RESEARCH ARTICLE

Study Protocol for the Most Effective Recall Method in a Cervical Cancer Screening Program in Klang, Malaysia

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Abstract

Background: Cervical cancer is the second most common cancer among Malaysian women with an ASR of 17.9 and a mortality rate of 5.6 per 100,000 population in 2008 (GLOBOCAN, 2008). The 5 year prevalence was estimated to be 14.5 per 100,000 population. As the second most common cancer affecting productive females, cervical cancer imposes an impact to the socioeconomic aspect of the country. However, the poor uptake of cervical cancer screening is a major problem in detecting early pre-cancerous lesions and thus, delay in initiating treatment for cervical cancer. Realizing the urgency to increase the uptake of PAP smear, besides enhancing the promotion of PAP smear screening for women above 35 years old, the call-recall system for pap smear screening had been piloted in one of the suburban districts which aimed to improve regular participation of women for cervical and breast cancer screening. This is of public health importance as identifying the best feasible option to increase patient's respond to participate in the screening program effectively in our setting will be helpful in implementing an organized regular population based screening program tailored to our setting. The pilot program of cervical cancer screening in Klang was an opportunity to assess different options in recalling patients for a repeat pap smear to increase their participation and adherence to the program. Methods and Results: This was a population based randomized control trial. Women aged 20-65 years in the population that matched the inclusion and exclusion criteria were re-called for a repeat smear. There are four different intervention groups; letter, registered letters, short messages services (SMS) and phone calls where 250 subjects were recruited into each group. Samples were generated randomly from the same population in Klang into four different groups. The first group received a recall letter for a repeat smear similar to the one that has been given during the first invitation. The intervention groups were either be given a registered letter, an SMS or a phone call to re-call them. The socio-demographic data of the patients who came for uptake were collected for further analysis. All the groups were followed up after 8 weeks to assess their compliance to the recall. Conclusions: The study will provide recommendations about the most effective methods for recall in a population based pap smear screening program on two outcomes: *i*) patients response; *ii*) uptake for repeat pap smear.

Keywords: Cervical cancer - screening - randomized control trial - recall - intervention - uptake

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Introduction

Cervical cancer screening in Malaysia has been carried out throughout Malaysia since 1969 by Ministry of Health Malaysia via its Maternal and Child Health Clinics. The service expanded with the development of the "National Pap Smear Screening Program" 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. Unfortunately, it is more of opportunistic screening where it is being overused by those in the reproductive years of age. Data from MOH (2005) showed that 52.0% estimated coverage of pap smear screening were done among those aged 30-49 years old. Only a small percentage of 9.7% and 2.5% coverage were among those in the 50-59 and 60-65 years age group respectively (Merican, 2006). This is ironic since MOH report in 2003 showed that incidence of cervical cancer is highest (71.6%) among those in the 60-60 years age group (MOH, 2009).

A great variation exists between countries throughout the world in terms of the coverage and uptake of cervical cancer screening. The national cervical cancer screening programs have been introduced in countries including the UK, Finland, Australia, Sweden and Spain aiming at those women most at risk of developing cervical cancer (i.e. usually women aged between 20 and 65 years). The recommendations may vary between countries (Rashid et al., 2013), but are usually screened every one to five years. The pap smear services are provided on a much more local basis in some countries with variable in uptake for the screening program. Differences in uptakes also exist within countries between different socio-demographic groups, according to factors including ethnic origin, age, education and socio-economic status. Lower uptake

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rates have been found to occur among women who are less educated, from lower socio-economic groups, older and reside in rural locations (Tacken et al., 2006; Dunn and Tan, 2010). However, lower uptake for pap smear also exist among educated career women (Abdullah et al., 2011). Thus, health education irrespective of the educational level plays an important role in improving the uptake of screening among women. A study done among Malaysian women found that lack of knowledge about cervical cancer screening using Pap smear, and the need for early detection for cervical cancer are among the main reasons for not doing the screening as well as lack of awareness of Pap smear indications and benefits, perceived low susceptibility to cervical cancer, and embarrassment (Wong et al., 2008). Other reasons include the fear of pain, misconceptions about cervical cancer, fatalistic attitude, and undervaluation of own health needs versus those of the family. This emphasized that health education, counseling, outreach programs, and community-based interventions are needed to improve the uptake of Pap smear in Malaysia.

A systematic review looking at the interventions to increase the pap smear uptake revealed behavioural interventions targeted to patients, such as mailed or telephone reminders, increased pap smear uptake of up to 18.8%. The cognitive and sociologic interventions were marginally effective, but a single culturally specific intervention which was the sociologic intervention using a lay health worker increased uptake by 18.0% (95%CI: 7.6, 28.4). Similarly, interventions that targeted both patients and providers did not appear to be any more effective than interventions targeted to either patients or providers alone. However, a system change by integrating a nurse-practitioner and offered same-day screening, appeared to be the most effective interventions that increased screening by 32.7% (95%CI: 20.5, 44.9) (Yabroff et al., 2003). Another systematic review concluded that nurse-led screening as one of the to promoting the attendance for pap smear. Other factors include assessing the women's health belief, inpatient cervical cancer screening, and cognition-emotion focused programs (Demirtas, 2013).

This study is of public health importance as identifying the best feasible option to increase patient's respond to participate in the screening program effectively in our setting will be helpful in implementing an organized regular population based screening program tailored to the local setting. The pilot program of cervical cancer screening in Klang is an opportunity to carry out different options in recalling patients for a repeat pap smear to increase their participation and adherence to the program. A meta-analysis performed to evaluate the efficiency of letters as reminder to patients showed a statistically significant difference pooled odds ratio of patients who received letter reminder to return for screening than those who do not (OR 1.64, 95%CI 1.49-1.80) (Tseng et al., 2001). This method was therefore being implemented in the current pilot project in Klang.

However, a study in UK showed that a letter of invitation is not sufficient to encourage women who have never or have infrequently undergone a Pap test to come in for cervical cancer screening. The author even suggested that effectiveness of added recruitment methods such as opportunistic screening by physicians, follow-up by telephone and the offer for a specific appointment should be evaluated (Buehler and Parsons, 1997).

A randomized control trial in Sweden that studied the different method of reminder to increase patient's compliance for cervical screening program found that a phone reminder increased the proportion of women attending up to 31.4% (95%CI 26.9-35.9) and the combinations of modified invitation, written reminder, and phone reminder almost doubled attendance within 12 months (Eaker et al., 2004).

Another randomized control trial carried out to compare the cost effectiveness of enhanced invitation methods for cervical screening program revealed that uptake for all the interventions i.e. telephone call, celebrity letter and commissioner letter were low (Stein et al., 2005). Telephone invitation was the most expensive and least effective among all the interventions. This might not be applicable to our setting and further studies should be carried out to investigate its possibility. However, it will be worth to examine the possibility of this method for recalling patients for a repeat smear in our setting.

Unfortunately, there is continuous debate about whether society's limited resources are better spent on reaching the underserved rather than on technology. Another question is whether the use of technology for example, phone call as a type of recall will create a disparity in delivering preventive care, in view that the socio-economic group of patients might be missed out. Thus, other options should be investigated similarly for example, using nurses' home visits in those areas. Intentionally, these choices will result in better patient's respond and fewer losses to follow-up and in long term will reduce the treatment costs via early case detections. These are the areas that we would like to explore by carrying out this study. Hopefully, by carrying out this study, we would be able to identify the best option to enhance the uptake of cervical cancer screening and eventually the most effective method to encourage the women to come forward and do pap smear.

Materials and Methods

Method of data collection

There were four methods of data collection: the point where patients contacted the clinic, face to face encounter with patients at the clinics, review of patients' SIPPS database and follow-up of the patients after 8 weeks.

Patients contacted the clinic

Irrespective of the type of intervention sent, once the patient contacted the clinic to ask further question, to state the reason why they can't come for a repeat smear or to re-scheduled the appointment whether by sending SMS or making a phone call to the clinic or to the district health office, data were collected as patients giving response to the re-call given.

Face to face encounter

Once the patients came to the clinic stating that they had received a recall for a repeat smear irrespective of

the type of intervention given, data on patients' response were collected whether or not they repeat the smear. Once the patients' repeat their smear, data on uptake for repeat smears were collected.

Review of patients' database

At the end of the 8 weeks period, patients' data in the database were examined for the response of a repeat smear and matched with the manual data collected at the clinics and the district health office to minimize any mistakes in recording patients' uptake.

Follow-up of patients

At the end of the 8 weeks period, all the patients were called by phone to determine whether they had received the recall sent or made. Data collected were matched with the data collected at the clinics and the district health office to minimize any mistakes recording the patients' response and uptake for pap smear.

Results

Intervention groups

Personal letters of recall similar to the invitation letter were sent to the patients in the postal letter and registered letter groups. The same personal message was sent through SMS to those in the SMS group. Similarly, the same personal messages were conveyed through the phone call made to the women in the phone call group. The message contained the patients' identification card (IC) numbers, patients' names and current addresses, the dates that they were supposed to repeat the screening (approximately within 1 month from the date of recall), the list of clinics that they can go to and phone numbers that they can call to re-schedule appointment if they necessary. Considering the time taken for letter to reach each woman, letters were sent three days earlier than sending messages via SMS and making telephone calls. This was to ensure that the women in each intervention arms received the recall within the same week. The time frame set for all recalled women to come for a repeat smear were 8 weeks.

Comparison group

All the intervention groups (registered letters, SMS and phone calls) were compared with the group that were sent the letters. This was because the first invitation was by sending letter and the proposed method of recall to be used in the program was sending letter. However, the re-call of patients for repeat pap smear in the program had not been initiated at the time when this trial was started.

Flowchart of study

Figure 1 displayed the flowchart of this study in detail for a better comprehension on patients selection and allocation.

Outcomes

The outcomes of this study are: *i*) To describe the characteristics of patients who responded to the recall in this study; *ii*) To compare the number of women who responded to the recalling/invitation via postal letters, registered letters, SMS and phone calls; *iii*) To compare the uptake of pap smear in the various mode of recall; *iv)* To determine the causes of non-respondents to the recall methods; *v)* To determine the predictors of respondents for future uptake of pap smear.

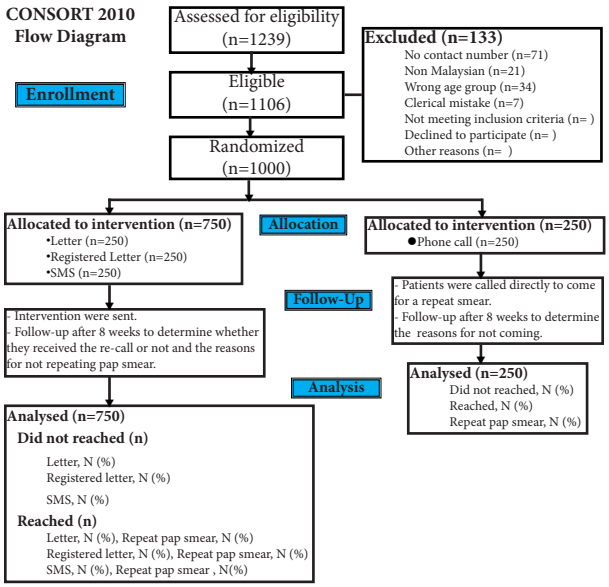

Figure 1. Flowchart of the Study

Statistical analyses

The statistical analysis was needed to analyse the outcome variables and their association with other independent variables. SPSS for Windows (version 16.0) was used for data entry and all analyses. The main outcome variable for this study was the response rate in each intervention. The associations between outcome variable and independent variables as well as comparisons of proportion between the groups were analyzed using the pearson chi-square test and bivariate logistic regression analyses. Bivariate logistic regression analyses was conducted to assess the independent influence of significant factors from the bivariate analyses in predicting the response rates in all four groups. The results will be interpreted using $p<0.05$ (2-sided) as the criterion for statistical significance.

Discussion

This research will provide recommendation for the most effective method of re-call to encourage patients who had previous negative smear to repeat a pap smear. This will give an evidence based data on the best method of recall to be used in a population based cervical cancer screening program in the developing countries that has not established any organised screening program such as Malaysia.

This study had approved from the University Malaya Medical Centre Ethics Committee (MEC Reference number: 781.10) and patient's voluntary consent. The patients were given a verbal and written explanation

to enable them to clearly understand the principles and procedures of the study. The patients also given opportunities to ask questions and to have the question answered. Agreement from the patients to participate in the study was obtained from the investigators. Patients were provided an information sheet and asked to sign a consent form. The patients' detail was kept confidential. The patients were informed that they could withdraw from the study at any time and this would not affect the intervention.

Acknowledgements

This trial had been reviewed by the Medical Ethics Committee Composition, University Malaya Medical Centre and had been approved on 21st April, 2010. The MEC Ref. No: 782.13. It is sponsored by Postgraduate Research Fund, University of Malaya (File no. PS238-2010A).

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