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## Research Articles

### Effect of energy expenditure on pregnancy outcome; A cohort study

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#### ABSTRACT

##### Objective:

To determine the trimester specific effect of energy expenditure on pregnancy outcome.

##### Study Design:

A population based prospective cohort study was carried out in two Medical Officer of Health areas in the Gampaha District from May 2001 to April 2002. Eight hundred and seventy five pregnant women were recruited on or before 16 weeks of gestation. Daily energy expenditure was assessed based on the activities resorted at home by housewives and both at home and at work by working mothers indicated in the three day activity record on two occasions during second (n=371) and third (n=271) trimesters. Information on potential confounding factors was gathered on average at 12<sup>th</sup>, 28<sup>th</sup> and 36<sup>th</sup> weeks of gestation. There were no statistically significant difference between responders and non-responders in terms of socio-economic characteristics. Multiple logistic regression was applied and the results are expressed as odds ratios (OR) and 95% confidence intervals (95%CI).

##### Results:

Energy expenditure >2550 kcal/day during second trimester was a risk factor for maternal complications [OR 6.30; 95%CI: 1.8, 21.9]. During third trimester it was a protective factor [OR 0.29; 95%CI: 0.09, 0.96] for small for gestational age defined as <5 centile. Energy expenditure had no association with low birth weight or preterm birth either in second or third trimesters.

##### Conclusion:

High energy expenditure was a risk factor for maternal complications and a protective factor against the birth of a small for gestational age infant in uncomplicated pregnancies.

##### Key words:

Birth weight; energy expenditure; preeclampsia; preterm birth; small for gestational age

#### Introduction

Physical activity refers to any bodily movement produced by skeletal muscles that results in energy expenditure (1) which may be measured either in kilo calories or kilo joules.

As Laporte (2) describes there are more than 30 different methods used to evaluate physical activity. These have been grouped into seven broad categories, namely calorimetry, job classification, survey procedures, physiological markers, behavioral observation, mechanical and electronic monitoring and, dietary measures. The objective way of assessing physical

activity is by measuring of energy expenditure. Energy expenditure however, occurs not only from physical activity but also from resting metabolism and the thermic effect of the food. Therefore total energy expenditure is a result of all the three components mentioned above (1). The determinants of energy expenditure with regard to each of the above categories however, are not similar (3). Survey procedures are the most practical way of assessing physical activity for large scale population studies. These may be grouped into four general types namely, Diary Surveys, Recall Surveys, Quantitative History Survey and General Surveys (2).

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The total amount of calories expended is arrived at by summing up the calories spent on each activity, which is based on previously estimated energy expenditure level and the time spent on each activity.

Several studies had investigated the effect of energy expenditure on pregnancy outcome. Magann (4) had reported that women with higher energy expenditure had significantly higher incidence of pregnancy induced hypertension and pre-term rupture of membranes. Schramm (5) had found that on comparison of very low birth weight (LBW) [ $< 1500\text{g}$ ] with normal birth weight infants, exercise during each of the three trimesters had a significantly beneficial effect on the birth weight. Hatch (6) also reported that women with moderate exercise at 36 weeks gave birth to infants with a significantly higher mean birth weight than women with no exercise. Campbell (7) had reported that women who participated in structured exercise in low or high frequency during the third trimester, had a higher risk of delivering small for gestational age infants than those who participated in moderate frequency. However, Rabkin (8) had reported that energy expenditure in paid work and at home had no association with birth weight.

As described above, there are inconsistencies with regard to the influence of energy expenditure on pregnancy outcome. Further it has revealed that the effect of energy expenditure varies from trimester to trimester. Therefore the objective of the study was to determine the trimester specific effect of energy expenditure on pregnancy outcome.

## **MATERIALS AND METHODS**

A population based prospective study was carried out in two Medical Officer of Health areas in the Gampaha District. The duration of the study extended from May 2001 to April 2002. All pregnant women eligible to participate in the study were recruited on or before 16 weeks of gestation and followed up until delivery. Exclusion criteria were age  $< 15$  years, rhesus negative blood group, pre-existing diabetes mellitus and hypertension, epilepsy, positive VDRL (Venereal Disease Research Laboratory) test and major psychiatric conditions.

The study instruments consisted of a questionnaire, which included four main components, namely 1) socio demographic and pregnancy related information and details related to occupation and environmental exposures, 2) Activity Record 3) Modified Life Events Inventory and 4) General Health carried out to determine the clarity of the questions. The first and the last two components of the ques-

tionnaire-30. The latter two instruments were used to assess the psychosocial status of the mothers.

Duration of different postures adopted at home in terms of walking, sitting, standing and sleeping were inquired from all women irrespective of whether they were in paid employment or not. For working women the number of hours spent per day in each posture at the work place was considered in addition to what was adopted at home and standardized for the number of working days to determine the number of hours spent per day in each posture.

The Activity Record was designed to extract information on physical activities for calculation of energy expenditure. Women were asked to complete this on two occasions, during the 20<sup>th</sup> week (2<sup>nd</sup> trimester) and during the 32<sup>nd</sup> (3<sup>rd</sup> trimester) week of gestation. On each occasion the activity record had to be completed on three different days. For housewives it was two-week days and the Sunday of the same week and for working mothers it was two working days and one routine off day of the same week. The dates on which the women had to complete during the 20<sup>th</sup> and the 32<sup>nd</sup> weeks were given in writing and reminded at the clinic visit just prior to the specified date.

In the activity record, a day is divided into 96 periods, each consisting of duration of 15 minutes (9) where a woman is expected to record the physical activities (according to the coded list on different activities made available to her) carried out every 15 minutes. In the event of engaging in two or more different activities within a given 15 minute time period, the woman was instructed to record the activity on which more time was spent. These activities had to be assigned into the nine broad categories for the calculation of energy expenditure, which was based on the median energy cost of each broad activity group (9). In assigning the activities reported by women to one of the broad categories, consensus of opinion was sought and this was helpful in deriving a more accurate estimate of the energy expenditure. The energy cost for of all 96, 15-min periods were summed up to determine daily energy expenditure for each of the three days. Energy expenditure of the three days were then summed up and divided by three to determine the average daily energy expenditure which was used for the final analysis. A reliability study (9) of 61 subjects indicated that it was highly reproducible procedure ( $r = 0.96$ ,  $p < 0.01$ ).

Face and content validity of all the components of the questionnaires were ensured and pre-tests were

tionnaire were administered at the time of recruitment to the study. The last two components and questionnaire related to employment and posture were administered at 28 weeks and 36 weeks in addition. Maternal weight and height, blood pressure and ultrasound scan measurements were carried out according to a standard protocol.

Four well-trained data collectors recruited to gather information under the supervision of the principal investigator. Each data collector was entrusted with eight to nine clinics, for which they were responsible for throughout the study. Each data collector maintained a register of all the relevant details necessary for the follow up of the pregnant women who were under their purview. The data collectors had to determine eligibility of the research participants to the study by scrutinizing the check list developed for that purpose at each antenatal clinic. Those who were eligible were detailed about the study and informed consent was obtained. The next clinic visit due for each woman was noted by the data collectors for follow up. When a recruited women failed to turn up for antenatal care on the due day, data collectors visited their home to gather the required information and to persuade them to continue attending clinics which are held regularly. Intention of migration to another area during the pregnancy or puerparium was also inquired from the women, in order to facilitate collection of outcome data.

Maternal complications was defined as presence of a diagnosis of pregnancy induced hypertension, gestational diabetes mellitus or ante partum hemorrhage during the third trimester. LBW was defined as infants with birth weight of less than 2500 g. Preterm birth (PTB) was defined as births that occurred at a gestational age of less than 37 completed weeks. All mothers were subjected to an ultrasound scan measurement before the 20<sup>th</sup> week of gestation. Gestational age was determined based on the bi-parietal diameter. Gestational age based on the last menstrual period was considered for the analysis, if the expected date of delivery determined using the last menstrual period and the ultrasound scan measurement were within 7 days. If not, the gestational age based on the ultrasound scan measurement only was used. Customized computer-generated software program was used for the assessment of SGA (10). Gestational age, fetal sex, maternal weight at first antenatal clinic visit, height, ethnic group and parity were entered into the program, which calculated the centile of the birth weight of an individual infant (11,12). SGA was defined as birth weights < 10<sup>th</sup> and < 5<sup>th</sup> centiles

Logistic Regression was applied and results were expressed as odds ratios (OR) and 95% confidence intervals (95% CI). Women with maternal complications were excluded for analysis on the effect of LBW, PTB, and SGA. Cutoff values with regard to hemoglobin level, height, weight and pre-pregnancy weight were determined by using Receiver Operator Characteristic curves to get a more accurate estimate of the association. Multivariate logistic regression was carried out to control for the confounding factors. Eligibility for including the variables into the regression model was based on both statistical basis (p-value < 0.25) as well as biological plausibility (13). It was ensured that the factors under study would remain in the model despite the probability level achieved during addition and deletion of other independent variables into the model. Variables were coded as 0 and 1 were entered into the model simultaneously and then removed one by one if it was ineligible. A two tailed probability of <0.05 was considered as significant. Interactions were tested and it was not statistically significant. No co-linearity between variables was observed. Cutoff value with regard to energy expenditure was determined by using Receiver Operator Characteristic curves to get a more accurate estimate of the association.

The Ethics Committee of the Faculty of Medicine, University of Kelaniya Sri Lanka, granted ethical approval to the study.

## RESULTS

Activity record was offered to 875 women at the time of recruitment. Only 833 women were left to complete it at 20 weeks of gestation after the exclusion of 42 women who ended up in spontaneous abortions. Of that only 384 women completed it, which gave a non-response rate of 54%. It was offered to 694 women at the time of the second interview. Of them only 273 women completed it at 32 weeks of gestation, which gave a non response rate of 60.7%. The mean energy expenditure at 20 weeks and 32 weeks of gestation were 2358 (SD 496) kcal / day and 2525 (SD 458) kcal / day respectively.

Demographic and socio-economic characteristics were compared between the groups who completed and did not complete the activity record during the second and the third trimesters. There was no statistically significant difference between the two groups either in the second or third trimesters.

**Table – 1 Unadjusted Odds Ratios for Energy Expenditure by Trimester and Maternal Complications**

Energy Expenditure (Kcal)	MC		OR value	95% C.I.	P
	Yes n (%)	No n (%)			
2 <sup>nd</sup> trimester	>2550	13 (72)	6.86	2.38, 19.75	0.00
	≤2550	5 (28)			
3 <sup>rd</sup> trimester	>2550	8 (89)	11.02	1.36, 89.24	0.02
	≤2550	1 (11)			

**MC: Maternal Complications; OR: Odds Ratio; 95%CI: 95% Confidence Interval**

**Table - 2 Adjusted Odds Ratios for Maternal Complications**

Exposure variable	b	SE	OR	95%CI	P value
Energy expenditure >2550 Kcal/day during 20 <sup>th</sup> weeks of gestation	1.96	0.67	7.10	1.91, 26.2	0.003
GHQ Score >5 during 2 <sup>nd</sup> trimester	1.65	0.62	5.21	1.54, 17.6	0.008
Standing >2.5 hours / day during 1 <sup>st</sup> or 2 <sup>nd</sup> or both trimesters	-1.68	0.72	0.19	0.05, 076	0.02
BMI > 26.0 kg/m <sup>2</sup>	1.11	0.68	3.02	0.80, 11.5	0.10
Education ≤ 5grade	2.67	0.95	14.5	2.25, 93.1	0.005

**b: co-efficient; SE: Standard Error; OR: Odds Ratio; 95% CI: 95% Confidence Interval;**

**Table – 3 Unadjusted Odds Ratios for Energy Expenditure by Trimester and LBW**

Energy Expenditure (Kcal)	LBW		OR	95% CI	P value
	Yes n (%)	No n (%)			
2 <sup>nd</sup> trimester	>2550	7 (20)	0.62	0.26, 1.48	0.28
	≤2550	28 (80)			
3 <sup>rd</sup> trimester	>2550	1 (4)	0.05	0.006, 0.36	0.003
	≤2550	24 (96)			

**LBW: Low Birth Weight; OR: Odds Ratio; 95%CI: 95% Confidence Interval**

### **Energy expenditure and maternal complications**

Of the 384 women who completed the activity record during the second trimester only 371 were available for analysis after excluding fetal deaths. Of them, 18 (4.8%) women had maternal complications. Of the 273 women who completed the activity record during the third trimester, only 271 were available for analysis after excluding of fetal deaths. Of them, nine women had maternal complications.

In the univariate analysis, energy expenditure in both second and third trimester was found to be significantly associated with maternal complications (Table 1). For the multivariate analysis for maternal complications 358 women were included in the final model. Hosmer and Lemeshow test for goodness of fit was observed to be satisfactory (p value 0.79). The number of events of maternal complications per variable was three. Adjusted OR for energy expenditure >2550 Kcal/day during 20<sup>th</sup> weeks of gestation was 7.1 [95% CI: 1.9, 26.2] controlling for psychosocial stress, standing hours, body mass index (BMI) and low educational level (Table 2). Therefore, higher energy expenditure during second trimester is considered as a risk factor for maternal complications.

### **Energy expenditure and LBW**

Of the 384 women who completed the activity record during the second trimester only 351 were available for the analysis after excluding those who ended up in fetal loss and maternal complications. Of them, 36 (10.2%) women delivered LBW infants. Of the 273 women who completed the activity record during the third trimester only 261 were available for analysis after excluding those who ended up in fetal loss and maternal complications. Of them, 26 (9.9%) women delivered LBW infants.

In the univariate analysis, energy expenditure during the third trimester was significantly associated with LBW, but not with energy expenditure during the second trimester (Table 3). When applying multivariate analysis, however energy expenditure was found to be unsuitable to be included in the final model.

### **Energy expenditure and PTB**

Of the 384 women who completed the activity record during the second trimester, only 351 were available for analysis after excluding fetal loss and

maternal complications. Of them, 36 (10.2%) women delivered PTB infants. Of the 273 women who completed the activity record during the second trimester only 262 were available for analysis after excluding fetal loss and maternal complications. Of them, 19 (7.2%) women delivered PTB babies. By univariate analysis, energy expenditure was not observed to be significantly associated with PTB either in the second or third trimester (Table 4).

### **Energy expenditure and SGA**

Of the 384 women who completed the activity record during the second trimester, only 335 were available for analysis after excluding those who ended up in fetal loss and /or maternal complications. Of them, 50 (14.9%) and 26 (7.7%) women delivered SGA infants defined as <10<sup>th</sup> and <5<sup>th</sup> centiles respectively. Of the 273 women who completed the activity record during the third trimester only 253 were available for analysis after excluding those who ended up in fetal loss and maternal complications. Of them, 37 (14.6%) and 22 (8.6%) women delivered SGA infants defined as <10<sup>th</sup> and <5<sup>th</sup> centile respectively.

In the univariate analysis, energy expenditure >2550 Kcal/day in the second trimester was not found to be significantly associated with either SGA defined as <10<sup>th</sup> or <5<sup>th</sup> centile (Table 5 and 6). Energy expenditure >2550 Kcal/day in the third trimester was significantly associated with SGA defined as <5<sup>th</sup> centile. For SGA defined as <10<sup>th</sup> centile the probability value for the association was 0.07. For the multivariate analysis, 231 women were included in the final model for SGA defined as <5<sup>th</sup> centile. Hosmer and Lemeshow test for goodness of fit was observed to be satisfactory (p value 0.74). The number of SGA events per variable was five. Adjusted OR for energy expenditure >2550 Kcal/day during the third trimester was 0.30 [95% CI: 0.09, 0.94] controlling for sleeping and walking hours and alcohol consumption (Table 7). The corresponding adjusted OR was 0.45 [95% CI: 0.20, 1.03] when SGA was defined as <10<sup>th</sup> centile. Therefore, higher energy expenditure during third trimester is considered as a protective factor for SGA infants.

**Table – 4 Unadjusted Odds Ratios for Energy Expenditure by Trimester and PTB**

Energy Expenditure (Kcal)	PTB		OR	95% CI	P value	
	Yes n (%)	No n (%)				
2 <sup>nd</sup> trimester	>2550	11 (31)	85 (27)	1.18	0.55, 2.51	0.65
	≤2550	25 (69)	229 (73)			
3 <sup>rd</sup> trimester	>2550	7 (37)	102 (42)	0.80	0.30, 2.10	0.65
	≤2550	12 (63)	140 (58)			

PTB: Preterm Birth; OR: Odds Ratio; 95%CI: 95% Confidence Interval

**Table – 5 Unadjusted Odds Ratios for Energy Expenditure by Trimester and SGA < 10<sup>th</sup> Centile**

Energy Expenditure (Kcal)	SGA < 10 <sup>th</sup> centile		OR	95% CI	P value	
	Yes n (%)	No n (%)				
2 <sup>nd</sup> trimester	>2550	12 (24.5)	79 (30)	0.84	0.42, 1.70	0.63
	≤2550	37 (75.5)	206 (70)			
3 <sup>rd</sup> trimester	>2550	10 (30)	95 (44)	0.49	0.22, 1.06	0.07
	≤2550	26 (70)	121 (56)			

SGA: Small for Gestational Age; OR: Odds Ratio, 95%CI: 95% Confidence Interval

**Table – 6 Unadjusted Odds Ratios for Energy Expenditure by Trimester and SGA < 5<sup>th</sup> Centile**

Energy Expenditure (Kcal)	SGA < 5 <sup>th</sup> Centile		OR	95% CI	P value	
	Yes n (%)	No n (%)				
2 <sup>nd</sup> trimester	>2550	5 (19)	86 (28)	0.62	0.23, 1.69	0.35
	≤2550	21 (81)	223 (72)			
3 <sup>rd</sup> trimester	>2550	4 (18)	101 (44)	0.29	0.10, 0.87	0.03
	≤2550	18 (82)	130 (56)			

SGA: Small for Gestational Age; OR: Odds Ratio, 95%CI: 95% Confidence Interval

**Table – 7 Adjusted Odds Ratios for SGA < 5<sup>th</sup> centile**

Exposure variable	b	SE	OR	95%CI	P value
Energy expenditure >2550 Kcal/day during 32 <sup>nd</sup> weeks of gestation	-1.21	0.58	0.30	0.09, 0.94	0.04
Sleeping ≤ 8 hrs / day during 2 <sup>nd</sup> or 3 <sup>rd</sup> or both trimesters	1.27	0.52	3.55	1.28, 9.85	0.02
Walking >2.5 hours / day during 3 <sup>rd</sup> trimester	-0.97	0.66	0.14	0.10, 1.37	0.14
Alcohol consumption during 3 <sup>rd</sup> trimester Yes	2.59	1.48	13.4	0.73, 246.0	0.08

β: co-efficient; SE: Standard Error; OR: Odds Ratio; 95% CI: 95% Confidence Interval; Prob: Probability

## DISCUSSION

The objective of the study was to determine trimester specific effect of energy expenditure on pregnancy outcome. The study revealed that energy expenditure >2550 kcal/day in the second trimester was a risk factor for maternal complications [OR 7.74; 95%CI: 1.74, 34.3] having controlled for confounding factors. However, energy expenditure in the third trimester had no significant association with maternal complications [OR 8.32; 95%CI: 0.75, 91.4]. For SGA defined as <5<sup>th</sup> centile, energy expenditure >2550 kcal/day during third trimester either in the univariate or the multivariate analysis. Energy expenditure >2550 kcal/day either in the second or the third trimester revealed no association with SGA defined as <10<sup>th</sup> centile, LBW or PTB.

Similar results were reported by Magann (4) according to which, women with higher energy expenditure (2501–2700 kcal /day) had a significantly higher incidence of pregnancy induced hypertension after adjusting for confounding factors, although the results were not statistically significant for ante-partum hemorrhage. The median energy expenditure levels in this study tallies with the cutoff used by the present study (2550kcal/ day). However, in the present study all the maternal complications were pooled together as the number of women with maternal complications were small. The 95% CI of the OR derived for association between energy expenditure and maternal complications were wide and this may be due to the small sample size, which was as a result of high non-response rate of the study.

In the present study no association was observed between energy expenditure in the second or the third trimester and PTB even in the univariate analysis. However, Magaan (4) had reported that women in the higher energy expenditure group had a higher incidence of preterm rupture of membranes.

Hatch (6) reported that women with moderate exercise at 36 weeks gave birth to infants with a significantly higher mean birth weight of 117g [95% CI: 17, 217g] than women with no exercise. Those who engaged in heavy exercise throughout pregnancy too had an increase of 276g [95% CI: 54, 497 g] of adjusted mean birth weight. Similarly Schramm (5) also had reported that exercise during each trimester had a protective effect on normal birth weight when compared to very LBW. According to the study carried out by Hall (14) birth weight had been more favorable in the high exercise group than in the low exercise group. In the prospective study conducted by Rabkin (8) the effect of total energy expenditure and energy expenditure at work place and at home

separately, on birth weight had been considered. The results revealed that energy expenditure had no association at all with the birth weight.

Growth retardation however, cannot be described by a single weight measure because; birth weight is dependant on two factors, namely duration of gestation and intrauterine growth rate. Further the use of the customised birth weight standards has been considered as a better means of discriminating retarded growth in comparison to other standards (15,16,17). SGA is a parameter which takes into accounts both, birth weight and gestational age. Campbell (7) had reported that those who participated in structured exercise 3 or 4 times a week had a lower risk of delivering SGA infants, defined as <15<sup>th</sup> centile after 33weeks of gestation, compared to the women who participated in structured exercise of less than 3 and more than 4 times a week. One possible reason is that women who are inactive are those with poor general health status than those who work moderately and as a result the latter group has a favourable pregnancy outcome. This hypothesis is favoured by the finding that women in the lower energy expenditure category had higher ante-partum hospital admissions (4). This may be a reflection of the concept that employed people are considered healthier than those in the general population. However this may be extended beyond working populations and applied in general and deduce that moderately active people are healthier than those who relatively inactive. Another explanation for the above observation may be based on the increase in maternal haem concentration through the release of catecholamines that takes place during exercise. This increase in haem levels is postulated to yield a net gain in fetal weight (18,19).

The results of the present study are consistent with the results of the other studies described, where moderate exercise / energy expenditure were found to have a protective effect on fetal outcome. The American College of Obstetricians and Gynecologists also advocate 30 minutes or more of moderate exercise a day on most days of the week for women who are free of medical and obstetric complications. However this should be implemented based on an evaluation of individual health status (20).

The daily energy expenditure was determined by using the activities indicated in the activity record. Completion of the activity record was carried out by individual woman either at home or at the work place depending on whether it was a mother engaged in paid employment or not. The study was heavily dependant on the corporation of the

individual subjects which in turn was dependant on the awareness of the woman, purpose of the study and the resultant motivation. Hence, it was not surprising that despite every step taken to minimize this, high non response rates were observed for the second (54%) and third (60%) trimesters. However, no significant difference was observed with regard to the demographic and socio economic characteristics between the respondents and non respondents.

The present study concludes that high energy expenditure has a favorable effect on SGA in uncomplicated pregnancies and an unfavorable effect on maternal complications during pregnancy.

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# Respiratory symptoms and ventilatory function among granite workers working in quarries installed with mechanical crushers in and around Kandy Municipality limits

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## Abstract

**Objectives:** To compare the presence of selected respiratory symptoms among granite workers with a control group and to assess ventilatory function (VF) and radiological changes in the lungs of granite workers.

**Methods:** A cross-sectional analytical study was conducted on workers employed in the granite quarries installed with mechanical crushers in and around the Kandy Municipality limits. The control group comprised persons accompanying patients to the outpatient department of a tertiary care hospital. The respiratory symptoms were compared using an interviewer administered questionnaire. Only granite workers were subjected to spirometry and chest radiography. *Forced vital capacity (FVC), forced expiratory volume in the first second of FVC and peak expiratory flow rate* were assessed. The observed values of above were compared with predicted normal values. Chest radiographs were read by two radiologists conforming to ILO classification of radiographic appearances.

## Results:

There were 51 granite workers and 51 controls. A higher proportion of granite workers had chronic cough (8%; n=4), and phlegm (16%; n=8) of  $\geq 3$  months duration and chronic bronchitis (16%; n=8) in comparison to the control group (2% [n=1], 6% [n=3] and 8% [n=4] respectively) but the differences were statistically not significant. A significantly higher proportion in the control group had dyspnoea (45%; n=23) and at least a single respiratory symptom (55%, n=28) in comparison to the granite workers (10% [n=5] and 31% [n=16] respectively).

The observed values of the three respiratory indices were significantly lower than the predicted norms. Twenty four (47%) had a restrictive type and one (2%) an obstructive type of ventilatory impairment. None had radiological evidence of silicosis or tuberculosis.

## Conclusions:

Ventilatory function of granite workers were affected significantly. Proportions with cough and phlegm of equal or more than three months duration and chronic bronchitis were higher among granite workers even though statistical significance was not reached. Proportions with dyspnoea and at least one respiratory symptom was significantly less among granite workers. There was no radiological evidence of silicosis or tuberculosis. Installation of exhaust ventilation, use of industrial masks and limitation of exposure time is recommended.

## Key Words:

Granite workers, Ventilatory impairment, Respiratory symptoms

## Introduction

Granite is a mixture of quartz (silicon dioxide), feldspar and other minerals (1). The granite industry in Sri Lanka is over 2000 years old (1). Stone statues, pillars and inscriptions of ancient Sri Lanka bear evidence to this. Presently granite is used on a large scale for building and road construction work.

Granite occurs in rock form, and dynamite is used to blast the rocks where large fragments are separated out and these are further broken into smaller pieces according to the requirements.

This was usually done manually with the help of a hammer. In some of the large quarries the manual process has been mechanised now with the installation of crushers. The use of crushers results in the release of large amounts of dust into the atmosphere where the workers are at risk of inhaling it.

Exposure to quartz or silica dust can lead to the development of chronic respiratory symptoms such as cough, phlegm and dyspnoea. In addition chronic exposure can lead to silicosis which is a form of pneumoconiosis that gives rise to fibrosis of the lungs

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leading to respiratory failure. This is generally progressive and removal from exposure will not reverse the condition. Although the granite industry has been in existence for several years, silicosis (1) is not a common condition in Sri Lanka. Manual chiselling does not generate large quantities of dust and the low prevalence of silicosis may be attributed to it, in combination with the open environment they work in, unlike in temperate climates.

The objective of the study was to compare the presence of selected respiratory symptoms among granite workers with a control group and to assess ventilatory function (VF) and radiological changes in the lungs of granite workers employed in quarry sites installed with mechanical crushers.

### Methodology

A cross sectional analytical study was conducted. The quarries fitted with mechanical crushers in and around the Kandy Municipality limits, were identified and all the workers employed at the crushers at these quarries, irrespective of the duration of service, were included in to the study.

The control group consisted of people accompanying patients to the outpatients' department of the Teaching Hospital, Peradeniya who were either unemployed, or employed in occupations not associated with specific dusts, fumes and gases. In order to ensure a similar socioeconomic background, the occupations selected were limited to health care minor staff, small scale traders, labourers, office support staff, and transportation workers. The unemployed recruited were from families with a similar employment background or those who have retired from similar occupations. Selection of controls was limited to the same age range and sex distribution as the granite workers.

The respiratory indicators (RI) studied were the forced vital capacity (FVC), forced expiratory volume in the first second during expiration (FEV<sub>1.0</sub>) and the peak expiratory flow rate (PEFR) using an electronic spirometer which conformed to the specifications of the American Thoracic Society (3). The technique of taking a deep breath followed by rapid and continuous exhalation into the spirometer was demonstrated to the research participants by an experienced technician. They were allowed a minimum of three practice blows. Three readings were obtained once they mastered the technique. The highest reading out of the two which had a variation of less than 5% was considered as final. The observed values of RI were compared with the predicted normal values computed using the regression

models developed for the Sinhalese by Udupihilla (4). The type of ventilatory impairment (VI) was assessed as described by Gildea *et al* (5).

An interviewer administered questionnaire was used to assess details of the current and previous occupations, presence of respiratory symptoms (2) and smoking status. The granite workers were subjected to normal sized postero-anterior chest radiography and the radiographs were read by two experienced radiologists using the International Labour Office classification system. Only the questionnaire on respiratory symptoms was administered to the control group as it was not possible to carry out spirometry due to logistical constraints and chest radiography owing to ethical considerations.

The respiratory symptoms includes were presence of cough and phlegm, dyspnoea, and asthma. Dyspnoea was defined as shortness of breath when walking with other people at an ordinary pace on level ground. Chronic bronchitis was defined as presence of either cough or phlegm or both over a duration of three or more months per year, for two or more consecutive years (6).

Statistical analysis consisted of Student T test for quantitative data and the chi square test for qualitative data. A probability of less than 0.05 was considered as significant.

Ethical clearance for the study was obtained from the Ethical Review Committee of the Faculty of Medicine, Peradeniya, Sri Lanka.

### Results

A total of 51 granite workers and 51 controls were included in the study. The response rate among the granite workers was 100%. The 51 controls who were purposively selected consisted of 42 males (84%) and 8 females (16%), the proportions which were same as for granite workers. The mean age of granite workers was 31.6 (SE = 1.7) years and that of the control group 35.7 (SE = 1.7) years, the difference of which was not statistically significant. Thirty three (64.7%) among controls were employed. The duration of service among granite workers ranged from 0.2 – 20 years with a median of one year ( Table 1).

The proportion with cough (8%; n=4) and phlegm (16%; n=8) with a duration of three or more months and chronic bronchitis (14%; n=7) was higher among granite workers than among controls (2% [n=1], 6% [n=3] and 8% [n=4] respectively) but none of the differences were statistically significant. The proportion with cough (18%; n=9) and

phlegm (20%; n=10) of less than 3 months duration, dyspnoea (45%; n=23), and any single respiratory symptom (65%; n=33) were higher among the control group (Table 2) in comparison to granite workers (8% [n=4]; 12% [n=6], 10% [n=5] and 37% [n=19]), of which, dyspnoea (OR=0.1; 95% CI: 0.04–0.42) and presence of any single respiratory symptom (OR=0.3; 95%CI: 0.1–0.8) were statistically significant.

The observed values for each RI of the granite workers were compared with the derived predicted values calculated for the individual subject for his/her age, sex and height (Table 3). The observed mean values of FVC (2.5 L), FEV<sub>1.0</sub> (2.4 L/sec) and PEFr (339.5 L/min) were significantly lower than the respective predicted values (3.2 L, 2.7 L/sec and 519.4 L/min). When analysing males and females separately, the male granite workers had significantly lower observed values for all the three RI in comparison to the predicted, whereas for females only PEFr was shown to have a significantly lower observed value.

The proportion of smokers among males in the study and control groups were 60.5% (26/43) and 48.8% (21/43) respectively and the difference was not statistically significant. The number smoked per day and the duration of smoking among the two groups also did not differ significantly (Table 1). On comparison of smokers and non-smokers among granite workers, the non smokers were found to be older (30.5 versus 29.2 years) and having a longer duration of service (26.3 versus 19.1 years) than smokers. However, none of these differences were statistically significant.

The proportion with symptoms in smokers (42%; [11/26] and 62%; [13/21] respectively) and non-smokers (32%, [8/25] and 66%; [20/30] respectively) among granite workers and the control group did not differ significantly. The proportion with symptoms in smokers among granite workers (42% [11/26]) and the control group (62% [13/21]) also did not differ significantly (Table 4). However, among the non-smokers, the granite workers (32%; [8/25]) were observed to have a significantly lower (p=0.02) proportion with respiratory symptoms than that of the control group (67%; [20/30]).

On comparison of RI of smokers and non-smokers among granite workers, the smokers were found to have higher mean values for all three indices namely FVC (2.6 versus 2.3 L), FEV<sub>1.0</sub> (2.7 versus 2.5 L/sec) and PEFr (375.1 versus 353.5 L/min) although the differences were not statistically significant.

Table 5 shows the distribution of granite workers according to the type of ventilatory impairment (VI). Among all workers, 24 (47.1%) had a restrictive type of impairment. This included 75% (6/8) of females and 41.9% (18/43) of males. Only one (2%) had obstructive type of impairment and that was a male. None had both types of impairment.

Seven (14%) among the granite workers with either type of impairment (47%; n=24) were found to present with symptoms. Only one (12.5%) female presented with respiratory symptoms but she was free of either type of ventilatory impairment.

None had radiological evidence of silicosis nor tuberculosis.

**Table 1 – Description of relevant variables among granite workers and the control group**

Variable	Description	Statistical test & Probability
Mean Age Study (n=51) Control (n=51)	31.5 (SE =1.7) years 36.0 (SE = 1.7) years	T Test 0.07
Smokers Study males (n=43) Control males (n=43)	26 (60.5%) 21 (48.8%)	Chi square 0.42
Mean number smoked /day Study Control	5 cigarettes or beedi or both (SE =0.7) 4 cigarettes or beedi or both (SE = 0.6)	T Test 0.49
Mean Duration of Smoking Study Control	9 (SE = 2.1) years 13 (SE = 1.7) years	T Test 0.11
Duration of service Study (n=51)	Median =1 year IQ range=0.4 -1.6 years Range= 0.2 – 20 years	Not applicable

**Table 2 - Comparison of respiratory symptoms in the two groups**

Respiratory Symptom	Granite n = 51	Control n = 51	Odds Ratio (95% CI)
Cough < 3months	4 (8%)	9 (18%)	0.4 (0.1- 1.6)
Cough ≥ 3 months	4 (8%)	1 (2%)	4.3 (0.4-104)
Phlegm < 3months	6 (12%)	10 (20%)	0.6 (0.2-1.8)
Phlegm ≥ 3 months	8 (16%)	3 (6%)	3.0 (0.7-15.0)
Chronic Bronchitis	7 (14%)	4 (8%)	2.2 (0.5-9.4)
Asthma	3 (6%)	2 (4%)	1.5 (0.2-13.8)
Dyspnoea	5 (10%)	23 (45%)	<b>0.1 (0.04-0.42)</b>
Other respiratory / heart illness	2 (4%)	5 (10%)	0.4 (0.1-2.4)
Total with any single respiratory symptom	19 (37%)	33 (65%)	0.3 (0.1-0.8)
Any single respiratory symptom with no other illness	17 (33%)	28 (55%)	<b>0.4 (0.2-0.91)</b>

**Table 3 - Comparison of pulmonary function with predicted values of granite workers (n=51)**

Respiratory Indicator	Observed Mean (SE)	Predicted Mean (SE)	Probability*
<i>FVC-L</i>	2.5 (0.10)	3.2 (0.05)	<0.0001
<i>FEV<sub>1,0</sub>-L/sec</i>	2.4 (0.10)	2.7 (0.05)	0.001
<i>PEFR-L/min</i>	339.5 (15.7)	519.4 (5.6)	<0.0001

\* T Test – Unequal variance

**Table 4 – Comparison of respiratory symptoms among smokers and non smokers in the two groups**

Presence of symptoms	Granite Workers (n=51)		Controls (n=51)	
	Smokers	Non Smokers	Smokers	Non Smokers
	(n=26)	(n=25)	(n=21)	(n=30)
No Symptoms	15 (58%)	17 (68%)	8 (38%)	10 (33%)
Chronic bronchitis	3 (12%)*	4 (16%)**	3 (14%)*	1 (3%)**
Other respiratory Symptoms	8 (31%)*	4 (16%)**	10 (48%)*	19 (63%)**

Statistical analysis: presence of symptoms among smokers in the two groups:

Smokers in the two groups: “no symptoms” versus “with symptoms” (\*pooled for the analysis); Chi Square value = 1.09; df=1; p = 0.3

Non smokers in the two groups: “no symptoms” versus “with symptoms” (\*\*pooled for the analysis); Chi Square value = 5.2; df=1; p = 0.02

**Table 5 – Type of ventilatory impairment among granite workers**

Type	Total n=51	Males n=43	Females n=8	FVC % of predicted	FEV <sub>1.0</sub> /FVC %
Restrictive (R)	24 (47.1%)	18 (41.9%)	6 (75.0%)	<75	≥70
Obstructive (O)	1 (2.0%)	1 (2.3%)	0 (0.0%)	≥75	<70
R + O	0 (0.0%)	0 (0.0%)	0 (0.0%)	<75	<70
Normal	26 (51.0%)	24 (55.8%)	2 (25.0%)	≥75	≥70

## Discussion

The study findings indicate that the respiratory function of the granite workers were significantly impaired with regard to all the indices studied in comparison to the predicted normal values. A higher proportion of granite workers had cough and phlegm, equal to or more than three months duration and chronic bronchitis, which were not statistically significant. They were free of radiological evidence of silicosis and tuberculosis.

The fact that the granite workers had a higher prevalence of chronic cough and phlegm (defined as lasting over equal or more than three months duration) and chronic bronchitis may be a reflection of the effect of exposure to silica dust. Lack of statistical significance may be explained by small sample included in the analysis.

There is epidemiological evidence to suggest that exposure to silica dust can give rise to chronic obstructive pulmonary disease (COPD) independent of silicosis (6). COPD (defined as presence of airflow obstruction due to chronic bronchitis or emphysema) arise due to chronic inflammation and remodelling of small airways and destruction of lung parenchyma in response to inhaled oxidants generated by smoking and other environmental exposures such as silica dust. There are two potential mechanisms through which silica is postulated to cause pathogenicity in the lungs: 1) by initiating a toxic and inflammatory processes in the conducting and peripheral airways and alveolar tissue which increases the production of oxidants, cytokines, chemokines and elastase leading to airways inflammation and emphysema or 2) by causing epithelial cell injury which facilitates penetration of silica particles of the small airways causing localised fibrosis (7).

The control group was on average 4.5 years older than the granite workers the difference of which was not statistically significant. It is unlikely that this small age difference could account for the observed higher proportions with cough and phlegm of less than 3 months duration, dyspnoea and presence of any single respiratory symptom among the controls. The episodes of cough and phlegm experienced by the latter group often did not exceed one to two weeks, suggestive of common acute respiratory illnesses. In comparison a higher proportion of granite workers were suffering from chronic (with a duration of equal or more than three months) respiratory episodes which may be attributed to their occupational exposures. Presence of dyspnoea among a significantly higher proportion of controls is difficult to explain, considering the lower proportion of them having chronic cough and phlegm (Table 2 - a total of three as one had both cough and phlegm). Of the 23 controls who presented with dyspnoea, eight (35%) were unemployed, and among them two were students of less than 25 years of age with no other concurrent illness. There were only four (17.4%) with other illness which could possibly account for the presence of it. Dyspnoea has a subjective element and the above finding may be a reflection of it.

The proportion of respondents suffering with other chest ailments was also higher among the control group which reflects the fact that controls were less healthier than the granite workers. This is may be attributed to the phenomenon of “healthy worker effect” given the fact that controls were selected from the general population. This is a phenomenon where the general population is considered to be less healthy than those working. The only way to overcome this is by selecting a control group from another industry. However, it is rather a difficult task, as selection of the control should meet the condition of absence of exposure to dust, fumes and gases. Hence the need to restrict the control group.

to the general population and as far as was feasible the respondents selected were ones who met the above criterion.

FEV<sub>1.0</sub> which is considered to be efficient in detecting large and medium sized airway function and PEF<sub>R</sub> which denotes large airway function (8) were observed to be significantly lower than the predicted values in the granite workers. Hence it may be deduced that granite workers were affected with both large and medium airway function despite the short median duration of exposure which was one year with a range of 0.2 to 20 years. The inability to assess FEF<sub>25%-75%</sub> in this study, which is a more sensitive indicator of small airways disease, is considered a limitation (8).

The short, median duration of work, may be suggestive of rapid turn over of workers. Individual susceptibility has a role to play in the development of respiratory illness and the workers who are able to withstand the adverse effects of silica dust will have the tendency to continue in the job. This may be further reinforced by working outdoors with limited exposure time. It is noted, that the maximum duration of 20 years was contributed by one single worker who was affected with chronic bronchitis and dyspnoea.

Forty seven percent (n=24) of all granite workers presented with restrictive lung disease. Forty two percent (n=18) of males and 75% (n=6) of females were affected with restrictive lung disease. Only one was affected with obstructive lung disease. Restrictive lung disease has been associated with production of collagen and fibroblast growth factors, resulting in fibrosis in the alveolar walls and to formation of silicotic nodules (7). However, in the present study it may be attributed purely to the former, in the absence of radiological evidence of silicotic nodules.

Even though 49% (24 [47%] restrictive and 1 [2%] obstructive) of granite workers showed evidence of either form of ventilatory impairment, only 28% (7/25) were observed to suffer from respiratory symptoms. This emphasises the need to intervene early before they become incapacitated with symptoms. Regular surveillance of the workers by carrying out lung function tests will help to identify these early cases, making application of early interventions (secondary prevention) possible. However, this should not at any cost, undervalue the importance of primary preventive measures such as reducing dust at the point of origin and the use of industrial masks.

The evidence available from other studies with regard to silicosis and VI are not consistent. Ng and Chan (10) showed that lung function impairment was directly attributable to fibrotic lung disease arising as a result of respirable silica. Longitudinal pulmonary function assessment carried out among Vermont granite workers between 1979 and 1987, had shown that VF loss is not accelerated by the dust levels, since its control conformed to Occupational Safety and Health Administration (OSHA) permissible exposure limits (11). However, a study reported in 2002 (12) in the United States indicates that there is still an associated decline in VF due to cumulative silica exposure even within the current allowable OSHA regulatory levels.

Silicosis has a long latent period. The short median duration of work in the granite industry which was one year, may not be sufficient enough to show any significant changes. In the study done on radiographic abnormalities among Vermont granite workers exposed to low levels of granite dust, only 3% showed abnormalities consistent with pneumoconiosis and of them only 0.7% showed clear evidence of uncomplicated silicosis (9). Undetected silicotic nodules in the lungs is postulated to give rise to airflow obstruction in granite workers even without radiological evidence of silicosis. This has been confirmed by computed tomography studies which are more sensitive in detecting confluent silicosis (7) than chest radiography. However, the applicability of the latter as a routine investigation in Sri Lanka is doubtful, owing to the prohibitive costs involved.

Exposure to silica dust is considered to increase the risk of tuberculosis even without the presence of silicosis. The absence of radiological evidence of tuberculosis which is a common condition in Sri Lanka, among the granite workers is therefore encouraging. However, long term follow up is required before being complacent about the findings in this study.

Evidence is available to suggest that smoking potentiates the effect of silica dust on lungs (7). When non-smokers show a decrease in residual lung capacity with restrictive impairment, smokers have been known to present with airflow obstruction with emphysema like functional changes (7). In the present study the smokers were observed to have better VF than the non-smokers although statistically not significant, it is contrary to the above findings.

With regard to the granite workers, the only possible explanation of the above findings is that the smokers were about one year younger and had a duration of service of seven years less than the non-smokers, and the amount smoked on average was five cigarettes/ beedi (local tobacco smoke) per day over an average duration of nine years. It is stated that smokers may initially have more robust lungs that can withstand the tobacco insult (13). This may have been further reinforced by the relatively younger age of the smokers combined with a lower duration of exposure to silica dust than the non-smokers. Based on the above findings it may also be postulated that the effect of silica on the respiratory system is far worse than the effect of smoking.

With regard to the symptoms, there was no significant difference observed in smokers and non smokers among granite workers and in smokers among granite workers and the control group. The statistically significant difference observed with regard to the symptoms were due to the difference in the proportions with symptoms among the non smokers in the two groups, where the non-smokers among the control group (66% versus 32%) were affected more. Thus the findings of this study reflect smoking as having a non-contributory role in the development of respiratory ill health in terms of both RI and respiratory symptoms in the study groups.

This is a cross-sectional analytical study associated with its characteristic limitation of not being able to assess temporal relationships. Inability to account for changes in the exposure levels is another deficiency in this design. A comparison of ventilatory function among controls may have improved the validity of the study which was made impossible due to logistical constraints. The spirometer was placed in the Medical Faculty and the research participants had to come there for the tests. Since the controls were scattered all over the community, it was not possible to arrange transport for them to come to the Medical Faculty for spirometry. The spirometer was placed in the Medical Faculty and the research participants had to come there for the tests. Since the controls were scattered all over the community, it was not possible to arrange transport for them to come to the Medical Faculty for spirometry. The situation with regard to granite workers was different as they were clustered in the few selected granite quarries.

The study was confined to the Kandy Municipality limits because of logistic constraints encountered in transporting workers from the work site to the Medical Faculty where the lung functions were carried out. The granite industry is a small scale indus-

try with an average of less than five workers at a given site. Even though transport was provided it is unlikely that all from a given work site would attend on the same day. Thus the total number of granite workers recruited was 51 as we had to limit the study to in and around the Kandy Municipality limits. A higher sample size would have enabled adequate power to detect significant differences had there been any.

This is the first study to report lung function among workers in quarries installed with crushers in Sri Lanka. Even though there is no evidence to suggest the presence of silicosis which is a progressive and a disabling disease, evidence of VI calls for the adoption of preventive measures. The ideal should be installation of exhaust ventilation to capture the dust generated at the crusher. Provision of industrial masks which prevent inhalation of respirable silica particles is the next option along with limiting exposure time. The need for follow up studies is also emphasised.

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# PREVALENCE AND PATTERN OF SUBSTANCE USE AMONG SECONDARY SCHOOL STUDENTS IN THE COLOMBO DISTRICT

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## ABSTRACT

### Aims

This study seeks to determine prevalence and pattern of substance use among school-going adolescents in the Colombo district.

### Methodology

Cross-sectional survey was conducted among 3454, 13-18 year-old adolescents from 29 schools selected proportionate to size using multi-stage cluster sampling. Validated Sinhala Adolescent Substance Use Student Questionnaire (ASUSQ) assessed: cigarettes, alcohol, marijuana, other drug use; age at first use; substance, source and place of first use; consequences and reasons for use and non-use. A standardised procedure was used to collect data. Analytical strategies eliminated returned questionnaires of questionable validity.

### Results

Sixteen percent (n=512) of adolescents had used at least one substance during their life. Prevalence of lifetime and current cigarette, alcohol, marijuana and other drug use were: 6.1% and 1.7%, 13.6% and 2.2%, 2% and 0.7%, and 1% and 0.1%, respectively. Significantly more males than female adolescents reported substance use. Substance use increased with age. Substance of first use was alcohol. Source and place of first use was friends and social gathering, respectively. Age at first use and the lowest age at first use varied with substance.

### Conclusions

Lifetime and current prevalence, and frequency of substance use indicated that a majority of users were experimenters. Use of a validated instrument and standardised procedure improved accuracy of prevalence estimates in this study.

### Key Words:

Adolescent substance use; prevalence of substance use; Sinhala Adolescent Substance Use Student Questionnaire (ASUSQ); school-going adolescents

## Introduction

There is much concern about use of psychoactive substances like alcohol, tobacco and other illicit drugs among youth in developing countries. Growing evidence indicates that the increasing burden of substance-related deaths and disease is rapidly shifting to developing nations, especially among their youth (1) (2) (3).

Adolescence is a developmental period marking transition from childhood to adulthood and begins with the onset of physiologically normal puberty (4). This period of development corresponds roughly to the period between the ages of 10 and 19 years, which is consistent with the World Health Organization's definition of adolescence (5). It is well established that use of tobacco and alcohol

usually begins during adolescence, and such use acts as a gateway to illicit drug use and/or dependence on tobacco and alcohol in adulthood (6) (7). In addition to more life-years use of substances, earlier onset of substance use contributes to an increased risk for a range of serious health consequences (7) (3). Thus, adolescents should be a primary focus for substance use preventive intervention strategies because they constitute the future society.

Effective prevention of health problems and other consequences of substance use require information on the prevalence, pattern and problems associated with use, and factors that influence use. With large populations, but considerably fewer resources, many developing countries are in urgent need of substance use prevention and intervention programmes base

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on reliable and valid epidemiological information (8).

### **Adolescent substance use in Sri Lanka**

Limited information is available on the epidemiology of substance use among adolescent populations in Sri Lanka. A study conducted in 1992 showed that among 12-20 year-old students in six districts, the prevalence for lifetime tobacco, alcohol and other drug use ranged from 12.2-19.3%; 18.3-38%; and 2.2-4.6%, respectively (9). The same study revealed that prevalence of current tobacco, alcohol and other drug use ranged from 3.4-6%; 3.9-17.2%; and 0.3-2.8%, respectively. In general, the study found that males reported lifetime and current use more than females. A substantial proportion of adolescents who reported lifetime use began using tobacco and alcohol before the age of 11 years. Social occasions such as parties and trips were the main instances when substance use occurred with friends being the main source of substances. A national survey on emerging issues among 10-18 year-old students revealed that lifetime and current prevalence of smoking was 18% and 6% for boys, with 6% and 1% for girls; drinking was 24% and 6% for boys, with 10% and 1% for girls; and approximately 2.3% of school-going adolescents admitted trying some form of mood altering drug (10). The study further revealed that, on average, most adolescents started using around the age of 14-15 years. The most cited reason for use was curiosity and the first smoke or drink was most frequently tried in the company of friends. Prevalence of smoking and drinking was lowest among those in the middle socio-economic quintile.

These findings indicate that substance use is prevalent among adolescents in Sri Lanka. Although providing information that may be of some assistance, current research is plagued with the lack of implementing standardized data collection instruments and procedures. Moreover, current study instruments fall short in their ability to detect validity of responses (11). Risk of over- and/or under-reporting is a major problem due to issues of social desirability and fear of reprisal (12). Planning and implementing research on substance use requires consideration of such methodological issues, which in turn can provide reliable and valid information about the prevalence of adolescent substance use (13).

The present study attempts to determine prevalence and pattern of lifetime and current substance use among 13-18 year-old adolescents attending schools in the Colombo district, which is the largest district in the Western province and commercial capital of

past 30-days preceding the study. Since the epidemiology of adolescent substance use is not developed in Sri Lanka, reliable and valid data would increasingly guide the allocation of prevention and intervention resources in the country.

### **METHOD**

#### ***Participants***

During September-November 2006, 3454 adolescents between ages 13-18 years studying in the Sinhala medium of 29 government schools in the Colombo districts participated in the present study.

#### **Sampling and recruitment of participants**

Sample size was calculated based on the formula for estimating a population proportion with specified relative precision (14). Prevalence for calculating the sample size was based on least prevalence rate reported in the study conducted by Alcohol and Drug Information Center (9). A list of Sinhala medium government schools and student populations in the Colombo district was obtained from the Statistical Division of Ministry of Education, Sri Lanka. A multistage cluster sampling technique where the clusters were allocated on probability proportionate to the size was used to identify 29 schools. A 1.5 correction for cluster design was used to increase the precision of the study (15). A 10% was added to account for non-response. A school was considered a cluster with each cluster comprising 120 adolescents equally divided by academic years 8-13. A class in a given academic year was considered the study unit. One class in the each of the academic years was selected randomly. Study participants were students randomly selected from the study unit. Inclusion criteria were male and female school-going adolescents from selected schools, between ages 13-18 years, and those who obtain parental consent. Exclusion criteria were those who did not have parental consent, who returned passive parental consent, and who refused to participate.

#### **Study instrument**

The Sinhala Adolescent Substance Use Student Questionnaire (ASUSQ) is a self-administered questionnaire consisting of an introduction; background and demographic characteristics; use of cigarettes, alcohol, marijuana and 'Relvin' (a fictitious substance); familiarity with and use of other drugs; age at first use; substance of first use; source and place of first use; consequences of use; reason (s) for use and non-use. The Sinhala ASUSQ has been validated in a sample of 13-18 year-old school-going adolescents in Sri Lanka (details of the validation study available on request). Lifetime and past

30-day use items have shown good test-retest reliability estimates of 0.98 and 0.92; 0.98 and 0.86; and 0.74 and 0.89 for cigarette, alcohol and marijuana, respectively. Test-retest reliability estimates (intra-class correlation coefficient) of age at first use item are 0.98, 0.98, and 0.92 for cigarette, alcohol, and marijuana, respectively. Substance of first use item has shown reliability estimate of 0.97. Sinhala ASUSQ has also shown good construct validity in that it is able to differentiate substance users and non-users. Questions in the Sinhala ASUSQ have the advantage of being logically structured to identify exaggerated and inconsistent patterns of responding and false reporting of the use of the fictitious substances.

### Data collection

Ethics clearance was obtained from the Ethical Review Committee of the Faculty of Medicine, University of Colombo. Approval was obtained from other relevant authorities and principals of selected schools. One class from each academic year 8-13 was randomly selected and prior parental consent was obtained. To avoid any bias and/or absenteeism, the actual date of the study was not informed to the participants. Voluntary and anonymous nature of the study was discussed with all participants. An explanation of the reasons for the study and assurance of confidentiality were also given. Teachers were not present during data collection. Students were asked to complete and return the questionnaire in a sealed envelope provided for this purpose. On completion, all participants were given prevention material (e.g. a brochure) on substance use, published by the Alcohol and Drug Information Centre, Colombo, Sri Lanka.

### Treatment of data and data analysis

Data was entered and analyzed using SPSS 15.0 for Windows package. The following analytical strategies were adopted to identify and eliminate respondents from the dataset who provided questionable responses: (i) false reporting via response to use of the fictitious substance, (ii) reporting unrealistically frequent use of illicit drugs (i.e., heroin, cocaine etc.) other than marijuana, which was defined as 40 or more uses in the past 30-days, and (iii) reporting logically inconsistent patterns of substance use (e.g., use in past 30-days but not in lifetime). Multivariate logistic regression models predicting substance use among adolescents were undertaken to estimate the adjusted odds ratios and 95% confidence intervals for relationships between substance use constructs and gender, age, sector, and socioeconomic status (based on father's occupation).

## RESULTS

### Sample characteristics

There were 203 (5.9%) non-respondents due to absenteeism, refusals, lack of parental consent or insufficient number of students in selected classes especially in small schools and/or higher academic years. Response rate was 94.1% (3251). Three (0.09%) participants were removed as they were age inappropriate. Fifty two (1.6%) were eliminated from analysis due to inconsistent (n=41, 1.2%) responding, false reporting of the fictitious substance (n=9, 0.3%) and reporting both inconsistent and false reporting (n=2, 0.06%). None of the returned questionnaire had exaggerated responses.

The final sample was 3196 (1550 boys and 1646 girls), with a mean age of 15.4 years (SD±1.69). Table 1 presents the sample by gender, age group, sector and socioeconomic status.

**Table 1 Description of study sample**

Demographic characteristics	N	%
Gender (n=3196)		
Female	1646	51.5
Male	1550	48.5
Age group (n=3196)		
13-14 years	1138	35.6
15-16 years	1091	34.1
17-18 years	967	30.3
Ethnicity (n=3193)*		
Sinhala	3024	94.6
Muslim	121	3.8
Tamil	28	0.9
Burgher	15	0.5
Other	5	0.2
Sector (n=3196)		
Rural	1001	31.3
Urban	2195	68.7
Father's occupation (n=3103)**		
Professionals/ senior managers	460	14.4
Associated professionals	751	23.5
Skilled workers	1156	36.2
Elementary occupations	520	16.3
Security forces	217	6.8

\*n=3 missing values

\*\*n=93 missing values include father unemployed and respondent does not know father's occupation.

## Prevalence of cigarette, alcohol, marijuana and other drug use

Prevalence of lifetime and current substance use for adolescent boys and girls is presented in Table 2. The most prevalent substance of lifetime and current use was alcohol, followed by cigarette, marijuana and other drugs. Significantly more boys than girls reported use. There was also a marked difference in lifetime and current use for all substances. Among girls there was hardly any experience of other drug use.

**Table 2-Comparison of lifetime and current cigarette, alcohol, marijuana and other drug use among adolescents by gender (N=3196)**

Substance use	Boys		Girls		Total		Significance
	n	%	n	%	n	%	
<b>Cigarette use</b>							
Lifetime	176	5.5	19	0.6	195	6.1	$\chi^2 = 144.9, df = 1, p < .001$
Current	49	1.5	6	0.2	55	1.7	$\chi^2 = 36.9, df = 1, p < .001$
<b>Alcohol use</b>							
Lifetime	319	10.0	115	3.6	434	13.6	$\chi^2 = 125.7, df = 1, p < .001$
Current	61	1.9	9	0.3	70	2.2	$\chi^2 = 42.7, df = 1, p < .001$
<b>Marijuana use</b>							
Lifetime	52	1.6	13	0.4	65	2.0	$\chi^2 = 26.3, df = 1, p < .001$
Current	18	0.6	3	0.1	21	0.7	$\chi^2 = 11.7, df = 1, p = .001$
<b>Other drug use</b>							
Lifetime	27	0.8	5	0.2	32	1.0	$\chi^2 = 16.6, df = 1, p < .001$
Current	4	0.1	-	0.0	4	0.1	$\chi^2 = 4.2, df = 1, p = .039$

As shown in Table 3, lifetime and current substance use significantly increased with age. Lifetime and current other drug use was highest among 15-16 and 13-14 year age category, respectively

**Table 3 Comparison of lifetime and current cigarette, alcohol, marijuana and other drug use among adolescents by age group (N=3196)**

Substance use	Age group (years)						Total		Significance*
	13-14		15-16		17-18		n	%	
	n	%	n	%	n	%			
<b>Cigarette</b>									
Lifetime	17	0.5	84	2.6	94	2.9	195	6.1	$\chi^2 = 63.6, df = 2, p < .0001$
Current	4	0.1	24	0.7	27	0.9	55	1.7	$\chi^2 = 18.9, df = 2, p = .00001$
<b>Alcohol</b>									
Lifetime	64	2.0	176	5.5	194	6.1	434	13.6	$\chi^2 = 95.4, df = 2, p < .0001$
Current	9	0.3	28	0.9	33	1.0	70	2.2	$\chi^2 = 17.1, df = 2, p = .00003$
<b>Marijuana</b>									
Lifetime	10	0.3	27	0.8	28	0.9	65	2.0	$\chi^2 = 11.0, df = 2, p = .00089$
Current	1	0.0	9	0.3	11	0.4	21	0.7	$\chi^2 = 9.0, df = 2, p = .00264$
<b>Other drug(s)</b>									
Lifetime	8	0.3	13	0.4	11	0.3	32	1.0	$\chi^2 = 1.0, df = 2, p = .30129$
Current	2	0.1	1	0.0	1	0.0	4	0.1	$\chi^2 = 0.2, df = 2, p = .62731$

\* $\chi^2$  for trends

Table 4 presents the frequency of lifetime and current substance use among adolescents in this sample. A majority were those who had tried at least one of the substances in their lifetime, never used daily, and had not used in the 30 days preceding the survey.

**Table 4 Frequency of lifetime and current cigarette, alcohol, marijuana and other drug use among adolescents**

Substance use	Number of occasions											
	1-2		3-5		6-9		10-19		20-39		≥ 40	
	n	%	n	%	n	%	n	%	n	%	n	%
Cigarette												
Lifetime (n=195)	85	43.6	33	17.0	26	13.3	11	5.6	16	8.2	24	12.3
Current (n=55)	32	58.2	13	23.6	10	18.2	-	-	-	-	-	-
Alcohol												
Lifetime (n=434)	182	41.9	117	27.0	51	11.8	40	9.2	20	4.6	24	5.5
Current (n=70)	51	72.9	19	27.1	-	-	-	-	-	-	-	-
Marijuana												
Lifetime (n=65)	39	60.0	15	23.1	5	7.7	6	9.2	-	-	-	-
Current (n=21)	16	76.2	5	23.8	-	-	-	-	-	-	-	-
Other drug(s)												
Lifetime (n=32)	20	62.5	9	28.1	3	9.4	-	-	-	-	-	-
Current (n=4)	3	75.0	1	25.0	-	-	-	-	-	-	-	-

\*All percentages are calculated according to number in each referent period.

As presented in Table 5, majority of substance users reported 16 years, 12 years or below, 15 years, and 14 years as age at first cigarette, alcohol, marijuana, and other drug use, respectively. The lowest age at first use for cigarette and alcohol was 12 years or below, while for marijuana and other drug use was 13 years.

**Table 5 Age at first use among cigarette, alcohol, marijuana and other drug users\***

Age at first use	Cigarette (n=195)		Alcohol (n=434)		Marijuana** (n=65)		Other drug(s)*** (n=32)	
	n	%	n	%	n	%	n	%
12 or below	42	21.5	144	33.2	-	0.0	-	0.0
13 years	14	7.2	43	9.9	7	12.7	5	20.8
14 years	35	17.9	61	14.1	5	9.1	7	29.2
15 years	40	20.5	79	18.2	21	38.2	4	16.7
16 years	49	25.1	68	15.7	10	18.2	5	20.8
17 years	13	6.7	30	6.9	11	20.0	3	12.5
18 years	2	1.0	9	2.1	1	1.8	-	0.0

\*All percentages calculated according to number in each substance use category.

\*\*n=10 missing

\*\*\*n=8 missing

## Pattern of substance use

Sixteen percent (n=512) of adolescents reported having used at least one of the substances at least once in their lifetime. A majority of substance users reported alcohol (n=325, 63.5%) as the substance of first use, followed by cigarette (n=158, 30.9%), other drug(s) (n=19, 3.7%) and marijuana (n=8, 1.9%). A majority reported source and place of substance of first use as friends (n=209, 55.4%), and at a wedding celebration (n=114, 30.1%), respectively. Reasons most frequently agreed upon for use of any substances were curiosity (n=140, 29.5%) and friends use (n=67, 14.1%). Consequences of substance use included feeling sick (n=53, 21.7%), trouble concentrating on the task at hand (n=51, 20.9%) and criticized by an adult (n=36, 14.8%). Reasons for non-use of any substance were just did not want to use (n=1459, 127.8%), would not be able to live up to one's expectations (n=985, 18.8%), family disapproval (n=896, 17.1%) and religious reasons (n=685, 3.1%). Reasons least frequently agreed upon for non-use of any substance were fear of addiction (n=118, 2.2%), fear of psychological effects (n=110, 2.1%), illegality (n=54, 1.0%) and cost of use (n=19, 0.4%).

## Logistic regression models

As shown in Table 6, the multivariate logistic analysis confirms the higher risk for males and older adolescents for lifetime and current substance use. Urban sector is a risk factor for lifetime alcohol use, but a protective factor for lifetime and current use of cigarette, current use of alcohol, and lifetime use of marijuana. Socioeconomic status was not associated with lifetime and current use any of the substances.

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**Table 6 Multivariate logistic regression of gender, age, sector, socio-economic status on lifetime and current substance use**

Predictors	Cigarette use		Alcohol use		Marijuana use		Other drug use**							
	Lifetime OR	Current 95% CI	Lifetime OR	Current 95% CI	Lifetime OR	Current 95% CI	Lifetime OR	Current 95% CI						
Gender														
Male	<b>13.06</b>	7.92-21.53	<b>12.63</b>	4.96-32.15	<b>3.63</b>	2.86-4.60	<b>9.04</b>	4.27-19.15	<b>4.94</b>	2.64-9.22	<b>7.54</b>	2.18-26.07	<b>5.81</b>	2.21-15.30
Age														
17-18 years	<b>7.98</b>	4.67-13.61	<b>9.16</b>	3.17-26.41	<b>4.56</b>	3.35-6.20	<b>4.72</b>	2.23-10.00	<b>3.36</b>	1.60-7.04	<b>14.24</b>	1.83-110.77	1.76	0.70-4.43
15-16 years	<b>5.53</b>	3.23-9.47		1.98-17.06	<b>3.30</b>	2.42-4.49	<b>3.08</b>	1.43-6.64	<b>2.97</b>	1.42-6.19	<b>9.22</b>	1.16-73.08	1.66	0.68-4.05
Sector														
Urban	<b>0.65</b>	0.46-0.91	<b>0.47</b>	0.26-0.84	<b>1.29</b>	1.00-1.66	<b>0.27</b>	0.43-1.26	<b>0.51</b>	0.30-0.86	0.54	0.22-1.35	0.82	0.19-3.49
SES*														
1	0.91	0.45-1.82	0.85	0.20-3.52	1.00	0.61-1.63	1.42	0.44-4.55	1.77	0.37-8.48	2.19	0.25-19.22	0.93	0.26-3.28
2	0.88	0.45-1.70	1.05	0.28-3.88	0.97	0.61-1.54	0.99	0.31-3.13	2.35	0.53-10.40	1.46	0.16-12.76	0.46	0.09-2.34
3	0.88	0.47-1.65	1.18	0.34-4.09	0.97	0.62-1.51	1.12	0.38-3.31	1.97	0.45-8.53	1.49	0.18-12.14		
4	1.25	0.64-2.45	1.82	0.50-6.63	1.33	0.82-2.14	1.71	0.55-5.31	3.46	0.78-15.34	0.82	0.07-9.30		

\*Socioeconomic status (SES) is based on father's occupation [1=professional/senior manager; 2=associated professional; 3=skilled worker; 4=elementary occupation; 5=security forces]

\*\*model for use of other drug(s) not presented as the multivariate logistic regression model did not converge

ORs that are significant on .05 p level are in bold

OR= odds ratio

CI= confidence interval

## DISCUSSION

This study has established the prevalence and pattern of substance use among adolescents attending school in the Colombo district. In applying a previously validated study instrument as well as implementing a standard data collection procedure, and identifying and eliminating questionable respondents, this study has produced valid and reliable data. The findings add to the existing evidence that adolescent self-report surveys have good reliability and validity (11) (16) (17) (18).

Results show that 16% of the sample had used at least one substance at some point in their lifetime. Lifetime and current prevalence of cigarette, alcohol, marijuana and other drug use was 6.1% and 1.7%, 13.6% and 2.2%, 2% and 0.7%, and 1% and 0.1%, respectively. Trends in prevalence, frequency and pattern of substance use indicate that a majority of users have used at least one substance in their lifetime, never used daily, and had not used in the 30 days preceding the survey. This suggests that a majority of self-reported substance users in this sample were experimenters (19). Similar to previous studies, males were more significantly likely to report use than females, and use increased with age (9) (10). This was further confirmed in the multivariate logistic analysis as well. Age at first use and lowest age at first use varied with substance. Interestingly, the lowest age at first licit substances of use (cigarette and alcohol) was 12 years or below, whilst for illicit substances of use (marijuana and other drug) was 13 years.

An accepted notion is that adolescents experiment with substances as part of exploration and growth (20). However, substance use as one aspect of this natural process is detrimental to the growth of the future generation. Even though a small proportion of adolescent substance users may meet the criteria for substance dependency, there is no way to detect who will progress to dependency and who will not (21). Hence, even though the results indicate that the users in this sample were experimenters and prevalence of use was lower than that of previous studies, it would be presumptuous to conclude that substance use among adolescents has declined. The considerable differences in study setting, population and methodology between previous studies and the present study restrict direct comparisons of findings.

The pattern of use indicated that a majority of adolescents reported alcohol as the first substance of use. Source and place of substance of first use reported by most adolescents was friends and at a

wedding celebration, respectively. The most prominent reason for use was curiosity and friend's use, whilst consequence of use was feeling ill. These findings are similar to previous studies, suggesting similar pattern of use irrespective of study setting and population. Unlike in previous studies, this study evaluated reasons for non-use of substances. Interestingly, the addictive nature, psychological and legal consequences of use did not take precedence for non-use, indicating the need to focus on interpersonal reasons for non-use in preventive interventions.

Contrary to previous findings, this study did not find an influence of socioeconomic status with lifetime and current substance use (10). Interestingly, urban sector had a negative influence on lifetime and current cigarette, current alcohol and lifetime marijuana use, with a positive influence on lifetime alcohol use. These findings dispel the notion that substance use is an urban problem and suggest the need in developing and implementing preventive interventions that consider unique characteristics of rural adolescents.

While the study findings are useful for preventive intervention purposes, it also has certain limitations which need to be born in mind when interpreting the results presented herein. A majority (95%) of adolescents in this study were of Sinhala ethnicity, with a minority representing those from other ethnic groups studying in Sinhala. In addition, the study sample represents adolescents from Sinhala medium schools located within the Colombo district. Hence, caution must be used when generalizing the present study findings. Further research with similar samples of adolescents from other districts is warranted to make direct comparisons. This study did not include adolescents who are not attending any school and those absent on day of data collection. In both groups, a higher proportion of adolescents using substances are likely to be found (13). However, dropouts and those adolescents not enrolled in any school are likely to be among those who may be missed even in community survey as well. Finally, the study examined the associations of only socio-demographic variables with substance use. Further research is recommended to identify psychosocial risk and protective factors associated with and predicting substance use, as they have promising implications for preventive intervention (22).

## CONCLUSION

This study has identified prevalence estimates of cigarette, alcohol, marijuana and other drug use among adolescents attending school in Colombo district of Sri Lanka. The existence of valid and reliable prevalence estimates add to the knowledge base and allow for the development of potentially effective prevention programs to combat adolescent substance use. Implementation of a standard instrument and procedure is a model to improve the reliability and validity of self-reported data of socially sanctioned behaviours, such as adolescent substance use.

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## Review Update

### **Strengthening the reporting of observational studies in epidemiology (STROBE) statement: New guidelines for reporting observational studies**

C Abeysena<sup>1</sup>

A vast majority of observational studies have been reported in journals compared to the experimental studies.<sup>1</sup> Many of those are cross sectional, case-control and cohort studies. These study designs are used not only to determine the risk factors for diseases but also to determine the prognostic factors as well. Observational studies also have a role in describing and determining harms of medical interventions. In some situations where the randomized trials are not appropriate or feasible for assessing interventions, observational studies are the alternatives. Therefore observational studies are useful not only for improving public health by changing policies but also for clinical practice.

However, the information provided in published observational studies have many deficiencies. The essential information is not reported at all or, though reported, sometimes appear to be unclear. For example, a review of longitudinal studies on stroke found that 17 out of 49 articles did not report eligibility criteria for recruiting participants.<sup>2</sup> Readers need to know what was planned (and what was not), what was done, what was found, and what the results mean. The assessment of the strengths and weaknesses of the studies reported in the medical literature is hampered by incomplete, inadequate and inaccurate reporting of research. Transparent reporting of research has many advantages. It allows the critical appraisal of the research articles and it will ultimately facilitate to assess the quality of the studies. It also facilitates adequate inclusion of data which are essential to be extracted for conducting systematic reviews.

The STROBE statement is a checklist of items that should be addressed in articles reporting the three main study designs of analytical epidemiology: cohort, case-control, and cross sectional studies.<sup>3</sup> The authors of the STROBE claim that the intention is solely to provide guidance on how to report observational research well.<sup>3</sup> These recommendations are used for neither prescriptions for designing/ conducting studies nor an instrument to evaluate the quality of observational research. The STROBE statement is being endorsed by a growing number of

biomedical journals to improve the quality of reporting ([www.strobe-statement.org](http://www.strobe-statement.org)). The authors strongly recommend using the STROBE checklist in conjunction with the explanatory article, which is available freely on the websites of the publishing journals.<sup>4</sup>

The STROBE initiative was established in 2004 including editorial staff from several international journals as well as epidemiologists, methodologists, statisticians, and practitioners. The STROBE statement is a checklist of 22 items that is considered essential for good reporting of observational studies (table). These items are related to the article's title and abstract (item 1), the introduction (items 2 and 3), methods (items 4-12), results (items 13-17), discussion sections (items 18-21), and other information (item 22 on funding). Eighteen items are common to all three designs, while four (items 6, 12, 14, and 15) are design specific, with different versions for all or part of the item. For some items (indicated by asterisks), information should be given separately for cases and controls in case-control studies, or exposed and unexposed groups in cohort and cross sectional studies. Although the table is a single checklist, the STROBE website provides separate checklists for each of the three study designs.

The STROBE statement should not be interpreted as an attempt to prescribe the reporting of observational research in a rigid format. The checklist items should be addressed in sufficient detail and with clarity somewhere in an article, but the order and format for presenting information depends on author preferences, journal style, and the traditions of the research field. The authors do not aim at standardising reporting.<sup>3</sup>

The authors stress the fact that STROBE and other recommendations on the reporting of research should be seen as evolving documents that require continual assessment, refinement, and, if necessary, change. They invite readers to submit their comments through the STROBE website.

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<b>Title and abstract</b>	1	(a) Indicate the study's design with a commonly used term in the title or the abstract
		(b) Provide in the abstract an informative and balanced summary of what was done and what was found
<b>Introduction</b>		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
<b>Methods</b>		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants
		(b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding
		(b) Describe any methods used to examine subgroups and interactions
		(c) Explain how missing data were addressed
		(d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy
		(e) Describe any sensitivity analyses

## Results

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

## Discussion

Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results

## Other information

Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based
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\*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

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## Short Communications

### **Reducing the delay in eligible couple registration through networking with marriage registrars**

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#### **Abstract**

##### **Introduction:**

The newly married couples are rarely encountered by the Medical Officer of Health (MOH) and there is a delay in registering them in the Eligible Couple Register (ECR). A new service model was developed with marriage registrars for newly married.

##### **Objective:**

To describe the delay in eligible couple registration before and after networking with marriage registrars (MR) and to describe the detected pre-pregnancy risk factors through this newly implemented model.

##### **Methods:**

A network was established with the MR to receive information of newly married in the Arachchikattuwa MOH area. Delay in eligible couple registration before and after the implementation of the new model was assessed using data from 06 January 2004 to 12 January 2006.

##### **Results:**

The mean delay in eligible couples registration before and after intervention were 518.9 days and 46.5 days respectively (p=0.001). Registered in the ECR on the same day or after pregnancy registration before and after intervention were 133 (71.1%) and 16 (50%) respectively (p<0.018).

The MOH had seen 52 newly married couples during the study period. The number of teenage pregnancies was 14 (26.9%). There were 17 (32.7%) females with a BMI, <18.5kg/m<sup>2</sup> and four (7.7%) were treated for malaria. Prevalence of each, consanguinity, short stature and high systolic blood pressure was 5.8% (n=3). Two (3.8%) had failed to obtain rubella vaccine. Rheumatic heart disease and anaemia were detected in one female (1.9%) each.

##### **Conclusion:**

Linking up with marriage registrars reduces the delay in eligible couple registration significantly. Through provision of services by MOH to newly married couples selected pre-pregnancy risk factors can be identified and addressed. It also provides an opportunity for provision of pre-pregnancy care.

##### **Key Words**

Newly married, pre-pregnancy risk factors, new service model, marriage registrars

#### **Introduction**

Sri Lanka lacks a formal institutional structure to counsel couples and newly married partners. On occasion Public Health Midwives (PHM) counsel during home visits. PHM seek and register newly married couples in the Eligible Couple Register (ECR) and provide necessary health advice (1,2), usually at the time of the registration of the first pregnancy. Newly married couples are rarely seen by the Medical Officer of Health (MOH). Thus an opportunity to identify modifiable risk factors of

pregnancy before conception is often missed.

We initiated a service model with registrars of marriage to facilitate pre-pregnancy services for the newly married by the MOH in the Arachchikattuwa MOH area.

The model recruits newly married couples for MOH clinics providing for counseling and assessment of pre-pregnancy risk conditions and also facilitates for early registration in the ECR.

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## Objective:

To describe the delay in eligible couple registration before and after networking with marriage registrars and to describe the detected pre-pregnancy risk factors through this newly implemented model.

## Setting

The study was carried out at Arachchikattuwa MOH area, which lies 12km North of Chilaw Town on the Colombo – Puttalam Road. The population is approximately 49,526 with 9,684 house holds. The MOH area of Arachchikattuwa has 13 PHM areas and 05 Public Health Inspector (PHI) areas. There are four marriage registrars (MR) serving the area. According to the records of Arachchikattuwa District Secretariat, on average 04 marriages per month are registered by each MR and none were seen by the PHM or MOH. For the study two marriage registrars were involved covering 7 PHM areas.

## Method

One of the authors (APDS) developed a simple referral form to be sent by the MR to the MOH office. The couples who visit the MR to obtain an appointment date for their registration were given the referral form and requested to meet their respective PHM prior to the date of marriage. No incentives were offered except to state that the form should be handed over to the MR on the date of registration. The couples took the referral form and met the PHM who counseled and advised them to come to the MOH clinic for screening for pre-pregnancy risk conditions. The PHM handed over the back-referral form to be given to the MR on the date of marriage registration, so that MR would know the couple had met the PHM. Those who sought emergency registration were also given the referral form at the time of the marriage and advised to meet the relevant PHM. Apart from the above referral methods PHM directed the newly married couples to the MOH at the time of the registration in the ECR.

The Office of MOH also receives a weekly return of newly married couples from the MR, which gave information for PHM to conduct home visits for early registration in the ECR. The PHM issued a booklet to the couple, titled “Blessing for Marriage” (“Yuga Diviyata Asiri”) published by the Population Division (available in Sinhalese and Tamil) of the Family Health Bureau to be read and returned.

The clinics for the newly married couples were conducted on the same day as the relevant polyclinic and they were given appointments usually after 11.30 am (after seeing the antenatal mothers and children). At the clinic the anthropometric measure-

ments, clinical examination and investigations (haemoglobin, urine sugar and urine albumin) were done. A record sheet was developed to record the data (socio-demographic data of the newly married couple and detected pre pregnancy risk conditions). The MOH also counseled the couples on pre-pregnancy screening, sexual health and contraception. If the necessity arose these newly married couples were referred to the General Hospital Chilaw (GHC).

The records of ECR from 06 January 2004 to 12 January 2006 and the records of all couples presented for MOH clinics in Arachchikattuwa MOH area from 23 May 2005 to 12 January 2006 were collected and analysed. Those who were residing outside the Arachchikattuwa MOH area before marriage were excluded from the study. The study was a quasi-experimental in design and the intervention commenced from the second week of May 2005. The delay in eligible couple registration was calculated as subtracting the date of marriage from the date of registration of the eligible couple in the ECR.

Delay of ECR registration = Date of ECR registration – Date of marriage

We also calculated the percentage registered in ECR on the same day or after pregnancy registration (among primigravidae) as an indicator to further compliment the delay in eligible couple registration.

Date of pregnancy registration – Date of ECR registration  $\leq 0$

Those who were reregistered in ECR on the same day or after pregnancy registration would have a value of 0 or less (minus value). Only primigravidae were included for this analysis as the inclusion of multigravidae would create a bias.

## Results

There were 235 couples registered in the ECR before the intervention period (approximately 16 months) from 06 January 2004 to 22 May 2005 while 52 were registered during the intervention period (approximately 7 months) from 23 May 2005 to 12 January 2006. During the intervention period 63 marriages registered by the MR were reported through the weekly return to the MOH Office. Although MR referred all of them, none of these couples had met their relevant PHM. From the weekly returns PHM recruited 24 newly married to the MOH clinic, while the rest has left the Arachchikattuwa MOH area as their place of residence. Table 01 describes analysis of ECR before and after the intervention. Among those registered in the ECR

before intervention, 219 were primigravidae while this was 32 in the after intervention group, at the time of data analysis.

**Table 01: Analysis of ECR before and after the intervention**

Analysis of eligible couples in the ECR	Intervention		Level of significance
	Before	After	
Couples registered in ECR	235	52	–
Mean delay of ECR registration (days)	518.9 (95% CI 390.52-647.28)	46.5 (95% CI 31.8-61.2)	p=0.001
*Reregistered in ECR on the same day or after pregnancy registration	133 (71.1%)	16 (50%)	P=0.018

\*Only Primigravidae were included (before n=219, after n=32)  
95% CI = 95% Confidence Interval

Of those registered during the intervention period 24 (46.2%) were detected from the weekly notifications of marriage registrars while other 28 (53.8%) were not notified by MR since their marriages were registered by MR who were not involved in the study as they were residing outside Arachchikattuwa MOH area. This group of 28 was detected by PHM. Table 02 describes analysis of ECR after the intervention among MR notified group and PHM detected group. There were 16 primigravidae each in the MR notified group as well as PHM detected group, at the time of data analysis.

**Table 02: Analysis of ECR after the intervention among MR directed group and PHM detected group**

Analysis of eligible couples in the ECR	After the Intervention		Level of significance
	MR notified group	PHM detected group	
Couples registered in ECR	24	28	–
Mean delay of ECR registration (days)	20.1 (95% CI 4.81-35.39)	69.1 (95% CI 48.32-89.88)	p=0.001
*Reregistered in ECR on the same day or after pregnancy registration	03 (18.8%)	13 (81.2%)	p<0.001

\*Only Primigravidae were included (before n=16, after n=16)  
95% CI = 95% Confidence Interval

All 52 (100%) newly married couples presented to 05 MOH clinics from the 07 PHM areas involving the referrals from two MR from 23<sup>rd</sup> May 2005 to 12<sup>th</sup> January 2006 after their marriage. Mean age of male partner was 26.17 years (SD±3.618 years) and female partner was 22.23 years (SD±4.4 years). Table 03 describes the individual and family history of risk conditions identified in the female partners. Four of the couples were referred to GH Chilaw.

**Table 03: The risk conditions identified in the female partners**

<b>Risk conditions</b>	<b>Number</b>	<b>Percentage</b>
<b>Individual</b>		
Low body mass index (<18.5kgm <sup>2</sup> )	17	32.7%
Teenage	14	26.9%
Past malaria infection	04	07.7%
Consanguineous marriages	03	05.6%
Short stature	03	05.6%
High systolic blood pressure (>140/90mmHg)	03	05.6%
Not vaccinated for rubella	02	03.8%
Rheumatic heart disease	01	01.9%
Anaemia (haemoglobin<10mg/dl)	01	01.9%
<b>Family history</b>		
Hypertension	13	25.0%
Diabetes mellitus	08	15.4%
Twins	05	09.6%
Abortions	03	05.6%
Congenitally abnormal children	03	05.6%

## Discussion

We described a service model initiated in Arachchikattuwa MOH area that reduces the delay in eligible couple registration and detection of pre pregnancy risk conditions. Prior to the intervention a substantial proportion of eligible couples were registered in the ECR only when the female partner presented for antenatal care. Even though following the intervention the majority (53.8%) of newly married couples was detected by PHM yet the overall reduction of the delay in registering the eligible couples was significant. Following the intervention the mean delay in registering the eligible couples among the PHM detected group is thrice higher compared to the mean delay among MR notified group yet it is significantly lesser ( $p<0.01$ ) than the mean delay observed before the intervention. Possible reasons for this could be the motivation created due to the intervention among the PHM and the intervention creating community awareness through MR. Another possibility is that most in the PHM detected group got conceived and therefore they were registered in the ECR when they presented for pregnancy registration. This seems to be more likely since 81.2% were registered in the ECR after pregnancy registration when compared with 18.8% of the MR notified group.

Before the commencement of the intervention the teenage pregnancy rate was 12% in the Arachchikattuwa MOH area and after six months it came down to 8% ( $p<0.05$ ).

The model helped to provide the following additional services:

- Relevant information was given to those who wanted to delay the first pregnancy
- The teenagers were counseled to delay their first pregnancy.
- Folic acid distributed to all those expecting a pregnancy.
- Health education (on one to one basis) by the MOH on following areas:
  1. Importance of folic acid
  2. Period of conception
  3. Delaying teenage pregnancies
  4. Natural family planning methods
  5. Early registration of pregnancy

The main limitation of this model is that the women who marry men from other MOH areas moves out of Archchikattuwa MOH area and thus unable to provide the above services.

It is feasible to replicate this model in areas (and countries) with a reasonably well developed marriage registration service and family health worker network.

Presently pre-pregnancy counseling and detection of pre-pregnancy risk conditions are done in Kalutara (3) and Beruwala (4) MOH areas administered by the National Institute of Health Sciences.

### **Conclusion:**

Linking up with marriage registrars reduces the delay in eligible couple registration significantly.

Through provision of services by MOH to newly married couples selected pre-pregnancy risk conditions can be identified and addressed.

### **Acknowledgements**

Dr. Sarath Amunugama, Director, Health Education Bureau  
Staff of Arachchikattuwa MOH Office  
Marriage registrars of Arachchikattuwa  
Consultants of GH Chilaw

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**Conflict of interests:** None

## **The Nutritional Status of Grade Eleven Students In The Medical Officer of Health Area Kalutara.**

S De Silva<sup>1</sup>

### **Abstract**

#### **Objectives:**

To describe the nutritional status of grade eleven school children in the Medical Officer of Health (MOH) area Kalutara.

#### **Methodology:**

A descriptive cross-sectional study was carried out among grade eleven school children in Type 1AB and Type 1C state schools in the MOH area Kalutara. Eighteen classes from a total of 14 schools were studied. Cluster sampling technique, probability proportionate to size was used to select the sample. The heights and weights were measured, and the Body Mass Index (BMI) was calculated for each child. The age and sex specific BMI charts developed by the National Centre for Health Statistics 2000 were used as standards. A structured, pre-tested self-administered questionnaire was used to collect the socio-demographic characteristics.

#### **Results :**

The prevalence of thinness (<5<sup>th</sup> percentile) was 35.4% and the prevalence of being at risk of overweight (≥85<sup>th</sup> percentile) was 6.7%.

#### **Conclusions:**

Under-nutrition is a problem among grade eleven school children in the MOH area Kalutara. Almost 7% of them were at risk of overweight.

#### **Key Words:**

Nutritional Status, School Children

### **Introduction**

The nutritional status of a population determines the overall health status which affects the growth and development of a society (1). The recent decade has experienced marked changes in demography, epidemiology, and nutrition, which is more prominent in the developed countries, yet with no exception in the developing countries. Nearly 46% of the global burden of disease and 56.5 million total deaths reported in the year 2001 have been attributed to chronic diseases (2). Sri Lanka too has experienced rapid urbanization with 21.5% of the population being urban (3), and with changes in the food consumption pattern.

Adolescents, the age group between 10 -19 years (4), represents the future work force of the nation. This is a critical period where more than 20% of the total growth in stature, and up to 50% of adult bone mass is achieved (5). Adolescents in Sri Lanka constitute 3.7 million (19.7%) according to the Department of Census and Statistics (6). In Sri Lanka both under-nutrition and over-nutrition prevail among the adolescents. The prevalence of thinness ranges from 12.3% - 47.2% and the prevalence of overweight ranging from 2.2% - 15.2% (7, 8) depending on the setting of the study.

### **Methodology**

This study was a cross-sectional descriptive study conducted in MOH area Kalutara, in the administrative area of the National Institute of Health Sciences (NIHS). This is situated 40 kilometers south of the city of Colombo. The estimated population was 120,776 for the year 2006 and the area spans 76 square kilometers. This area is a part of Kalutara district where the urban rural population ratio is 1: 8.41(9).

The study population consisted of all children enrolled in grade eleven classes in the government schools in the type 1AB and 1C schools in the MOH area Kalutara. There were 14 schools of the above type with 35 classes out of which 18 were chosen for the study by cluster sampling done according to probability proportionate to size during a period of a 3 weeks starting from mid September 2006.

A data sheet was used to record the anthropometric measurements, date of birth and the sex of the child. The latter two data were extracted from the class register. A structured self-administered questionnaire (SAQ) was used to collect information on socio-demographic and economical variables. The SAQ was translated to Sinhala and was pre-tested in

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a school in the adjoining MOH area. Retired Public Health Nursing Sisters (PHNSs) and area Public Health Inspectors (PHIs) and two medical officers assisted the principal investigator (PI) in data collection. The PHNSs were trained in taking anthropometric measurements, and the area PHII assisted them. Standard procedures in making the measurements were demonstrated by the PI and the data collectors were trained each for two hours on two days.

Body weight was measured with an accuracy of  $\pm 100\text{g}$  using the electronic weighing scales, and the standing body height was measured to the nearest 0.1cm using a height measuring board. Both instruments were calibrated. The instruments were obtained from the Nutrition Department of the Medical Research Institute. Duplicate measurements were taken by the PI in 10% of the sample to ensure reliability of data.

Ethical clearance for the study was obtained from the Ethical Review Committee of the Faculty of Medical Sciences, University of Sri Jayewardenepura.

Analysis was done using the SPSS version 13.00. The nutritional status was assessed using the age and sex specific body mass index (BMI) calculated using the height and the weights of the children.  

$$\text{BMI} = \text{Weight (Kg)} / \text{Height}^2 (\text{m}^2)$$

The National Centre for Health 2000 (10) reference values and World health organization cutoff (4) were used for categorization. Those below the 5<sup>th</sup> percentile were categorized as Thin while those at risk of overweight were those at the 85<sup>th</sup> percentile and above.

## Results

The study included 639 school children where the great majority were Sinhalese (99.5%, n= 636), Buddhists (95%, n=607). There were no Tamils or Hindus. Females accounted for 55.7% (n=356) of the sample. Most (84.8%, n=542) of the students were residing in rural areas. The mean age of the study sample was 16.1(SD $\pm$ 0.4) years. The age range was 15.5 to 18.5 years.

More than half (58.4%; n=373) the children belonged to social class 4 and 5, and those in social class 1 & 2 constituted 20.8% [n=133]. The social class was measured by the occupation of the father (11). Seventy nine percent (n=502) of the children were able to record their monthly family income and 265 families had a monthly income of less than 10,000 rupees. Ninety eight percent [n=627] of the

students were residing in their own homes where as 12 (1.9%) were residing outside home (Table 01).

**Table 1: Description of the study sample**

Variable (n=639)	No	%
<b>Sex</b>		
Female	356	55.7
Male	283	44.3
<b>Residence by sector</b>		
Rural	542	84.8
Urban	97	15.2
<b>Ethnicity</b>		
Sinhalese	636	99.5
Non Sinhalese	3	0.5
<b>Religion</b>		
Buddhism	607	95.0
Non Buddhist	32	5.0
<b>Social class</b>		
Class 1 & 2	133	20.8
Class 3	133	20.8
Class 4 & 5	373	58.4
<b>Total monthly family income</b>		
< 10,000	265	41.5
$\geq$ 10,000	237	37.1
Do not know	137	21.4

The prevalence of thinness was 35.4% (n=226) and prevalence of being at risk of overweight was 6.7% (n=43). Out of the males 43.8% (n=124) were in the thinness category compared to the girls (28.7%, n=102). Among those at risk of overweight, females (8.7%, n=31) had a higher prevalence than the males (4.3%, n=12). This finding was statistically significant (p=0.0001).

More of the rural children were in the thinness category (36.3%, n=197) and more urban students were at risk of overweight (10.3%, n=10), yet not statistically significant. Although there was no statistically significant difference between the nutritional status and parental factors, a higher proportion of thinness was observed when the mothers did not reside with the children and where mothers' education was less than G.C.E. O/L [Table 2].

**Table 2: Distribution of the nutritional status of the children according to socio demographic and parental factors**

Variable	Nutritional Status						Total	Test of significance
	Thinness		Normal		At risk of overweight			
	No	%	No	%	No	%	No	
<b>Sex</b>								$\chi^2 = 19.9$
Female	102	28.7	223	62.6	31	8.7	356	df=2
Male	124	43.8	147	51.9	12	4.3	283	P=0.0001
<b>Residence by sector</b>								
Rural	197	36.3	312	57.6	33	6.1	542	$\chi^2 = 3.2$
Urban	29	29.9	58	59.8	10	10.3	97	df=2 p=0.2
<b>Social class</b>								
Class 1 & 2	48	36.1	73	54.9	12	9.0	133	$\chi^2 = 3.97$
Class 3	45	33.8	76	57.1	12	9.0	133	df=4
Class 4 & 5	133	35.8	221	59.1	19	5.1	373	p=0.41
<b>Monthly family income</b>								
< Rs 10,000	107	<b>40.4</b>	149	56.2	9	3.4	265	$\chi^2 = 11.53$
>= Rs 10,000	77	32.5	137	57.8	23	9.7	237	df=2
Do not know *	42	30.7	84	61.3	11	8.0	137	p= <b>0.021</b>
<b>Employment status of father</b>								
Employed	201	36.2	316	56.8	39	7.0	556	$\chi^2 = 4.12$
Not employed	8	32.0	17	68.0	0	0	25	df=4
Retired	10	29.4	23	67.6	1	2.9	34	p= 0.39
Do not know *	3	29.2	14	58.3	3	12.5	24	
<b>Education level of the mother</b>								
< G.C.E. O/L	129	<b>37.6</b>	195	56.8	19	5.6	343	$\chi^2 = 3.54$
> G.C.E O/L	79	32.9	139	57.9	22	9.2	240	df=2
Do not know *	18	32.1	36	64.3	2	3.6	56	p=0.17
<b>Presence of parents at residence</b>								
Both present	200	35.4	327	57.9	38	6.7	565	$\chi^2 = 3.68$
Father only present	7	41.2	10	58.8	0	0	17	df=6
Mother only present	11	28.2	25	64.1	3	7.7	39	p=0.719
Both not present	8	44.4	8	44.4	2	11.2	18	
<b>Total</b>	<b>226</b>	<b>35.4</b>	<b>370</b>	<b>57.9</b>	<b>43</b>	<b>6.7</b>	<b>639</b>	

## Discussion

Nutrition of adolescents is the cornerstone of a healthy nation. In the nutrition policy special emphasis has been given to promote the nutritional status of the youth by appropriate behavioural change communication that promotes healthy food habits and adequate physical activity (14).

As compared to a study carried out among adolescents in urban schools in the Colombo district (7) where the prevalence of thinness was in the range of 15.6% to 29% depending on the age category, the present study shows a higher prevalence of thinness (35.4%). Both studies show that the prevalence of thinness was higher among the boys indicating the need for a targeted approach for the different sexes. The inclusion of private schools and the level of urbanization may have contributed to the low level of thinness in the Colombo district.

The present study revealed that 6.7% of children were at risk of overweight with a male to female ratio of 1:3.7. In the national study (8) those at risk of overweight was 2.2% with the above ratio being 1:1.6. It is no secret that with the change of life styles and the level of urbanization overweight is becoming a problem in many parts of the world including the developing nations (13). This leads to the double burden of both under nutrition and obesity. Global prevalence of overweight and obesity in school aged youth from 34 countries in the year 2001-2002 have shown that the two countries with the highest prevalence of overweight was Malta (25.4%) and the United States of America (25.1%) (14). Even in India a considerable increase in the prevalence of overweight is seen over the past 20 years (13).

The higher prevalence of thinness in the rural children and higher prevalence of at risk of overweight in the urban children was seen in the present study which is comparable with the national study (8). Thinness was observed more in the student in poor income families. This association was statistically significant and similar associations are seen in other studies done in Sri Lanka (7). The association of poor nutritional status with thinness indicates that the household food purchasing power maybe a contributing factor for the nutritional status of the adolescents.

Parents are the main source of influence for growth and development of the children especially during infancy and childhood. They have significant effects on the adolescent nutritional status as well, as they

are the providers of food and other resources, although there is some element of independence in the dietary habits in adolescents (15). In the Sri Lankan setting parents may play a bigger role with reference to the diet of the children than in the western world. A statistically significant association was observed in our study between the nutritional status and the education level of the mother indicating the possible parental influence on adolescent nutrition.

## Conclusions

Under-nutrition (35.4%) is a problem among grade eleven school children in the Kalutara Medical Officer of Health area. Almost 7% of them were at risk of overweight. The nutritional status showed statistically significant associations with the sex of the child and the monthly family income.

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## Introduction

We as doctors have a moral obligation to the patients as well as to the society to equip ourselves with the latest advancements of medicine, which are for the benefit of the patients and this is pursued through continuing medical education (CME). In the modern version of the Hippocratic oath it is expressed as “I will continue with diligence to keep abreast of advances in medicine”<sup>1</sup>. The corporate sector has intervened and extends a hand to facilitate achievement of this goal by creating a conducive environment. This has led to a situation where we as a profession are caught in the dilemma between the need to promote continuing professional development utilizing this generosity and on avoiding conflict of interest.

The interaction established between the pharmaceutical industry and the doctors is two fold. One is at the individual and the other at the organizational level through the professional bodies.

Free drug samples, meals, free travel and lodging for educational events, financial incentives to participate in clinical trials, honoraria for delivering lectures, lavish leisure trips, expensive text books and items of low monetary value such as pens and notepads are some of the benefits received at individual level. Sponsorship of annual scientific meetings and special projects and funding of research are the organizational activities supported by them<sup>2</sup>.

The word “Sponsorship” has many definitions and are based on the objective of the organization that deals with it. A more widely applicable definition describes it as a “business relationship between a provider of funds, resources or services and an individual, event or organization which offers in return, rights and association that may be used for commercial advantage in return for the sponsorship investment”<sup>3</sup>. Therefore, it is evident that the corporate sector involvement with the medical profession is with the aim of influencing the prescription behaviour<sup>3</sup>.

It is not only the cash incentives and offer of other services and gifts that could influence the prescription behaviour. Friendship and flattery combined with food are considered as powerful tools, instru-

mental in changing individual behaviour<sup>2,4,5</sup>. The industry have excelled in establishing good public relations and the mere personal contact with industry officials itself could be seductive<sup>6</sup>.

## Individual influence

Doctors in favour of maintaining links with drug companies are said to be of strong belief that they are immune and invulnerable to promotional influences<sup>2,6,7</sup>. They attribute such resistance to the type of training they receive where patients’ interest take priority above other concerns. In addition they are said to feel that patients benefit from such relationships through a two pronged process. One is through advancement of knowledge of the prescribing doctor which has a direct bearing on patient care and the other through offer of free drug samples<sup>2</sup>. The latter has advantages such as ability to help indigent patients, availability of drugs to commence therapy immediately and the opportunity to test for drug reactions before full prescriptions<sup>8</sup> are issued.

However, there are counter arguments put forward, and as quoted, “any type of gift or gesture can create a feeling of indebtedness on the recipient, which in turn creates a sense of obligation to reciprocate consciously or unconsciously”<sup>2</sup>.

According to social science literature the doctors who deny being influenced by company largesse and claim to be resistant to change in behaviour are considered as fundamentally different to their fellow human beings<sup>2</sup>. Also described is the phenomenon of “self serving bias” where individuals fail to identify themselves as prejudiced when such offers and services are to their benefit<sup>2</sup>.

Strong evidence is surfacing that industry sponsored research is biased in favour of sponsors than studies that were not sponsored<sup>4,9,10,11</sup>. In a review of 29 papers, Wazana<sup>12</sup> reports that attending sponsored CME events and accepting funds to participate in such conferences were associated with higher prescription rates for medications of the sponsoring company. Thus the links between doctors and the industry are considered as partly responsible for the soaring costs of drugs<sup>4</sup>. According to Kalantri<sup>13</sup>, attending a sponsored banquet could mean adding significantly to the drug prices.

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We need to be aware that it is the patient who is at the mercy of the doctor, who pays for it, which is not by choice ironically, but due to lack of a choice when it comes to his/her health. Falling ill and the need to seek medical help cannot be compared to purchasing an item that one fancies, where he/she has the option of reconsidering, if it is not within the means of the pocket. Sadly, this choice is not available in regard to illness.

### **Research.**

According to Ray Moynihan<sup>4</sup> a visiting editor of the British Medical Journal, a quarter of university researchers in the USA receive industry funding and a third have established personal ties with them. As quoted<sup>4</sup> Arnold Ralman, a Harvard professor and a former editor of the New England Journal of Medicine feels disgraced that the pharmaceutical industry has bought over the medical profession in terms of practice, research and teaching and that the academic institutions act as paid agents of the industry.

Further, ambitious academics embracing drug company hospitality are said to have the advantages such as organization of lecture tours and having much wanted publications which are essential to build up successful medical careers<sup>4</sup>.

### **CME**

Controversies also surround the corporate involvement in conducting medical meetings. It has the advantage of the ability to invite speakers from outside the local area and from abroad (which elevates the conference standards to international levels), as the travelling costs of such speakers are borne by the sponsors. This may not be feasible without such funds.

Despite the above, the main concern as Ray Moynihan<sup>4</sup> describes in his write up in the British Medical Journal, is the influence exerted by drug companies in the selection of speakers and the topics of these meetings, so that the content of these are more in favour of the company products or in the least does not contradict the company's message<sup>14,15</sup>. However, the drug companies and the educational providers who obtain sponsorship deny this allegation<sup>14</sup>.

In addition, the dependence exerted on the individual doctor on company sponsorship can also be immense. A deputy editor of the Journal of American Medical Association (JAMA) Drummond Rennie, who is also a researcher attached to University of California in San Francisco has expressed his concerns that there will come a day when "doctors

won't walk fifty yards at a big medical meeting without being transported in a drug company bus"<sup>4</sup>. This reflects the extent of the entanglement between doctors and sponsorship by industry and the future plight, in the absence of regulations imposed.

### **Measures of regulation**

While appreciating the role of drug companies in the advancement of medicine<sup>16-18</sup> several measures have been suggested to regulate the liaison between doctors and the corporate sector to overcome the untoward consequences that have arisen.

One option recommended is the "pooled approach" where the funds received are combined and the sponsoring company has no involvement in deciding the event funded by their contributions<sup>19</sup>.

Other measures include disclosure of conflict of interest and establishment of a code of practice (COP). The most drastic is to sever all ties and the CME to be totally independent of industry sponsorship<sup>2,17</sup>. According to Blumenthal<sup>2</sup> the only professional group to support this view is the American Medical Student Association which has already requested the physicians to do so.

As a measure of transparency some industry representatives themselves have suggested to disclose their involvement when they have any. The opinion of a member of the pressure group "No free lunch" as quoted is that such explicit disclosures will not be a reality and that the sponsored events are merely "marketing masquerading as education"<sup>14</sup>.

Several professional organizations including the American Medical Association and various interest groups in the USA had made an attempt to address the above concerns by revising the existing COP. However, it has been observed that apart from direct receipt of cash payments which is illegal and amounts to bribery, other forms of interactions are more or less endorsed by these professional bodies<sup>2,4</sup>. This stand reflects the belief that some of these relationships are "ethical, often beneficial and certainly unavoidable"<sup>2</sup>. However, Mildred Cho a biomedical ethicist at the Stanford university disagrees with the above assumption<sup>4</sup>.

The Editorial in the BMJ by Abbasi and Smith<sup>17</sup> had been critical of formulating COP which they refer to as "mere window dressing" and insists on distancing from the industry. In India, there is a call for doctors to pay their own conference fees citing examples of such conferences held in clinical fields, which will help maintain academic independence and uphold the integrity of the profession<sup>10</sup>.

According to the Canadian Paediatric Society (CPS) which is the national association of paediatricians, all sponsored activities are ones that are consistent with the Code of Ethics of the CPS<sup>20</sup>.

In the UK the relationship between pharmaceutical industry and the doctors are governed by a COP where the level of hospitality provided at meetings is suggested to be “appropriate and not out of proportion to the occasion and costs must not exceed that level which the recipients would normally adopt when paying for themselves”<sup>21</sup>.

Capozzi and colleageus<sup>22</sup> who hold a moderate view with regard to the corporate involvement, suggests that the product of interest should initially be independently evaluated through review of literature and other means. Assistance of the industry should be sought only when further exploration is warranted, and that information is available only through industry. This seems a rational proposition.

### **Local situation**

With respect to the local industry, the situation is not different to the above and the pharmaceutical industry has openly criticized the policy on “rational drug use” put forward by the famous pharmacologist Professor, Senake Bible<sup>23,24</sup>, stating that it is archaic and does not agree with the open economy policy currently in operation.

We must applaud companies who provide funds with no anticipation of any form of reciprocation, not in the least the display of their company name. Without the benefits of reciprocation it does not qualify to be referred to as sponsorship according to its’ definition. However, isn’t it self deception that we as beneficiaries enjoy their hospitality but take a concerted effort to make it invisible to the outside world?

We preach on the concept of “self reliance” but behave to the contrary by continuing with this unholy nexus between the doctors and the corporate sector expecting CME to be provided free of charge? As quoted “The doctors being some of the most well off in the society being unable to pay for their lunches, education and conferences should be ashamed of themselves when the poorer people have to pay every step of the way”<sup>16</sup>.

Corporate sponsorship and its influence on individual prescribing patterns has no direct relevant to us as public health personnel because we are not involved with prescribing, apart from those few of us

who are engaged in private practice after working hours, which is their legitimate right as those in the curative sector. However, we do involve ourselves in CME. Therefore, we have a moral obligation towards the society to suggest corrective measures.

### **Suggested measures**

One of the main issues that concerns everyone is the high cost of drugs. Efforts made to control drug prices have failed and would not be a reality in the foreseeable future.

However, if the medical profession is either directly or indirectly responsible through its entanglement with pharmaceutical companies, then it is essential that we distance ourselves from such association, in order to orchestrate a reduction in the drug prices. This is certain to bring down the health care costs drastically. However, from the wealth of literature available and the debate that goes on, it is evident that this too is not easy<sup>25</sup>.

As a compromise, we should attempt to divert the sponsorship money for the benefit of the society at large. The next option then should be to adopt the concept of public private partnership, referred to as PPP or P3 which describes a government service or private business venture which is funded and operated through a partnership of government<sup>26</sup>. It is also defined as a method of procuring public services and infrastructure by combining the best of the public and private sectors with an emphasis on value for money and delivering quality public services<sup>27,28</sup>. It is important to discern the differences between sponsorship and PPP which are totally unrelated concepts. Sponsorship entails reciprocation but PPP is formation of partnerships to achieve a common goal.

Concerning industry, PPP amounts to “corporate social responsibility” which is imperative for their long term survival. It will be a great relief to the government which is committed to provide a free health care service to the masses and thus struggling to provide minimum facilities required, leave aside quality care. It is still the patient who pays for this money, but the knowledge that this money is spent for the benefit of other patients and the country at large and not to provide for the comfort of a handful of doctors could be more consoling, justifying and morally satisfying.

A classical example of PPP is the contribution made by the drug company “Novartis” in the elimination of Leprosy in Sri Lanka and other developing countries. Another is the Global Alliance for

Vaccines and Immunization (GAVI) initiated by the Bill and Melinda Gates Foundation. Government of Sri Lanka receives its hepatitis B vaccines, the auto disabled syringes, cold chain monitors and many more through this partnership.

There are hospitals in Sri Lanka which experience perennial shortages of essential drugs, stationery and other basic requirements. Routine investigations are very often done at the private sector owing to shortages in the laboratory equipment, reagents etc. Due to non affordability of health insurance schemes, these costs are often borne by the individual patients. Provision of basic sanitary facilities in the hospitals is a fundamental human requirement and is elementary to prevention of communicable diseases. How many government hospitals in Sri Lanka can afford to provide a decent sanitary service?

Thus it is proposed that corporate funding on doctors be diverted to establish a sustainable PPP with the Ministry of Health which will enable to solve many of the problems faced in maintaining basic health care facilities.

The guidelines adopted by the UK<sup>22</sup> mentioned above, may be used in setting standards for us to determine where the line should be drawn when soliciting any form of sponsorship, may it be from pharmaceutical or food industry or the international agencies such as the World Health Organization, UNICEF, UNFPA etc. Accepting funds from the UN agencies may also be perceived as unethical. However, the benefits of such funding are not self directed as in corporate funding but meant for the society at large.

In conclusion I am of the view that as a professional body we should steer clear of the controversies surrounding sponsorship related to drugs, food and other industrial products, which has a direct bearing on health, because we as experts are relied upon by the community, to express an honest and evidence based view with regard to the associated health implications of those products. We should make a conscious effort to avoid the extremes of too little and too much and resort to the 'middle path' in conducting our professional activities. Our College has been esteemed as a professional body which did not depend on sponsorship by industry but stood on our feet (with the limited funds provided through UN agencies) and yet conducted our academic events in a decent, glamorous and fruitful manner. Let us join hands to trek on the same path our predecessors chose, leaving no space for us to be the centre of discussions and controversy related to ethicality of accepting corporate sponsorship.

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