COMMENTARY

Adapting the Australian System: Is an Organised Screening Program Feasible in Malaysia? – An Overview of the Cervical Cancer Screening in Both Countries

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Abstract

Cervical cancer is the third most common form of cancer that strikes Malaysian women. The National Cancer Registry in 2006 and 2007 reported that the age standardized incidence (ASR) of cervical cancer was 12.2 and 7.8 per 100,000 women, respectively. The cumulative risk of developing cervical cancer for a Malaysian woman is 0.9 for 74 years. Among all ethnic groups, the Chinese experienced the highest incidence rate in 2006, followed by Indians and Malays. The percentage cervical cancer detected at stage I and II was 55% (stage I: 21.0%, stage II: 34.0%, stage III: 26.0% and stage IV: 19.0%). Data from Ministry of Health Malaysia (2006) showed a 58.9% estimated coverage of pap smear screening conducted among those aged 30-49 years. Only a small percentage of women aged 50-59 and 50-65 years old were screened, 14% and 13.8% coverage, respectively. Incidence of cervical cancer was highest (71.6%) among those in the 60-65 age group (MOH, 2003). Currently, there is no organized population-based screening program available for the whole of Malaysia. A pilot project was initiated in 2006, to move from opportunistic cervical screening of women who attend antenatal and postnatal visits to a population based approach to be able to monitor the women through the screening pathway and encourage women at highest risk to be screened. The project was modelled on the screening program in Australia with some modifications to suit the Malaysian setting. Substantial challenges have been identified, particularly in relation to information systems for call and recall of women, as well as laboratory reporting and quality assurance. A cost-effective locally-specific approach to organized screening, that will provide the infrastructure for increasing participation in the cervical cancer screening program, is urgently required.

Keywords: Cervical cancer - screening - prevention - Malaysia - Australian model

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Introduction

Cervical cancer accounted about 9.1% of all female cancers in 2006 worldwide (Omar et al., 2006) and is the third most common form of cancer among Malaysian women (Castellsagué et al., 2007). Approximately 70.1% of invasive cervical cancers in the world attributed to HPVs 16 or 18. More than 85% of the global burden occurs in developing countries, where it accounts for 13% of all female cancer (Ferlay et al., 2008). Lowest rates are in Western Asia, Northern America and Australia/New Zealand with ASRs less than 6 per 100,00. Incidence and mortality are higher in the less developed regions compared to the more developed regions (Ferlay et al., 2008). For example, in England where the organised screening was started in 1988, the incidence has almost halved. The Age-Standardised Incidence Rate (ASIR) was 16.2 per 100,000 population in 1988 and has reduced to 8.3 per 100,000 population in 2008 according to the National Cancer Intelligence Network (NCIN, 2010). Similarly, in New Zealand, the incidence of cervical cancer has reduced from 12 per 100,000 population in 1991 to below 7 per 100,000 population after the initiation of National Cervical Screening Program (NCSP) (Lewis et al., 2005).

Many efforts had been implemented to improve the cervical screening program in Malaysia. Unfortunately, campaigns and health education on the need for cervical screening among women even after the reproductive years has not shown great improvement in increasing the uptake. The situation is still worrying whereby a vast majority of those in the high risk age group, which is between 50-65 years old, are not screened. The aim of this paper was to examine the current cervical cancer screening program in Malaysia and compare it with the system in Australia by focusing on gaps and needs, as well as to provide an overview of other cervical cancer screening activities.

Cervical Cancer in Malaysia

Cervical cancer remains as one of the leading cause of

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cancer in Malaysia with high-risk human papillomavirus (HPV) types, particularly HPV 16 and 18 being consistently identified in these cases (Domingo et al., 2008). It is the second most common cancer and the fourth most common cause of death for women in Malaysia. The ASR was 15.7 per 100,000 in 2002 which was similar with Indonesia. However, other South East Asian countries such as the Philippines, Thailand and Vietnam had higher ASR at 20.9, 19.8 and 20.2 per 100,000 respectively (Ferlay et al., 2004).

Among all the ethnic groups, Chinese have the highest incidence at 13.6 per 100,000 population, followed by Indians and Malays at 11.3 and 7.3 per 100,000 respectively (Omar et al., 2006). However, the National Cancer Registry Report in 2007, showed that Indians has the highest incidence at 10.3 per 100,000, followed by Chinese and Malays at 9.5 and 5.3 per 100,000 respectively (Omar and Tamin, 2011). Incidence rates are declining among all the races over these 2 years with some variations. These differences may be attributed to the difference in lifestyle, reproductive behaviour between these races or even due to the outreach programs by the government for those under screened groups in the more rural areas.

The cumulative risks were similar for both Chinese and Indians at 1.1 but the Malays experienced a lower cumulative risk at 0.6. It is uncommon before the age of 30 years old; the risk of developing it increases with age, with a peak incidence at ages 65-69 years, and declining thereafter (Omar and Tamin, 2011).

Generally, more than half of the cases (55%) presented at an early stage (stage 1 and stage 2) and the rest presented at stage 3 (26%) and stage 4 (19%) (Omar and Tamin, 2011).

International Cervical Cancer Screening Policy

Screening policies for cervical cancer differ widely among countries with regards to targeted age range, screening intervals and total number of scheduled examinations (as summarised in Table 1). The International Agency for Research on Cancer (IARC) recommended that the screening interval for cervical cancer should be between 3-5 years depending on the resource available and should from the age of 25 up to age 64 or 65 years (WHO, 2005). However, there is wide variation in actual recommendations at the national level across Europe. For example, in the Germany and Austria, the recommended number of pap smears during a woman's lifetime is more than 25, but it is only 7 in Netherlands and Finland. The recommended interval between screening examinations in Germany and Australia is 1 and 2 years respectively, whereas in the United Kingdom, the Netherlands and Finland it is 5 years (Marle et al., 2002). In Sweden, the screening guidelines are 3-yearly tests between 23-50 years old and 5-yearly tests between 50-60 years age (Dillner, 2000), whereas in Australia, the recommended target age range is between the ages of 18 and 70 years old (Creighton et al., 2010).

According to WHO guidelines (2006), 4 important components of a national cancer control program includes; primary prevention by preventing HPV infection and risk factors known through education and development of HPV vaccine, early detection of cases through organized screening programs and encouraging women to screen, follow-up of cervical abnormalities, treatment of precancer lesions and invasive cancer, and finally, carrying out palliative care (Jacob et al., 2006). Various strategies recommended by the Alliance for Cervical Cancer Prevention (ACCP) to overcome this to achieve optimal public health impact that include; the screening age between 30-40 years, screening at least once either using HPV DNA testing or Visual Inspection (VIA) and using cryotherapy to treat pre-cancerous lesion in a single visit to prevent loss to follow-up (Sherris et al., 2009).

An organised screening program is designed to reach the highest number of women at greatest risk for the disease with existing resources and specific target population, screening intervals, coverage goals, invitation mechanisms, screening tests used, strategies to ensure positive tested women informed of results, referral mechanisms for diagnosis and treatment, treatment recommendations as well as evaluating and monitoring indicators for the program (Jacob et al., 2006). However, economic barriers are a major problem in implementing organised screening in low-resource settings where there are higher incidence and mortality rates from cervical cancer. According to the report on the cervical screening in Australia in 2000 (Mitchell, 2000), to ensure succesful change in the implementation of the organised screening, several factors needed to be looked into. There is the need to have a broad coalition of support involving a diversed discipline and interest groups including the media that is crucially needed especially at the establishment of a Pap test registry. At the moment, Malaysia has not established a cancer registry for the whole country yet. The pilot project only involved the population in the 2 districts mentioned and screening is mainly done in the health clinics by the staff nurses. Only confirmed cases are referred to hospitals for further management by gynaecologists. Government eventually will need to play a strong leadership role which is another important factor, after the establishment of a registry in this pilot project to

Table 1. Screening Guideline for Several Countries

1) Recommended number of pap smear per life time	Germany and Austria	More than 25 times
	Netherlands and Finland	7 times
2) Recommended interval between screening examination	Germany	1 year
	Australia	2 years
	UK, Netherlands and Finland	5 years
3) Recommended target age range	Australia	Between 18-70 years old
	Sweden 23-50 years of	old (3 yearly)/50-60 years old (5 yearly)

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allow the progressive establishment of the cancer registry for the whole country. However, the most important factor in the Malaysian context is the the provision of funding to trial new approaches which may be lacking in the current cervical screening program. Further research needed to experiment the most effective method in a low resource setting such as Malaysia.

Cervical Cancer Screening Policy in Malaysia

Cervical cancer screening in Malaysia began in 1969, after the intergration of the family planning services into the Maternal and Child Health Program of the MOH Malaysia and expanded across the country following the launching of the "Active Lifestyle" campaign, in 1995 to strengthen both primary and secondary prevention of cervical cancer (MOH, 2009). Its main objective was early detection of cervical cancer and ensuring early treatment as well as follow up of patients.

The service expanded with the development of the "National Pap Smear Screening Programme" in 1998, to all eligible women aged 20-65 years old yearly for the first 2 years and 3 yearly after that if the results are normal. The agencies involved in the program include the MOH, National Population and Family Development Board (LPPKN), University hospitals, private clinics and hospitals, military hospitals and other non-governmental agencies such as Federation of Family Planning Association of Malaysia and National Cancer Society Malaysia (MOH, 2004).

Three guidelines have been published by the MOH to ensure that the program runs smoothly which include; Guidebook for Pap Smear Screening in August 2004, Management of Abnormal Pap Smear that has been amended in accordance to the Bestheda System, 2001 in December, 2007 and the Clinical Practice Guidelines (CPG) on Management of Cervical Cancer in 2002 (MOH, 2009) aimed to ensure the quality of the smears at the clinic level and also the proper management of all abnormal smears. The reporting system for the program has been establish to ensure that related data will be collected and stored accordingly for future reference (MOH, 2009). However, the major failure of the screening program has been it's low coverage: the current program only covers pap smear screening for majority (63.7%) among those between 30-49 years old. A vast majority of those in the high risked group, which is between 50-65 years old are not screened (only 35% screened) (MOH, 2009).

A survey done in NHMS II in 1996 revealed that only 26% of the women had been screened and in NHMS III (2006), only 43% women were screened. The percentage is higher among women in the reproductive age group as they will be seen at the antenatal, postnatal and family planning clinics. This is ironic since MOH report in 2003 showed that incidence of cervical cancer is highest (71.6%) among those in the 60-60 age group. It is more of an opportunistic screening and thus, further interventions are needed to provide an organised screening for the population.

There are many studies that had showed the effectiveness of an organised cervical cancer screening program as opposed to the opportunistic or other non-

systematic methods of screening to improve the patients participation rates and eventually reduce the incidence rate (Pierce et al., 1989; Adab et al., 2004; Veerus et al., 2010). In New Zealand for example, the incidence decreased from about 12 per 100,000 population in 1991 to below 7 per 100,000 in 2002 (approximately a 40% fall) after the introduction of the National Cervical Screening Programme Register (NCSP-R) (Lewis et al., 2005).

Furthermore, a qualitative study done in our setting showed that all the participants involved perceived an organized cervical screening program as an acceptable approach by women and government to practice in Malaysia (Abdullah and Su, 2010).

Following the poor uptake in the current cervical cancer screening program in Malaysia, there are several initiatives carried out by MOH in order to improve it. One of them is the call-recall system for pap smear screening piloted in Klang, Selangor and Mersing, Johor, which aims to improve regular participation of women for screening, designed to follow the current system in Australia with some modification to suit the local setting (Mohamed et al., 2008; MOH, 2010).

Pilot Project for Cervical Screening

The pilot project was initiated as an initiative to move from the opportunistic screening of cervical cancer to a population based approach where there will be regular participation of women for screening. By doing this, women will be able to be monitored through the screening pathway, especially those in the high risk age group (women aged 50-69 years). The project was design in such a way that it follows the current system that is being implemented Australia with some modification of the program to suit the setting in Malaysia with the objectives to increase the pap smear coverage of target group, to screen at least 75% of eligible women, to ensure cases are appropriately managed, providing a quality and continuous screening services at every level of care and finally, and to develop a pap smear registry to facilitate follow up and recall.

Two areas were chosen due to their difference in the setting that include; Klang which is an urban area and Mersing, an area with the rural setting. The time frame for the pilot project was 5 years from 2007 till 2011 and the target group was all women aged 20-60 years old living in these two areas. All Malaysian women who are married or have been married who had consented to be screened were included in the project. Women aged less than 20 years and more than 65 years old, history of hysterectomy and all confirmed case of cervical cancer were be excluded from the project.

The data for all the women in the population was obtained from the National Registry Department/ Jabatan Pendaftaran Negara (JPN) where their identification card number, age and addresses will be available. The data flow for the call-recall system is displayed in Figure 1. All the data for the about 60,000 eligible women were entered in the Sistem Informasi Pap Smear/Pap Smear Program Information System (SIPPS). These data were then selected randomly at the district level by a trained

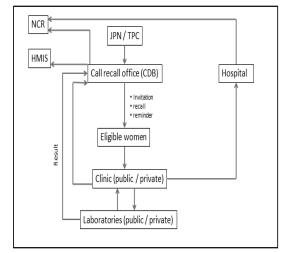


Figure 1. Division of Family Health Development, Ministry of Health Malaysia. NCR=National Cancer Registry, HMIS=Health Management Information System, JPN=Jabatan Pendaftaran Negara/National Registration Department, TPC=Teleprimary Care

information Technology (IT) officer where invitation letters were generated for the chosen women. This is being done at a monthly interval at the District Health Office (DHO) at the rate of about 1,500 letters per week. Those who received the letters will be invited to go to the nearest community clinic within two months period from the date of the letters sent. If any of the women failed to do so within 2 months, another reminder letter will be sent to her giving her another 2 months to come for screening. The system will stop after the second attempt of invitation in Klang area but continue to sent another (third invitation letter) in Mersing area.

At the clinic level, once the woman responded to the invitation and turn up for screening, other data will be entered into the system including her phone number, other relevant medical history and the result of her pap smear done will be entered by the laboratory which her slide were sent to. These data on that particular woman will be able to be access by the health care workers in the clinic she visited as well as at the national level i.e. the Women's Health Unit. All the patients details are kept confidential and should not be expose to the public. Women who needed further intervention will be contacted manually by the health care workers for referral to specialist at the nearest hospital.

This project has just begun its operation in July 2008 and had just ended recently. Data is still being analysed at the ministry level and the report has yet to be published (MOH, 2012).

Cervical Cancer Screening Policy in Australia

In Australia, screening for cervical cancer was introduced in the 1960s on an ad hoc basis. Following this, a structured program called the National Cervical Screening Program commenced in 1991, after being pressured by multiple interest groups including the gynaecologists, public health practitioners, women's health movement international articles critiques and finally the publication by International Agency for Research on Cancer (IARC) which provided the framework for the change. Each state and territory manages its own cervical screening program overseen by the national cervical screening program. The Australian policy states that women should have 2-yearly pap smear till the age of 70 and should start having Pap smears between the ages of 18 and 20 years, or one or two years after first having sexual intercourse

According to Victoria's Cancer Action Plan 2008-2011 (2009), each state and territory in Australia operates its own Pap test registries. The Victorian registry, the Victorian Cervical Cytology Registry (VCCR) was the first established in 1989 and is a voluntary "opt-off" confidential database of Victorian women's Pap test results. Laboratories provide the data on all Pap tests taken in Victoria, unless a woman chooses not to participate. VCCR works with the PapScreen Victoria which is responsible for the communications and recruitment program aimed to maintain high rates of participation among women. The recall of patients are according to the VCCR Registry Reminder and Follow-up Protocol, which was based on the National Health and Medical Research Council, Australia (NHMRC) guidelines for the Management of Asymptomatic Women with Screen Detected Abnormalities. Information provided on the cytology report of Pap tests are pre-coded by the pathology laboratory to the Registry's Cytology Code Schedule that will be summarized in a six digit numeric code according to the National Pathology Accreditation Advisory Council Australia and Commonwealth of Australia (NPAACA).

Laboratories reporting cervical cytology in Australia are required to adhere to certain performance measures set by NPAACA which includes the proportions of unsatisfactory specimens and proportions of abnormal histology report. Compliance to these performance measures has been facilitated by the existence of cervical cytology registries in all states and territories.

The cervical cancer screening program in Australia has been successful in increasing the patients' participation rate according to the Victorian Cervical Cytology Registry Report (VCCR). It is clear that in an organized screening program, the number of individuals being screened will be increased the longer the program exists. The number of women aged 20-69 years screened over the 5 year period (2004-2008) was more than 85% (87.5%), compared to the 2 year period in 2007-2008, which was only 62.3%.

Similarly, the participation rate of women in the national cervical cancer screening program in every state in Australia especially among the higher risk age groups increased over the years, although has plateaued recently, based on the report by Australian Institute of Health and Welfare and The Australian Government Department of Health and Ageing (AIHWA) in 2012. Participation among the target group (20-69 years) was 61.0% when reporting commenced in 1991-1997 but has increased to 63.4% in 1998-1999 after the media campaign. The participation increased from 61.0% in 2004-2005 to 61.5% in 2006-2007 which equates 142,305 women aged 20-69 years. These high participation rates are underpinned by the Pap test registry infrastructure which is responsible for reminders and follow-up of abnormalities.

Discussion

The major shortcoming of the Malaysian screening program is that it has not achieved high population coverage as it does not have all the elements of an organised screening program. A pilot project was implemented in Malaysia based on the Australian program to determine whether this model can overcome the shortcomings of the present Malaysian program. Unfortunately, early results suggest that the pilot also did not manage to improve the participation rates. After analysing the current program in Australia, there may be a few issues that needed to be addressed to before the organised program is applied in Malaysia as the pilot project differs slightly from the Australian system.

The current pilot program utilises data from National Registration Department/Jabatan Pendaftaran Negara (JPN) to obtain the population data on eligible women including addresses and contact numbers. However, the proportion of outdated addresses were quite high according to the Women's Health and Development Unit, Malaysia (Mohamed, 2008). The Australian program on the other hand, utilises the population data of the screened patients obtained directly from the laboratories, thus minimising the outdated addresses. However this is not possible in Malaysia as a vast majority of Malaysian women are still unscreened. Thus, sending reminders to women already screened will not increase the participation rates. Using the electoral roll name lists as another alternative maybe considered as the database to overcome problems related to old addresses. The similar method is being used by the BreastScreen Registry in Australia in their 'Call-Recall System' for breast cancer screening throughout the country as reported by the BreastScreen Victoria Coordination Unit, 2009.

Another aspect that needed attention is the effective type of methods of reminder and recall to be used in the local setting. At the moment, the only recall/reminder used in the pilot project in Klang and Mersing is the postal letters. The possibility of using other types of reminder/ recall methods similar to those used in the Australian system needed to be explored to increase the patients' participation rates such as registered letters, phone calls, Short Messages Service (SMS) or even home visits. However, home visits may not be feasible in the local setting as the expertise, human and funding resources are limited compared to Australia.

The Australian registry data have good quality control measures as opposed to the current program in Malaysia. Their data information is matched electronically (and possible matches are reviewed by an operator) with the lab results before entry into the system to prevent errors. The system used the coding system for diagnosis that is easier for data entry and also to prevent entering wrong diagnosis. There is double entrance of results (forward & backward) at the data entry centres (VCCR). The VCCR staff carry out a double checking of patients' details for quality assurance. The system will automatically detect the patients who need further intervention and generate recall/ reminder letters for respective patients. There are three major types of reminders used in the program which is the

postal reminder letters, the registered reminder letters and reminder lists sent to the nominated General Practitioners (GPs). However, in the current program in Malaysia and even in the pilot project, the results are being sent back to clinics/hospitals manually. The current pilot project had not even established its recall system and the recall of women with abnormal results is still done manually. There is even the possibility that the results may be delayed in reaching the patients or even loss in the process. In order to adopt this system effectively, a method for accurately receiving and processing results similar to the Australian system is urgently required.

A strong quality assurance system has been established for laboratories reporting cervical cytology. All cervical cytology is reported according to the Australian Modified Bethesday System (according to NHMRC guidelines) and all laboratories are accredited by a national body (National Association of Testing Authorities/NATA). Each laboratory conducts internal and external quality assurance and laboratories are required to report on standard performance measures twice yearly to the Quality Assurance Program (NPAACA, 2006). In Malaysia, there were a few quality indicators set by the MOH Malaysia that needed to be adhered to that are being emphasized in all the processes of sampling, reporting and colposcopy services. Each has their own indicator and standard that needed to be adhered to. For example, it should not be more than 5% of unsatisfactory samples during the sampling proceedure. This is being used as a guideline for the current program as well as the pilot program. Similarly, the standard performance measures are reported twice yearly to the Quality Assurance Program. Unfortunately, there are so many private laboratories operating on their own throughout Malaysia that do not report their quality indicators directly to the MOH Malaysia. This may impede the quality control of the slides in the cervical screening.

The current pilot project in Malaysia is a good stepping stone before any transition to the organised cervical screening program throughout the country. The project had just ended in 2011 and the final report is still being analysed at the ministry level. However, it will be beneficial if the screening program is improved in such a way, to enable the system to automatically generate the call/recall for patients with abnormal results once their results are entered into the system, as well as for other women in the system that should be reminded at the correct interval for their next test when it is due according to Malaysian guidelines. Thus, it will ensure prompt intervention of malignant cases and prevent loss to follow-up due to missing of results.

Conclusion

Cervical cancer will still remain a major problem in Malaysia as long as there is no establishment of an organised and effective screening program, resulting in poor screening participation. Based on similar successful programs in other countries, for example Australia and New Zealand, effective data registries for follow-up and reminders as well as systems for quality assurance for laboratories reporting cervical cytology are necessary.

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Most importantly is to ensure that the screening program is sustainable and accessible to the target groups to ensure high-coverage and the follow-up of positive cases for treatment are available nationwide.

A screening program must be tailored to local requirements in order to maximise participation. Further work is needed in Malaysia to evaluate the most cost effective methods to be used for a call-recall system, within the constraints of government funding.

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