SUBMISSION TO

Australian Senate

COMMUNITY AFFAIRS REFERENCE COMMITTEE

GYNAECOLOGICAL CANCER INQUIRY

AUTHOR: **Alan Carless MBBS MPH MRCP (UK) FAFPHM FRACMA**
Chief Medical Officer, CommInsure
W: +612 99474317
8/17-19 Prince St CRONULLA 2230
alan@carless.com

The Community Affairs References Committee will make inquiry and report by 19 October 2006 on Gynaecological cancer in Australia, and in particular the:

a) Level of Commonwealth and other funding for research addressing gynaecological cancers;

b) Extent, adequacy and funding for treatment services, and for wider health support programs for women with gynaecological cancer;

c) Capability of existing health and medical services to meet the needs of Indigenous populations and other cultural backgrounds; and those living in remote regions;

d) Extent to which the medical community needs to be educated on the risk factors, symptoms and treatment of gynaecological cancers;

e) Extent to which women and the broader community require education of the risk factors, symptoms and treatment of gynaecological cancers; and

f) Extent to which experience and expertise in gynaecological cancer is appropriately represented on national health agencies, especially the recently established Cancer Australia.

This submission addresses cervical cancer early detection and optimal treatment through mass population screening and is relevant to all the above, but is particularly relevant to (b) and (c).

Control over cervical cancer in Australia has been suboptimal. It has relied on costly, complex systems with all too evident capacity to fail at several points, rendering the process haphazard. The current system involves registration of women at risk, notification when periodic screening is due, sampling of cells from the uterine cervix, cytological screening through microscopic analysis, reporting of positive results, recall of patients screened positive and followup treatment. Each step must be efficient and effective if the process is to achieve world's best practice in cost and outcomes. We need the highest possible gains in quality adjusted life years (QALYs) for the dollars the community is prepared to allocate. But we cannot achieve this without major change, because at several points the current system is in crisis.

Sampling of cervical cells by skilled primary care practitioners is under-resourced in some populations, particularly remote communities such as those of far north Queensland. Experience has shown that the cultural barriers and skill shortages have been difficult to address and screening rates have been unacceptably low. Even in generally well served communities with high levels of awareness and acceptance of screening, the proportion of general practitioners currently offering pap smears to all their at risk patients appears to be diminishing. Older male GPs, in particular, seem reluctant to do this, even though their care is otherwise comprehensive and dedicated. This trend is particularly evident in poorer communities with high proportion of people of non-English speaking backgrounds. Going to a gynaecologist or another GP on another occasion adds to Medicare-supported cost and, to a huge degree, to the inconvenience of an already unpopular imposition on the busy lives of our womenfolk.

Another crisis is particularly grave and Australia wide; the increasingly inadequate number of skilled cytologists. Cytologist training is costly and has been undertaken by laboratories, not universities. In the 1980s, in Victoria where I was taking pap smear samples and posting them to the Victorian Cytology (Gynaecological) Service, cytologist training was part of this dominant, grant-funded service and was well provisioned. But since pap smear analysis became an almost exclusively Medicare fee for service entity, training has been starved of funding. Even grant-funded pap smear taking entities like Family Planning Australia have, for decades, sent samples to commercial laboratories where fees are charged for the services of cytologists. These laboratories have not been training cytologists in a sustainable manner. Training represents a high proportion of the whole cost of current cervical cancer screening and has been constrained in the competitive commercial environment of human pathology. The attrition rate of trained cytologists is exceeding the rate of training. The Australian Society of Cytologists has demonstrated this in a survey of its membership that shows how alarmingly fast it is ageing. There has been no significant response to this skill shortage crisis from tertiary training bodies.

One short term solution to this skill shortage lies in the progressive replacement of relatively hard to prepare, inefficient and error-prone dry glass slide preparation of cervical cells with liquid based cytology (LBC). Coupled with efficient and more accurate computer-facilitated image analysis screening for cancer cells this allows many times greater productivity of trained cytologists. It has long been obvious to all significant cervical cancer programs outside Australia and to major cytology service providers within Australia that this step has to be taken. Medicare funding of LBC as an alternative to its outdated alternative is long overdue. It was refused in 2000

because of perceived inadequacy of locally collected data but the decision was heavily criticised at the time by cervical cancer experts including Professor Neville Hacker and Professor Michael Quinn. The adjudicating body had heavy representation from commercial laboratories who undoubtedly perceived commercial advantage at that time in perpetuating Medicare funding of dry slide cytology while on-selling LBC to women who, in reality, needed only the latter. Many GPs understand this and also realise that this splitting of samples reduced the efficiency of LBC and adds to the time, complexity and discomfort of sampling. But in a litigious world, they are waiting for clear statements from authoritative sources before they do what common sense and world best practice clinical guidance dictates and drop dry slide sampling. The pathology companies are in general showing no leadership and have not offered to process LBC without a dry slide sample, recognising that the loss of profit from this would probably mean that hey had to charge women more for the LBC analysis. Some Australian women, presumably those who had GPs who could persuade them to do it, are getting better screening but all are getting an inferior service.

Data on LBC from Australian laboratories is now available, thanks to the enthusiasm of women and their primary care doctors who have recognised its worth, even at an unsubsidised price. Outright funding refusal is no longer justifiable and the only realistic question is the level of subsidy that should be offered. International experience and detailed analysis of Australian data by Dr Munro Neville and Professor Michael Quinn shows that this change can be made now and will yeild a highly acceptable outcome in terms of cost per QALY gained.

There is justification for better Medicare funding for this approach than for the existing one, at laboratory level, because of improved efficiency of sampling and detection. Saving some women from the consequences of errors would be significant and in the long term would benefit all, but the overall short term dollar cost to the community from such a change would probably increase, to a degree depending on the ability of the government to negotiate sensible volume discounts for the more expensive consumables. The costs of this cytological approach to early cancer detection will remain of concern, with its continued inherent reliance on the human judgement of cytologists and the skill of culturally acceptable sampling practitioners. For the same reasons, there will always be a significant potential for errors of interpretation and service inadequacies.

There is a practical solution to both the cost and skill shortage concerns. For over a decade it has been recognised that cervical cancer is caused by human papilloma viruses (HPV). The cells of over 99% of mature cervical cancers contain the DNA of this virus and this DNA can also be detected in cervical cells that are not yet cancerous but are showing the potential to become so, because of virus infection. Sophisticated tests for this DNA are now available and can be automated, promising a highly efficient and effective alternative to primary cytological screening of cervical samples. Laboratory staffing requirements are minimal by comparison with cytology. Furthermore, the sampling required for this testing is not dependent on costly professional skill. Self-sampling, using devices inserted like tampons but removed immediately, is relatively comfortable, convenient, private and (in all likelihood) much preferred by women who commonly loathe the thought of Pap smear collection. With basic training, community based health workers could facilitate a highly efficient service with reach into populations such as remote aboriginal communities

and night shift factory workers. There would relatively insignificant cultural barriers and few problems of distributing the service to remote communities. Return of samples could be though the postal system to as few as two centralised laboratories for maximal efficiency while still retaining appropriate competitiveness. Note that the time frame for development of cervical cancer from initial HPV infection is measured in years, so that there is no clinical advantage from return of results within hours rather than a few days.

Samples collected in this way are likely to detect HPV in about 12-15% of those prone to cervical cancer. These women thus identified as at risk can then be managed appropriately (using cytological analysis) and the remaining 85-88% can be safely reassured that they need no further testing until their next DNA screen in three years. All women screened in this way can also be tested for sexually transmissible diseases such as Chlamydia. These invaders also leave detectable DNA traces long before they are evident in any other way. Their early detection and eradication can eliminate the cause of much future misery and expense, for example that associated with the infertility and ectopic pregnancy these diseases can cause.

A cervical cancer screening system based on this DNA detection approach would be, on face value, affordable, sustainable and effective, It would be far more likely to achieve the national cervical cancer screening goal (approximating 100% of at-risk women screened at recommended intervals) than the program we have now and must inevitably either accept as doomed to fail, or fund at an increased level or replace. DNA analysis of self-collected samples promises to reach the goal while yielding long term highly desirable reductions in program cost. There is nothing else on the horizon that can do this.

In conclusion, I recommend that

1. LBC be facilitated through Medicare funding without delay and
2. DNA analysis of self-collected samples is evaluated as an alternative primary screen for cervical cancer.