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Detection of progression or regression of gynecologic cancers by circulating tumor DNA (CTDNA)

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INNO-LiPA Extra-II kit (Fujirebio), based on PCR-reverse hybridization.

Results Among 110 women with CIN2/3 (n=19) and invasive cancer (n=91), early antibodies to any HPV early antigen were detected in 58(53%). The difference between CIN2/3 (47.4%) and cancer (53.8%) was not significant (p=0.62). All 58 were positive for antibodies to HPV16 CE2/NE6/E7. HPV18/31/45 E7 antibodies were detected additionally in 1,1 and 2 cases, respectively. Among 40 controls (normal cytology and negative HPV DNA on Hybrid Capture), any early HPV antibodies were detected in 8(20.0%) cases with HPV16 CE2/NE6/E7 in 3(7.5%), HPV18 E7 in 2(5%), HPV31 E7 in 5 (12.5%), and HPV45 E7 in 3(7.5%). On HPV genotyping, 88 (80.0%) cases had any high-risk (hr)HPV type, commonest being HPV16(69%), HPV18(5%), HPV31/33(3% each), HPV35/45/59(2% each). Single hrHPV infections were detected in 77 patients, 7 had single hrHPV infections other than HPV16. Multiple hrHPV infections were detected in 11 (10%) patients.

Conclusions The serological test detects a high proportion of cases detected by INNO-LiPA. Further development of this simple, affordable technology holds promise to facilitate cervical screening and triage in community settings.

EP345/#758 BREAST CANCER SCREENING PROGRAM IN UZBEKISTAN- REPORT FROM A BUKHARA PILOT

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Objectives The main purpose of the study is to organize population- based mammography screening.

Methods Bukhara region has 13subdivisions with an overall population of about 2 million. Every subdivision was equipped with a digital mammograph (all together 13 fixed and 2 mobile units). The paramedical personnel were appropriately trained on the use of technology. A specialized uniquely designedregistration process records all important data including ID, family status, history, menopausal status, hormonal usage, medical history including ovarian or other malignancies and more. The target group planned is women between age group of 45–65. With target women population estimated to be 200,000, it was decided to perform about 70–80000 mammograms over a year.

Results Women were reached using state television, radio and other channels of communication. Data generated by mammography machine is directly sent to central reporting center based at National Republican Cancer Center in Tashkent in real time. Standard BIRADS scoring is used.A total of 55013 women were screened. Out of this group 388 (0.7%) were found to have BIRAD 5 (highly suspicious of cancer, 95 % probability of malignancy) 2033 women (3.7 %) were found to have BIRADs 4 (suspicious of cancer 20–35 % probability) and BIRADS 1–2 category was reported in 50765 women (92.3%). The follow up plan is well lead out and is being executed.

Conclusions Establishment of national large level population-based mammography screening appears to be feasible. Women can be mobilized to attend. Substantial number of early cancers can be detected which would lead to cancer mortality reduction.

EP346/#388 DEEP LEARNING BASED PREDICTION OF CERVICAL INTRAEPTHELIAL NEOPLASIA ON COLPOSCOPY

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Objectives Deep learning is a type of machine learning that uses a neural network structure composed of multiple layers through data learning. Among artificial neural networks used for deep learning, convolutional neural networks show excellent performance in image recognition and classification, and are mainly used to analyze visual images. However, there have been few studies about CNN based prediction of cervical intraepithelial neoplasia yet. The purpose of this study is to examine whether the accuracy of CNN model to detect high grade squamouse intraepithelial lesion(HSIL) on colposcopic image can be improved when segmentation information for acetowhite epithelium is added.

Methods We collected 3,699 images of colposcopy conducted at Jeju National University Hospital from 2008 to 2021. The images were labeled with negative (negative colposcopic findings without biopsy, chronic cervicitis and low grade squamous intraepithelial lesion on biopsy) and positive (HSIL on biopsy). We composed dataset with collected images and augmented dataset to 20,000 images, and using Resnet-18, -50, -101 model, we classified colposcopic images into negative and positive. Then, we segmented acetowhite epithelium on colposcopic images using SegNet, and add these segmented images for classification.

Results Using Resnet-18, -50, and -101 model, the sensitivity to detect HSIL was 0.66, 0.62, and 0.64, respectively, and the specificity was 0.75, 0.74, and 0.75 respectively. After adding segmentation information, the accuracy to detect HSIL was improved, which was consistent across all different types of Resnet.

Conclusions HSIL of cervix can be detected through convolutional neural network that learns colposcopic images with comparable accuracy by adding segmentation information for acetowhite.

EP347/#879 DETECTION OF PROGRESSION OR REGRESSION OF GYNECOLOGIC CANCERS BY CIRCULATING TUMOR DNA (CTDNA)

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Objectives The use of post-operative circulating tumor DNA (ctDNA) to detect cancer recurrence has been reported in various studies but the literature describing variable changes in ctDNA is limited. The objective of this study is to describe the utility of single and serial ctDNA values in detecting the progression or regression of gynecological cancers.

Methods This is a retrospective observational study including nineteen patients, aged >=18 years who had the ctDNA test completed at hematology/oncology clinic of William Beaumont – Royal Oak and Troy Hospitals, Michigan, USA.
Results Among the nineteen patients, fifteen had breast, three had ovarian, and one had endometrial cancer. The median age at diagnosis was 57 years, and 73.7% of patients had either stage III or IV disease. Our primary endpoint, the correlation of single ctDNA results with imaging showing either progression or residual disease, showed a sensitivity and specificity of 100% and 93.3%, respectively. Secondarily, serial ctDNA analysis in ten patients revealed both sensitivity and specificity of 100% for up-trending ctDNA to detect progression, down-trending to detect regression, and negative results to detect the absence of disease. The positive ctDNA results detected disease progression with a median lead-time of 36.5 days compared to imaging.
Conclusions Given the high sensitivity and specificity to detect disease progression and regression in gynecologic cancer by single and serial values in our study, we conclude that ctDNA can be a valid way to monitor for changes in disease status. Further clinical studies are required to prove the utility of ctDNA in detecting changes in disease status

EP348/#107 ROLE OF HPV IN PREDICTION OF RECURRENCE/ PERSISTENCE AFTER TREATMENT FOR CERVICAL PRECANCER

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Objectives 1. To determine the role of HPV testing after excisional treatment of cervical precancer. 2. To determine clinical factors associated with persistence of cervical precancer post-treatment.
Methods A retrospective chart review was conducted on patients who had a LEEP for cervical precancer (CIN3/AIS/HSIL) between 2016–2018 at a colposcopy unit in a university-affiliated centre in Toronto. Persistence/recurrence of disease was defined as a finding of high-grade cytology or pathology results during the time of follow-up. Univariate and multivariate regression models were run with persistence/recurrence and HPV positivity at exit testing as an outcome.
Results A total of 284 patients were included. The median follow-up time was 19 months. Of the LEEP specimens, 90.8% (n=258) demonstrated HSIL and 3.9% (n=11) had AIS. 28.5% (n=81) of the LEEP specimens had positive margins. In follow-up, 72.9% had negative cytology, 17.6% had ASCUS/LSIL, 1.8% had ASC-H/LSIL-H and 6.7% had HSIL. At the final follow-up, 27.8% (n=79) were HPV+. Overall rate of persistence/recurrence was 11.3% (n=32); median time to persistence/recurrence was 6.5 months. Multivariate regression models demonstrated that follow-up HPV positivity (OR=22.0) and positive margins (OR=3.7) were significant for predicting persistence/recurrence. Similarly, in univariate regression models, positive margins were significant (OR=2.2) for predicting HPV positivity in exit testing.
Conclusions Persistence/recurrence of precancer can occur due to incomplete treatment of lesions by local excision and by persistence of HPV infection. Surveillance strategies for women treated for cervical precancer require a risk-based approach such as that suggested in the ASCCP guidelines.

EP349/#554 LOGISTICS OF TIME REQUIRED TO IMPLEMENT A SCREEN-AND-TREAT STRATEGY USING POINT-OF-CARE HPV TESTING FOR THE PREVENTION OF CERVICAL CANCER

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Objectives We conducted a time-motion study to assess implementation feasibility of POC HPV testing within a SAT program.
Methods We recruited women from a primary health care facility in Khayelitsha, Cape Town between February 2015-May 2016. We identified the following critical steps necessary if POC HPV testing is to be integrated into a SAT protocol: consent, history and examination, and sample testing on-site. Since HPV Xpert was used, which requires 60 minute run time, we estimated that the total visit time until a treatment decision could be made, assuming no delays, would be 95 minutes. If treatment is indicated, an additional 30 minutes would be needed to complete the visit
Results We enrolled 715 women, 223 (31.2%) were HPV-positive. Women were aged 42.7 (SD 8.6) years on average. Median visit time until a treatment decision could be made was 2.93 hours (range: 0.58–6.73; IQR 1.38) overall, 3.13 hours (range: 1.71–6.73; IQR 1.23) for participants who stayed to receive their HPV results and 1.97 hours (range: 0.58–5.00; IQR 1.64) for those who did not (figure 1). The decision to stay for receipt of HPV results was associated with earlier arrival in the day (table 1).
Conclusions Staying to receive results adds almost an hour to the visit, but it enables treatment at the same visit as screening. Patients who arrived later in the day were less likely to stay for their results. The logistics of POC testing are complex and require careful consideration to ensure efficient visits with as little wait-times for patients as possible.

Abstract EP349/#554 Table 1

Characteristic	Receipt of Same Day HPV Results		p-value*
	Yes	No	
	N=531 (74.3%)	N=184 (25.7%)	
Arrival time			<0.001
Before 09:00	98 (89.0%)	12 (11.0%)	
09:00-09:59	183 (86.3%)	29 (13.6%)	
10:00-10:59	142 (72.4%)	54 (27.6%)	
11:00-11:59	66 (64.1%)	37 (35.9%)	
12:00-12:59	36 (59.0%)	25 (40.1%)	
After 13:00	6 (18.2%)	27 (81.8%)	