Response to Senate Inquiry into Gynaecologic Cancer: a very brief summary

By

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This very brief summary has been compiled at very short notice and as a consequence is shorter than the author would like. Space and time precludes adding all the necessary supporting references. Its strength lies in its broad brushstrokes. The views expressed herein represent the author's personal views and are not necessarily those of his employer. There are no declared conflicts of interest. The author has neither sought nor been offered any advantage from the expression of these views.

- Cervical Screening has been very successful in reducing cervical cancer incidence and mortality.
- Cervical screening PREVENTS cancer by identification of and removal of precursor lesions. cf. other screening programs which identify small invasive good prognosis CANCERS.
- High quality Cervical Screening is required more than ever, due to the effects of the "sexual revolution" of the 1960s.
- Cervical Screening has relied on the Pap smear for this success.

Recent advances:

- Recognition of HPV infection specifically persistent infection as central but not sole cause of cervical cancer.
- Identification of High Risk HPV types as responsible for most cervical cancers
- Development of safe effective vaccines protective against HR HPVs will allow primary prevention of cervical cancer. Vaccine already FDA approved in USA. Such vaccines will prevent 70% of cancers. **Vaccinated women will still need to be screened.**
- Development of reliable tests based on detection of HR HPV DNA. Compared with the Pap smear, these tests are more sensitive more precise and easier to quality assure than the Pap smear. They are also less labour intensive and offer opportunities for full automation in the future.
- Self-administered sampling offers a chance to properly screen ATSI populations- Pap smear based screening is failing these women.

Use of HR DNA Tests:

- For triage of Pap smears reported as ASCUS/Borderline/Possible LSIL. Good level 1A evidence for their use. US guidelines under review will state unequivocally that HPV DNA triage of such smears is the preferred method of management of these smears and that repeat smears (as is recommended by the NH&MRC guidelines) is NOT preferred- see ASCCP guidelines review website.

- HPV DNA testing for triage has been shown to be cost effective- recent cost effectiveness studies from US ALTS trialists, from UK Pilot Studies and a cost effectiveness study comparing UK, Netherlands, France, Italy.
- 2002 Medical Service Advisory Committee (MSAC) decision only allows HPV DNA testing for "test of cure". MSAC decision has been rendered obsolete by multiple additions to scientific literature. MSAC decision is anomalous as the evidence for triage is at least as good as that for test of cure. **MSAC decision needs to be revisited urgently. <u>Senate Inquiry should request MSAC to revisit this issue.</u>**

Use of HR HPV Testing for Primary Screening:

- HR HPV DNA testing is showing great promise for use as a primary screening tool with Pap smear used to triage those who test positive for HR HPV ie combine the sensitivity (ability to detect precursors) of the HR HPV test with the specificity (ability to rule out benign look-alikes) of the Pap smear.
- **5 randomised controlled studies of HR HPV testing for Primary Screening are already underway. UK ARTISTIC study due to report first published results in 2-3 months. The ARTISTIC study commenced in 2001 and cost AU$3 million to conduct. Hence Australia has probably already missed the boat on conducting a randomised trial on primary HPV testing in this country. Australia will thus have to rely on overseas data on the efficacy of introducing HPV testing.**
- Conducting these expensive trials is not done for fun/academic exercise. They are performed to confirm the well-founded theoretical expectation that HR HPV testing will replace or supplant Pap smear as primary screening tool.
- Hence these trials are a prelude to HR HPV testing for primary screening.
- Benefits of this approach: much longer screening interval(5 years), cost efficiencies, better use of scarce skilled manpower.
- Much of screeners' time is currently taken looking at normal Pap smears. Using HR HPV with Pap smear triage of abnormal results, the screeners will be looking at much fewer smears with more likelihood of finding an abnormality.
- Looming labour shortage of screeners in Australia as well as UK. There will be no loss of jobs for screeners, as we are already short of screeners and the screeners will be spending more of their time looking at the abnormal smears, and performing Quality Assurance activities.
- The use of vaccine will result in a cohort of women with a very low incidence of precursor lesions who still have to be screened.
- For any test, if the prevalence of the disease declines, the positive predictive value declines (Bayes theorem). Hence, screening vaccinated women with the Pap smear will be unsustainable and not cost effective. Another method will be required ie HR HPV testing.
- Implementation will require a well thought out strategy-we have only one bite of the cherry.
- There is little/no research on this area within Australia. See point above on ARTISTIC Trial.
- The new structure of the advisory committees disperses expertise across a number of large committees rather than concentrates it. The New Technologies committee has to cover cervix, breast, colon ovary and prostate.

Its membership reflects this. It is foolish to expect experts in colorectal screening to be expert in HR HPV testing. This committee will not be able to plan and for and execute any change to primary HPV screening.

- **Senate inquiry should recommend that a group like the National Breast Cancer Centre (NBCC) be set up to plan for and conduct relevant research (possibly funded by NH&MRC or separately funded), into the introduction of Primary HPV testing, with Pap smear triage of abnormal results.**
- **The Senate Inquiry should recommend that such a group use best practice regardless of its source, and that attempts to "reinvent the wheel" should be at all times resisted.**
- Australia can cling to old ways if it choses but ultimately change will come and be more painful if we delay.