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台灣子宮頸抹片篩檢的回顧與展望

衛生福利部國民健康署

我國自民國84年起補助30歲以上婦女每年1次子宮頸抹片檢查，30-69歲婦女子宮頸癌3年篩檢率自86年的37.6%提升至110年的51.5%；曾篩率亦提升達83.0%。子宮頸癌標準化發生率由84年每10萬人25.2人下降至108年每10萬人7.7人；109年子宮頸癌死亡人數為668人，子宮頸癌標準化死亡率由84年每10萬人11.0人下降至109年每10萬人3.1人，降幅均達約7成。目前每年約200萬人接受子宮頸抹片檢查，其中發現約1,200名子宮頸癌個案及約12,000名癌前病變個案，並由醫療院所與衛生單位合作執行子宮頸抹片陽性個案之追蹤，陽性個案追蹤完成率達約9成。

研究證實，子宮頸癌大多是因為持續感染人類乳突病毒所致，預防子宮頸癌的發生，除安全性行為及定期接受抹片篩檢外，接種HPV疫苗亦能有效預防7成以上的子宮頸癌，為降低子宮頸癌對婦女健康的威脅，我國參考世界衛生組織(WHO)建議，自107年12月底開始，推動國一女生公費接種HPV疫苗的服務，109學年度接種率為84.4%。國民健康署已於110年起試辦6年以上未做子宮頸癌篩檢之婦女HPV檢測(HPV test)服務，未來將檢視成效及實證資料，提供婦女HPV檢測服務。

未來我國將持續推動子宮頸癌防治，以達2030年WHO加速消除子宮頸癌之90/70/90目標：(1)90%的女孩，到15歲時已完整接種HPV疫苗、(2)70%的女性在35歲前接受高效能的子宮頸癌篩檢，到45歲前再次篩檢、(3)90%被確診為子宮頸癌(癌前病變或癌症)的女性能得到治療及照護，期能持續降低子宮頸癌標準化發生率至每10萬人小於4人。

賴瓊如
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子宮頸癌篩檢的挑戰

我國的子宮頸癌篩檢防治政策自民國八十四年起國民健康署以公費給付 30 歲以上婦女每年一次子宮頸抹片檢查，執行迄今成效卓著，歷經超過廿五年的努力後，不論是子宮頸侵襲癌的發生率還是死亡率，皆有大幅度的降低，子宮頸抹片的篩檢、追蹤、與品質管理系統亦發展成熟且建置完備，與其他先進國家相比毫不遜色。但唯有抹片覆蓋率一直無法再提高，造成仍有大量的婦女仍然沒有規律做抹片檢查，無法有效防止子宮頸癌的發生，這個問題可說是目前子宮頸抹片面臨最大的難題。

為了增加覆蓋率，也增進篩檢間隔過長的婦女保護力，國民健康署於民國 110 年起規劃 HPV 檢測試辦計畫，以子宮頸抹片合併 HPV 檢測的協同檢測模式，針對六年以上未接受抹片的婦女，合併進行 HPV 檢測，110 年起也可單獨以 HPV 檢測作為第一線篩檢（primary screening）的工具。透過此試辦計畫，除了可以達到篩檢的目的外，更能收集本土的 HPV 檢測數據，結合子宮頸抹片的資料庫，做為日後子宮頸癌篩檢的政策參考。

世界衛生組織（WHO）也在 2020 年提出了「子宮頸癌根除倡議」，為了使子宮頸癌不再是全球的公共衛生問題，設定了年齡標準發生率需小於每 10 萬人口發生 4 人的目標。而為了加速達到此目標，又進一步提出了「90-70-90」的全球策略，希望在 2030 年前各國必須實現：90%的女孩到 15 歲時已完整接種 HPV 疫苗、70%的女性在 35 歲前接受高效能的子宮頸癌篩檢，並在 45 歲前再次篩檢、以及 90%被確診為子宮頸癌(癌前病變或癌症)的女性能得到治療及照護。所謂高效能的子宮頸癌篩檢包含了好的抹片檢查及 HPV 檢測。

今日將重點介紹抹片的瓶頸、HPV 檢測的優缺點與實驗室認證及檢測平台的規格，期與各位先進做更深度的討論。

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台灣抹片篩檢的挑戰與機會

在台灣子宮頸癌是受重視的婦女癌症之一，自 1995 年的發生率第一位(24.9/100,000)及死亡率第四位，而在 2019 年的發生率為第九位(7.7/100,000) 及死亡率第八位。這最重要的關鍵在於政府(國民健康署)自 1995 年開始提供 30 歲以上婦女每年接受子宮頸抹片檢查。目前政府的子宮頸癌防治網分為三部分。初級(primary) 防治，對國中女生施打人類乳突病毒疫苗。次級(secondy)防治，提供 30 歲以上婦女每 1 至 3 年接受子宮頸抹片檢查。三級(tertiary) 防治，被診斷為子宮頸中度癌前病變以上(CIN2+)的婦女接受完整的治療。

我將呈現目前台灣子宮頸癌防治的現況、挑戰及機會。而如何解決這些挑戰及機會，讓台灣早日達到世界衛生組織(WHO) 90/70/90 (90% 15 歲青少年施打 HPV 疫苗；70% 35-45 歲婦女接受高品質的子宮頸癌篩檢；90%被診斷子宮頸疾病的婦女接受治療及照顧) 子宮頸癌消滅目標，將是我們未來努力的方向。

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Primary HPV Screening for Cervical Cancer
子宮頸癌初級的 HPV 篩檢

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Cytology-based screening for cervical cancer has significant limitations which reduce the overall effectiveness --- 1.Cytology has low sensitivity for detecting CIN2 or worse. 2. Cytology is less effective in detecting AIS and adenocarcinoma. 3. Subjectivity of cytology leads to low reproducibility and intra- and inter-laboratory variability. 4. Identifies individuals with cancer *precursors* but not women at *risk* of developing these. While **HPV DNA testing:** (Addresses limitations associated with cytology-based screening) --- 1. Increases sensitivity of CIN2+ and CIN3+ detection compared to cytology and leads to a reduction in incidence of cervical cancer. 2. Provides a higher negative predictive value than cytology and longer safety interval. 3. Is more effective in detecting AIS and adenocarcinoma. 4. Is able to predict short-and long-term risk of developing high-grade lesions and HPV 16/18 genotyping is able to further stratify this risk. **The Recommendations and Benefits of primary HPV screening** --- 1. A negative hrHPV test provides greater reassurance of low CIN3+ risk than a negative pap (cytology) result. 2. Because of equivalent or superior effectiveness, primary hrHPV screening can be considered as an alternative to cytology based cervical cancer screening. 3. More reproducible than Pap cytology. 4. Negative test (and most women will test negative) associated with very low risk of developing precancer / invasive cancer (also, a much better predictor). 5. More sensitive than cytology (lower FN rates): pick up most women with precancers. **Why is HPV Testing an Attractive Option for Cervical Cancer Screening?** --- 1. More sensitive and reproducible than the Pap test. 2. More "upstream" in the carcinogenic process, thus enabling a longer safety margin for screening intervals. 3. Assesses future risk (and not just the presence of current disease). 4. Can be automated, centralized, and be quality-checked for large specimen throughput. 5. May be more cost-effective than cytology if deployed for high volume testing, such as in primary screening. 6. A more logical choice for screening women vaccinated against HPV infection. **Conclusions of Clinical implications of HPV primary screening** --- 1. Cytology

based screening has been successful, but has limitations. 2. HPV primary screening allows for improved clinical sensitivity over cytology while maintaining high efficiency. 3, HPV primary screening utilizing integrated HPV 16/18 genotyping and cytology reflex of the 12 other hrHPV genotypes, demonstrates a good balance of clinical resources --- (a) Provides improvements in clinical sensitivity while maintaining high efficiency (colposcopies per disease case detected),--- (b) In younger women, the primary screening algorithm finds more disease while addressing concerns about unnecessary follow-ups. 4. Primary HPV testing is now an alternative option to current cytology-based screening methods due to equivalent or superior effectiveness.

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HPV vaccination in men

HPV-related diseases in men include anal cancer, penile cancer, and oropharyngeal cancers, as well as their precancer lesions. Ano-genital wart is another benign disease caused by HPV. Data from many studies revealed that the prevalence of HPV in the genital organ and oral cavity is much higher in men than in women. Gender-neutral vaccination not only protects man from persistent infection and subsequent diseases caused by HPV, but also protects their sexual partners. Taiwan is the 2nd country in the world that approved HPV vaccine indication of preventing HPV-related oropharyngeal cancer. Therefore, it justified to promote HPV vaccination in men.

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The use of molecular testing in ovarian cancer

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BRCAm and Homologous recombination repair deficiency (HRD) are frequent features of high-grade ovarian, fallopian tube and peritoneal carcinoma (HGOC) and associated with sensitivity to PARP inhibitor (PARPi) therapy. Many phase 3 clinical trials confirmed the promising benefits and PARPi maintenance therapy became the standard care of ovarian cancer in patients with BRCAm and also got NHI reimbursement since Nov. 2020. But in patients with HRD & BRCAw, PARPi maintenance still have survival benefit, but didn’ t have NHI-reimbursement.

HRD testing provides an opportunity to optimise PARPi use in HGOC but the methodologies of genetic testing are diverse. Today, we will discuss about best practice for BRCA testing and HRD testing in HGOC. The main aims were to (i) define the term 'BRCAm, HRRd and HRD test'; (ii) provide an overview of the biological rationale and the level of evidence supporting currently available HRRm or HRD tests; (iii) provide recommendations on the clinical utility of BRCA, HRD tests in clinical management of HGOC.; (iv) discuss about current kit solutions in Taiwan.

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WHO 2020 婦癌病理主要改變

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The revision of the WHO classification of tumors of the female genital tract is released in 2020. There are significant changes and increased emphasis on the use of molecular data to classify tumors.

The significant update listed here:

- HPV-independent cervical carcinomas, in particular adenocarcinomas (ADC) and rare squamous cell carcinomas (SCC), has been described. They are generally more aggressive than HPV-associated carcinomas. The HPV-independent ADCs are dividing into gastric, clear cell, mesonephric, and endometrioid types.
- According to the FIGO 2018 staging system, the assessment of stage IA cervical carcinoma is based on the the depth of stromal invasion only.
- The Cancer Genome Atlas integrating genomic data and identified four groups of endometrial carcinomas: 1, with POLE mutations; 2, with microsatellite instability; 3, low-copy-number alterations; and 4, with high-copy-number alterations & *TP53* mutation.
- The spectrum of high-grade endometrial stromal sarcoma is widening according to the molecular genetic findings.
- The ovarian low-grade and high-grade serous carcinomas are two completely different tumor types rather than low- and high-grade forms of the same neoplasm.
- Ovarian seromucinous carcinoma has been removed and is considered a subtype of ovarian endometrioid carcinoma. Serous carcinoma of the cervix and adenofibroma of the cervix & endometrium have been removed.
- Any percentage of a second type of carcinoma is enough to called mixed carcinoma of the ovary or endometrium.

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免疫療法在子宮頸癌跟子宮內膜癌的應用

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Antibody blocking of programmed cell death protein 1 (PD-1) receptor at the cell surface of T cells, B cells, monocytes, natural killer T cells and dendritic cells, or blocking of programmed death-ligand 1 (PD-L1), to inhibit the negative regulation of cancer-associated immune response is the backbone of current immuno-oncology therapy.

Clinical trials showed adding the anti-PD-1 monoclonal antibody to chemotherapy improved overall survival of cervical cancer patients with disease progression after platinum-based chemotherapy. Anti-PD-1 antibody, along with first-line chemotherapy for persistent, recurrent, or metastatic cervical cancer, compared to placebo and chemotherapy, showed improved median progression-free survival and two-years overall survival rates. Adverse effects related to PD-1 antibody are common and severe diarrhea, marked increase of liver function markers are observe while thyroid disorders, as hypothyroidism or hyperthyroidism, can be managed well.

Endometrioid adenocarcinoma is the most common histology of endometrial cancer. Molecular profiling becomes the current interest in managing endometrial cancer. A substantial proportion of endometrioid endometrial cancer is associated with the deficient DNA mismatch repair (dMMR), or high level of microsatellite instability (MSI-H). Such endometrial cancer tends to present as a large tumor arises from the lower uterine corpus, with a higher risk of advanced disease and recurrence. Anti-PD-1 antibody has demonstrated antitumor activity in patients with MSI-H/dMMR endometrial cancer. For advanced (metastatic and/or unresectable) non-MSI-H/dMMR endometrial cancer that was incurable and had disease progression on or intolerance to standard therapies, the combination of anti-PD-1 antibody and lenvatinib, a multiple receptor tyrosine kinase inhibitor, showed a significant better effect compared to conventional treatments.

The affordability of immune therapies may determine the popularity of such treatments for cervical cancer and endometrial cancer, both are common malignancies in Taiwan.