYSTEMATIC REVIEW AND NETWORK META-ANALYSIS

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### **Introduction / Background**

There are several techniques for cervical intra-epithelial neoplasia (CIN). There is evidence suggesting that CIN treatments increase the risk of adverse obstetric outcomes in subsequent pregnancies and that this risk is greater for more radical treatment modalities which remove or burn a larger part of the cervix. On the other hand, less radical treatments might compromise oncological safety. However, the data is conflicting.

### Aims / Methodology

Our aim was to compare and rank all local excisional or ablative CIN treatments in terms of oncological and reproductive outcomes by performing a network meta-analysis (NMA). Our primary outcomes were treatment failure defined as any abnormal cytology or histology after treatment, and preterm birth less than 37 weeks of gestation. We conducted a random-effects NMA of randomised clinical trials and non-randomised studies and compared different CIN treatment techniques with each other and/or to untreated women with CIN (colposcopy group). We calculated odds ratios (OR) with 95% confidence intervals, and we ranked treatments based on their P-score.

### Results

71 and 28 studies were eligible for inclusion in the NMA for recurrence and preterm birth, respectively. Compared to LLETZ, cold knife conisation (CKC) and laser conisation were associated with lower rates of recurrence [CKC: OR=0.67 (0.53-0.85); laser conisation: OR=0.62 (0.46-0.85)], whilst ablative techniques with higher rates [laser ablation: OR=1.74 (1.33 to 2.28); cryotherapy: OR=1.91 (1.42-2.57)]. Cold coagulation had a similar risk of recurrence as LLETZ, but there was some uncertainty in the estimate. Compared to the colposcopy group, the excisional techniques [CKC: OR=2.29 (1.71-3.06); laser conisation: OR=1.77 (1.29-2.43); LLETZ: OR=1.37 (1.16-1.62)] were associated with a higher risk of preterm birth, whilst ablative techniques did not increase the risk. However, there was uncertainty around the estimates for ablative treatments, especially for cold coagulation. As a conclusion, more radical techniques were associated with better oncological but worse reproductive outcomes. LLETZ achieved the optimal balance between the risk of recurrence and preterm birth.

### **SETTING UP A 2WW ONE STOP VULVAL SERVICE**

### Mrs Claire Carr<sup>1</sup>

<sup>1</sup>Shrewsbury and Telford NHS Trust, Shropshire, United Kingdom

### Setting up a 2ww one stop vulval service

At SaTH we set up a new clinic allowing all 2ww vulval referrals to be seen in a one stop clinic.

Allowing consultation/examination and diagnostic biopsies to be taken.

The poster will include how we set up the service- problems encountered and solutions to overcome issues identified.

How does this improve the patient journey

The poster will also include what has been referred into the service and the outcomes of any biopsies taken.

Conclusions and learning from setting up a one stop service.

## INFLUENCE OF DEPTH OF EXCISION ON TEST OF CURE FOLLOWING EXCISIONAL TREATMENT FOR HIGH-GRADE CIN IN A DISTRICT GENERAL HOSPITAL IN KENT

### Dr Melin Dokmeci<sup>2</sup>, Prof Haseeb Ahmed<sup>1</sup>

<sup>1</sup>Medway Maritime Hospital, Gillingham, United Kingdom, <sup>2</sup>Darent Valley Hospital, Dartford, United Kingdom

### Introduction/Background

NHS Cervical Screening Programme (NHSCSP) has determined the depth of excision standards for high-grade CIN treatment. Standards vary according to Transformation Zone Type and are to be met for >=95% of the patients.[1] Patients receive Test of Cure(ToC) smears to assess success of treatment. Excisions of >10mm in women of reproductive age, lead to an increased risk of preterm delivery without improvement in recurrence rates. Therefore guidance suggests <10mm excision in >85%.[2]

### Aims/Methodology

Our aim was to determine the influence of NHSCSP excision standards on ToC success rates. Data on women who had loop excision for high grade CIN from January 2020 to April 2020 was collected and analysed using OpenExeter, Telepath databases and Microsoft Office, Excel.

#### Results

A total of 123 women received loop excisional treatment for high-grade CIN. Our success of ToC was 65%(n=80), failed ToC was 19%(n=23) and ToC was not recorded for 16%(n=20). For TZT-1, 2 and 3; when standards were not met, success rates for ToC were 80% (n=20), 67%(n=10) and 48%(n=7) respectively. When standards were met, success rates for ToC were 70%(n=27) for TZT-1, 86%(n=6) for TZT-2 and 0%(n=1) for TZT-3. For patients of reproductive age(n=32), 75%(n=24) had excision depth <10mm.

Our unit took shallower loops than recommended by the NHSCSP. This adversely affected the success of ToC with TZT-2. Due to limited numbers, we are unable to comment on TZT-3.

- 1. NHS Cervical Screening Programme, Publication Number 20, Third Edition, last update 28/09/21
- 1. Khalid S, Dimitriou E, Conroy R et al. The thickness and volume of LLETZ specimens can predict the relative risk of pregnancy-related morbidity. Br J Obstet Gynaecol, 2012,119: 685-69

### OBSTETRIC OUTCOMES FOLLOWING THERMAL ABLATION VERSUS LLETZ TREATMENT OF HIGH-GRADE CIN

<u>Dr Sarah Mansfield</u><sup>1</sup>, Miss Caitlyn Gallagher, Ms Kerrie Fortune, Miss Emily Mander, Miss Rachel Choong, Dr Kalpana Ragupathy

<sup>1</sup>NHS Tayside, Dundee, United Kingdom

### **Introduction / Background**

Our study provides insight into obstetric outcomes following excisional and ablative methods of treatment of high-grade cervical intraepithelial neoplasia (HGCIN). This is of relevance in the current environment of renewed interest in thermal ablation.

### Aims / Methodology

This was a retrospective cohort study of women (1086) aged 20 to 45 between 2012 and 2015 who had a large loop excision of the transformation zone (LLETZ;n=409) or thermal ablation (TA;n=677) for HGCIN. Outcomes of first pregnancy and first delivery after 23+6 weeks were studied for a duration of 6 to 9 years following the treatment episode. Descriptive statistics and odds ratio (OR) was calculated to assess differences in obstetric outcomes.

### **Results**

Rate of first trimester miscarriage was equal in both groups (11.9%). There were 209 deliveries (60 following LLETZ and 149 following TA) beyond 23+6 weeks. Women who underwent TA had higher rate of delivery at term compared to those following LLETZ (90.6% vs 88.3%,OR=1.27,p value 0.68). Women had higher rate of delivery at 32-36+6 weeks gestation following LLETZ than TA (10% vs 7.4%). There was one delivery after a LLETZ at 24 weeks gestation that had 3 other risk factors for early delivery. There were 3 deliveries between 28 and 31+6 after TA which had 1-2 risk factors. There was higher caesarean section rate in LLETZ group compared to TA (31.7% vs 20.1%,OR=1.767,p value 0.07). Greater number of caesarean sections were carried out for failure to progress (FTP) in LLETZ group (36.8% vs 10%,OR=3.3,p value 1.11).

### **Conclusion**

Thermal Ablation appears to be associated with lesser rate of preterm delivery and caesarean sections especially those due to FTP. In our previous studies, we have shown comparable treatment success rates between TA and LLETZ; this study further reiterates the need for wider adoption of TA in colposcopy units UK-wide.

### VALCOLP: A PROTOCOL FOR CLINICAL VALIDATION OF PORTABLE COLPOSCOPY DEVICES

Professor Marc Arbyn<sup>1,2</sup>, Ms Iman Jaafar<sup>1</sup>, Dr Glenn Vergauwen<sup>3</sup>, Prof Steven Weyers<sup>2,3</sup>, Prof Dr Pekka Nieminen<sup>4</sup>, Prof Dr Yin Ling Woo<sup>5</sup>, Prof Dr David Wrede<sup>6</sup>, Prof Dr Peter Hillemanns<sup>7</sup>, Prof Dr Murat Gultekin<sup>8</sup>, **Prof Dr Maggie Cruickshank<sup>9</sup>**, Prof Dr Gino Venegas Rodriguez<sup>10</sup>, Dr Jean Doyen<sup>11</sup>, Dr Michael Chung<sup>12</sup>, Prof Dr Patrick Petignat<sup>13</sup>, Prof Dr Marleen Temmerman<sup>14,15</sup>, Prof Dr Walter Prendiville<sup>16</sup>, Dr Partha Basu<sup>16</sup>, Dr Maribel Almonte<sup>16</sup>

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### **Background**

Technical advances in medical imaging and artificial intelligence-based interpretation of digitized images have generated new optical devices that allow assisted visual assessment of the cervical surface applicable in remote low-resource areas as well as adjunctive sophisticated tools (e.g., spectroscopy, other optical processes) that may improve the quality of current colposcopy practice in well-equipped gynaecologic centres in high-income countries. However, their clinical accuracy for cervical precancer is poorly documented in peer-reviewed scientific literature and there is an urgent need for robust clinical validation of these new devices.

### **Objectives**

VALcolp is a framework for validation and comparison of colposcopy devices involving a group of centres-of-excellence with world-widely recognized expertise in the field of management of cervical precancer. VALcolp aims to evaluate the relative sensitivity and specificity of new visual devices (simplified or advanced) to detect cervical precancerous lesions compared to high-quality standard colposcopy using histological assessment of biopsies as reference.

### Study design

The core VALCOLP protocol follows principles of diagnostic test accuracy where the index test (new colposcopy device) and the comparator test (standard colposcopy) are applied to 500 women enrolled at colposcopy clinics and who subsequently have biopsies taken. The histological assessment of biopsies will be used as reference standard. All tests are applied at the same colposcopy visit and the result of the firstly performed test will be blinded to the assessor prior to performing the second test, unless not practically applicable.

Local adaptation of the generic protocol according to context and capacity may be considered.

### **Results**

VALcolp will generate robust test accuracy data for multiple new colposcopy devices. These data completed with literature data will yield a rich database that may be used to define internationally agreed criteria for validation of new generation colposcopy devices.

**Conclusion:** ValCOLP is an ambitious concept that finally will inform stakeholders which new colposcopy devices may be considered as clinically validated.

**Keywords:** Cervical cancer; Cervical cancer screening; Diagnostic test accuracy; colposcopy; Test validation

### **References**

- 1. Arbyn M, Depuydt C, Benoy I, et al. VALGENT: a protocol for clinical validation of human papillomavirus assays. *J Clin Virol* 2016; 76 (Suppl 1): S14-S21.
- 2. Arbyn M, Peeters E, Benoy I, et al. VALHUDES: a protocol for VALidation of HUman papillomavirus assays and collection DEvices for HPV testing on Self-samples and urine samples. *J Clin Virol* 2018; 117: 52-6.

### FOLLOW UP AFTER COLD COAGULATION TREATMENT OF HIGH-GRADE CIN UNDER THE 'HPV TEST OF CURE' PROTOCOL

<u>Dr Hafsa Yousaf</u><sup>1</sup>, Dr Humaira Tabassum<sup>1</sup>, Dr Sandhya Babu<sup>1</sup>, Dr M Byrne<sup>1</sup> <sup>1</sup>Wexford General Hospital, Wexford Town, Ireland

### **Introduction / Background**

LLETZ (Large loop Excision of Transformation zone) is the most commonly performed treatment for high grade CIN. Cold coagulation, which is an ablative technique, has been established as equally successful as LLETZ in selected cases of high grade CIN, when using negative cytology as the test of cure. When compared to LLETZ, Cold Coagulation has added benefits of being less traumatic, and is not associated with pregnancy complications such as preterm labour, which can happen after LLETZ procedures. Furthermore, it has no documented impact on fertility.

### Aims / Methodology

We undertook an audit in Wexford General Hospital to determine the success rates of cold-coagulation using Negative HPV status as the test of cure. We also looked into the percentage of the women and the time -frame that they were discharged back to routine recall after a negative test of cure using this standard. For this purpose we reviewed clinical data captured via Compuscope of 60 patients attending our colposcopy services.

### Results

Of the 60 women 35 had CIN 2 and 23 had CIN 3. Type 1 transformation zone was recorded in 56 cases.

At 6-month follow-up after treatment 52 of the women were found to have been discharged to GP. 5 needed follow-up at 18 to 24 months as they were HPV positive at 6-month follow-up post-treatment.2 women remained had persistent HPV positive and abnormal smears needed further treatment and 3 of patients were lost to follow-up.

This audit supports the fact that cold coagulation is an effective management option for treating high-grade CIN in clinic settings using negative HPV status as the test of cure.

### HPV001: CHADOX1 AND MVA HETEROLOGOUS PRIME BOOST VACCINATION IN LOW-GRADE HPV-RELATED CERVICAL LESIONS

<u>Karin Hellner</u><sup>1</sup>, Philippe Simon<sup>2</sup>, Gemma Hancock<sup>1</sup>, Andrea Swadon<sup>3</sup>, Ana Maria Walley<sup>3</sup>, Raisha Kennerley<sup>3</sup>, Vicky Wheeler<sup>3</sup>, Margaret Marshall<sup>3</sup>, Katie Anderson<sup>3</sup>, Jakub Kopycinski<sup>3</sup>, Lucy Dorrell<sup>1</sup> <sup>1</sup>University of Oxford, United Kingdom, <sup>2</sup>Hospital Erasme University Libre de Bruxelles, Brussels, Belgium, <sup>3</sup>Vaccitech Ltd, Oxford, United Kingdom

### **Introduction / Background**

Therapeutic vaccination is a promising approach to restore the T cell immunity that appears central in clearance of persistent high-risk HPV infections. VTP-200 is a heterologous ChAdOx1-HPV prime and MVA-HPV boost regimen of two viral vectors that contain 59 conserved regions from 6 early proteins of 5 high risk HPV genotypes. HPV001 is evaluating the safety, immunogenicity and efficacy of VTP-200 in participants with persistent cervical high-risk HPV (hrHPV) infection and coexisting low-grade cervical lesions.

### Aims / Methodology

The lead-in phase of enrolment is complete and evaluated three dosing regimens. The main phase is a blinded, randomised, placebo-controlled study investigating 3 varying doses of ChAdOx1 (Day 0) and 2 doses of MVA (Day 28) with a 12-month follow-up period (N=96, with 32 participants receiving placebo). A protocol-specified interim analysis occurs when the first 60 participants reach their 6-month timepoint.

### **Results**

Enrolment of lead-in groups A, B and C is completed and the main phase is underway; no safety signals are noted to date. The immunogenicity (antigen-specific ELISpot and flow cytometry ICS) shows responses across multiple antigens without a clear dose response.

## EFECTIVENESS OF A MULTI-INGREDIENT CORIOLUS VERSICOLOR-BASED VAGINAL GEL IN HPV+ and HIV+ PATIENTS: A PILOT OBSERVATIONAL STUDY

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### **Introduction / Background**

Immunosuppressed human immunodeficiency virus (HIV) -positive patients are at greater risk of incident, persistent, or recurrent human papillomavirus (HPV) infection. They also have lower clearance rate, higher viral load, and a marked predisposition for being colonized by several serotypes; all leading to more frequent and severe HPV-dependent lesions. A Colorius versicolor-based vaginal gel have shown to repair HPV-dependent low-grade cervical lesions and to increase high-risk HPV clearance in immunocompetent HPV-positive patients

### Aims / Methodology

The aim is to provide evidence about the effectiveness of a multi-ingredient Coriolus versicolor-based vaginal gel on HPV-dependent cervical alterations and HPV clearance in HIV+ patients Pilot, prospective, one-cohort, observational study. 15 HIV-positive patients colonized by HPV in the endocervix region with an anomalous cervicovaginal cytology were included to receive a Coriolus versicolor-based vaginal gel 1 cannula/day for 21 days during first month + 1 cannula/alternate days for 5 months. Analysis of HPV patients with normal cytology and colposcopy image (improved alterations) and patients with HPV cleared (measured using hybrid capture test) is presented. The study was approved by an IRB and informed consent was signed by patients.

### **Results**

The overall HPV clearance and cytological normalization rates were 73.33% and 80%, respectively. Endocervical colonization by HPV also partially cleared in 13.33% of the cases. At the end of the study, the normalization of the colposcopy anomalies associated to HPV was achieved in 55.56%. Our results suggest that the proposed Coriolus versicolor-based vaginal gel treatment scheme could be an effective therapy in the management of endocervical HPV infection in HIV + patients. Its effects are similar to those obtained in patients without immunosuppression

### CO-TESTING HPV AND CYTOLOGY - SURVEY LONDON COLPOSCOPY

<u>Miss Deirdre Lyons</u><sup>1</sup>, Ms Theresa Freeman-Wang<sup>2</sup>, Ms Anne Jackson<sup>3</sup>, Mr. Joe LLahi<sup>4</sup>

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### Co-testing - HPV and Cytology testing - Survey of London Colposcopy

HPV Primary Screening was introduced in London in December 2019. The reasons for the introduction of HPV Primary Screening in the UK, were increased sensitivity for identification of cervical disease.

There have been questions raised by some clinicians as to whether primary HPV screening is suitable for all conditions.

Patients who have had radical trachellectomy, have previously had cytology undertaken for follow-up and most of the follow-up data is based on cytology. Other conditions which exhibit HPV negative neoplastic disease – for example DES exposed patients and those Peutz-Jehgers syndrome, may not always be suitable for HPV testing alone.

London Colposcopists undertook a survey of London Colposcopists to assess their views on cotesting (HPV and cytology).

The survey was sent to 50 Colposcopy clinicians, 31 responded (62%). Most were Lead Colposcopists, with 5% Gynaecological Oncologists. Most clinicians did see patients with CGIN follow-up, post-hysterectomy and multizonal disease patients. A small proportion (22%) saw DES exposed women. Most survey respondents (>70%) felt that Primary HPV testing was not / were unsure that primary HPV screening was the most suitable method of follow-up for these cohorts of patients. Some clinicians (45%) undertook non-gynae cytology samples in these patients, although this was limited by having a cytopathologist at their local laboratory, who could read these samples. Over 90% repondents felt that certain conditions should have the option of co-testing for certain conditions. This was highest in post- hysterectomy patients, but was also 70-90%, for DES exposed, post- CGIN treatment and multizonal disease patients.

Most clinicians felt that trachellectomy and post-hysterectomy for cervical cancer patients, should have co-testing, until the evidence is available to ensure primary HPV testing is a suitable alternative to cytology.

### POST-HYSTERECTOMY VAGINAL VAULT SAMPLING AUDIT

<u>Dr Helen Doran</u>, Dr Dorota Hardy<sup>1</sup>, Dr Helen Doran<sup>1</sup>

\*\*James Cook University Hospital, Middlesbrough, United Kingdom

### **Introduction / Background**

Vault sampling is not part of the routine screening programme (1). Individuals who have had a hysterectomy with CIN present are potentially at risk of developing vaginal intraepithelial neoplasia and invasive vaginal disease (2). There is no clear evidence that colposcopy increases the detection of disease on follow up. Responsibility for implementing follow up policies rests with the treating gynaecologist (1,2). We audited post-hysterectomy vaginal vault sampling adherence to national guideline.

### Aims / Methodology

100 patients post hysterectomy operated between 2020-2021 were assessed for indications for vaginal vault sampling. They were divided in 5 groups: 1) no CIN, up to date negative smears, 1A) no CIN, no up to date smear, 2) completely excised CIN on hysterectomy, 3) incompletely excised CIN1, 4) incompletely excised CIN 2 or CIN 3, 5) cervical cancer in a non-radical hysterectomy, 6) subtotal hysterectomy.

The patients were 28-54 years all and the indication for hysterectomy was endometriosis. We used Open Exeter national database and NHAIS database to access vaginal vault smear tests results. We evaluated if a written advice was given on discharge by a gynaecologist regarding a need of a vault smear.

### **Results**

Overall, the audit demonstrated 11% of patients didn't get vaginal smear at 6 months despite not having up to date smears before hysterectomy.

Our results triggered development of Standard Operating Procedure for triaging for vault smears in gynaecology outpatient clinic.

Our recommendation are: the pathologists to send hysterectomy specimens to Colposcopy MDT if CIN found and to highlight guidelines if CIN found on hysterectomy specimen to general gynaecologist. All hysterectomies request forms are to have smear history.

#### Reference

- 1. Guidelines for the NHS cervical screening programme
- 1. NHS publication February 2020 follow-up after hysterectomy

# CERVICAL SCREENING WITH PRIMARY HIGH-RISK HUMAN PAPILLOMAVIRUS TESTING ALLOWS EXTENSION OF SCREENING INTERVALS: AN OBSERVATIONAL STUDY OF ENGLISH SCREENING PILOT DATA

Dr Matejka Rebolj<sup>1</sup>, Dr Kate Cuschieri, Mr Christopher Mathews, Dr Francesca Pesola, Dr Karin Denton, **Professor Henry Kitchener** 

<sup>1</sup>King's College London, United Kingdom

### **Introduction / Background**

Human papillomavirus (HPV) testing is replacing cytology in primary cervical screening in many countries, because clinical trials have shown it to be more sensitive in the detection of high grade CIN, and to permit longer screening intervals. The English Pilot study was performed to demonstrate within the National Programme, the safety, and ultimately the benefit of HPV primary screening.

### Aims / Methodology

We used the Pilot data, which included 1.3 million women, to determine the detection of CIN3+ and cervical cancer following a negative HPV test compared with negative cytology. These were used as indicators of the safety of extended screening intervals.

### **Results**

For women with negative HPV tests at 25-49 years, these data confirm a substantially decreased risk of both interval cancer (HR<sub>adj</sub>: 0.44, 95% CI: 0.23-0.84) and CIN3+ detected at screening in the subsequent routine recall (OR<sub>adj</sub>: 0.26, 95% CI: 0.23-0.30), compared with women with negative cytology. The risk of an incident CIN3+ detected at the subsequent routine recall following a negative HPV test was even lower in women older than 50, with an OR<sub>adj</sub>: 0.46 (95% CI: 0.27-0.79) compared with women younger than 50. Women with negative HPV tests at early recall following a positive HPV screening test without cytological abnormalities had a higher detection of CIN3+ at the subsequent routine recall compared with those women whose baseline HPV test was negative (OR<sub>adj</sub>: 3.27, 95% CI: 2.21-4.84). These data support an extension of the screening intervals: to five years following a negative HPV test in women aged 25-49, and even longer for women aged 50 and older. The screening interval for HPV positive women who have negative HPV tests at early recall should be kept at three years.

### **Poster Numbers**

Α			
Abdul, Summi	P-1	Altunel, Melis	P-3
Abu, Jafaru	P-13	Anantharachagan, Arisudhan	P-19
Addley, Susan	P-1	Anderson, Katie	Proffered Paper 3
Ahmed, Haseeb	P-98	Arain, Sumaira	P-4
Ahmed Ainuddin, Iman	P-20	Arbyn, Marc	P-14, P-96, Proffered Paper 1
Alexandrou, Demitra	P-2	Asher, Viren	P-1
Alkatib, Maha	P-59	Athanasiou,	P-96
Almonto Maribal	Dueffered Denoy 1	Antonios	D 07
Almonte, Maribel Alomar, Ohoud	Proffered Paper 1 P-65	Augustin, Yolanda	P-87
Alomar, Onoud	r-05		
В			
Babu, Sandhya	Proffered Paper 2	Bhatia, Ramya	P-73
Badcock-Scruton, Autanza	P-5	Bhatte, Deepali	P-8
Badcock-Scruton, Autanza	P-5	Bowden, Sarah	P-79, P-83, P-96
Bali, Anish	P-1	Brookes, Jane	P-52, P-53, P-54
Bano, Farida	P-7, P-8	Brown, Brian	P-84
Bano, Farida	P-6	Brown, Teresa	P-29
Basu, Partha	Proffered Paper 1	Brown , Ruby	P-47
Bates, Mark	P-91	Buduru, Indira	P-23
Bautista, Oliver	P-74, P-75	Bunce, Kim	P-6, P-7, P-8
Beamer, Liam	P-51, P-52, P-53, P- 54	Burgess, Helen	P-9
Bennett, Phillip	P-83, P-96	Byrne, M	Proffered Paper 2
Beynon, David	P-42	Byrom, Jenni	P-17, P-18
Gareth		<b>2</b> , . e, <b>3</b> e	. 17,1 10
С			
Cameron, Simon	P-83	Connor, Linzi	P-73
Carr, Claire	P-97	Cortés, Javier	P-104, P-105
Carter, Marguerite	P-90	Costanzo, Italo	P-11
Carter, Suzanne	P-72	Criscuolo, Anna Angela	P-105
Chachan, Sonia	P-66	Crosbie, Emma J	P-72
Chatterjee, Bidisha	P-10	Crossland, Harriet	P-1
Chen, Ya-Ting	P-82	Cruickshank,	Proffered Paper 1
enen, ru ring	. 52	Maggie	o . c . c a . a p c . z
Choong, Rachel	P-99	Cummings, Fiona	P-49
Chrelias, Georgios	P-85	Cunningham, Brian	P-12
Chung, Michael	Proffered Paper 1	Currie, Heather	P-73
Clinton, Susan	P-48	Cuschieri, Kate	Proffered Paper 7
Cocuzza,	P-14	Cuschieri, Kate	P-14
Clementina		•	
Comer, Rachael		Cushieri, Kate	P-73

D

Daniel, Jessica	P-78	Dinas,	P-100
		Konstantinos	
Daniilidis, Angelos	P-100	Disu, Stewart	P-69
Daponte, Alexandros	P-85	Dokmeci, Melin	P-98
	P-85	Doran Holon	D 62 Drofforod
Daponte, Nikoletta	P-03	Doran, Helen	P-63, Proffered Paper 6
D'Arcy, Tom	P-68	Doran, Helen	Proffered Paper 6
Das, Nivedita	P-13	Dorrell, Lucy	Proffered Paper 3
Davies-Oliveira,	P-72	Douglas, Daniel	P-15
Jennifer C	2	Douglas, Damer	. 13
Davis, Michael	P-67	Doyen, Jean	Proffered Paper 1
Denton, Karin	Proffered Paper 7	Doyle, Deborah	P-51
Dexeus, Damian	P-105	Drysdale, Hannah	P-86
Dexeus, Demian	Proffered Paper 4	Dunin de	P-76
,	•	Skrzynno, Sophie	
Dhillon, Sharon	P-14	Dutta, Debriatti	P-89
de Santiago, Javier	P-104		
E			
Efthimiou, Orestis	P-96	Ellis, Kay	P-9
Elasifer, Hana	P-73	Elnahas, Ahmed	P-89
Elder, Jackie	P-52, P-54	Enabor, Obehioye	P-27
El-Hadidy, Ahmed	P-16	English, Deborah	P-29
ElKattan, Eman			
F			
Fahy, Lorraine	P-41	Flannelly, Grainne	P-80
Faroooq, Samina	P-17, P-18	Flores, Sheryl	P-75
Fisher, Lauren	P-19	Formoy, Emma	P-52, P-53, P-54
Fitzgibbon, Sarah	P-93	Forson, William	P-73
Fitzpatrick, Myra	P-35	Forsyth, Sophie	P-78
Fitzpatrick, Patricia Fitzpatrick ,	P-41, P-80 P-50	Fortune, Kerrie Freeman-Wang,	P-99 Proffered Paper 5
Patricia	r-30	Theresa	Proffered Paper 5
Flannelly, Graine	P-48	Freeman-Wang,	P-2
riamieny, Grame	1 40	Theresa	1 2
Flannelly, Grainne	P-68	meresu	
,,			
G			
Gajino, Clara	P-105	Giwa, Maria	P-74, P-75
Gajjar,	P-13	Gleeson, Grainne	P-41, P-50
Ketankumar			
Galani, Apostolia	P-79	Gleeson, Grainne	P-34
Gallagher, Caitlyn	P-99	Goel, Roopam	
Gallagher, Maeve	P-20	Goldsmith, Hilary	P-36
George, Mary	P-3	Goodwin, Claire	P-28
George, Reji	P-37	Gorton, Matthew	P-76
George, Smitha	P-66	Gosakan, Radhika	P-60
Giannos,	P-79	Gouloumi, Alina-	P-85
Panagiotis		Roxani	
Gilham , Clare	P-72	Grant, Marie-	P-67
		Therese	
Gillespie, Alan	P-9	Group, Thomas	P-75
Giubbi, Chiara	P-14	Gultekin, Murat	Proffered Paper 1
Giuliano , Anna	P-74		

Н			
Hancock, Gemma	Proffered Paper 3	Hijona Elósegui, Jesús Joaquín	Proffered Paper 4
Hardy, Dorota	Proffered Paper 6	Hillemanns, Peter	Proffered Paper 1
Harkin, Rosemary	P-44, P-45	Hollingworth,	P-62
,		Antony	
Harper, Charlotte	P-8	Hoss, Elaina	
Hayes, Kevin	P-87	Huseyin, Naci	P-96
Hellner, Karin	Proffered Paper 3	, ,	
, -			
1			
Ibrahim, Elzhara	P-48	Illah, Ojone	P-77
Ibrahim, Ola	P-68	Imcha, Mendinaro	P-29
J			
Jaafar, Iman	Proffered Paper 1	Johnston , Lorraine	P-38
Jackson, Anne	Proffered Paper 5	Joura, Elmar	P-74
Jamieson , Jackie	P-33	Joyce, David	P-80
Jayaram, Divya	P-25	Judd, Michelle	P-10
Johnson, Racheal	P-21	Juliana, Anita	P-22
K			
Kalliala, Ilkka	P-96	Khinder , Sangeeta	P-2
Kamaruddin, Tuan	P-22	Kitchener, Henry	Proffered Paper 7
Kandanearachchi,		Knight, Emily	P-52, P-53, P-54
Priyantha			
Kapadia, Wioletta	P-24, P-69, P-88	Kopycinski, Jakub	Proffered Paper 3
Karri, Kamakshi	P-23	Kottaridi, Christine	P-85
Kasina, Venkata	P-19	Krishna, Sanjeev	P-87
Kaur, Jatinder	P-24, P-88	Krishnamoorthy,	P-25
		Uma	
Keating, Emily	P-78	Krishnan, Shiv	P-26
	D 70 D 00	Ranjini	
Kechagias,	P-79, P-83	Kulkarni, Akshatha	P-27
Konstantinos	D 22 D 70 D 00 D	Variable a	
Keegan, Helen	P-33, P-70, P-90, P-	Kumar, Vanitha	
Kennerley, Raisha	91 Proffered Paper 3	Kuar Dhuu Mua	P-28
Khalil, Haytham	Proffered Paper 3 P-24, P-88	Kyar Phyu, Mya Kyrgiou, Maria	
Khan, Maria	P-31	Kyrgiou, iviaria	P-79, P-83, P-96
Usman	F-31		
Osiliali			
L			
Latimer, Abigail	P-65	Lim, Anita	P-86
Leventakou, Danai	P-85	LLahi, Joe	Proffered Paper 5
Liaw, Ying	P-23	Luxembourg,	P-74, P-75
Liuw, Ting	. 23	Alain	1 74,1 73
Liew, Nyan Chin	P-29	Lyons, Deidre	P-64
Liew, Yeneit	P-30	Lyons, Deirdre	P-96, Proffered
,		,	Paper 5
			· •
M			
Ma, I Teng	P-31	Mat Ali, Nafeesa	P-87
Macdonald,	P-9	Mathews,	Proffered Paper 7
Madeleine		Christopher	•
MacIntyre, David	P-83	McArdle, Ciara	P-35

MacLeod, Alison	P-39	McCauley, Jennifer	P-75
MacLeod, Alison	P-20	Mcelhinney,	P-36
		Bernadette	
Magaliou, Ioulia	P-85	McGuckin, Leah	P-12
Magzoub, Reem	P-32	MCGUCKIN, Leah	P-37
Maharajan,	P-28	McGuckin , Leah	P-31
Pushpakala			
Majeed, Gulnaz	P-11, P-76	McMullan, Josh	P-38
Malkin, Alison	P-90, P-91	Michail, Georgios	P-85
Malone, Victoria	P-90, P-91	Milliken, Sarah	P-39
Mander, Emily	P-99	Minhas, Uzma	P-47
Mansfield, Sarah	P-99	Mitra, Anita	P-83
Marano, Joseph	P-68	Mooney, Therese	P-40, P-41
Margari, Niki	P-85	Mooney, Therese	P-80
Margioula-Siarkou,	P-100	Mooney , Therese	P-50
Chrysoula	. 100	mooney, merese	. 50
Margioula-Siarkou,	P-100	Moreman,	P-27
Georgia	. 100	Catherine	,
Marín, Elena	P-105	Morgan , David	P-38
Marlow, Laura	P-86	Morgan , Margaret	P-67
Marshall,	Proffered Paper 3	Muggeridge,	P-42
Margaret	Frontered Faper 3	Catherine	F-42
Martin, Cara	P-33, P-68, P-80, P-	Mukhapadhyay,	P-6, P-7
iviai tiii, Cara	70, P-90	Debjani	P-0, P-7
Martinelli,	70, F-90 P-14	Debjaili	
Marianna	F-14		
	D 06	Multanadhuau	D O
Martin-Hirsch, Pierre	P-96	Mukopadhyay, Debjani	P-8
	D 24 D 41	<u>-</u>	D 02
Mason Mohan, Caroline	P-34, P-41	Mulcahy, Ciara	P-93
	P-93	Mullan Zara	P-15
Mason Mohan, Caroline	P-33	Mullan, Zara	P-12
Caronne		Myerson, Nicholas	P-61
		iviyerson, iviciiolas	P-01
N			
Nagib, Hany	P-21	Nistor, Sabina	P-81
Naik, Padmaja	P-70, P-90	Nunns, David	P-13
Nayak, Sumita	P-81	Nuttal, DS	P-33
Ness, Fiona	P-34	Nuttall, David	P-90
Nieminen, Pekka	Proffered Paper 1	Nuttaii, Daviu	F-30
Mieilillell, Pekka	Fioriered Faper 1		
0			
O'Dwyer, Sinead	P-76	O'Leary, John	P-68
O'Brien, Roisin	P-33, P-70	O'Leary, John	P-80
O'Connor, Mairead	P-80	O'Leary, John J	P-33
O'Donnelle, Sheila	P-29	O'Leary, John	P-91
O Donniene, Snena	F-25	James	P-31
O'Donovan,	P-80	Oo, Thida	P-3
Bernadine	F-80	Ou, Tillua	F-3
	P-106	O'Pagan	P-44
Ogunremi,	L-100	O'Regan,	r- <del>44</del>
Adeyemi Ohn, Nang	P-43	Catherine O'Regan,	P-45
Oilli, Nallg	F-43	Catherine	F-43
Okazia Chidiahara	P-101		P-68
Okezie, Chidiebere Olaitan, Adeola	P-101 P-77	O'Toole, Eilis O'Toole, Sharon	
Oldfield, Nadine		•	P-70
Oluliela, Naalne	P-90	Ovcinnikova, Olga	P-82

O Leary, Joini J	F-70		
O'Leary, JJ	P-90		
P			- "
Packet, Bram	P-71	Petignat, Patrick	Proffered Paper 1
Palacios, Santiago	P-105	Petousis, Stamatios	P-100
Palaparthy,	P-47	Phillips, Andrew	P-1
Sangeetha		• ,	
Palmer, Julia	P-9	Phillips, Merlin	
Panagopoulos, Periklis	P-85	Pilknigton, Loretto	P-70
Panayiotides,	P-85	Pinggera, Elisabeth	P-72
loannis G.			
Paraskevaidi, Maria	P-79, P-83, P-96	Plans, Consol	P-29
Paraskevaidis,	P-96	Pontre, Jennifer	P-36
Evangelos			
Park, Claire		Poppe, Willy	P-71
Parthenis, Christos	P-85	Pouliakis ,	P-85
		Abraham	
Paton, Jenna	P-102, P-49	Power, Maria	P-93
Pearmain, Philippa	P-47	Prasad, Malini	P-10
Pemmett, Faye	P-25	Prendiville, Walter	Proffered Paper 1
Pesola, Francesca	Proffered Paper 7	Price, John	P-40, P-50
Petch, Sarah	P-48		
R			
Raglan, Olivia	P-92	Riera, Margarita	P-105
Ragupathy,	P-102, P-26, P-49,	Rimmer, B	P-80
Kalpana	P-99	- ,	
Rainey, Laura	P-38	Ring, Martina	P-90
Rains, Jane	P-11	Rourke, Micheal	P-40
Ramsbottom,	P-93	Russell, NE	P-90
Debbie			
Rebolj, Matejka	Proffered Paper 7	Russell, Noirin	P-50, P-80, P-93
Reginald, Philip	P-81	Russell, Noirin	P-34
Reynolds, Stephen	P-70	Russell, Noirin E	P-33, P-40, P-41
Robinson, Rebecca	P-91		
S			
Saah , Alfred	P-74	SHETA, AHMED	P-66
Sadiq, Seema	P-106	Shoeir, Samar	P-59
Salanti, Georgia	P-96	Short, Mary	P-50
Sanmartín, Patricia	P-104, P-105	Silva, Shamitri	P-62
Sanmartín Salinas,	Proffered Paper 4	Simon, Philippe	Proffered Paper 3
Patricia	D 104	Cinale treat	D F0
Santiago, Palacios	P-104	Singh, Jyoti	P-59
Sargent, Alexandra	P-72 P-86	Sinha, Mayurika	P-25, P-30
Sasieni, Peter	P-86 P-51	Smith, Hayley So, Sabrina	P-20
Sawyer, Rosamund Saxena, Kunal	P-82	Sokol, Filip	P-20 P-91
Caluareth Dritte	P-02	Sokoi, Filip	L-2T

O'Leary, John J

Seivereth, Britta

Selvamani, Sassi

P-68

P-101

P-70

Soliman, Suzan

Spain, Geraldine

P-64

P-55

Semertzidou, Anita	P-83	Spathis, Aris	P-85
Semple, David Sereni, Maria Isabella	P-52, P-53, P-54 P-55	Staines, Henry Stuart, Greer	P-87
Serrano, Luis Shandil Singh, Nidhi	P-105 P-103, P-56, P-57, P-58, P-94	Swadon, Andrea Sweeney, Philip	Proffered Paper 3 P-47
Shankar, Letchuman	r-30, r-3 <del>4</del>	Swinburne, Lynn	P-93
Sharp, Linda Shesha, Vishanthi	P-80 P-27	Syed, Shireen	P-60
Т			
Tabassum, Humaira	Proffered Paper 2	Thomas, Zebia	P-61
Tabassum, Neha	P-79	Thompson, Kate	P-91
Takats, Zoltan	P-83	Thompson, Kate	P-90
Tamizian, Onnig	P-16	Tidy, John	P-84
Tan, Linda	P-24, P-88	Torbe, Emma	P-78
Temmerman,	Proffered Paper 1	Tsampazis,	P-100
Marleen		Nikolaos	
Teppler, Hedy	P-75	Tsiodras, Sotirios	P-85
Tewari, Prerna	P-68, P-70	Tzafetas, Menelaos	P-83
Thamke, Diana	P-68		
V			
Valasoulis, George	P-85	Vergauwen, Glenn	Proffered Paper 1
Vanherck, Miet	P-71	Veroniki, Areti Angeliki	P-96
Veck, Steve	P-95	Vicheva, Teodora	P-8
Vella, Simone	P-65	Vicheva, Teodora	P-6, P-7
Venegas	Proffered Paper 1	Von Bunau,	P-32
Rodriguez, Gino		Gunther	
v			
von Bunau, Gunther	P-68		
w			
Waddington, Tammy	P-25	Whelan, Eilbhe	P-83
Wales, Nick	P-92	White, Christine	P-70
Waller, Jo	P-86	Widschwendter, Martin	P-77
Walley, Ana Maria	Proffered Paper 3	Williamson, Lydia	P-37
Warner, Charlotte	P-6, P-7	Wong, Jun Ching	P-29, P-62
Webb, Sophie	P-87	Woo, Yin Ling	Proffered Paper 1
Weyers, Steven	Proffered Paper 1	Wrede, David	Proffered Paper 1
Weynand, Birgit	P-71	Wuntakal, Rekha	P-6, P-8
Wheeler, Vicky	Proffered Paper 3		
X			
Xynos, Apostolos	P-63		

Υ

137

Yongue, Gabriella P-64 Yousaf, Hafsa Proffered Paper 2

Z

Zainuddin, Puteri P-81