ECONOMIC ANALYSIS AND OUTCOME ASSESSMENT OF CLINICAL BREAST EXAMINATION AND MAMMOGRAPHY SCREENING FOR BREAST CANCER DETECTION AMONG WOMEN IN KLANG, SELANGOR

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Field of Study: Public Health (Family Health)

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ABSTRACT

Introduction: Breast cancer is the most common cause of cancer death among women in Malaysia. Screening for breast cancer are by opportunistic clinical breast examination (CBE) followed by mammogram if breast abnormality is detected, and by mammography screening among women with risk factors. An increasing number of developed countries recommend mammogram screening in the general population. This study aimed to compare economic aspects and outcome of CBE followed by mammogram when breast abnormality is detected, and mammogram only among women with risk factors in Selangor, Malaysia.

Methodology: This was an economic analysis and outcome assessment on breast cancer screening comparing CBE followed by mammogram when abnormality is detected, and mammogram only among women with risk factors. The costs were calculated from the provider's perspective which was the Ministry of Health Malaysia. Cost items were identified and measured using micro costing applying the activity based costing approach. The output for cost analysis was cost per breast cancer screening. The outcome measured was the number and rate of breast cancer detected. Cost per breast cancer detected was also calculated for each breast cancer screening approach. To calculate outcome of CBE followed by mammogram when abnormality is detected, records of 15,279 women who came to the health clinics for Pap smear screening and CBE were reviewed. Outcome of mammography only among women with risk factors were obtained by reviewing 1,427 records of women attending the mammography screening in a general hospital. The breast cancer status was ascertained from the Selangor Breast Cancer Registry.

Results: The cost of CBE and mammography were RM 6.68 (USD 2.11; 1USD=RM3.17) and RM 197.30 (USD 62.26) per screening, respectively. Largest proportion of cost of CBE was contributed by cost of staff (61.1%), followed by cost of utilities and communication (20.1%). For cost of mammography, majority was contributed by cost of equipment and furniture (57.0%), followed by cost of staff (29.0%). The rate of breast abnormality detected by CBE was 0.55% (84 women) of which 0.07% (10 women) had breast cancer. For mammography among women with risk factors, abnormality rate was 4.7% (67 women) of which 2.0% (29 women) had breast cancer. Among breast cancer cases detected, 3 (30.0%) women were detected early (stage 1&2), while 7 (70.0%) detected late (stage 3&4) for CBE followed by mammography when breast abnormality detected, while for mammography among women with risk factors, 10 (34.5%) women were in early stage, while 19 (65.5%) were in late stage. Cost per breast cancer detected (excluding treatment costs) for CBE followed by mammogram when abnormality is detected, and of mammogram among women with risk factors were RM 11,864 (USD3, 744) and RM 9,709 (USD 3,064), respectively.

Conclusion: The current practice of CBE followed by mammography when abnormality is detected, and mammogram of women with risk factors should be strengthened as the costs of breast cancer detection were relatively cheap. Efforts should be focused on improving the participation rate for CBE and increasing the budget allocation for mammogram for women with breast abnormality and risk factors of breast cancer.

ABSTRAK

Pengenalan: Kanser payudara merupakan penyebab utama kematian akibat kanser dikalangan wanita di Malaysia. Saringan kanser payudara adalah secara oportunistik melalui Pemeriksaan Klinikal Payudara (PKP) diikuti dengan mamografi sekiranya keabnormalan dikesan, dan melalui saringan mamografi kepada wanita dengan faktor risiko kanser payudara. Beberapa buah negara mengesyorkan mammografi sebagai kaedah saringan bagi wanita dalam populasi. Kajian ini bertujuan untuk membandingkan analisis ekonomi dan hasil saringan bagi PKP diikuti dengan mamografi sekiranya keabnormalan dikesan, dan juga mamografi sahaja dalam kalangan wanita di Selangor, Malaysia.

Metodologi: Kajian ini adalah analisis ekonomi dan hasil bagi saringan kanser payudara membandingkan Pemeriksaan Klinikal Payudara (PKP) diikuti dengan mamografi sekiranya keabnormalan dikesan, dengan saringan mamografi dikalangan wanita berisiko. Pengiraan kos adalah daripada perspektif Kementerian Kesihatan Malaysia. Kos terlibat dikenalpasti dan dikira menggunakan kaedah pengiraan mikro dengan menggunapakai pendekatan kos berdasarkan aktiviti. Hasil analisa kos adalah kos bagi setiap saringan kanser payudara. Hasil saringan adalah bilangan serta kadar kanser payudara dikesan. Pengiraan kos bagi setiap kanser payudara dikesan juga dilakukan. Untuk mendapatkan hasil saringan PKP diikuti dengan mamografi sekiranya keabnormalan dikesan, sebanyak 15,279 rekod pesakit di klinik kesihatan dianalisa. Bagi saringan mammografi bagi wanita berisiko, sebanyak 1,427 rekod pesakit di hospital dianalisa. Status kanser payudara diperolehi daripada Registri Kanser Payudara Selangor.

Keputusan: Kos bagi setiap PKP dan mamografi adalah RM 6.68 (USD 2.11; 1USD=RM3.17) dan RM 197.30 (USD 62.26), masing-masing. Sebahagian besar kos

bagi PKP disumbang oleh kos kakitangan (61.1%), diikuti dengan kos utiliti dan komunikasi (20.1%). Untuk kos mamografi, majoriti disumbangkan oleh kos peralatan dan perkakasan (57.0%), diikuti dengan kos kakitangan (29.0%). Kadar pengesanan PKP abnormal adalah sebanyak 0.55% (84 orang wanita), di mana 10 (0.07%) daripadanya mempunyai kanser payudara. Bagi mamografi dikalangan wanita berisiko, kadar abnormal adalah 4.7% (67 wanita), dimana 2.0% (29 wanita) daripadanya mempunyai kanser payudara. Diantara kanser payudara dikesan, 3 (30.0%) wanita dikesan awal (tahap 1&2), manakala 7 (70.0%) dikesan lewat (tahap 3&4) bagi PKP diikuti mamografi sekiranya keabnormalan dikesan, manakala bagi mamografi dikalangan wanita berisiko, 10 (34.5%) wanita dikesan pada tahap awal, manakala 19 (65.5%) pada tahap lewat. Kos bagi setiap kanser payudara dikesan (tidak termasuk kos rawatan) bagi PKP diikuti mamografi sekiranya keabnormalan dikesan, dan mamografi dikalangan wanita berisiko adalah RM 11,864 (USD3, 744) dan RM 9,709 (USD 3,064), masing-masing.

Kesimpulan: Kaedah saringan semasa iaitu PKP diikuti dengan mamografi sekiranya keabnormalan dikesan, dan mamografi bagi wanita yang berisiko perlu diperkukuhkan memandangkan kos pengesanan kanser payudara secara perbandingannya adalah murah. Usaha perlu ditumpukan kepada meningkatkan kadar penyertaan saringan dan meningkatkan peruntukan untuk mamografi bagi wanita dengan payudara abnormal, dan wanita yang berisiko.

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LIST OF SYMBOLS AND ABBREVIATIONS

ABC	:	Activity Based Costing
ASR	:	Age Standardised Rate
BEMS	:	Biomedical Engineering Maintenance Services
BHGI	:	Breast Health Global Initiative
BI-RADS	:	Breast Imaging – Reporting and Data System
BRCA	:	Breast Cancer Gene
BSE	:	Breast Self-Examination
BTL	:	Bilateral Tubal Ligation
CBA	:	Cost –Benefit Analysis
CBE	:	Clinical Breast Examination
CEA	:	Cost-Effectiveness Analysis
CER	:	Cost-Effectiveness Ratio
CLS	:	Cleansing Services
CMA	:	Cost-Minimisation Analysis
CNBSS2	:	Canadian National Breast Screening Study 2
CPG	:	Clinical Practice Guideline
CT scan	:	Computed Tomography scan
CUA	:	Cost-Utility Analysis
CWMS	:	Clinical Waste Management Services
CXR	:	Chest X-ray
DALY	:	Disability Adjusted Life Year Gained
ER	:	Oestrogen Receptor
FEMS	:	Facilities Engineering Maintenance Services
FNAC	:	Fine Needle Aspiration Cytology

GDP	:	Gross Domestic Product
GHE	:	Government Health Expenditure
HER-2	:	Human Epidermal Growth Factor Receptor – 2
HIC	:	High Income Countries
HIP	:	Health Insurance Plan
HRT	:	Hormone Replacement Therapy
HTAR	:	Hospital Tengku Ampuan Rahimah
IARC	:	International Agency for Research on Cancer
ICER	:	Incremental Cost Effectiveness Ratio
ICF	:	Inflation Correction Factor
IUCD	:	Intra Uterine Contraceptive Device
KK	:	*Klinik Kesihatan* (Health clinic)
LMIC	:	Low- and Middle- Income Countries
LLS	:	Linen and Laundry Services
LPPKN	:	*Lembaga Penduduk dan Pembangunan Keluarga Negara*
MCH	:	Maternal and Child Health
MMG	:	Mammography
MOH	:	Ministry of Health
MRI	:	Magnetic Resonance Imaging
NCR	:	National Cancer Registry
NHMS	:	National Health Morbidity Survey
OCP	:	Oral Contraceptive Pill
O&G	:	Obstetrics and Gynaecology
OOP	:	Out of Pocket
OPD	:	Outpatient Department
PPPM	:	Per Patient Per Month

PPV	:	Positive Predictive Value
PR	:	Progesterone Receptor
QALY	:	Quality Adjusted Life Years
RCT	:	Randomised Controlled Trial
RM	:	*Ringgit Malaysia*
SIPPS	:	*Sistem Informasi Program Pap Smear*
SOPD	:	Surgical Outpatient Department
SPSS	:	Statistical Package for the Social Science
UK	:	United Kingdom
UMMC	:	University Malaya Medical Centre
USG	:	Ultrasonography
USPSTF	:	United States Preventive Services Task Force
VIA	:	Visual Inspection of the cervix after application of 4% to 5% acetic acid
WHO	:	World Health Organization

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CHAPTER 1: INTRODUCTION

1.1 Disease Burden of Breast Cancer

According to the World Health Organization (WHO), breast cancer is the commonest cancer among women both in the developed and developing countries (World Health Organization, 2013, 2015). It is the second most common cancer in the world and it was estimated that 1.67 million new cancer cases were diagnosed in 2012 (25% of all cancers) (Jacques Ferlay et al., 2015; International Agency for Research on Cancer, 2012). In 2012, it was estimated that 522, 000 women died of breast cancer worldwide (Global health estimates, WHO 2013).

The developed countries showed higher incidence for breast cancer as compared to the developing countries (Michelle D Althuis, 2005; Torre et al., 2015). In 2012, the GLOBOCAN report showed that the incidence rates worldwide for breast cancer vary nearly four-folds across regions where the age standardized rates ranges from 27 per 100,000 population in Middle Africa and Eastern Asia and 96 per 100, 000 population in Western Europe (Jacques Ferlay et al., 2015; International Agency for Research on Cancer, 2012). The report also showed that this incidence rate variation has not changed much over the four years. However, more cases were reported in the less developed (883,000 cases) compared to the developed world (794,000 cases) (International Agency for Research on Cancer, 2012). The age standardized rates per 100,000 women is illustrated as in Figure 1.1.

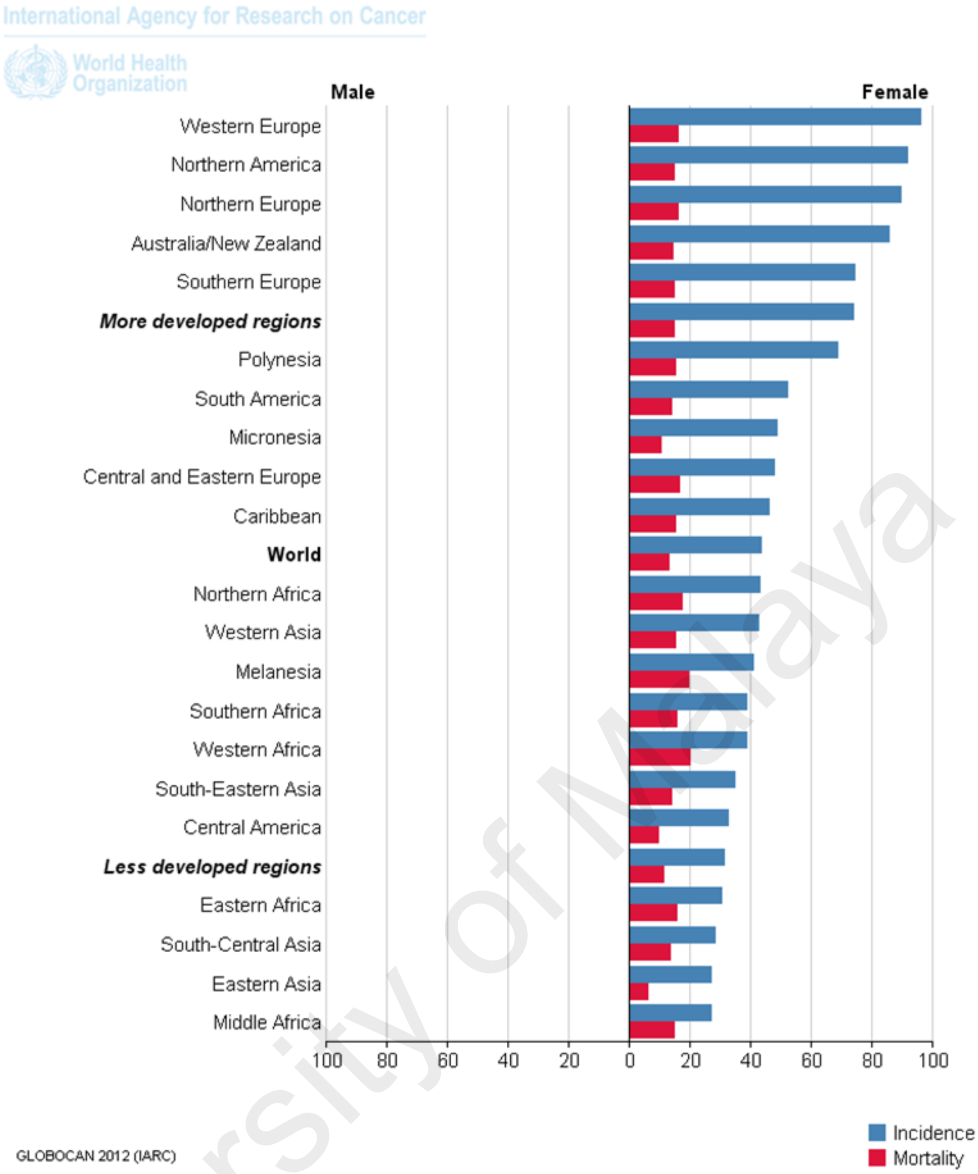

Figure 1.1: The Age Standardized Rates per 100,000 women for the different regions in the world

(Source: Globocan 2012 (IARC). Cancer Fact Sheet.Breast Cancer Incidence and Mortality Worldwide)

The breast cancer mortality rates are decreasing in most high-income countries despite having an increase or stable incidence. However, the lower- and middle-income countries are facing increasing trends for both incidence and mortality rates. This is likely due to the increasing life span, rapid urbanization and also the changing lifestyle towards western lifestyles. (DeSantis et al., 2015). Early detection is the basis for breast cancer control to improve breast cancer outcome and survival in these countries.

In Malaysia, breast cancer is the most common cancer in women (Zainal Ariffin Omar & Tamin, 2011). According to the Third Report of the National Cancer Registry (2008), breast cancer accounts for 31.3% (N=11, 952 cases) of the new cases reported in Malaysian women for three year period from 2003 to 2005 (G. Lim, Rampal, & Yahya, 2008). The Age-Standardised Rate (ASR) for females was 47.1 per 100,000 women. Incidence was highest for the Chinese followed by the Indians and the Malays with ASR of 59.9, 54.2, and 34.9 per 100,000 women, respectively (G. Lim et al., 2008; Zainal Ariffin Omar & Tamin, 2011).

1.1.2 Breast cancer mortality

Over the four years (from 2008 to 2012), breast cancer still ranks as the fifth cause of death from all cancer deaths (458,000 deaths in 2008 and 522,000 in 2012). It remains the most frequent cause of cancer death in women in the less developed region (324,000 deaths, 14.3% of total) and is the second cause of cancer death (198,000 deaths, 15.4% of total) after lung cancer in the developed region (J. Ferlay et al., 2010; International Agency for Research on Cancer, 2012). There are more deaths in the developing world although there are more cases of incident breast cancers in the developed world. Better breast cancer survival in developed regions contributed to lower variation in breast cancer mortality rates across regions worldwide as compared to incidence rates (Jacques Ferlay et al., 2015).

According to the GLOBOCAN 2012 Report, about 40% of all breast cancer deaths occurred in the developing countries. The GLOBOCAN 2008 report by the International Agency for Research on Cancer (IARC) reported that the breast cancer mortality to incidence ratio was 0.23 in the developed world while for the developing world the ratio was 0.40 (J. Ferlay et al., 2010). The mortality to incidence ratio have not changed much in 2012 for both developed and developing regions, 0.25 and 0.37, respectively

(International Agency for Research on Cancer, 2012). The lower mortality to incidence ration in developing regions may be due to the availability of a more organized breast cancer screening programme, better technologies, and availability of breast cancer treatment centres.

The survival rates of breast cancer differ among countries around the world ranging from 80% or more in North America, Sweden and Japan to around 60% in middle-income countries, and below 40% in low-income countries (Coleman et al., 2011). These variations in survival rates may be due to lack of early detection programmes which results in higher percentage of advanced cancer detection, and inadequate diagnosis and treatment facilities in the low- and middle-income countries. Therefore, in low- and middle-income countries, early detection programme is still the basis for breast cancer prevention and control programme to improve breast cancer survival (Anderson et al., 2008).

In terms of the 5-year survival of breast cancer, the developed countries generally have higher survival rates compared to the developing countries such as Asia and Africa. Unfortunately, Malaysia does not have the 5-year survival data for the whole country. In one study in Malaysia, the 5-year survival rate was 59.1% and factors associated with survival were clinical stage, lymph node status, size and grade of the breast cancer (Taib, Yip, & Mohamed, 2008). The highest 5-year survival rate for breast cancer was for stage 1 (82.6%), followed by stage 2 (72.8%), stage 3 (39.8%) and finally stage 4 (13.2%) (Taib et al., 2008). In a more recent study, it was shown that the 5-year survival rate for breast cancer was 43.5%, and poor survival rate was associated with the size of tumour of more than 3 cm, lymph node involvement, oestrogen receptor (ER), progesterone receptor (PR) and Human epidermal growth factor receptor 2 (HER 2) status, delayed presentation and involvement of both breasts (Ibrahim, Dahlui, Aina,

& Al-Sadat, 2012). These studies showed that the earlier the detection and diagnosis, the better the prognosis of the patients. Ethnicity is also associated with breast cancer survival among Malaysians. Malays have poorer survival rates or shorter survival time as compared to the Chinese and Indians (Ibrahim et al., 2012; Redhwan Ahmed Mohammed Al-Naggar et al., 2009; Taib et al., 2008).

1.1.3 Breast cancer distribution/ epidemiology

In Malaysia, the most common age at presentation for breast cancer in women is between the ages of 50-59 years with age specific cancer incidence of 154.0 per 100,000 populations (G. Lim et al., 2008). According to the different ethnic groups, the peak age incidence of breast cancer for both Chinese and Malays were 50-59 years, whereas for Indians, it occurred after the age of 60 years. This is shown in Table 1.1 and Figure 1.2.

Table 1.1: Female Breast Age Specific Cancer Incidence per 100,000 populations by ethnicity, Peninsular Malaysia 2003-2005

		Age groups, year								
		0-9	10-19	20-29	30-39	40-49	50-59	60-69	70+	CumR
Female	All races	0.1	0.2	3.7	37.3	117.4	154.0	141.5	105.1	5.0
	Malay	0.1	0.2	2.8	33.0	94.9	113.0	89.6	59.8	3.6
	Chinese	0.1	0.1	3.7	40.4	149.7	194.0	188.8	140.5	6.3
	Indian	0	0.4	4.7	29.6	100.1	174.0	200.0	202.9	6.0

. (Source: The Third Report of the National Cancer Registry, Malaysia (2008))

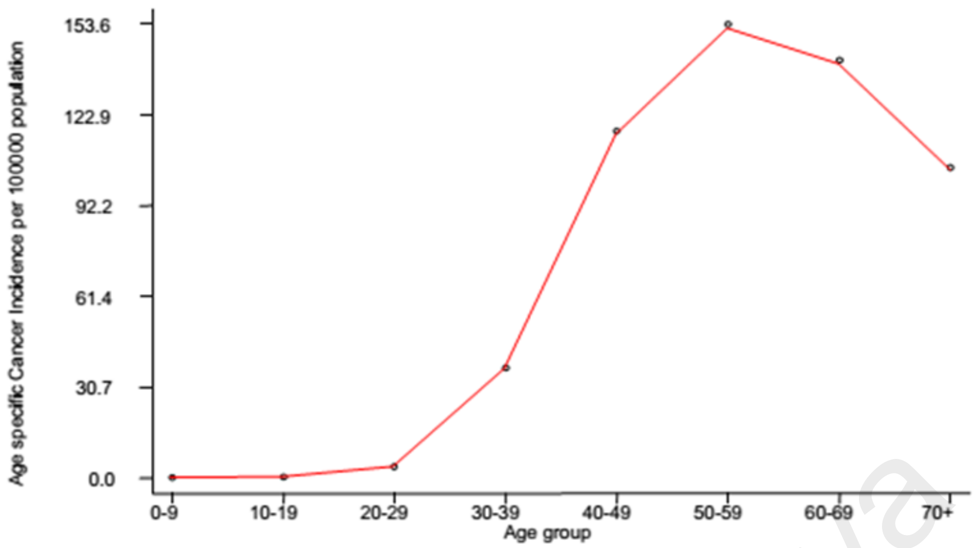

Figure 1.2: Female Breast Age-specific Cancer Incidence per 100,000 population, Peninsular Malaysia 2003-2005

(Source: The Third Report of the National Cancer Registry, Malaysia (2008))

In Malaysia, the most common symptoms of breast cancer at presentation was a lump in the breast, where over 90% of cases reported this (Cheng Har Yip, Taib, & Mohamed, 2006). The mean size at presentation was 4.2 cm, and in some other studies the mean tumour size at presentation was 5.4cm (ranged between 1 to 20cm) (Abdullah Noor Hisham, 2003). According to CH Yip et al. (2006), among breast cancer cases presented to the University Malaya Medical Centre (UMMC) between 1993 to 2004, about 60-70% of breast cancer cases presented at stage 1 and 2 (early stage), whereas another 30-40% of cases presented at a later stage (stage 3 and 4). The National Cancer Registry Report (2007) showed that the percentage of breast cancer detected at stage I and II was 58%, which suggests, that there were not much changes seen regarding the stage of breast cancer detection (Omar; & Tamin, 2011). This finding is contrary to the findings in developed countries, where 80% of cases present at an early stage and the mean size of the mass is 2 cm. A study by Lim et al (2014), showed that no major improvement was seen in terms of presentation where late presentations were seen among 40% of women with breast cancers (G. C. C. Lim et al., 2014).

Late or advanced presentation of breast cancer is not only a problem in Malaysia but also other developing countries. This is due to several factors which are ignorance or poor health awareness, geographical isolation or inadequate access to medical care, absence or inadequate screening programme, social and cultural barriers, financial barriers and sorting to traditional treatments.

1.2 Breast Cancer

1.2.1 Breast cancer pathology

Breast cancer is derived from the epithelial cells that lined the terminal duct and its lobular unit as shown in Figure 1.3. Any of these parts can become malignant if exposed to several factors that can affect the risk factors for breast cancer. If there is dissemination of cancer cells beyond the basement membrane of these cells and invades the normal surrounding tissue, than it is termed invasive breast cancer.

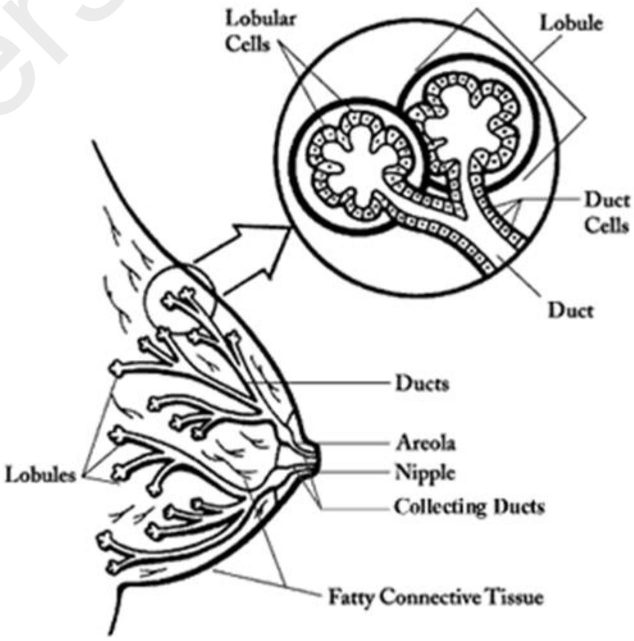

Figure 1.3: The breast anatomy showing the terminal duct lobular unit where breast cancer is derived.

Breast cancer can be diagnosed at preclinical stage, where the individuals do not have signs and symptoms of disease or during the clinical stage where the signs and symptoms had occur. The early diagnosis is usually done for asymptomatic individuals via breast screening activity. Early screening allows early detection and early intervention to avoid complications. The gold standard method for breast cancer screening is by mammography screening.

1.2.2 Breast cancer risk factors, signs and symptoms

There are few factors that are identified as risk factors for breast cancer such as age (incidence of breast cancer increases with age), having a first degree relative with breast cancer, and ethnicity. For example, Whites are at a higher risk to develop breast cancer as compared to the African-American women (American Cancer Society, 2009), and in Malaysia, the Chinese have higher risk for breast cancer than the Malays and the Indians (National Cancer Registry, 2006).

Other factors that increase the risk for breast cancer are early age at menarche (less than 11 years), late menopause (more than 55 years), nulliparous, late child birth (more than 30 years), postmenopausal obesity, higher socio-economic group, exposed to exogenous hormones (oral contraceptives or hormone replacement therapies), alcohol intake and having limited breast feeding. (Chlebowski et al., 2013; Collaborative Group on Hormonal Factors in Breast Cancer, 2001; "Familial breast cancer: collaborative reanalysis of individual data from 52 epidemiological studies including 58,209 women with breast cancer and 101,986 women without the disease," 2001; McPherson, Steel, & Dixon, 2000).

There are also studies suggesting genetic predisposition exposes an individual to higher risk for breast cancer. It is shown in a study that individuals with Breast Cancer gene 1 (BRCA1) and Breast Cancer gene 2 (BRCA2) mutation carriers will have a life time risk of 80-85% to develop breast cancer (Emery J, 2001).

1.2.3 Breast cancer screening methods

There are three main breast cancer screening methods that are available namely breast self-examination, clinical breast examination and mammography. Breast self-examination is when a woman examines one's own breast regularly to detect any changes in their breast while clinical breast examination is when women have their breasts examined by a trained healthcare provider to detect any breast abnormality. Mammography examination is a radiological procedure using the mammogram machine where an X-ray of the breasts is taken to detect any breast abnormality. Mammography is established as the gold standard screening modality for breast cancer and is used as a breast cancer screening method especially in developed (high income) countries. Each of this method has its own advantages and disadvantages.

The Breast Health Global Initiative developed consensus guidelines for early detection, diagnosis and treatment of breast cancer in areas with limited healthcare resource based on the 4-tiered system depending on the availability of resource (C. H. Yip et al., 2008). In general, the recommended screening strategies for low- and middle-income countries with basic and limited resource (tier 1 and 2) are awareness of early signs and symptoms of breast cancer, screening by clinical breast examination in demonstration areas, and diagnostic breast imaging for women with positive CBE or mammographic screening for the target groups depending on the available resources. Mammography are implemented in countries where there are good health infrastructure and can afford a long-term programme.

1.2.4 Treatment of breast cancer

To make a breast cancer prevention and control programme successful does not depend only on good early detection programme but also providing adequate essential treatment services. There are few treatment methods available for breast cancer which includes surgery, radiation therapy, chemotherapy, hormone therapy, targeted therapy and bone directed therapy. However, providing adequate and quality treatment services is also a major challenge in most developing countries where the priority of public health programmes focused more on infectious disease as compared to cancer prevention programmes. The lack of financial resources for healthcare also contributes to the lack of availability for treatment services for breast cancer which plays an important role as the receiving end of the screening programme.

1.3 Economic burden of breast cancer disease and treatment

According to the World Health Organization, the world's leading cause of death in 2015 is ischaemic heart disease and stroke accounting for a combined 15 million deaths, while cancer is the second leading cause of death globally with 8.8 million deaths. According to The Global Economic Cost of Cancer Report (2010), cancer has been shown to give the greatest economic impact from premature death and disability of all causes of death worldwide which cost $895 billion in 2008 and represents 1.5 percent of the world's GDP (Ross, 2010). It was also shown that in 2008, cancer death and disability caused 83 million years of 'healthy life' lost globally. Breast cancer were listed as among the top three cancers that caused the highest economic impact globally costing an amount of $88 billion after lung cancer ($188 billion) and colon/rectum cancer ($99 billion) (Ross, 2010).

The greatest sources of economic burden that were reported among breast cancer survivors were loss of income, health service expenditure and loss of unpaid work

(Gordon, Scuffham, Hayes, & Newman, 2007; Lidgren, 2007). According to Gordon et al. (2007), significantly higher cost were reported among those with positive lymph nodes compared to those with negative lymph nodes (US$6,674 versus US$3,533) and also among the younger women whereby women aged 50 years and below experienced 80% higher cost than older women in the first 18 months post diagnosis of breast cancer (US $8,800 versus US$4,937) (Gordon et al., 2007).

In US, a study by Barron et al. (2008) showed that the mean attributable per patient per month (PPPM) costs associated with breast cancer were shown to be 2.28 times higher than non-breast cancer as controls (Barron, Quimbo, Nikam, & Amonkar, 2008). The study by Barron et al. (2008) showed that the mean PPPM costs associated with breast cancer were $2,896 whereby 46.3% of the costs was contributed mainly by hospitalization cost, followed by cost of pharmacotherapy (18.5%) and surgical intervention (16.2%) (Barron et al., 2008).

A systematic review on economic burden of metastatic breast cancer showed that the only data available for total per-patient cost of metastatic breast cancer from Sweden ranged from $17,301- $48,169 annually depending on patient’s age (2005 USD) (Foster et al., 2011). Nationally, the gross national costs of metastatic breast cancer were reported for the UK whereby the estimated cost of incident for metastatic breast cancer was $22 million annually (2002 GBP) (Remak & Brazil, 2004).

1.4 Breast cancer screening program in Malaysia

1.4.1 The Malaysian healthcare system

The Malaysian healthcare system can be divided into two sectors that are the public and the private healthcare system under the administration of the Ministry of Health (MOH). The main healthcare provider is the public sector whereby the MOH is the largest public provider of health and is highly subsidized. The structure of the healthcare system starts with the community clinics or also known as the 'klinik desa' which are then linked to the health clinics or known as 'klinik kesihatan'. The community clinic is run by the community nurses while the health clinics usually have at least one medical and health officer or some may have Family Medicine Specialist as the Head of Clinic. The community clinics offer the maternal and child health (MCH) services while the health clinics offer MCH and also outpatient clinic services with its own medical laboratory and pharmacy units. Cases which need referrals to a medical officer will be referred from the community clinic to the respective health clinic. The health clinics are linked to the hospitals which can either be a primary hospital that is district hospital with or without specialists, secondary level hospital with specialist services and the tertiary level hospitals with sub specialty services.

The public healthcare services are heavily subsidized where its financial funding comes from general taxation and very minimal co-payment. A visit to the government health clinic for Malaysians would cost only RM1 while RM5 charge is incurred for those needing in patient care. Some services are free for Malaysian citizen for example the maternal and child health services which include antenatal care, children immunization, school health services, government servants and the elderly population. However, statistics showed that the trend of health expenditure in Malaysia is increasing each year. The trend for total health expenditure, 1997-2011 (RM Million and Per cent GDP) generally showed increasing trend as illustrated below in Table 1.2 (Malaysia National Health Accounts Unit, 2013). The health system in Malaysia is currently heavily burdened not just with the increasing trend of communicable diseases and non-communicable diseases but also with the overwhelming number of immigrants into Malaysia. Therefore, the need for careful planning of health programmes is essential including funding, budgeting and allocation for health programmes. Table 1.2 showed the total health expenditure for the year 1997 to 2011 in Malaysia.

Table 1.2: Total Health Expenditure, 1997-2011 (RM Million & Per cent GDP) (Source: Malaysia National Health Accounts Unit, 2013)

Year	Total Health Expenditure, Nominal (RM Million)	Total Health Expenditure as % of GDP	Total GDP, Nominal (RM Million)
1997	8,121	2.88	281,795
1998	8,819	3.11	283,243
1999	9,666	3.21	300,764
2000	11,579	3.25	356,401
2001	12,824	3.64	352,579
2002	13,995	3.65	383,213
2003	17,662	4.22	418,769
2004	18,896	3.99	474,048
2005	19,122	3.52	543,578
2006	23,198	3.89	596,784
2007	25,703	3.86	665,340
2008	28,651	3.72	769,949
2009	31,031	4.35	712,857
2010	35,075	4.41	795,037
2011	37,542	4.26	881,080

The health care services and products sources of funding in Malaysia are contributed by the public and the private sector. According to the Health Expenditure Report 1997-2011 by the Ministry of Health (2013), the public-private share of 53:47 pattern in 2011 is similar for the period of 1997-2011 and public sector has always been higher than the private sector except for the year 2005 (Malaysia National Health Accounts Unit, 2013). The same report also showed that the Ministry of Health had the highest expenditure as compared to other sources of financing in 2011 with expenditure of RM 16,856 million or 45% of the total health expenditure. This is followed by private household Out-of-Pocket (OOP) and private insurance, spending about 38% (RM 14,152 million) and 7%

(RM 2,626 million) of total health expenditure respectively. Figure 1.4 showed the total health expenditure by source of financing for the year 2011 in Malaysia.

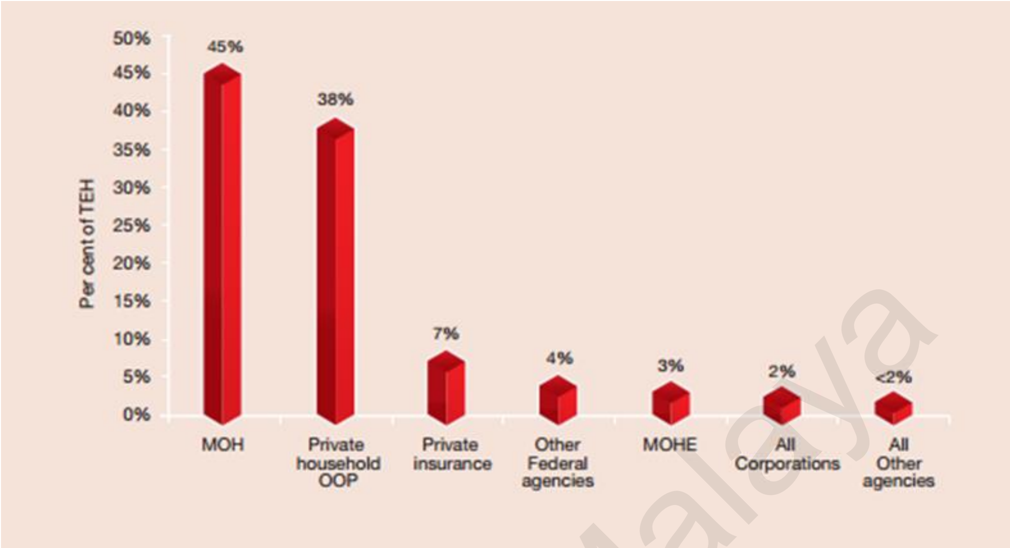

Figure 1.4: Total Health Expenditure by Source of Financing, 2011

Source: Health Expenditure Report 1997-2011 by the Ministry of Health (2013)

1.4.2 Breast self-examination, clinical breast examination and mammography screening policy

Malaysian Ministry of Health promotes primary and secondary prevention of breast cancer. Primary prevention includes dietary modification, healthy lifestyle changes and modification of reproductive behaviour, while secondary prevention includes breast self-examination (BSE) as part of breast self-awareness activity, clinical breast examination (CBE) and mammography examination either for diagnosis or screening for breast cancer. Most of breast cancer screening programs started in the Maternal and Child Health (MCH) clinics either in the community or in the health clinics. The approach is opportunistic screening whereby women who came to any of the health care facility will be offered for clinical breast examination. Most of time, the women will also be taught on breast health awareness including how to perform breast self-examination.

Breast cancer has been the focus of women cancer prevention program in Malaysia other than cervical cancer. Since the year 1995, Malaysian Ministry of Health has been promoting breast self-examination (BSE) and annual clinical breast examination among women as part of the breast cancer screening program. Currently, the Malaysian Ministry of Health's policy on breast screening is to promote BSE as part of breast self-awareness program in all women. In addition to that, women between the ages of 20 to 39 years should be screened three yearly for clinical breast examinations (CBE), while annual CBE should be done for those above 40 years old and for women with breast cancer risk factors regardless of age (Family Health Development Division, 2010). In 2010, a manual was developed by the Family Health Development Division (F.H.D.D), Ministry of Health of Malaysia to guide the health care providers to perform CBE (Family Health Development Division, 2010).

Other than BSE and CBE, mammography screenings were offered for women with high risks of getting breast cancer such as women with a history of breast atypia on previous breast biopsy, history of cancer in one breast and or ovarian cancer and also women with family history of breast cancer in one or more of first or second degree relatives (mother and sisters) before the age of 50 years as according to the Ministry of Health (2010) Clinical Practice Guidelines for Management of Breast Cancer (Ministry of Health Malaysia, 2010). For women under 40 years of age, mammography may be offered at the discretion of a doctor or if the women wishes to do so. However, these mammography services are only available in the government hospitals with mammography machine.

Currently in Malaysia, there is no organized population based breast cancer screening programme. Breast cancer screening is offered opportunistically to women utilizing the healthcare facility. According to the Malaysian Third National Health and

Morbidity Survey (NHMS III) in 2006, 70.35% of the women interviewed had breast examination using any of the three screening methods (BSE, CBE or mammography) where the most common methods used was BSE (57.14%), followed by CBE (51.77%) and mammography (7.57%). Despite the poor uptake for breast examination, the prevalence rate was higher for younger age group with lower breast cancer risk where 82.04% of the women falls in the age group between 30-34 years (National Health Morbidity Survey Malaysia, 2006). In 2010, the government health clinics started to collect data on clinical breast examination where the overall performance of CBE was 12.5% and the average abnormality detection rate was 0.2% (Family Health Development Division, 2010). This suggests that more effort is needed to reach women in the target age group to improve the overall breast cancer burden in Malaysia.

Apart from the Ministry of Health, the Ministry of Women, Family and Community Development also started the RM50 subsidy program in 2007 for mammography done in private clinics and hospitals that are registered with the National Population and Family Development Board Malaysia (which is also known as Lembaga Penduduk dan Pembangunan Keluarga Negara (LPPKN)). This RM50 subsidy is to make the mammography services more accessible to women. However, it is only open for women who are at high risks with a monthly household income below RM5,000.

Among other milestones in breast cancer prevention programme, a memorandum to the ministry cabinet for a pilot project on a population based mammography screening in one of the state in Malaysia was rejected due to the inadequate financial resource to implement the programme. This includes setting up the facility, preparing and training of manpower and also strengthening the treatment services. This limitation showed that population based mammography screening is not yet feasible in Malaysia. Other adaptive strategy for early detection is needed to overcome the breast cancer burden in Malaysia.

In addition to the efforts made by the MOH, a pilot study was done which indirectly has an implication to the breast screening efforts. This pilot study by the MOH was done starting from the year 2007 to 2011 in two randomly chosen districts that were Mersing (in Johor state) and also Klang (in Selangor state). This pilot study was known as the SIPPS or '*Sistem Informasi Program Pap Smear'* which means Pap Smear Programme Information System that involved only the government health facilities. It was a call-recall pilot study for population based Pap smear screening. Women aged 20 to 65 years were invited via personal letter invitation for Pap smear at their nearest health clinic facility. These women were offered clinical breast examination at the same time as their Pap smear screening. Women who agreed had their Pap smear and CBE done at the same setting, and the results of the findings were recorded in the Pap smear registry book which was located in each health clinic. Those women with abnormal findings were referred for further investigations. With this call-recall system in place for these two districts, more women turn up for both Pap smear and CBE screenings as compared to other districts in Malaysia during that period of time. The study findings showed that the overall response rate was 13.3%, while the response rate for Pap smear screening was 11.7% (unpublished data SIPPS, Family Health Development Division, Ministry of Health Malaysia, 2011).

Starting from the year 2009, the Ministry of Health provides clinical breast examination services in the government health clinics nationwide as part of the breast cancer early detection program. Cases with breast abnormalities detected were referred for further investigations and management in any major public hospitals.

In 2011, a revised breast cancer screening guideline and protocol was developed to standardised and structure the breast cancer screening program. Starting from the year 2012, more women were offered mammography screening as part of breast cancer promotion and prevention programs in the government health facility. This effort was made to encourage not just those women with high risks of getting breast cancer but also other women who are 40 years of age and above and are at risk (including low to moderate risk). This was done by opportunistic approach through the government health clinics whereby mammogram requests were made from the health clinics by the medical officers to the nearest hospital with mammogram services. Women were screened using a checklist to check for mammography eligibility. However, the number of cases for screening mammography examinations is limited due to the high workload in the hospitals.

Malaysia is continuously making efforts to improve the accessibility and uptake of women to breast cancer screening services. However, there is limitation to the number of women who can access mammography examination in the government hospitals at any one time due to the limited health care resource. Moreover, clinical breast examination is only opportunistically done on women who utilize the government health clinics.

1.4.3 Current breast cancer screening programme in Klang

Breast cancer screening services can be obtained either from the public or private health care services. There are two main breast cancer screening programmes in Klang under the Ministry of Health, namely clinical breast examination followed by mammography if abnormality is detected, and mammography screening for women with risk factors.

There are eight government health clinics in Klang which offers clinical breast examination (CBE) services. Women attending the government health clinics are opportunistically offered for CBE. In each health clinics, there are several entry points that a woman may be offered clinical breast examination. These are women attending outpatient clinics, antenatal clinics, postnatal clinics, family planning clinics and Pap smear screening services. Clinical breast examination findings were documented in individual patient's health records, while for those who attended Pap smear screening will also have their CBE findings documented in the Pap smear registry books in each health clinic. This study focused on the clinical breast examination done among women who attended Pap smear screening in the Maternal and Child Health Clinic. This was because the findings of CBE were well documented in the Pap smear registry books as compared to individual patient's health records from other settings. Women whom were found to have abnormal CBE findings were then referred for further investigations to the nearest hospital. These women were later followed up by the nurses to ensure that they went for further investigations until final diagnosis were made. This system of close follow up of patients is further strengthened with the currently practiced 'personalized care' which means that patients would have their designated staff that will be in charge of their follow up and clinic appointments.

Mammography screenings were also done opportunistically among women who came to the health clinics. Women who came to the health clinics with risk factors for breast cancer were offered mammography screening by their health care providers. These women were referred to the Mammography Suite in the Radiology Department, Hospital Tengku Ampuan Rahimah, a general hospital in Klang. Those whom were found to have abnormal breast findings by mammography later proceeded for further diagnostic tests.

Currently, all breast cancer cases diagnosed either in public or private hospitals were notified to the Breast Cancer Registry in the relevant State Health Department. As for Klang district, all breast cancer cases diagnosed were notified to the Selangor Breast Cancer Registry in the Selangor State Health Department. The State Health Department also conducts audits to hospital facilities for notification of cancer cases diagnosed in both public and private hospitals.

1.5 Economic analysis

The focus of economic analysis is on making decision and choices about the production and also the consumption of economic goods. These economic goods are defined as any goods or services that are scarce relative to society's wants for them (Morris, Devlin, Parkin, & Spencer, 2012). Health care is an example of economic goods because of its scarcity of its resources such as workforce, capital and raw materials, and unlimited wants by the society.

Economic analysis is important as it offers a unique and systematic intellectual framework for analysing important issues in health care, and for identifying solutions to common problems (Morris et al., 2012). In the modern health care systems, evidence on efficiency, productivity and value for money are increasingly the way forward to decision making in health care service delivery. For every decisions made on the choice of health care services, there will be benefits forgone for the next best alternative that would otherwise have been enjoyed by others; also known as opportunity costs.

The decision of the way in which a production and consumption of economic goods and services are made is by allowing the market forces to determine who gets what. Simple economic models of demand and supply predict the behaviour of producers and consumers. In the absence of government intervention, producers decides how and how much to produce with an aim on making profit, while consumers decides on how much and how to purchase according to their interest. The demand and supply economic curve shows that when the price of a good or services fall, the demand increases (indicated by the downward sloping of the demand curve). The supply curve showed that, when the price rises, the supply also rises (indicated by the upward sloping of the supply curve) (as shown in Figure 1.5)

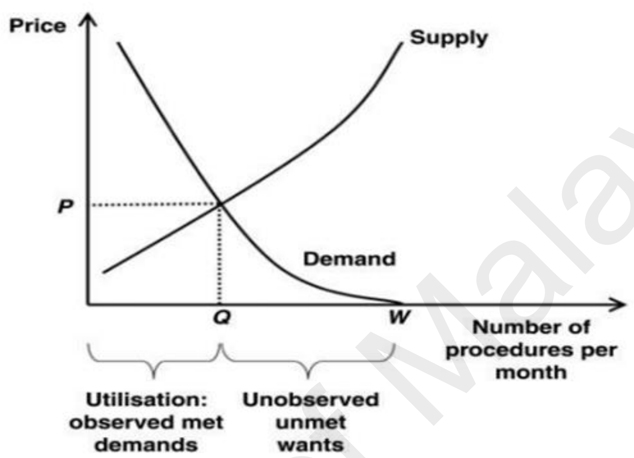

Figure 1.5: Simple economic model of demand and supply

(Source: Economic Analysis in Health Care. (Morris et al., 2012))

1.6 Economic evaluation study

Economic evaluation study in healthcare has been an important aspect in health sector research for quite some time. Incorporating and integrating the economic perspective into clinical and epidemiological research has become more and more important as the advancement in healthcare technologies accelerates as well as the escalating healthcare expenditures. It has become an essential tool in decision making process and policy making in the health sector. Now researchers are not only interested in looking into the clinical outcome of a disease but also interested in assessing the economic implications of a disease.

Cost data can be collected as primary data collection for example as part of clinical trials or clinical studies or even using the available administrative database of healthcare payment. Cost analysis approaches include top down and bottom up. There are four cost-effectiveness analysis tools that are frequently used which are cost-minimization analysis (CMA), cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost-benefit analysis (CBA). However, there are also other approaches such as cost of illness analysis and cost of consequence analysis. The former involves determination of an economic impact of an illness within a specified population including associated treatment costs while the latter is a form of cost-effectiveness analysis that presents the costs and outcomes in its discrete categories, without aggregating or weighting them.

Cost-minimisation analysis is comparing the least costly among the different alternative interventions that have equivalent outcomes. Cost-effectiveness analysis (CEA) is a comparison of costs in monetary units to its outcomes in non-monetary units or its natural units for example they can be expressed as per morbidity or mortality reduced. In order to implement any health policy, the term cost-effectiveness is frequently asked especially where few alternatives are available to achieve the same objectives. The usual outcome measurement is cost per life year saved, cost per death avoided or cost per cases detected (as in the case of a screening procedure) (Petiti, 2000; Tom Jefferson, 1996).

Cost-utility analysis (CUA) on the other hand, is a form of cost-effectiveness analysis that compares cost in monetary form to its outcomes in its utility units usually of the patient's, example QALYs or DALYs gained (quality adjusted life year gained or disability adjusted life year gained). Cost benefit analysis (CBA) compares costs and benefits of alternative interventions in common monetary units. The choice of which cost analysis approach to be used will depend on the aim of the research, the availability of source of data and other resources.

This study focused on economic analysis and outcome assessment of the two currently practiced breast cancer screening programme that are clinical breast examination followed by mammography screening when breast abnormality is detected, which being offered in government health clinics, and mammography only among women with risk factors that is being done in the general hospital in Klang district.

Mammography examination, although is the gold standard for early breast cancer detection, is very costly compared to the clinical breast examination if it is to be implemented as a population based screening. This is an important issue to be considered especially in the developing countries with scarce health care resources and where healthcare financial allocation is challenging. In order to allocate health care resources effectively, evidence base findings on cost and outcome of the current breast cancer screening approaches is essential as baseline data and can be used for future planning for breast cancer screening programmes in Malaysia .

It is established that mammography screening is the chosen screening modality for breast cancer in most countries in the west. Despite its high cost, the sensitivity and specificity outweigh CBE in detecting breast cancer. Moreover, it detects breast cancer at an earlier stage giving a better prognosis as compared to CBE. On the other hand, CBE is considered feasible in most developing countries due to its lower cost, although it has lower sensitivity and specificity than mammography. Therefore, mammography is more costly but with better cancer detection rate, whereas CBE is at lower cost with less detection rate for breast cancer.

1.7 Problem Statement

Breast cancer is the most common cancer and is the most common cancer death in women in Malaysia. The age-standardized incidence rate (ASR) is 47.1 per 100, 000 women, and the age specific cancer incidence is highest in the 50 to 59 years age group (154 per 100, 000 population) for the period of 2003 to 2005 (G. Lim et al., 2008). Approximately 1 in 20 women in Malaysia develop breast cancer in their lifetime. Generally, Malaysian women presents at later stages of breast cancer compared to other counterparts in the developing countries whereby 30-40% present at stage 3 to 4 where the prognosis of the disease is poor (Cheng Har Yip et al., 2006).

Despite nationwide breast cancer prevention and control programme and also the breast awareness campaign since 1995, breast cancer remains to be the number one cancer killer among women in Malaysia. The incidence of breast cancer remains high and the problem of presenting at an advance stage is still unresolved. Numerous efforts have been made by many stakeholders towards increasing early detection and improving the prognosis of breast cancer in Malaysia. The current opportunistic breast cancer screening is still underutilized among women in Malaysia. However, the growing burden of breast cancer cannot be ignored and need to be addressed. Therefore, there is need for adaptive strategies to address this situation. However, with very tight economies and financial situation of the current health budget, ensuring optimum resource use in any health programme would be the way forward in ensuring optimum health care services to be delivered to the most in need. Therefore, in the context of breast cancer screening programme in Malaysia, it is timely to conduct economic analysis and assess the outcome of the two current breast cancer screening activities that are clinical breast examination followed by mammography screening, and mammography screening among women with risk factors. This will later help in future planning for breast cancer screening programme activities especially on planning towards population based breast cancer screening programme for women in Malaysia.

1.8 Rationale of the study

Breast cancer remains to be the most common cause of cancer death among women in Malaysia. Compared to other countries, Malaysian women presents at a relatively advanced stage and they frequently have larger palpable tumours. In Malaysia, breast cancer affects women of younger age groups compared to its counterpart in the western countries. Women in the reproductive age groups whom are economically productive groups are also affected. Therefore, preventing breast cancer morbidity and mortality is very important. Data from the Malaysia Medical Insurance Organization (2013) had shown that costs of treating breast cancer patients are also very costly ranging from RM 10,000 to RM 140,000 per patient depending on the severity of the disease. Screening is currently the most effective available method for secondary prevention that can improve the disease prognosis. Early breast cancer detection improves patients' outcome.

Malaysia adopts opportunistic screening for clinical breast examination and mammography screening for women with breast cancer risk factors. Meanwhile, women are also encouraged to do breast self-awareness (BSA). However, both CBE and mammography are still underutilized. Up to today there is no population based breast screening programme that is done nationwide in Malaysia.

Given the high percentage of advanced presentation of breast cancer in Malaysia, lack of population based screening programme in Malaysia and limited resources for health programmes, it is essential to conduct economic analysis and assess the outcome of the current breast cancer screening methods that are clinical breast examination followed by mammogram when breast abnormality is detected, and mammography screening among women with risk factors.

Therefore, the aim of the study was to conduct economic analysis and assess the outcome of the two currently practised screening modalities that are clinical breast examination followed by mammogram when breast abnormality is detected, and mammography screening among women with risk factors. This study will later provide data on understanding the cost composition, the factors affecting the cost and the outcome of the current breast cancer screening programmes. Thus, planning for the appropriate resources allocation, expansion of the current program or incorporation of additional programmes could be taken up.

1.9 Summary of Chapter 1

Chapter 1 describes the epidemiology of breast cancer and also the burden of breast cancer globally and also in Malaysia. Breast cancer is still the number one cancer causing death among women in Malaysia. Therefore, the need to do early detection is very important to improve the prognosis of women affected by breast cancer. There is no population based breast cancer screening currently in Malaysia. As for now, Malaysia is practicing CBE screening followed by mammogram when breast abnormality is detected in health clinics, and also offering screening mammography to women with risk factors for breast cancer. There is lack of previous literatures on economic analysis and outcome assessment on breast cancer screening methods in Malaysia, especially in government health facilities, and there were plans made to promote mammogram as the routine screening for all women. Therefore, this study was designed to conduct economic analysis and assess the outcome of CBE screening followed by mammogram when breast abnormality is detected, and mammography screening among women with breast cancer risk factors. The findings of this study will be able to inform the health care providers and the policy makers on the cost and outcome of the two current breast cancer screening activities, and can be used for future planning on making more efficient programmes for early detection of breast cancers.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

This chapter covers literatures on six main areas that are breast cancer in low- and middle-income countries (LMICs), early detection of breast cancer, breast cancer screening modalities, breast abnormality and breast cancer detection rates of clinical breast examination (CBE) followed by mammography when breast abnormality is detected, and mammography screening, costing and cost-effectiveness of CBE and mammography.

As for breast cancer screening modalities, previous literatures on the three main breast cancer screening modalities were discussed. These include breast self-examination, clinical breast examination and mammography examination. This chapter also discussed the outcomes of CBE and mammography screening that is breast cancer detection rate. The factors that influenced the outcome of breast cancer screening will also be discussed in the relevant studies mentioned.

Later in this chapter, previous literatures on costing and cost-effectiveness were discussed. In addition to that, activity based costing approach were also discussed as part of the methodology used in this study.

2.2 Epidemiology of Breast Cancer

In general, breast cancer incidence is increasing worldwide. Due to the underlying differences in the accessibility and affordability of screening, diagnostic equipment and availability of effective treatment, breast cancer incidence, and breast cancer survival and mortality rates vary fourfold across different regions in the world (Althuis, Dozier, Anderson, Devesa, & Brinton, 2005). The higher income countries showed higher incidence and mortality rates whereas the lower income countries has higher fatality rates (Ferlay J, 2005). A population-based study over five continents (CONCORD) in

2008 showed that the range of the relative survival at 5 years were higher in countries such as North America, Sweden, Japan, Finland and Australia where there were 80% or more survived as compared to Brazil and Slovakia with less than 60% survival rate while in Brazil the survival rate is below 40% (Coleman et al., 2008). There is also disparity in long term mortality trends where in some countries mortality rising in parallel with incidence while in others mortality declines despite the rising incidence which could be attributable to the effect of earlier detection and effective treatment (Robert A. Smith, 2006).

There is evidence suggesting the growing burden of breast cancer in limited-resource countries where late presentation of breast cancer is more common and need adaptive strategies to improve the prognosis of the disease (Robert A. Smith, 2006). In Asia particularly the rate is increasing at a more rapid rate as compared to the western countries possibly related to the changing diet and lifestyles (Cheng Har Yip, 2009). At least half of the women in limited resource countries have advanced or metastatic breast cancer at the time of diagnosis and by reducing the stage at diagnosis will result in overall benefit in terms of both survival and costs (Anderson et al., 2003). Early detection of breast cancer strategies should focus on cost-effective approaches depending on the availability of resources (Anderson et al., 2003).

The WHO stratifies countries according to three levels of resources that is low-resource, medium-resource and high-resource countries by defining three scenarios based on the national economic status and healthcare organization (World Health Organization, 2002). Countries with low- and medium-level resource can also be collectively called "countries with limited resources" (Anderson et al., 2003). According to the WHO, in low-resource settings, low cost and effective community approaches should be implemented in the first phase to promote early detection of one or two priority detectable tumours while in a medium resource setting this is done for all priority detectable tumours (World Health Organization, 2002). Therefore, it is essential to implement early detection methods that has sufficient evidence on efficacy and cost-effectiveness as healthcare costs are scarce (World Health Organization, 2002). The implementation of a more advanced early detection method can be carried out as and when the resources are available.

There are few factors that correlate with the outcome of breast cancer in low- and middle-income countries (LMICs) that are; cancers are detected at early stages, newly detected cancers can be diagnosed correctly, and appropriately selected multi-modality treatment can be provided properly in a timely fashion (Anderson et al., 2008). It is well established that breast cancer mortality can be reduced by detecting breast cancer at earlier stages. Important steps for early detection of breast cancer for LMICs that were identified are programs to promote breast self-awareness and clinical breast examination, and resource-adapted mammographic screening (Anderson et al., 2008).

2.3 Early detection of breast cancer

Screening is defined as tests and exams used to find a disease, such as cancer, in people who do not have the disease while early detection means to be able to diagnose breast cancer earlier than otherwise might have occurred using an approach. This means that the goal of screening is to detect cancers before that cause symptoms (American Cancer Society, 2012). Due to the growing burden of breast cancer in the less developed nations, the Early Detection and Access to Care Panel of the Breast Health Global Initiative (BHGI) recommended certain interventions and levels of service for early detection of breast cancer according to the level of health care resources in any country (Table 2.1) (Robert A. Smith, 2006).

Table 2.1: Resource Allocation for Early Detection and Access to Care (Robert A. Smith, 2006)

Level of resources	Detection method(s)	Evaluation goal
Basic	Breast health awareness (education ± self –examination) Clinical breast examination (clinical education)	Baseline assessment and repeated survey
Limited	Targeted outreach/education encouraging CBE for at-risk groups Diagnostic ultrasound ± diagnostic mammography	Down staging of symptomatic disease
Enhanced	Diagnostic mammography Opportunistic mammography screening	Opportunistic screening of asymptomatic patients
Maximal	Population-based mammographic screening Other imaging technologies as appropriate: high-risk groups, unique imaging challenges	Population-based screening of asymptomatic screening

Currently, Malaysia is practicing opportunistic screening for clinical breast examinations, opportunistic mammography screening for asymptomatic women with risk factors and also offering diagnostic mammography screening for women with abnormal breast findings or symptoms. According to the level of resources (table 2.1), Malaysia is ranked in the enhanced level of resources group. There were plans previously to consider population based mammography screening for women in the general population. However, due to the limited health care resources, this programme was not feasible to be implemented. Therefore, this study aimed to determine the cost and outcome of the current breast cancer screening programme that is clinical breast examination followed by mammography when breast abnormality is detected, and mammography screening for women with breast cancer risk factors.

The effectiveness and efficiency of any of a breast screening modality must be considered by taking into account the population needs and resource availability. With the positive findings of breast cancer screening in the developed countries, it is hoped that Asia Pacific countries may benefit from population screening (S.M. Tan, 2007). Among the fundamental principles of a successful screening programme are the target disease being a common form of cancer which has high morbidity and mortality, availability of effective treatment and the test procedure should be acceptable, safe, and relatively inexpensive (World Health Organization, 2002). In an ideal situation a screening test should be one that is simple, inexpensive and effective (Mittra, Baum, Thornton, & Houghton, 2000).

Generally in previous studies that were done, it was demonstrated that the participation rate is higher for clinical breast examination as compared to mammography breast screening. In a population based study in Philippines, 92% participated in the CBE screening programme but the programme failed after one year because only 35% of the women with detected lump completed the diagnostic test (Paola Pisani, 2006). (Paola Pisani, 2006). The mammography screening however has a lower participation rate where population based studies in Singapore and United States only covers around 42% of the population (Eng-Hen Ng, 2000; Janet K Bobo, 2000). Therefore, for a breast cancer screening program to be successful would need good screening coverage among the target group.

2.4 Breast screening modalities

The basis for breast cancer screening is to detect breast cancer before they become palpable while early breast cancer detection is the application of a strategy to detect palpable or non-palpable breast cancer which results in earlier diagnosis of breast cancer that otherwise would have occurred (Smith et al., 2003). Breast cancer is a progressive disease that when detected at a smaller size (<15mm) and lymph node negative could result in better prognosis, survival and also reduce the need for radical treatment (Tabar, Duffy, Vitak, Chen, & Prevost, 1999). The three most common breast screening modalities are breast self-examination, clinical breast examination and mammography screening.

2.4.1 Breast-self Examination

Breast self-examination (BSE) is the most practical and easy to implement breast screening method among women. However, its use has been debated by researchers and clinicians. Due to lack of evidence, the United States Preventive Services Task Force (USPSTF) in its breast cancer screening guidelines (2002) concluded that there was insufficient evidence to recommend for or against BSE practice (U.S Preventive Services Task Force, 2002). This finding was supported by the Cochrane Review on breast self-examination which includes two large population-based trials (388,535) in Russia and Shanghai that compared breast self-examination and no screening which showed that there was no significant difference in breast cancer mortality between the groups but instead increased harm to women screened by BSE (Kosters & Gotzsche, 2003). There was an increase in number of benign lesions detected and biopsies performed in the screening arm. However, a study by Maznah Dahlui et al. (2011) suggested that BSE is still relevant. The study showed that 87% of those women whom were found to have breast abnormalities from having done BSE, do go to the health facilities for further check-ups to confirm their findings (Dahlui, Ng, Al-Sadat, Ismail, & Bulgiba, 2011). Currently in Malaysia, BSE is taught by nurses in health clinics as part of the breast awareness programme among women but not as a routine examination.

2.4.2 Clinical Breast Examination

The current evidence discouraged routine screening for breast cancer using BSE. Clinical Breast Examination (CBE) on the other hand has a potential role in early detection of breast cancer especially for low- and middle-income countries (LMICs). Clinical breast examination (CBE) has been used as a breast cancer screening modality with or without combination with other breast screening modality. Clinical breast examination is either used as screening for asymptomatic women or diagnostic purposes to evaluate any breast complaints to rule out breast cancer. Moreover, it can also be used to detect interval breast cancers (Baines, 1992). Women who are below 40 years of age with average risk and asymptomatic for breast cancer may also benefit from CBE as mammography is not recommended for this group (Smith et al., 2003). However, there are evidences that supports that there was an improvement in the stage of detection of breast cancer by CBE (Mittra et al., 2010).

Previously, no clinical trial has compared CBE alone with no screening. Some regarded it as unethical since trials has shown that mammography alone reduce breast cancer mortality (Barton, Harris, & Fletcher, 1999). One large population based trial in Philippines which compared clinical breast examination combined with instruction of breast self-examination with no screening were discontinued after the first round due to the poor compliance with follow up whereby only 35% completed diagnostic follow up (Paola Pisani, 2006). Because of this reason, the Cochrane review concluded that screening by clinical breast examination cannot be recommended because no conclusion can be drawn from the trial. Another study in Mumbai in May 1998 was conducted to determine the effectiveness including the effect on mortality reductions and cost-effectiveness of cancer screening for both cervical (using visual inspection of the cervix after application of 4–5% acetic acid) and breast cancers (using CBE screening) (Mittra et al., 2010). This study concluded that VIA significantly reduced cervical cancer mortality among women screened by 31% (Shastri et al., 2014). However, the results of CBE outcome and the cost-effectiveness of these interventions have not yet been reported.

Previous randomised controlled trials in Edinburgh and Greater New York have shown that CBE when used in combination with mammography was associated with lower breast cancer mortality whereby each showed difference of mortality rates by 13% and 25% lower than the control groups respectively (Alexander et al., 1999; Shapiro, 1997). Meta-analyses of screening mammography studies which involved randomised control trials and case-control studies, with or without combination of CBE, demonstrated that there were reduction in the breast cancer mortality in the 50 to 69 years age group by 26% (Kerlikowske, Grady, Rubin, Sandrock, & Ernster, 1995) and among women aged 40-49 by 18% (Hendrick, Smith, Rutledge, & Smart, 1997). According to Miller AB et al. (2001) and Mittra I et al. (2000), there are other studies which suggest that well conducted CBE alone can be as effective as mammography in averting deaths from breast cancer (Miller, To, Baines, & Wall, 2000; Mittra et al., 2000).

In addition to that, CBE was also shown to detect cancers that were not detected by mammography (Alexander et al., 1999; Seidman, Gelb, Silverberg, LaVerda, & Lubera, 1987; Shapiro, 1997). The range of proportions of breast cancers detected by CBE but were missed by mammography was 3.4% in the Edinburgh trial (Roberts et al., 1990) and 45% in the HIP (Health Insurance Plan) study (Shapiro, 1997). However, the mortality is higher in this group compared to those detected by mammography. In another study which is the CNBSS-2 (Canadian National Breast Screening Study-2) that compared combination screening (mammography and CBE) and CBE alone among women aged 50-59 years demonstrated that there was no additional impact on mortality reduction at 7-years and 13-years follow up (Miller, Baines, To, & Wall, 1992; Miller et al., 2000). This leads to suggestion by Indraneel et al. (2000) that CBE may be as effective as mammography in reducing breast cancer mortality as it is more likely to detect potentially lethal breast cancers (Mittra et al., 2000).

However, according to the United States Preventive Services Task Force (USPSTF), clinical breast examination alone is not recommended to be used as a breast cancer screening tool due to the insufficient evidence to support its use and also increasing the likeliness of further clinical investigations including those which are invasive invasive (U.S Preventive Services Task Force, 2002). According to the USPTF, there was also insufficient evidence to show the incremental benefit of adding CBE to mammography (U.S Preventive Services Task Force, 2002). A study by Bancej at el. (2003), in four Canadian breast screening programmes using combination of CBE and mammography involving women aged 50-69 years showed that the rate of small invasive breast cancer detection by CBE was only minimally increased by 2-6% compared to rate of detection by mammography alone (C Bancej, 2003). This suggests that CBE played a limited role in breast cancer detection.

Previous study has also demonstrated that the sensitivity, specificity and the positive predictive value of mammography were superior to clinical breast examination. Clinical breast examination sensitivity was shown in a meta-analysis to be 54% while specificity was at 94% (Barton et al., 1999). However the sensitivity is lower in the community setting ranging from 28% to 36% (Elmore, Armstrong, Lehman, & Fletcher, 2005). This difference could be due to the controlled environment in a clinical trial whereby in a trial the CBE was done in a more stringent way compared to those in the community.

2.4.3 Mammography screening

The two major determinants of survival rates for breast cancer are tumour size and stage at diagnosis where the best prognosis is those with smaller cancers which has not spread to the regional lymph nodes (Feig & Duffy, 2011). Smaller tumours are more likely to be detected by mammography compared to CBE or BSE whereby the mean size of mammography detected tumours were 1.4cm (SD0.6), followed by 2.1cm (SD1.3cm) and 2.7cm (SD1.7, P<0.01) for CBE and BSE respectively (Senie, Lesser, Kinne, & Rosen, 1994). Mammography has been shown to have a higher sensitivity and specificity for detecting breast cancer compared to CBE and BSE.

The effectiveness of mammography has been demonstrated in randomised controlled trials (RCT) and observational studies. Meta-analysis of clinical trials showed that mammography screening reduces breast cancer mortality by 20 to 35% (Fletcher & Elmore, 2003). Due to the limitation of breast cancer screening RCTs, service screening evaluation was done to demonstrate the impact of screening in the community setting (Smith et al., 2003). Few studies have shown that organized screening with high degree of quality assurance and high participation rates has equal or greater breast cancer mortality reductions than those in randomized trials (Smith et al., 2003). Tabar et al. (2001) reported that there were mortality reductions of 63% of those aged 40-69 years who actually went for screening in two Swedish countries (Tabar et al., 2001). Duffy et al. (2002) in a study in seven Swedish counties also demonstrated mortality reduction of between 40%-45% among women screened (Duffy et al., 2002). Similarly in a study in Florence comparing pre- (1985-1985) and during (1990-1996) screening programme also showed that there was 50% breast cancer mortality reduction (Paci et al., 2002).

2.5 Breast Abnormality and Breast Cancer Detection Rate of CBE and Mammography Screening

2.5.1 Clinical breast examination outcome

The effectiveness of clinical breast examination in terms of abnormality detection and breast cancer detection are illustrated in Table 1.3 below. Few studies including randomized controlled trials and observational studies have reported the abnormality detection rate by CBE. These studies showed that the range of breast abnormality detection by clinical breast examination (CBE) lies between 0.46% in Mumbai and 11.7% in Cairo (Mittra et al., 2010; S Boulos, 2005). The abnormality detection rate was slightly higher in high income countries (HICs) and lower in the low- and middle-income countries (LMICs) with the exception of the study done in Cairo.

Generally, the range of abnormality detection rate in higher resource countries is between 0.8% in New York to 11.2% in the Canadian National Breast Screening Study 2 (CNBSS2). The higher detection rate was seen in a randomized controlled trial while lower abnormality detection rate was seen in observational studies. In the CNBSS2 trial, CBE was done according to the breast examination protocol by trained nurses or a physician (Baines, Miller, & Bassett, 1989). However, in one of the observational studies in Canada showed that even though it has a lower CBE abnormality detection rate (6.9%) than in clinical trials, it has higher breast cancer detection rate (0.5%) compared to 0.3% cancer detected in the CNBSS2 trial. Bobo et al. (2000) in this large scale observational study, showed that CBE performed in the community setting can detect breast cancers as effective as those performed in the clinical trials whereby the sensitivity and specificity CBE was 58.8% and 93.4% respectively which is similarly seen in clinical trials (Janet K Bobo, 2000). This is supported by Barton et al. (1999), which in their meta-analysis of pooled trial data showed that the CBE sensitivity was at 54% while specificity was 94% (Barton et al., 1999).

Comparing the breast cancer detection rates by CBE in high income countries, the rates ranged from 0.02% to 0.5%. Generally, cancer detection rates are higher in the clinical trial being compared to observational studies except for the large observational study reported by Bobo et al. (2000) as mentioned above.

In contrast, in the low- and middle-income countries (LMICs), the range of abnormality detection was lowest in Mumbai (0.46%) and highest in Cairo (11.7%) which is comparable to the observational study in Canada (11.2%). This high abnormality detection rate in Cairo could be attributed to the high prevalence of advanced stage of breast cancer at presentation due to delay of early palpable breast cancer in seeking medical attention (S Boulos, 2005). This is also true for another pilot study in rural Egypt having a CBE abnormality detection rate of 3.2% with mean tumour size of 1.3 cm (Denewer et al., 2010). In both studies the clinical breast examination was done by doctors and surgeons respectively.

Lower CBE abnormality detection rate was seen in other LMICs such as those seen in a population based randomized controlled trial (RCT) in Phillipines (0.04%) (Paola Pisani, 2006) and two cluster RCTs in Kerala (0.06%) (Sankaranarayanan et al., 2011) and Mumbai (0.04%), India (Mittra et al., 2010). The clinical breast examinations were done by trained nurses or midwives in Philippines and trained primary health workers recruited among women with 10th grade (in Mumbai) or those with a bachelor's degree (in Kerala). This may imply that with proper training, CBE performed by trained primary health workers could achieve similar results as those performed by nurses and is practical in countries where there are shortages of healthcare workers to conduct CBE screening. Although the CBE abnormality detection rate is lower in LMICs, the sensitivity and specificity of CBE was similar to those reported in clinical trials for Kerala being 51.7% and 94.3% respectively but lower sensitivity was reported for the

Philippine trial that is 25.6% (Paola Pisani, 2006; Sankaranarayanan et al., 2011). However, the positive predictive values (PPV) were similar in both studies that were 1% (Paola Pisani, 2006; Sankaranarayanan et al., 2011). Therefore, in a country with scarce healthcare resource, CBE is suggested as the more appropriate approach for breast cancer screening compared to mammography screening (Mittra et al., 2000).

Poor or low compliance to investigation is an important issue that needs to be addressed in the LMIC settings as only half of those with positive CBE screen in the Kerala trial went for further investigation (Sankaranarayanan et al., 2011) while only 35% of women in the Philippine trial completed diagnostic work out (Paola Pisani, 2006). In the latter, despite home visits, more than 40% among women with positive CBE findings refuse further diagnostic investigations (Paola Pisani, 2006). However, higher compliance rate to diagnostic investigations was shown in the Mumbai trial where the rate was 68%, 70.6% and 78.06% during the first, second and third screen (Mittra et al., 2010). In the Mumbai trial, the intervention arm consisted of CBE together with cervical cancer screening by visual inspection of the cervix after applying 4% acetic acid (VIA) and health education while the control arm had health education only. The increase in compliance rate to diagnostic investigation in the Mumbai trial could be attributed to the combination of CBE with other health screening such as cervical cancer screening and also health education given to participants. In a limited resource country with high incidence of breast and cervical cancer, this approach could benefit women even more in terms of improving compliance rate to diagnostic investigation.

Looking from the perspective of stage of diagnosis, the trial in Philippines showed no significant difference in the stage of presentation of breast cancer between the screened and the control group. However, the disease staging at diagnosis showed 70%

of breast cancers were detected in early stages while the remaining 30% were detected in the late stages (Mittra et al., 2010).

In Taiwan, mass breast cancer screening programs showed that out of 896,596 women screened by CBE between 1999 and 2001, about 6.48% were suspected to have breast cancer and referred for further investigation, and while about 0.1% (0.97 per 1000 women screened) were diagnosed to have breast cancer (Yen et al., 2016). The breast cancer status was obtained by linking the cohort with the national breast cancer registry. Table 2.2 showed the percentages of breast abnormality and breast cancers detected by clinical breast examination (CBE) from other studies.

Table 2.2: Percentages of breast abnormality and breast cancers detected by clinical breast examination (CBE) from other studies

Place of study	Year	Sample size	Study design	Abnormal CBE (%)	Breast cancer (%)
Canada (C Bancej, 2003) (CBCSD)	1996-1998	300,303	Observational	3.5 (1st screen)	0.03 (1st screen)
U.S (NBCCEDP) (Janet K Bobo, 2000)	1995-1998	752, 081	Observational	6.9	0.5
Japan (Honjo et al., 2007)	1999-2000	25,974 (CBE & USG) 3455 (plus MG)	Observational	4.6	Not reported
New York (Kimberly N. Feigin, 2006)	1197-1998 & 2001-2002	60,027	Observational	0.8	0.02
CNBSS2 (Miller et al., 1992)	1980-1985	39 405	RCT	11.2 (1st screen)	0.3
Egypt (Denewer et al., 2010)	Not stated	5900	Pilot study	3.2	0.3
Cairo (S Boulos, 2005)	2005	4116	Pilot study	11.7	0.8
Philippines (Paola Pisani, 2006)	1996-1997	138,392	RCT (population-based)	2.5	0.04*
Kerala, India (Sankaranarayanan et al., 2011)	2006	115 652	Cluster RCT	5.7	0.06
Mumbai, India (Mittra et al., 2010)	1998	151538	Cluster RCT	0.46	0.04
Andhra Pradesh, India (Reddy, Ninan, Tabar, & Bevers, 2012)	2010	68	Observational	<40yrs- 32.6 >40yrs- 48	Not clear
Taiwan Yen et al. (2016)	2014	896,596	Observational	-	0.097

* Cancer cases detected among CBE screen positive women

2.5.2 Mammography screening outcome

In this section, the effectiveness of screening mammography in terms of the rate of abnormal mammogram and rate of breast cancer detected by mammogram shall be discussed. Until today, the only single modality that is proven to show improvement in breast cancer mortality is through screening mammography, which has been proven from prospective randomized trial (Benjamin O. Anderson, 2008). Mammography is still regarded as the gold standard for early breast cancer detection as compared to CBE and is used extensively as breast screening modality.

It was shown from studies in few countries that the cancer detection rate was higher for women who were screened by mammography as compared to those who were screened by clinical breast examination (CBE) alone except for Cairo as shown in table 2.2 and table 2.3. For example in Philippines and Canada the detection rate for breast cancer by CBE were 0.4 per 1000 populations screened and 0.3 per 1000 populations screened respectively (C Bancej, 2003; Paola Pisani, 2006). Whereas for screening mammography, the detection rate for breast cancer is higher using this modality whereby the rate was 4.8 per 1000 women screened in Singapore, 4.1 per 1000 women screened in Canada, 2.9 per 1000 women screened in Japan and 0.5 per 1000 women screened in New York as shown in table 2.3 (C Bancej, 2003; Feigin, Keating, Telford, & Cohen, 2006; Honjo et al., 2007; Ng et al., 1998). The latter showed the lowest rate due to the limitation of the study whereby 23% of women whom requires conversion to diagnostic examinations were lost to follow up (Feigin et al., 2006). Another study in Hong Kong which studied opportunistic breast screening by mammography also has similar results of breast cancer detection rates of 0.5% of women screened (5.0 per 1000 women screened) (Lui et al., 2007). A more recent observational study on mass breast cancer screening programmes in Taiwan by Yen et al. (2016), showed that higher recall rate that was 10.21% (calculated as the number of cases with BI-RADS scores of 0, 4 or

5 divided by number of participants) and breast cancer detection rate (4.86%) among 594,345 women screened by universal biennial mammography screening. Lower recall rate (8.7%) and breast cancer detection rate (2.8%) were reported for women screened by risk-based biennial mammography screening (Yen et al., 2016). Table 2.3 showed the abnormality and breast cancer detection rates by mammography screening.

Table 2.3: Abnormality rates and breast cancer detection rates by mammography screening

Place of study	Year	Sample size	Methods	Abnormal MMG (%)	Breast cancer (%)
Singapore (Eng-Hen Ng, 2000)	1995	166,600	RCT	-	0.48
Canada (C Bancej, 2003) (CBCSD)	1996-1998	300,303	Observational study	0.4	0.41 (for 1st screen)
Japan (Honjo et al., 2007)	1999-2000	3,453	Observational study	8.1	0.29
New York (Kimberly N. Feigin, 2006)	1197-1998 & 2001-2002	60,027	Observational	-	0.05
Hong Kong (Lui et al., 2007)	1998-2002	46,637	Observational	-	0.5
Taiwan Yen et al. (2016)	2014	298,334	Observational -risk-based biennial mammography	8.7	2.8
Taiwan Yen et al. (2016)	2014	594,345	Observational -universal biennial mammography	10.21	4.86

2.6 Cost Analysis

2.6.1 Costing terms

Cost is defined as a resource sacrificed or forgone to achieve a specific objective (Charles T. Horngren, 2012). Costs can be considered as an actual cost which is the cost incurred (a historical or past cost), or as a budgeted cost, which is a predicted or forecasted cost (a future cost) (Charles T. Horngren, 2012). Whenever a measurement of cost is desired for something, this is known as a cost object.

According to Horngren et al. (2012), costs may also be divided into direct cost and indirect cost. There are two methods to assign these costs to cost objects. Direct cost is related to the particular cost object and can be traced to it in an economically feasible (cost-effective) way. Cost tracing is a terminology used to describe the direct costs assigned to particular cost object. Examples of direct costs used in this study were cost of equipment used, cost of consumables and cost of staff salary.

Indirect costs on the other hand are related to the particular cost object but cannot be traced to it in an economically feasible (cost-effective) way (Charles T. Horngren, 2012). Indirect costs used in this study included the cost of utilities such as electricity, water and telephone bills that were used to run breast cancer screening activities in the relevant health facility. Horngren et. al. (2012) also defined the term cost allocation which is used to describe the assignment of indirect costs to the cost objects while cost assignment refers to both tracing direct costs to a cost object and also allocating the indirect costs of a cost object.

Opportunity cost is defined as the contribution to operating income that is forgone by not using a limited resource in its next-best alternative use (Charles T. Horngren, 2012). For example, the cost of a caregiver accompanying a patient to the hospital is not just the costs of transportation and meals but also the income loss (opportunity cost) for having to take time off from work. However, in this study, opportunity cost was not measured as this information was not available in the secondary data collected.

2.6.2 Costing methods

There are two basic types of costing systems in assigning costs to products or services namely job-costing system and process-costing system. The former is where the cost object is a unit or multiple units of a distinct product or service called a job which accumulates costs separately for each product or service. In contrast, in process-costing system the cost object is masses of identical or similar units of a product or service. The unit cost per product or service is obtained by dividing the total costs of producing an identical or similar products or service by the total number of unit product or service produced (Horngren, Datar, & Rajan, 2012). This study will focus on job costing system.

The general approach to job costing involved seven steps that are; firstly, identify the job that is the chosen cost object. Secondly, identify the direct costs of the job. Thirdly, select the cost allocation bases to use for all allocating indirect costs to the job. Fourthly, identify the indirect costs associated with each cost-allocation base. The fifth and sixth steps are the rate per unit of each cost-allocation base used to allocate indirect costs to the job, and compute the indirect costs allocated to the job. Finally, compute the total cost of the job by adding all direct and indirect costs assigned to the job (Horngren et al., 2012).

2.6.3 Costing in health services

Cost accounting is important in decision-making process in many sectors including the health sector. Comparative costs of alternative interventions in medicine and health are common to all forms of economic evaluation. According to Gujral et al. (2010), cost accounting is used in healthcare organizations to estimate the unit cost of services they provide (Gujral et al., 2010). It is essential too that the viewpoint of the cost is specified before an economic evaluation study takes place which can be either from the viewpoint of Ministry of Health, patient, societal, employer, agency that provides the programme and others (Drummond M.F, Sculpher M. J, Torrance G. W, O'Brien B.J, & Stoddart G.L, 1987).

The approach to costing in health care services can either be macro costing or top down or micro costing or bottom up. According to Drummond et al. (1987), there are two types of costs mainly capital costs and overhead costs. For capital cost, one of the best methods to measure is by annuitize the cost over the useful life of the asset while for overhead costs there are a number of methods that can be used depending on the likely importance of overhead cost. This includes direct allocation of overhead costs to the final cost centres (Drummond M.F et al., 1987).

2.6.4 Activity based costing

Traditional cost accounting takes account of direct material and labour cost that are directly linked to the product. Activity based costing (ABC) identifies cost pools and activity centers in an organization where costs were assigned to cost drivers based on the number of each activity used. These activities may occur at several levels that are unit level, batch level, product level and facility level which vary in the form of inputs (Derya Eren Akyol, 2007).

According to Drury (2006), activity based costing has several steps which are; identifying the major activities, assigning costs to cost pools or cost centres for each activity, determining the cost driver for each activity, and assigning the costs of activities to products (Drury, 2006). Other publication regarding the ABC application in health care by Popesko (2013) also discussed similar steps in ABC as mentioned above by Drury (Popesko, 2013) In addition to that, the application of ABC in hospital inpatient care services was also reported in previous literatures (Lin et al., 2007; Udpa, 1996).

There were examples of activity-based costing approaches in health care services that were shown in previous studies such as in haematopathology laboratory in India (Gujral et al., 2010), in a heart centre (Ridderstolpe et al., 2002), in the chest x-ray service (Atif, Sulaiman, Shafie, Saleem, & Ahmad, 2012) and in the outpatient department (Demeere, Stouthuysen, & Roodhooft, 2009). The advantages of using activity based-costing were discussed by other authors in previous publications which states that ABC system strive for cost-efficiency (Cardinaels, Roodhooft, & van Herck, 2004; Horngren et al., 2012).

However, despites its superiority against traditional costing, ABC has disadvantages that renders users in adapting to its system mainly due to the high costs and time consuming. Cokins (2001) states that the disadvantages of ABC lies in the high complexity of the system or large amount of non-financial data requirements (Cokins, 2001).

2.7 Cost Effectiveness Analysis of CBE and Mammography

Previously, cost-effectiveness analysis was done to compare different screening tools for early detection of breast cancer. This is especially essential when a country is in the process for decision making to implement health policies regarding breast cancer screening especially for population based screening. This issue is more important in limited resource countries where other health priorities are also as important or more important such as providing basic health care needs and in the prevention and control activities for infectious disease.

2.7.1 CEA of breast cancer screening in the developed countries

Cost-effectiveness studies on breast cancer screening were mostly done in the developed nation. Most of these studies were based on mammography screening. The results of mammography cost-effectiveness studies varies across the developed nation being more cost-effective in the Europe compared to the United States where the cost-effectiveness of mammography screening ranged from US$3000 to US10,000 per YLS and US20,000 to 100,000 per YLS respectively (Brown ML, 2006). These studies aimed at screening women between the ages of 45 to 69 years of age in the developed countries.

A retrospective observational study in United States showed that the cost of clinical breast examination (CBE) was $ 122, 598 per cancer detected solely with positive CBE (i.e. which was not detected by mammography). Breast cancer detected by CBE represents 3% of the sample population studied (n=60,027 population) (Kimberly N. Feigin, 2006).

2.7.2 CEA of Clinical Breast Examination and Mammography screening in the developing countries

A recent systematic review by Zelle et al. (2013) on studies involving economic analysis of breast cancer control in low- and middle-income countries reported that the economic evidence are limited and generally of poor quality (Zelle & Baltussen, 2013). Among these studies, there were only ten that evaluated on breast cancer screening in combination with treatment, out of which nine assessed mammography screening while another three assessed CBE.

In India for example, the estimated cost-effectiveness of CBE screening for breast cancer is comparable to the cost effectiveness of mammography in developed countries (Quirine Lamberts Okonkwo, 2008). The CEA study in India that was done by

Okonkwo et al. (2008), used the MISCAN (micro simulation screening analysis model) model was able to demonstrate that the estimated mortality reduction was highest for women between the ages of 40-60 years (23.3%) screened by annual CBE and that the efficacy of annual CBE for this age group was predicted to be similar to biennial mammography screening for reducing cancer deaths (Quirine Lamberts Okonkwo, 2008). Biennial mammography for the 40-60 years age group showed mortality reduction of 25.8%, costing at approximately 50 percent higher cost. The cost per life year gained for biennial mammography were reported as Int.$3,468 while annual CBE costs Int.$1,913. The calculated overall costs for a single screening test for mammography and CBE are Int.$13.23 and Int.$3.96 respectively which means that cost of one mammography examination is 3.34 times higher than cost for CBE (Quirine Lamberts Okonkwo, 2008).

Similarly, Brown et al. (2006) also reported in a cost-effectiveness study using microsimulation model that at 36 percent less cost, annual CBE could save almost the same number of life years saved in India compared to biennial mammography (Brown ML, 2006). The cost per life year saved is US$ 522 (in 2001 value) and US$ 1,709 (in 2001 value) for annual CBE and biennial mammography, ages 50-70, respectively (Brown ML, 2006). These two microsimulation models that were done for India by Okonkwo et al., (2008) and Brown et al., (2006) favours CBE to mammography in terms of cost-effectiveness.

Another cost-effectiveness study in Mexico using microsimulation model, showed that nationwide population based screening with CBE and mammography at different age group together with the norm of breast cancer treatment was potentially cost-effective with an incremental cost effectiveness ratio of Int.$22,000 per disability-adjusted life years (DALY) (Salomon et al., 2012). The screening comprised of annual

CBE for women more than 25 years of age, annual mammography for more than 50 years of age and biennial mammography for those aged more than 40 to 49 years of age.

Another study in China studied the effectiveness of mammography by measuring the DALYs averted and the associated screening and treatment costs. The study showed that the opportunistic screening for breast cancer with mammogram was inefficient and that mass screening could increase health benefits and reduced costs (Pauline P. S. Woo, 2007).

This difference (reported cost of cancer detection) might have been influenced by many factors since the number of cancer detected is the product of screening sensitivity, incidence of breast cancer in the eligible population, and percentage of women screened. Screening programme requires large resources and budgets which needs careful consideration before being implemented (Corbex, Burton, & Sancho-Garnier, 2012).

2.8 Summary of Literature Review

The literature review showed that different countries used different methods and approaches for breast cancer screening depending on the level of health care resources that is available in the country. However, from these literatures, there were few factors that were discussed which can influence the outcome of a breast cancer screening programme in a country as illustrated in Figure 2.1 below. Among the factors that can influence the breast cancer screening outcomes in terms of breast abnormality and breast cancer detection are the types of breast cancer screening modality used, the socio-demographic characteristics of the population screened, the presence or absence of breast cancer risk factors, the epidemiology of breast cancer in the population screened, the characteristics of the examiner, the setting or approach of the breast cancer screening activity, the knowledge, attitude and practice of the population to be screened, and also compliance to diagnostic investigation and follow up.

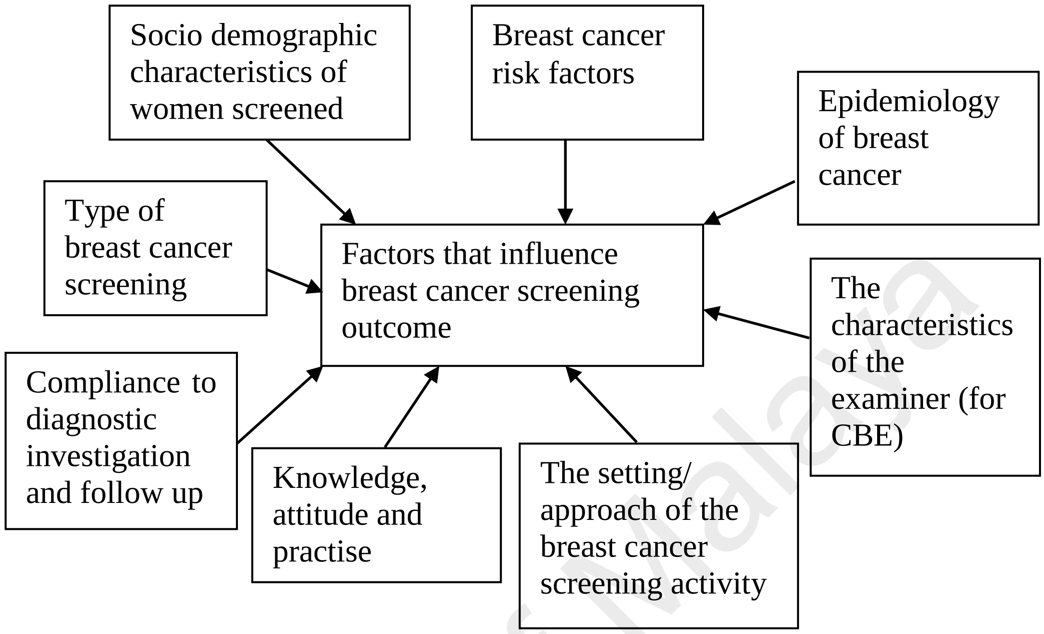

Figure 2.1: Factors that influence the breast cancer screening outcome

This study measured the cost and outcome of two breast cancer screening modalities namely CBE followed by mammography if abnormality is detected, and mammography screening among women with risk factors for breast cancer. To determine the cost of each breast cancer screening modality, the cost incurred for each screening modality were calculated by identifying the activities and the cost items involved in the screening activities. The conceptual framework for the economic analysis and outcome assessment of the two screening approaches that are clinical breast examination followed by mammography when breast abnormality is detected, and mammography only of women with risk factors is as shown in Figure 2.2.

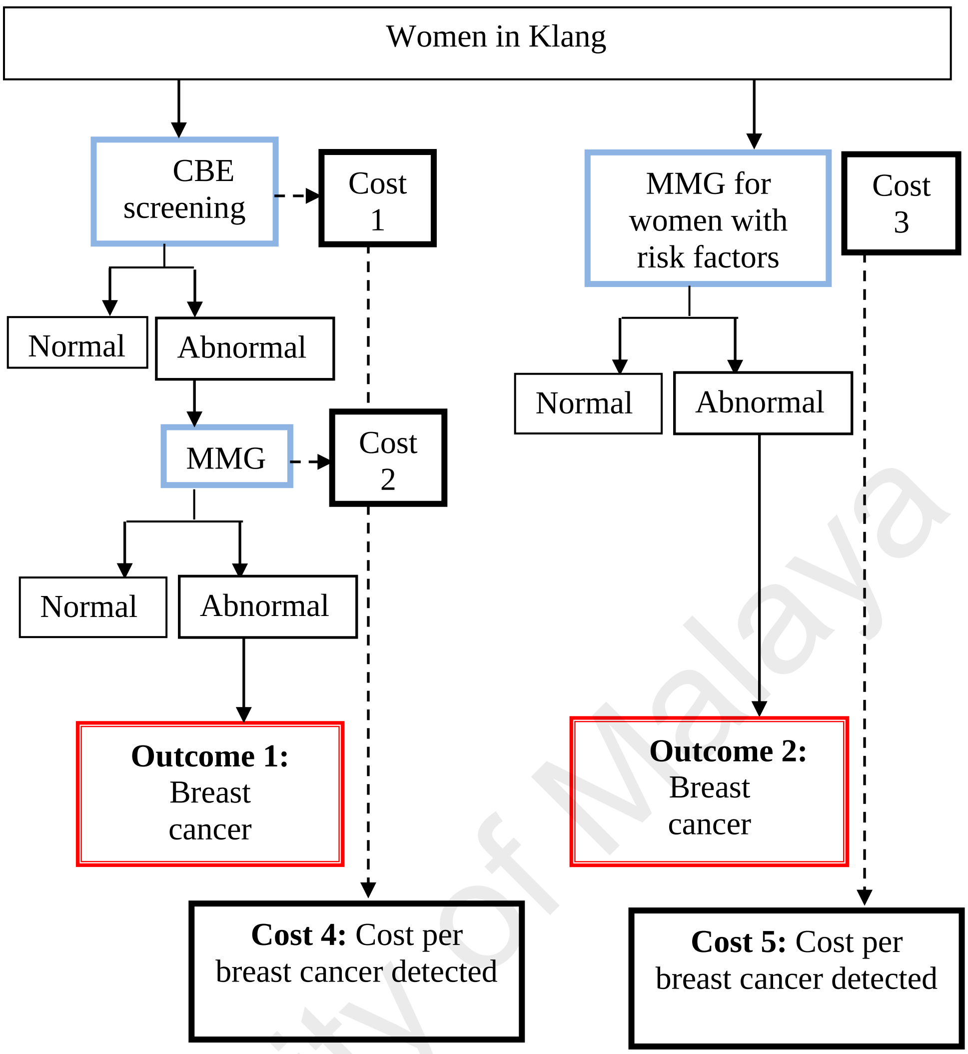

Figure 2.2: Conceptual Framework of the study

This study aimed to compare the cost and outcome of two breast cancer screening approaches namely, CBE followed by mammogram if abnormality is detected, and mammography screening among women in Klang. To calculate the outcome of CBE followed by mammogram if abnormality is detected, the breast abnormality detection rate among women who participated in CBE screening were obtained from the medical records in the health clinics. The breast cancer outcomes were obtained by matching the identity of women with abnormal breast findings by CBE with the State Breast Cancer Registry (Outcome 1). As for the outcome assessment for mammography screening among women with risk factors, abnormal mammography findings were obtained from the mammogram reports for those who participated in the mammography examination in the hospital. The breast cancer outcomes among women with abnormal mammography findings were obtained by matching the identity of these women with the State Breast Cancer Registry (Outcome 2).

Costs were calculated for all breast cancer screening approaches that were CBE followed by mammogram if abnormality is detected, and mammography screening among women with risk factors. The total costs included cost of equipment and furniture, cost of operation and maintenance, cost of utilities, cost of consumables and cost of staff salary. Total cost for CBE followed by mammogram if abnormality is detected (Cost 1 and Cost 2), and mammography screening among women with risk factors (Cost 3) were calculated by adding the different cost items involved in each activity. Subsequently, the cost per breast cancer detected was calculated for CBE followed by mammography if abnormality is detected (Cost 4) and mammography screening among women with risk factors (Cost 5). These were obtained by dividing the total cost of breast cancer screening with the number of outcome respectively.

2.9 Research Questions

1. What is the cost of clinical breast examination and cost of mammography screening?
   a. Cost per clinical breast examination?
   b. Cost per mammography screening?
2. What are the factors that affect the cost of clinical breast examination and cost of mammography screening?

3. What are the characteristics of women screened by clinical breast examination followed by mammography when breast abnormality is detected?
4. What are the detection rates for abnormal breast findings by CBE followed by mammography if abnormality is detected?
5. What are the breast cancer detection rates and the stage of breast cancer detected by CBE followed by mammography if abnormality is detected?
6. What are the characteristics of participants screened by mammography among women with risk factors for breast cancer?
7. What are the detection rates of abnormal mammography screening among women with risk factors?
8. What are the breast cancer detection rates and the stage of breast cancer detected by mammography among women with risk factors?
9. What is the cost per breast cancer detected by CBE followed by mammography when breast abnormality is detected, and by mammography among women with risk factors?
10. How much is the cost needed to screen women in the general population in Malaysia according to the target set by the Ministry of Health, Malaysia by clinical breast examination and by mammography screening for ten years period?

2.10 Objectives of study

2.10.1 General Objective

The compare the cost and outcome of clinical breast examination (CBE) followed by mammography when abnormality is detected, and mammography screening among women with risk factors in Klang.

2.10.2 Specific Objectives

1. To determine the cost of clinical breast examination and cost of mammography screening:
    a. Cost per clinical breast examination (CBE).
    b. Cost per mammography screening.
2. To determine the cost of CBE followed by mammography when breast abnormality is detected among women screened.
3. To determine the outcome of clinical breast examination followed by mammography when breast abnormality is detected, among women screened in the government health facilities in Klang:
    a. Socio-demographic and reproductive characteristics for CBE participants.
    b. Abnormality detection by CBE.
    c. Breast cancer detection by CBE followed by mammography when breast abnormality is detected.
4. To determine the outcome of mammography screening among women with risk factors who came to Hospital Tengku Ampuan Rahimah, Klang:
    a. Socio-demographic characteristics of mammography participants.
    b. Breast cancer risk factors and other characteristics of participants.
    c. Abnormality detection by mammography among women with risk factors.
    d. Breast cancer detection by mammography among women with risk factors.
5. To calculate cost per breast cancer detected by:
    a. CBE followed by mammography when breast abnormality is detected.
    b. Mammography among women with risk factors.

6. To calculate cost projections to screen women in the general population in Malaysia according to the target set by the Ministry of Health, Malaysia for ten years period (2015 to 2024) by:
    a. Clinical breast examination
    b. Mammography screening

CHAPTER 3: METHODOLOGY

3.1 Introduction

This chapter describes the economic analysis of breast cancer screening by clinical breast examination (CBE) followed by mammography when breast abnormality is detected, and mammography screening among women with risk factors. The costing analysis were conducted from the provider's perspective using the top down and activity based costing approach to determine the cost per CBE and cost per mammography examination.

As for the outcome of breast cancer screening by CBE followed by mammography when breast abnormality is detected, the data was obtained from registry books and medical records in eight health clinics in Klang. For mammography screening among women with risk factors, outcome data were obtained from medical registry and medical records from the Radiology Department of a general hospital in Klang. Subsequently, the calculations for cost per breast cancer detected by the two breast cancer screening approaches were demonstrated. Finally, cost projections were calculated if we were to screen women in the general population in Malaysia by CBE and mammography screening for ten year period (discussed in Chapter 6).

3.2 Costing analysis

3.2.1 Cost analysis of CBE

Cost analysis for clinical breast examination activity was done from the provider's perspective which is the Ministry of Health (MOH) Malaysia. The method of costing used the activity based costing approach which involved several steps. These include firstly, identifying the major activities, secondly, assigning costs to cost pools or cost centres for each activity, thirdly, determining the cost driver for each activity, and fourthly, assigning the costs of activities to products.

Data on costs incurred in each and every step in the activity were collected. The costs included two types of costs that were the capital cost and recurrent cost. The former included the cost of furniture and equipment used in conducting clinical breast examination. However, cost of building was not included in the capital costs analysis as all health clinic buildings were more than 20 years old. Moreover, the clinical breast examination is one of the many other health services offered in the maternal and child health clinics and represents a small portion of the MCH clinic activities.

Recurrent costs were divided into direct and indirect costs. Direct recurrent cost included staff salary while indirect recurrent costs were the bills for utilities, communication, operation and maintenance. Costs of consumables were not included in the cost analysis as the clinical breast examination procedure did not require significant usage of any consumables. In addition, CBE activity only involved clinical palpation of the breasts and recording the findings into registry books and patient records. Cost per CBE screening was obtained by adding all the capital and recurrent costs involved in CBE screening and was presented as cost per CBE screening. The details of cost analysis of CBE are further explained in section 3.2.1.1.

3.2.1.1 Data collection for Costing of CBE

Costing data were obtained from few main sources. They were the administration office and the financial unit of the Klang District Health Office, and the assets and inventories documents that were kept in the respective Maternal and Child Health (MCH) clinics and in the Klang District Health Office. These cost data covered most of the capital and recurrent costs. The time motion study was also carried out as part of the activity based costing to measure the staff contact time per patient to enable the calculation of cost of staff salary per patient.

As for the capital costs, data were obtained for all eight health clinics. These included the year at which those buildings started its operation and the land area as well as the building area for all health clinics. However, cost of building was excluded from the capital cost as all of the buildings were more than 20 years old.

Other than cost of building, capital costs also included the cost of equipment and furniture. For cost of equipment and furniture, only those which are present in the Pap smear or CBE room and related to CBE activity were included for cost analysis. These included the examination bed, two steps stool, a pillow, pillow case, couch cover and a mattress or blanket to cover patient, a consultation table, chairs, cabinets to store documents and others. The list of equipment and furniture together with the year of purchase, cost per unit and the number of units were collected for each Pap smear or CBE room in all the eight health clinics which will be explained later in the cost analysis section.

As for the recurrent costs, costs included were utilities and communication, costs of operation and maintenance as well as costs of staff salaries for all the eight health clinics. Cost of utilities included the annual costs of electricity and water usage, while cost of communication was the annual telephone charges of the health clinics. As for the operation and maintenance, the costs included were costs of security and cleaning. Costs were taken for the year of 2009, 2010 and 2011 respectively for the each cost items. However, only costs of 2011 were available from the Klang District Health Office for utilities, communication, cleaning and security. Therefore, costs incurred for the year 2009 and 2010 were estimated by assuming that the costs for these years were the same as the costs for 2011. Adjustments for inflation were done using the Annual Malaysian Inflation Rate from the Department of Statistics Malaysia (Appendix A). The method of cost analysis for each cost item is further discussed in the next section.

Costs of staff salaries included were for staffs that were directly involved with the clinical breast examination activity. Annual salaries for these staffs according to their respective job grades were obtained from the salary unit of the administrative department for the respective years. These were staff nurses (grade 29) and community nurses (grades 24 and 19). This was done to calculate the salary per hour of staff involved. The staff salaries for administration department of Klang District Health Office were not included in the total cost of staff as its contribution to the CBE activity was very minimal as compared to the rest of other activities or services under the district health office.

Activity based costing was used to calculate salary cost per CBE activity. The CBE activity was divided into small job steps. This started from the arrival of the patient at the maternal and child health clinic and ended once the patient leave the clinic as illustrated in Appendix B. A time motion survey was carried out to measure the contact time of staff with the patient in each job step. This was done by observing the CBE activity, recording the relevant staff involved and the time taken for each activity in the data collection form as in Appendix C. The contact time of each staff involved were measured because the nurses also do other tasks other than CBE such as handling child health clinics, immunization and family planning services.

3.2.2 Cost analysis for mammography examination

Cost analysis for mammography activity was done from the provider's perspective which was the Ministry of Health Malaysia. This involved collecting data on costs incurred in each and every step in the activity. These included the capital costs and recurrent costs. The former included the cost on equipment and furniture used in conducting mammography screening. However, cost of building was not included in the capital costs analysis as the hospital building was more than 20 years old. Moreover, the mammography activity was one of the many other health services offered in the hospital.

Recurrent costs included the staff salary, cost of operation and maintenance, utilities and communication. Costs of consumables that were included in the cost analysis were those that were directly related to mammography screening activity. In this study, the cost analysis did not include costs for diagnostic workup such as fine needle aspiration (FNAC) and other biopsies. However, cost of ultrasonography was included as ultrasound of the breast was needed in some cases for confirmation of mammography findings to decide on the Breast Imaging Reporting and Data System (BI-RADS) classification for each case. Cost per mammography examination was calculated by adding the cost items per mammography examination for both capital and recurrent costs involved. The details of cost analysis of mammography examination will be further explained in section 3.2.2.1.

3.2.2.1 Data collection for Costing of Mammography

Costing data were obtained from two main sources namely the administration and financial unit of the Tengku Ampuan Rahimah Hospital (HTAR) for the capital and recurrent costs, and secondly by conducting activity based costing to measure costs related to the mammography activity.

As for the capital costs, data were obtained for the cost of HTAR building. This included the year at which the building started its operation, the land area and the building area. However, as mentioned, the building cost was later excluded due to the old age of the building being more than 20 years.

Other than cost of building, capital costs also included costs of equipment and furniture. For cost of equipment and furniture, only those directly related to mammography activity were included for cost analysis. These included the mammography machine and its accessories, ultrasound machine, examination bed and equipment needed for mammogram reporting.

As for the recurrent costs, costs included were utilities and communication, costs of operation and maintenance, cost of consumables as well as costs of staff salaries for all staff that were directly involved in the mammography activity. Utility costs included annual costs of electricity and water, while communication cost was the annual telephone charges of the mammography unit. These were collected for the year 2008 to 2011. As for the operation and maintenance, the costs included were costs of security and waste management for the same period. The latter were provided by Radicare Sdn. Bhd. administrative office which was located in the HTAR building. The Radicare is an outsourced company that provides non-clinical support services to the healthcare sector in Malaysia including managing hospital maintenance services.

Cost of staff salaries included the salary of staffs who were directly involved with the mammography activity. Annual salaries for these staffs were according to their respective job and job grades which were obtained from the salary unit of the administrative department of HTAR for the respective years. The staff salaries for administration department of Hospital Tengku Ampuan Rahimah, Klang (HTAR) were not included in the total cost of staff as its contribution to the mammography activity was very minimal as compared to the rest of other major activities in the general hospital. Therefore, it was considered insignificant contribution to the mammography screening activity.

A time motion survey was used to measure the patient contact time by each staff in order to calculate the cost of salary per mammography activity using micro-costing approach. The mammography activity was divided into small job steps. This started from the arrival of the patient at the mammography suite and ended once the patient leave the mammogram facility as illustrated in Appendix D. The time spent by each staff with the patient at each job step was measured using a digital clock. Other data included were the job title and the job grades of the staff involved in each job step. This was then recorded in the time motion study data collection form (Appendix E).

3.2.3 Cost analysis for CBE followed by mammography when breast abnormality is detected

The total cost for CBE followed by mammography when breast abnormality is detected, was calculated by adding the total cost to screen 15,279 women by CBE with the total cost of mammography examination for women with abnormal CBE findings. The total cost to screen 15,279 women by CBE was calculated by multiplying cost per CBE with the total number of women screened. Cost of mammography needed for women found to have abnormal CBE findings was obtained by multiplying cost per mammography with the number of women with abnormal CBE findings. Therefore, the total cost to screen 15,279 women by CBE followed by mammography when breast abnormality was then calculated by adding the total cost to screen 15,279 women by CBE with the cost of mammography of women with abnormal CBE findings.

3.3 Methodology for outcome assessment

3.3.1 Outcome assessment of CBE

This study used intermediate outcome for breast cancer screening. There were two outcomes that were measured for clinical breast examination followed by mammography when breast abnormality is detected. These were the number of abnormalities detected by CBE and the number of breast cancer cases detected among women who had abnormal CBE findings. The study design that was used to measure these outcomes was cross sectional study design that was done in the year 2011 looking at the prevalence of abnormal breast findings among women screened by CBE in government health clinics in Klang district from the year 2009 to 2011. These data was extracted retrospectively from the Pap Smear Registry book. Breast cancer status was obtained for women with abnormal CBE findings by matching with the Selangor Breast Cancer Registry.

Usually, CBE were done in an opportunistic manner alongside other health activities such as family planning clinic, Pap smear screening, postnatal clinics, antenatal clinics and outpatient clinics. However, this study only included CBE that were done alongside Pap smear screening. This was because the findings of the clinical breast examination done alongside Pap smear screening were recorded for individual patients into specific registry books, whereas CBE done alongside other activities were not recorded into any registry, instead were captured as aggregated data that were reported monthly at the district level. The entry points for Pap smear screening came from either the outpatient clinics or the maternal and child health clinics.

Clinical breast examinations (CBE) by trained community nurses and staff nurses were routinely offered to women undergoing Pap smear screening. The findings of the CBE either normal or abnormal were recorded into a specific column in the Pap smear registry book. Thus, the number of women with abnormal CBE was extracted from the clinic Pap smear registry book. The breast cancer cases among those with abnormal CBE findings were obtained by linking the abnormal CBE cases with the Selangor State Breast Cancer Registry.

A few assumptions were made for this study in order to calculate the outcome of the clinical breast examination. Firstly, it was assumed that there was no difference in the effectiveness of CBE among the different operators or examiners. This assumption has to be made in view of the unavailability of the information on the CBE examiner or operator who did the CBE. It was assumed that the nurses were trained for CBE according to the Clinical Breast Examination Manual by the Ministry of Health, and the CBE results were recorded correctly in the Pap smear registry books. Another assumption was that, women with abnormal CBE findings went for further investigation including mammography examinations either in a public or private health facility. In practice, women found to have abnormal clinical breast examination findings were referred to the hospital and subsequently followed up by the nurses to ensure that these women went for further investigation. Finally, it was assumed that all confirmed breast cancer cases from public or private hospitals were notified according to the cancer notification policy by the MOH. The State Health Department of Selangor does visits and audits to hospitals in Selangor to check on the compliance of this policy. Data in the Selangor Breast Cancer Registries were compared with the breast cancer cases that were diagnosed in the hospital. The details of methods of data collection for the outcome of CBE will be explained in the subsequent sections below.

3.3.1.1 Study area

The study area was in Klang District, Selangor. In 2010, the Klang City has a total population of 240,016 whereby 10,445 were in the city centre, while the population of Klang District was 842,146 (Klang Municipal Council, 2010). The study centres included the Klang District Health Office, eight government health clinics in Klang and the Selangor Health Office. The eight government health clinics were Klinik Kesihatan Kapar, Klinik Kesihatan Bukit Kuda, Klinik Kesihatan Pulau Indah, Klinik Kesihatan Pulau Ketam, Klinik Kesihatan Pandamaran, Klinik Kesihatan Meru, Klinik Kesihatan Pelabuhan Klang and Klinik Kesihatan Klang/ Botanic.

Klang was one of the two areas chosen by the Ministry of Health for a population based cervical screening pilot project known as '*Sistem Informasi Program Pap Smear'*

(SIPPS) or Pap Smear Programme Information System. In this pilot project which was introduced in 2007, women aged 20-65 were invited through mail for cervical cancer screening and those who participated will be offered clinical breast examination at the same time. This study specifically focused on the clinical breast examination component of those women who participated in the Pap smear screening in the government health clinics.

3.3.1.2 Study population

(a) ***Inclusion criteria for CBE***

According to the health clinic procedure, any women who came for Pap smear screening will be registered in the clinic Pap smear Registry Book. Sampling method used to select CBE cases was universal sampling. Therefore, this study included all women registered in the Pap smear Registry Books in each government health clinic from January 2009 to September 2011 who had Pap smear screening and clinical breast examination done at the same time. This included all women whom were registered for Pap smear whether or not they received any mail invitation for Pap smear screening.

(b) ***Exclusion criteria for CBE***

Women who were diagnosed with breast cancer or cancer at other sites were excluded from this study. In addition to that, those with known breast abnormality that has been investigated or referred before or already under follow up in any health institution whether public or private were also excluded from the study. Women who were registered in the Pap smear book with no documentation of the CBE findings were excluded as this is the main outcome without which analysis is not possible.

3.3.1.3 Sample size estimation for clinical breast examination

For the assessment of clinical breast examination, the data was obtained from the Pap smear registry book. The sample size was calculated using Open Epi Statistical

Software. For clinical breast examination (CBE), the sample size was estimated using data from an observational study done in the United States by Bobo et al. (2000), whereby the breast cancer detection rate was 0.5%. In this large scale observational study involving 752, 081 women screened (National Breast and Cervical Cancer Early Detection Programme (NBCCSP)), CBE data showed that CBE performed in the community setting can detect breast cancers as effective as those performed in the clinical trials whereby the sensitivity and specificity CBE was 58.8% and 93.4% respectively which is similarly seen in clinical trials (Janet K Bobo, 2000). As for the percentage of unexposed to outcome, data from study by Ng et al. (1998) was used that was 0.13% (cancer incidence in the control group) (Ng et al., 1998).

The sample size required was 8,248 samples for CBE screening to achieve the precision of 0.05 (5%) and the power of 80% of the study. However, universal sampling was used in this study and a total of 15,279 samples of women who had clinical breast examination done in health clinics were included.

3.3.1.4 Flow chart of CBE outcome

Figure 3.1 showed the flow chart for obtaining the CBE outcome. From 15,279 CBE sample population obtained from health clinics, those with abnormal CBE finding were identified and were linked to the Selangor State Breast Cancer Registry to identify their breast cancer status.

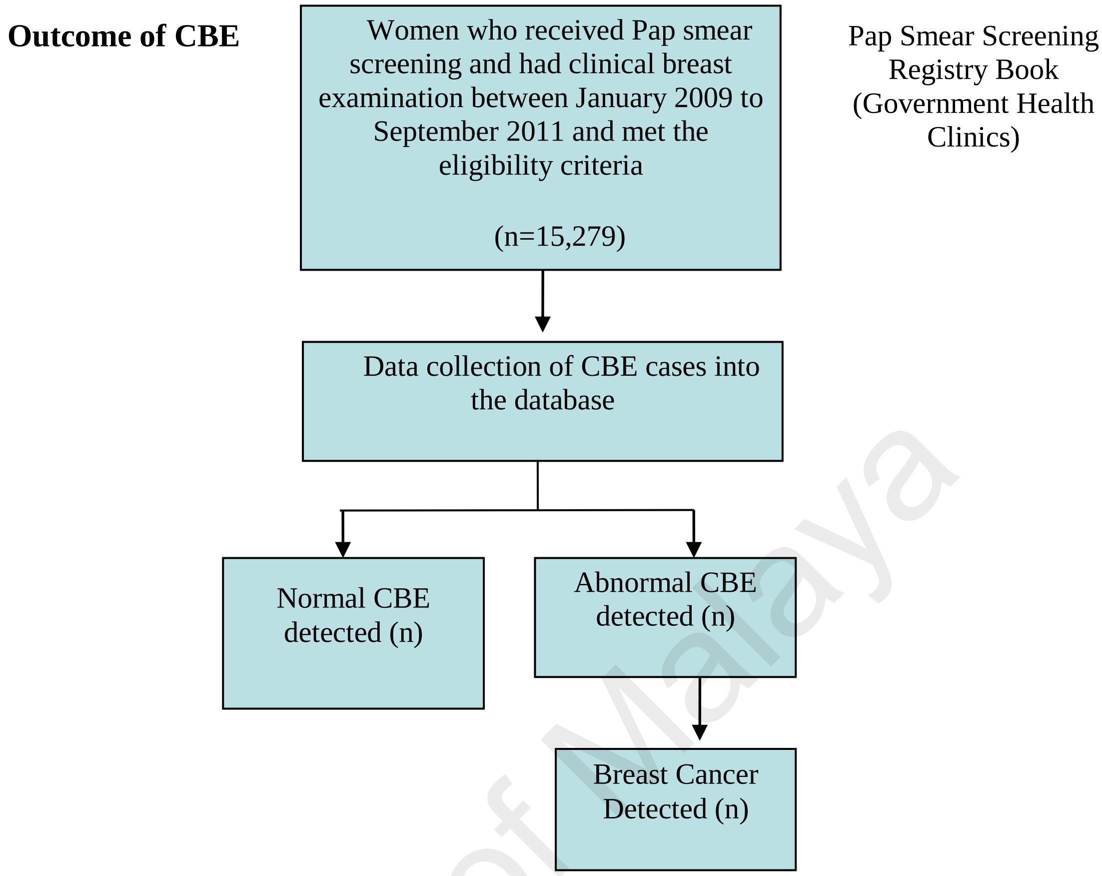

Figure 3.1: Flow chart for CBE outcome

3.3.1.5 Study variables for CBE

In this study, the study variables were collected from the Pap smear Registry Books. Therefore, there are only limited variables that were available to study the characteristics of the participants. Data that were relevant to the clinical breast examination activity were collected. These were divided into independent and dependent variables.

(a) ***Independent (Explanatory) variables***

The independent variables that were included in this study were age, nationality, ethnicity, parity and family planning methods used. Due to the small number of non-Malaysians, these cases were combined with the rest of the sample population. Therefore, this study only has four independent variables that were age, ethnic group, parity and family planning methods used.

(b) ***Dependent (Outcome) variables***

The dependant variables were the abnormal clinical breast examination (CBE) findings among women who were screened and breast cancer cases detected among those with abnormal CBE findings.

3.3.1.6 Operational definitions for CBE

In this study, clinical breast examination (CBE) was defined as the physical examination or physical palpation of the breast by a trained nurse either by a staff nurse or a community nurse in a government health setting. Normal clinical breast examination (CBE) finding was defined as normal or benign finding during the CBE sessions. The latter included findings that do not need referral for further investigation, for example, nipple inversion since childhood, any congenital breast disorder or previous scars on breast.

Abnormal CBE findings on the other hand were defined as having abnormal or suspicious CBE findings that needed further referrals. Abnormal or suspicious breast findings included breast lumps, breast pain, nipple inversion, any skin changes, axillary lumps, and nipple discharge (except milk discharge).

3.3.1.7 Scales of measurements and coding

Independent and dependent variables identified were given codes according to their classifications and outcome. Each variable were classified according to their subgroups and codes were assigned to each of the subgroups. The variables and the codes assigned for each variable and their subgroup is as shown in table 3.1.

Table 3.1: Scales of measurements and coding for CBE

Variables	Coding	Details
1. Independent variables		
a) Age groups		
<= 24 years old	• 1	Age at which the
25-39 years old	• 2	participants were
40-49 years old	• 4	registered in the
50-59 years old	• 5	Pap smear
>= 60 years old	• 6	Registry Book
b) Ethnicities		
Malay	• 1	Ethnic group as
Chinese	• 2	recorded in the
Indians	• 3	registration book
Others	• 4	
c) Parity		
Nulliparous	• 0	Never given birth
Parous	• 1	Ever given birth
Missing	• 99	
d) Family planning methods		
Non users		
IUCD	• 0	Methods of
Implants	• 1	family planning
Condom	• 2	used as recorded
Injection	• 3	in the registry
BTL	• 4	book
OCP	• 5	

Variables	Coding	Details
Others	• 6	
Missing data	• 7	
	• 99	
2. Dependant variables		
CBE findings		
Normal CBE	• 0	Normal / Benign findings of the breasts
Abnormal CBE	• 1	Abnormal CBE which needs further referrals

3.3.1.8 Study Instruments

There were three study instruments used for cost analysis and outcome assessment of CBE followed by mammography when breast abnormality is detected. The first three study instruments were related to CBE screening outcome and cost analysis for CBE screening. These were the data collection form for the effectiveness or outcome of CBE (Appendix F), two others were for cost analysis for CBE which included the data collection form for CBE cost analysis and the data collection form for CBE time motion study to measure the patient contact time by the health staff.

3.3.1.9 Data collection for CBE Outcome

Data collection was done in the eight government health clinics. The data for effectiveness or outcome of CBE were manually extracted from the Pap Smear Registry Books ('Buku Daftar Pap Smear') in each government health clinics and were entered electronically into the study database. The CBE were done alongside Pap smear examination in the Maternal and Child Health Clinics (MCHC). There was no other registry book that contains information on CBE findings for individual women screened that was available in the clinic. Findings of the clinical breast examination done by the nurses were recorded in the CBE column which captured only two information regarding CBE that were, the date of CBE done and the findings of CBE. However, other data related to the participants were collected such as the registration date, registration number, serial number, patient's name, identification number, nationality, birth date, age, ethnicity and the CBE date and findings. Remarks that were found to be relevant to the CBE findings that were recorded in the notes section were also collected. All of these data were recorded into the CBE outcome data collection form as shown in Appendix F.

In the case of missing data, incomplete data or illegible hand writing of any of the variables, data were compared with patient's Pap smear outpatient department (OPD) card to verify the information. The electoral roll website was also used in the case of verifying patient's name or identification number.

Data were also captured in the form of digital photography which allowed the researcher to access the data at any time when needed. The data collected were then entered into SPSS software for further analysis according to the coding that was set. Cases with abnormal clinical breast examination findings were then linked with the Selangor State Breast Cancer Registry to ascertain their breast cancer status. This will represent the breast cancer detection rate among the women screened.

3.3.1.10 Data checking and cleaning

Data collected were checked and cleaned for missing, incomplete and inappropriate data or outliers. Eyeballing method was initially used for data checking and cleaning. Frequency and descriptive statistics were run using SPSS 15.0 (Statistical Package for the Social Science version 15.0) to look for data error and outliers. Any missing, incomplete or error in data were checked by comparing with the data collection form and also checked with the original source of data wherever relevant.

3.3.1.11 Data analysis of CBE Outcome

Data analysis for CBE was divided into analysis of the outcome data using univariate analysis. Statistical analysis for the effectiveness data were done by SPSS version 15.0 while statistical analysis was done using Microsoft Excel for costing data. The outcome for CBE screening was the CBE abnormality detection rate which is defined as the number of breast abnormality detected among women screened by CBE, while breast cancer detection rate for clinical breast examination is the number of breast cancer detected among women with abnormal CBE findings.

3.3.1.12 Data analysis of the socio-demographic data of CBE

Data analysis was also done for socio-demographic data of women screened by CBE which included age, ethnicity, parity, family planning method. Chi square test for categorical variables was used to test the differences in proportions between the subgroups of the age groups and ethnic groups. The chi-square test was used to determine the statistical significance of differences in proportions. A two-sided alpha level of 0.05 was used as the cut off for statistical significance. Data analysis was done using the SPSS version 15.

3.3.2 Outcome of mammography screening among women with risk factors

There were two outcomes of mammography findings in this study that were used to represent the effectiveness of mammography activity. These were the number of mammogram abnormalities detected and the number of breast cancer cases detected among women who had mammogram screening. The study design used to measure the outcomes were cross sectional study in the year 2011 of all women who had undergone the mammography examination in a general hospital in Klang district from the year 2008 to 2011.

The abnormal breast findings of mammography screening were obtained from the mammogram report form for each case compiled in the hospital mammography suite. The operational definition for the abnormal mammography findings will be explained later in section 3.3.2.9. Breast cancer status among those with abnormal mammography findings were determined by linking cases with abnormal mammography findings with the Selangor State Breast Cancer Registry. The details of methods of data collection will be explained in the respective section below.

A few assumptions were made in order to measure the outcome for screening mammography. Firstly, it was assumed that there was no significant difference in the results made by the different radiologists in interpreting the mammography findings and arriving to the final BI-RADS classification. All radiologists were trained to report on mammography examinations using the standardised BI-RADS classification system. Secondly, it was assumed that the information provided in the mammography request and report forms were correctly recorded. Thirdly, it was assumed that there was no difference between the radiographers in positioning clients and performing the mammography examinations.

3.3.2.1 Study area and duration

The study area was in Klang district where there was only one mammography screening centre under the government health setting which was located in the Radiology Department of Hospital Tengku Ampuan Rahimah (HTAR). This mammography centre served as the referral centre for the Klang district for any breast findings that needed mammography services. Thus, the eight government health clinics in Klang referred cases for mammogram screening to HTAR for further investigation.

In addition to that, this mammography centre also served as the mammography referral centre for other nearby districts like Sepang, Kuala Selangor, Kuala Langat and few others.

3.3.2.2 Study population

The study population was women residing or working in Klang area. This included women who were referred from both government and private facilities for further breast abnormality investigations. Among clinics that refer cases to the mammography unit were government health clinics, private clinics, surgical outpatient department (SOPD) and obstetrics & gynaecology clinic (O&G), HTAR Staff Clinic and also referrals from other nearby district hospitals without mammography facility such as Hospital Banting, Hospital Sabak Bernam and Hospital Tanjung Karang. Women were referred for either screening mammogram or diagnostic mammogram. The former included women who are asymptomatic of breast cancer while the latter were women with symptoms of breast cancer such as breast lumps, breast pain, nipple inversion, nipple discharge, skin changes or eczema of the breast and axillary lumps.

3.3.2.3 Selection of cases

The study population was selected from the mammography registry in the Mammography Suite, Radiology Department Hospital Tengku Ampuan Rahimah and also by checking with mammogram report for each case that agreed with the selection criteria.

(a) ***Inclusion criteria***

Study population included all women who came and registered for bilateral mammography screening for the year 2008 to 2011 and were asymptomatic for breast cancer.

(b) ***Exclusion criteria***

Women who were previously diagnosed with breast cancer or cancer at other sites were excluded from the study population. In addition to that, those with previous benign breast disease or who is under follow up for breast disease were also excluded. This study also excluded women who came to the mammography suite for procedures other than bilateral mammography such as cone compression, spot magnification, biopsies, hook wire localization or breast ultrasound only. Cases with missing mammogram report or incomplete mammogram report were also excluded. In addition to that, mammogram findings that have BI-RADS classification of 0 were also excluded due to incomplete assessment and therefore cannot be classified into either normal or abnormal outcome.

3.3.2.4 Sample size estimation

This study involved mammography screening among women with risk factors for breast cancer. The sample size was calculated using a recent data from a study by Yen et al. (2006), where 298,334 women were screened by risk-based biennial mammography screening. The recall rate was 8.7% (measured as the number of cases with BI-RADS scores of 0, 4 or 5 divided by number of participants), while the breast cancer detection rate was 2.8% (Yen et al., 2016).

Therefore, for sample size calculation, the breast cancer detection rate that was used was 2.8% for risk-based biennial mammography screening, while for the percentage of unexposed to outcome, data from study by Ng et al. (1998) was used that was 0.13% (cancer incidence in the control group) (Ng et al., 1998; Yen et al., 2016). Therefore, the calculated sample size for outcome or effectiveness measure for mammography screening is 776 samples in order to achieve the precision of 0.05 (5%) and the power of 80% of the study. However, for this study universal sampling was used and the total sample population was 1427 women screened by mammography for women with risk factors for breast cancer.

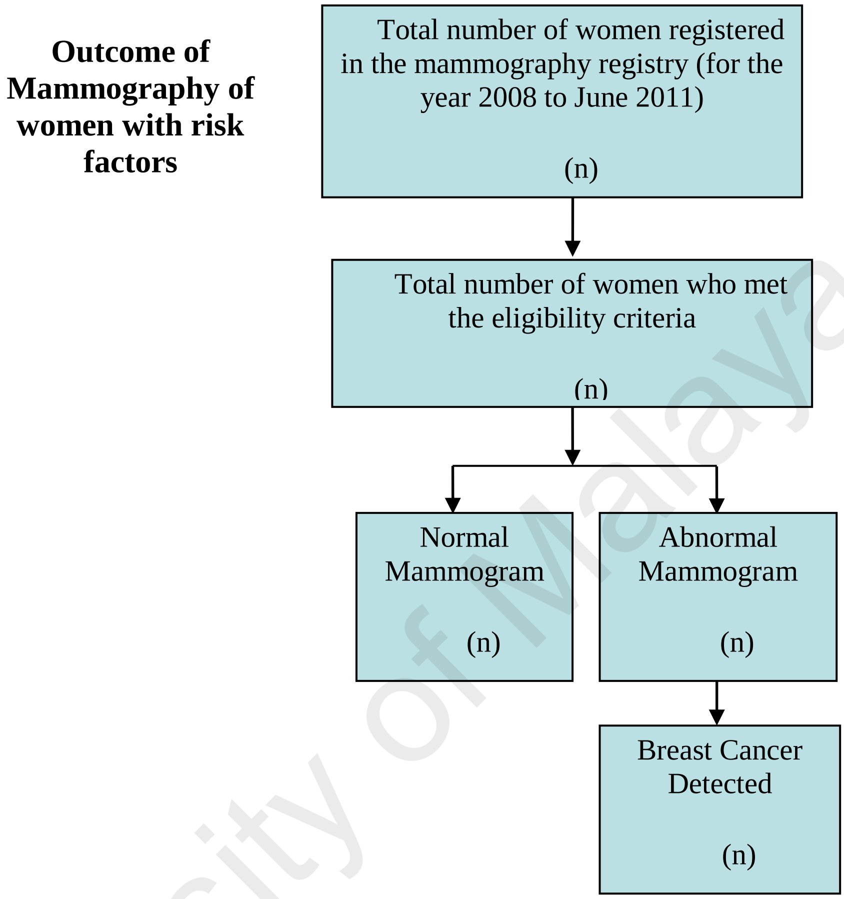

Figure 3.2: Flow chart for the outcome of mammography of women with risk factors

3.3.2.5 Sampling procedure

The sampling method of the study population was universal sampling of all women who were asymptomatic for breast cancer who came for screening mammography in the mammography suite of Hospital Tengku Ampuan Rahimah (HTAR) that met the inclusion and exclusion criteria. These cases were among those registered in the HTAR mammography registry (as shown above in Figure 3.2).

3.3.2.6 Study variables

The study variables for mammography activity were obtained from the mammography registry and the mammogram report form for each of the cases. Therefore, the study variables were limited to data recorded or captured in these medical records.

3.3.2.7 Independent variables

The independent variables for mammography screening were the socio-demographic characteristics, breast cancer risk factors and presence of signs and symptoms of breast cancer. The two socio-demographic variables were age and ethnicity, while the seven variables related to breast cancer risk factors comprised of family history of breast cancer, parity, ever on oral contraceptive pills, ever on hormone replacement therapy, ever breastfed their children, early menarche and late menopause. As for the seven variables related to the signs and symptoms of breast cancer, these included breast pain, breast lump, nipple inversion, nipple discharge, nipple or skin changes, nipple retraction and axillary nodes. These independent variables were obtained from the mammography registry and the mammogram report forms for each patient.

3.3.2.8 Dependent (Outcome) variables

There are two main outcomes or dependent variables for mammography screening. Firstly, the number of abnormalities among those screened by mammography and secondly, the number of breast cancer cases detected among those with abnormal mammogram results. The operational definitions will be explained below in section 3.3.2.9.

3.3.2.9 Operational definitions

There were few terminologies used in this study that were defined in this section. These were screening mammography (asymptomatic mammography), diagnostic mammography (women with signs or symptoms), normal mammogram, abnormal mammogram, mammogram abnormality detection rate and mammogram cancer detection rate.

There are two types of mammography examinations. Screening mammography is defined as mammography that is done in women with no clinical abnormality to suggest breast cancer, while diagnostic mammography is one which is done to evaluate a clinical sign or symptom or to evaluate an abnormality detected at screening (Stephen A. Feig, 2011). Clinical signs and symptoms include breast lump, breast pain, nipple inversion, nipple discharge, nipple eczema, nipple retraction and axillary nodes swelling.

Mammogram results were interpreted using the Breast Imaging Report and Data System (BI-RADS) classification which was developed by the American College of Radiology in 1993. It was developed to standardize mammographic reporting, to reduce confusion on mammographic findings and to facilitate outcomes monitoring (American College of Radiology, 2003). It shows the correlations of the mammography findings to the likelihood of breast cancer. In Hospital Tengku Ampuan Rahimah (HTAR), in most cases additional images or studies will be undertaken immediately in order to complement the mammographic findings in order to reach a result that can later be classified using the BI-RADS classification. In most circumstances an ultrasound examination was used.

There are few ways of categorizing abnormal (positive) and normal (negative) mammogram. According to the Breast Cancer Surveillance Consortium, positive mammogram includes BI-RADS classification of 0, 4, 5 and 3 (if there was recommendation for immediate workout), while negative mammogram refers to BI-RADS classification of 1, 2 and 3 (with a recommendation of short term or normal follow up) (Barlow et al., 2002). Similarly, according to the National Breast Cancer Screening Programme Guideline, abnormal mammogram is defined as BI-RADS 0, 4 and 5 (Family Health Development Division, 2011). In this study, a normal mammography finding (with negative mammogram findings) is defined as a mammogram report with a BI-RADS classification of either 1, 2 or 3 whereas abnormal mammography finding (or positive mammography findings) is defined as a mammogram report with a BI-RADS classification 0, 4 or 5 (Sickles et al., 2005). For BI-RADS classification of 0, the first subsequent examination with a non-zero assessment (within 180 days) were taken as the outcome of the assessment, otherwise they would be excluded from the analysis (Sickles et al., 2005). However, in this particular study all 4 (0.1%) of cases with BI-RADS 0 were excluded due to missing data for subsequent examinations. The evidence table for clinical management recommendations for mammograms by Breast Imaging Report and Data System (BI-RADS) is as shown in Appendix G (Margaret M. Eberl, 2006).

Abnormality detection rate for mammogram findings is defined as the percentage of women who were classified as having BI-RADS classification of 4 or 5 (abnormal) with a suspicious for or highly suggestive of malignancy among those who were screened.

Women who underwent mammography examination were considered to have breast cancer if they are indicated as so when matched with the Selangor State Breast Cancer registry within 12 months after the date of the mammography examination done. This method was similarly done in other study on diagnostic mammography cases by Sickles et al. (2005) (Sickles et al., 2005). Breast cancer detection rate by mammography examination is defined as the number of cancer cases identified at mammography divided by the number of mammography examinations done.

3.3.2.10 Scales of measurements and coding

The scales measurements and coding for the variables collected for the mammography screening study population is as shown in Appendix H. These variables included the socio-demographic characteristics of the patients, reproductive health related variables, risk factors and signs and symptoms for breast cancer and other clinical and surgical characteristics. The variables collected included the age of patient, ethnicity, age at menarche, menopausal status, age at menopause, marital status, number of children, breast feeding practice, family history of breast cancer, breast pain, breast lump, nipple inversion, nipple discharge, nipple and/ or skin changes, nipple retraction, previous surgery/ implant, axillary nodes swelling, on birth control pills, on hormone replacement therapy, any previous mammogram or breast ultrasound, any breast FNAC or biopsy, other co-morbidities, positive history of benign breast lesion, BI-RADS classification and patient's breast cancer status.

3.3.2.11 Data collection of outcome

Data collection was done in the Radiology Department of the Hospital Tengku Ampuan Rahimah in Klang district. The data for the outcome of mammography were manually extracted from the mammogram report forms for each patient registered in the mammography registry. The outcomes were in the form of BI-RADS classification at the end of the mammogram report. Mammogram report forms that have a final conclusion or result but did not have BI-RADS classification were discussed with the radiology consultant based on the BI-RADS classification table. The results on the mammogram report will be matched with the BI-RADS table and given a BI-RADS classification.

Other data related to the participants were collected such as the registration date, registration number, patient's name, identification number, age, ethnicity, reproductive history, breast cancer risk factors, signs and symptoms of breast disease and past medical or surgical history. Variables were collected based on what were recorded on the mammogram report form. In the case of missing data, incomplete data or illegible hand writing of any of the variables, data were compared with the electronic mammography registry to verify the information. However, this is only for certain data like patient particulars, the type of procedures the patient underwent and the doctors on duty on the day of the mammography examination. The electoral roll website was also used in the case of verifying patient's name or identification number.

Data on the signs and symptoms of breast cancer were collected to classify the cases into screening mammography (absence of signs and/or symptoms of breast cancer) and diagnostic mammography (presence of any signs and/or symptoms of breast cancer). These are abstracted from the recorded checklist in the mammography forms and also from the documentation made by the health care provider who requested the mammography examination, the radiologist who attended the case or the radiographer who did the clinical breast examination before the mammography examination. The data collected were then entered into SPSS software for further analysis according to the coding that was set.

The lists of cases of women with abnormal mammography findings were then sent to the Selangor State Breast Cancer Registry to ascertain their breast cancer status. These cases were then matched and compared with the breast cancer registry database that was registered. These cases were matched by using their names and identification card number. Cases which matched with the breast cancer registry were then checked for the date of diagnosis and the date of the mammography screening that were done. Cases with abnormal mammography report were considered to have breast cancer if the registry database indicated the diagnosis of breast cancer within 12 months after the date of the mammography examination. The list of cases that matched the breast cancer registry and fulfil the definition for breast cancer were then entered and updated into the SPSS database for further analysis.

3.3.2.12 Data analysis for outcome

Data analysis was done for independent variables and the outcome data. Chi square test for categorical variables were used to test the difference of proportions between the subgroups of the age groups and ethnic groups. Data analysis was done using the SPSS version 15.0.

The abnormality detection rate is the number of abnormal mammogram defined by having BI-RADS classification of 4 and 5 among women screened by mammography. The breast cancer detection rate for mammography screening is defined as the number of breast cancer diagnosed among women screened with abnormal (BI-RADS 4 and 5) mammogram results.

3.4 Cost per Breast Cancer Detected

In the previous sections, methods to analyse and measure the costs incurred and the outcome of breast cancer screening by CBE followed by mammography when breast abnormality is detected, and mammography screening among women with risk factors were measured. In the next section, calculation methods for cost per breast cancer detected by both breast cancer screening activities were shown.

Average cost-effectiveness ratio (CER) is often a useful method for considering the cost per additional outcome achieved by a single program as compared to a baseline of doing ‘nothing’ (Amanda A. Honeycutt et al., 2006). This is calculated by dividing the total costs of the activity by the change in outcome generated:

CER (CER) = Cost / Δ Outcome

In the next section, the cost per breast cancer detected for CBE followed by mammography when breast abnormality is detected, and mammography screening for women with risk factors for breast cancer were calculated.

3.4.1 Cost per breast cancer detected by CBE followed by mammography when breast abnormality is detected

Cost per breast cancer detected was calculated by dividing the total costs incurred in the activities for CBE followed by mammography when abnormality is detected, divided by the number of breast cancer detected by this screening approach. The outcome calculated was cost per breast cancer detected. The formula for the calculation is shown below:

Cost per breast cancer detected =

$$\frac{\text{(Cost of CBE screening + Cost of mammography when abnormality is detected by CBE)}}{\text{Number of breast cancer detected by CBE}}$$

The total cost for CBE screening was calculated by multiplying cost per CBE with the number of women screened that was 15,279 (cost A). The cost needed to do mammography for women found to have abnormal breast findings by CBE was calculated by multiplying the cost per mammography with the number of women with abnormal CBE findings (cost B). The total cost for CBE followed by mammography when breast abnormality is detected was calculated by adding cost A and cost B. Therefore, the cost per breast cancer detected by CBE followed by mammography when breast abnormality is detected was obtained by adding cost A and cost B divided by the number of breast cancer cases detected as shown below:

Cost per breast cancer detected by CBE followed by mammography when abnormal breast was detected

= Cost A + Cost B / number of breast cancer cases detected

3.4.2 Cost per breast cancer detected by mammography among women with risk factors

Cost per breast cancer detected by mammography among women with risk factors was obtained by calculating the total costs incurred for 1,427 asymptomatic women with risk factors that were screened, and divided it with the number of breast cancer cases detected by mammography. The formula for the calculation of cost per breast cancer detected by mammography only among women with risk factors is as shown below:

Cost per breast cancer detected:

$$\frac{\text{Total cost of mammography screening}}{\text{Number of breast cancer detected by mammography screening among women with risk factors}}$$

Total costs of screening mammography were obtained by multiplying cost per mammography examination by the number of women screened by mammography. Cost per breast cancer detected by screening mammography were obtained by dividing the total cost with the number of breast cancer detected by screening mammography among women with risk factors.

CHAPTER 4: RESULTS ON COST ANALYSIS

4.1 Introduction

This chapter is divided into four main sections which comprise of the results of cost analysis of clinical breast examination (CBE) followed by mammography when breast abnormality is detected (section 4.2), the results of cost analysis of mammography among women with risk factors of breast cancer (section 4.3). This will be followed by the comparison of cost per CBE and cost per mammography (section 4.4). Finally, results on cost analysis for breast cancer screening approaches were discussed in section 4.5.

4.2 Cost Analysis of Clinical Breast Examination

The next section illustrates the calculation of costs for CBE activity. Costs for each cost item were calculated for the respective health clinics based on the year of the costs incurred. An average cost per CBE for each cost item was obtained for the respective health clinics. This was done for costs incurred in the year 2009, 2010 and 2011. All nominal costs were adjusted according to the inflation rate for the respective years by taking 2011 as the base year.

4.2.1 Costs of equipment and furniture

Costs of equipment and furniture were obtained for each health clinics based on their purchased price and year of purchase. The costs of equipment and furniture were then annualized. Annualization values the cost of capital by estimating an average combination of depreciation and interest on the un-depreciated portion over the useful life of the capital item (Levin 1983). To annualize the cost of capital item, the replacement cost, the useful life of the capital item and the discount rate were identified (Walker & Kumaranayake, 2002). The replacement costs of the capital were divided by the annualization factor to obtain the value of capital for one time period; as shown below:

$$[(1+r)^n - 1] / [r(1+r)^n]$$

where r is the discount (interest) rate and n is the useful life of the capital item (Walker & Kumaranayake, 2002). A readily available annualization factor tables were used to determine the annualization factor which are presented by the discount rate and various years (Shepard, Hodgkin, & Anthony, 2000). This is shown in Appendix I. For each equipment and furniture, the useful life was determined based on the effective life of depreciating assets from the Australian Taxation Office for the year 2011 (Australian Taxation Office, 2011). The discount rate chosen for cost calculation was 3 percent which is the average nominal rate of the central bank of Malaysia (*Bank Negara Malaysia*) (Central Bank News, 2013).

By using both the useful life for the capital items and the discount rate at 3 percent, the annualization factors were obtained. The purchased values were then divided by the annualization factor to obtain the annualized cost for each item. The total annualized cost of equipment and furniture were then calculated by multiplying the annualized cost with the quantity of the items respectively. The calculation for the cost of equipment and furniture for each health clinic is shown in Appendix J1 to J8.

The total annualized cost of equipment and furniture for each item were then expressed in RM2011 value which was done by adjusting the total annualized cost for each item, taking 2011 as the base year.

Inflation rate is accounted for over time, in order to avoid under estimation of the level of resources that are currently needed and adjustment need to be made when comparing cost information from one intervention for more than one year

(Kumaranayake, 2000). Therefore, cost data was expressed in real terms by adjusting the inflation rates. The nominal cost data (purchased price) expressed in Ringgit Malaysia were converted to year 2011 Ringgit Malaysia (RM) value. Adjustment for inflation was done by calculating the inflation correction factor (ICF). The inflation correction factor were calculated taking 2011 as the base year, and adjustment were done using the Malaysia inflation rate for the respective years from the year 2000 to 2012 (EconStats, 2012). The use of ICF has been described by Kumaranayake (2000) (Kumaranayake, 2000).

The inflation correction factor (IFC) for the chosen base year, in this case was 2011 was given a value of 1.000. To calculate the ICF for year 2010 and 2012, the ICF for 2011 which was 1.000 was added to the Malaysia inflation rate for the year 2011 which was 3.2% or 0.032 giving a value of 1.032 (1.000+(1.000x3.2/100)=1.032). To obtain the ICF for the year 2009, the ICF value for 2010 which was 1.032 was added to the product of 1.032 and the 2010 inflation rate which was 1.7 percent or 0.017, giving an inflation correction factor for 2009 as 1.050 (1.032+(1.032x1.7/100)=1.050). This calculation was repeated for the years when purchase of equipment and furniture were made as in table 4.1 below.

Table 4.1: Malaysia inflation rate and the inflation correction factor (ICF)

Year	*Inflation rate (%)	ICF
2014	3.14	1.074
2013	2.11	1.052
2012	1.7	1.032
2011	3.2	1.000
2010	1.7	1.032
2009	0.6	1.050
2008	5.4	1.056
2007	2.027	1.113
2006	3.621	1.136
2005	2.937	1.177
2004	1.42	1.212
2003	1.074	1.229
2002	1.793	1.242
2001	1.427	1.264
2000	1.551	1.282

(Source: International Monetary Fund - 2011 World Economic Outlook)

The ICF were then multiplied by the total annualized cost of equipment and furniture for each item (refer to Appendix J1 to J8) to obtain the total annualized cost of equipment and furniture for each item expressed in 2011 Ringgit Malaysia (RM). The total annualized costs of equipment and furniture expressed in 2011 Ringgit Malaysia were then calculated for all health clinics as shown in table 4.2.

Table 4.2: Total annualized costs of equipment and furniture in CBE room in each health clinics in Klang district (in 2011 Ringgit Malaysia value)

No	Health clinics	*Total costs (RM2011)
1	KK Pandamaran	629.09
2	KK Bukit Kuda	820.35
3	KK Bandar Botanic/ Klang	664.37
4	KK Kapar	1,857.57
5	KK Meru	636.06
6	KK Pulau Indah	744.60
7	KK Pulau Ketam	623.02
8	KK Pelabuhan Klang	629.57
	Total	**6,604.63**

* Corrected for inflation (base year 2011) and annualized using the 3% discount rate

Cost of equipment and furniture per patient was calculated by dividing the total annualized cost of equipment and furniture by the average number of patients who used the Pap smear or CBE room per year. Other than Pap smear, this room was also used for other activities such as family planning. The total number of patients who used the room is as shown in table 4.3.

Table 4.3: Total patients using the Pap smear / CBE Room in 2009 to 2011

No	Health clinics	2011	2010*	2009
1	KK Pandamaran	3,133	2,988	2,843
2	KK Bukit Kuda	2,807	2,677	2,547
3	KK Bandar Botanic/ Klang	3,606	3,441	3,276
4	KK Kapar	1,924	1,837	1,749
5	KK Meru	2,744	2,619	2,494
6	KK Pulau Indah	1,835	1,750	1,665
7	KK Pulau Ketam	378	361	343
8	KK Pelabuhan Klang	2,205	2,105	2,005
	Total	18,632	17,777	16,922

*The 2010 data was interpolated as the real data was unavailable. Interpolation was done by taking an average of 2009 and 2011 data. Source: Information Data System (IDS), Klang District Health Office.

Cost of equipment per patient for each health clinic was calculated for the respective years (2009 to 2011). This was done by dividing the total annualized cost by the number of CBE patients for the respective years. This procedure was repeated for each health clinics. The number of patient in all health clinics were prorated for the year 2011 (calculated for 9 months) as the data collection for 2011 ends on the 30th September, whereas the total annual CBE patients were used for the year 2009 and 2010. The calculation of cost of equipment and furniture per patient for each health clinic is shown in Appendix K1 to K8 (line 'j') under the capital cost section.

The average cost of equipment and furniture per patient for the each health clinic and the average cost per patient for all eight health clinics were then calculated by averaging the costs of equipment for 2009 to 2011 in each health clinic and averaging the costs among the eight health clinics respectively. The overall average cost of equipment and furniture for the eight health clinics was RM0.55 (±RM0.03). Table 4.4 shows the obtained average cost of equipment and furniture per patient.

Table 4.4: Average cost of equipment and furniture per patient in health clinics in Klang for the year 2009 to 2011 (expressed in 2011 RM)

	Cost of equipment & furniture per patient		
Health clinics	**Mean**	**SD**	**Range**
a) KK Pandamaran	0.21	0.010	0.20-0.22
b) KK Bukit Kuda	0.31	0.015	0.29-0.32
c) KK Bandar Botanic/Klang	0.19	0.009	0.18-0.20
d) KK Kapar	1.01	0.048	0.96-1.06
e) KK Meru	0.24	0.012	0.23-0.25
f) KK Pulau Indah	0.43	0.021	0.41-0.45
g) KK Pulau Ketam	1.73	0.084	1.65-1.82
h) KK Pelabuhan Klang	0.30	0.014	0.29-0.31
Average cost	**0.553**	**0.026**	**0.18-1.82**

4.2.2 Cost of utilities and communication

The cost of utilities and communication comprised of electricity, water and telephone charges. The annual utility and communication costs for each health clinic were provided by the administrative department only for the year 2011 for all eight health clinics which included the outpatient department (OPD) and the maternal and child health clinics (MCHC) as shown in table 4.5.

Table 4.5: Cost of utilities and communication in health clinics in Klang district for the year 2011 (RM2011)

	Annual cost of utilities and communication for 2011			
Name of facilities	**Electricity**	**Water**	**Telephone**	**Total (RM2011)**
a) KK Pandamaran	135,078.60	5,508.48	9,412.08	149,999.16
b) KK Bukit Kuda	157,663.20	4,733.40	15,703.32	178,099.92
c) KK Bandar Botanic/Klang	497,233.20	46,290.72	2,598.00	546,121.92
d) KK Kapar	58,000.00	9,183.00	1,776.00	68,959.00
e) KK Meru	51,625.80	9,003.12	6,459.12	67,088.04
f) KK Pulau Indah	25,039.20	579.60	4,470.00	30,088.80
g) KK Pulau Ketam	17,280.60	204.00	1,776.00	19,260.60
h) KK Pelabuhan Klang	51,000.00	8,472.96	3,634.32	63,107.28
Total (2011)	992,920.60	83,975.28	45,828.84	1,122,724.72

The utility and communication costs for the year 2010 and 2009 were not available for data collection. Therefore, the utility and communication costs for the year 2010 and 2009 were estimated using the 2011 utility and communication costs by assuming that the utility and communication costs for 2009 and 2010 were the same as that obtained for 2011.

The annual costs of utilities and communication in each health clinics for the year 2009 to 2011 is shown in Appendix K1 to K8 (for each health clinic respectively) under the recurrent indirect cost section (line 'k' to 'm'). All costs are expressed in 2011

Ringgit Malaysia (RM) value. However, the cost of utility and communication for the year 2011 has to be prorated to take account for the 9 months study period and not one year. This was because the data for 2011 collected ended in September 2011. Therefore, the annual cost and the total number of patients (both in the MCH and the OPD) were apportioned for 9 months by dividing the value with 12 months and multiplied with 9 months of study period included.

The calculation for the cost of utilities and communication per patient was calculated for each health clinic for the respective years that were 2009 to 2011 as shown in Appendix K1 to K8 (line 'o') for the eight health clinics. This was done by dividing the total cost of utilities and communication (as shown in Appendix K1 to K8, line 'n') with the total patients (MCH and OPD) (as shown in Appendix K1 to K8, line 'f') in each health clinic for the respective years (2009 to 2011). This was because the space area for CBE activity was not available for all health clinics. Therefore, the cost of utilities per patient was calculated as above by using the building as the cost centre.

The average cost of utilities and communication per patient for each health clinic and the average cost per patient for the eight health clinics were then calculated. This was done by averaging the cost per patient for 2009 to 2011 in each health clinic, and averaging the costs among the eight health clinics respectively. The overall average cost of utility and communication for the eight health clinics was RM1.342 (±RM0.061). Table 4.6 shows the obtained average cost of utilities and communication per patient.

Table 4.6: Average cost of utilities and communication per patient in health clinics in Klang for the year 2009 to 2011 (expressed in 2011 RM)

Name of facilities	Cost of utilities & communication per patient		
	Mean	**SD**	**Range**
a) KK Pandamaran	1.08	0.098	0.97-1.15
b) KK Bukit Kuda	1.78	0.168	1.60-1.92
c) KK Bandar Botanic/Klang	2.67	0.191	2.45-2.80
d) KK Kapar	0.84	0.050	0.78-0.87
e) KK Meru	0.88	0.063	0.81-0.92
f) KK Pulau Indah	1.21	0.057	1.18-1.28
g) KK Pulau Ketam	1.50	0.056	1.44-1.56
h) KK Pelabuhan Klang	0.77	0.019	0.75-0.79
Average cost	1.342	0.061	0.75-2.80

4.2.3 Cost of operation and maintenance

The costs of operation and maintenance included the costs for cleaning and security services. However, these data were only available and complete for some of the health clinics. As for the cleaning cost, data were provided for four clinics (KK Pandamaran, KK Bukit Kuda, KK Kapar and KK Pelabuhan Klang) out of the eight health clinics. For cleaning costs, annual cleaning costs data were available only for 2011 for one of the health clinic (KK Kapar), while for KK Pandamaran, KK Bukit Kuda and KK Pelabuhan Klang, data were available only for 7 months (for the year 2011). Therefore, the seven months costs were annualized by dividing with seven and multiplied with 12 months to obtain the annual cost.

Cost of cleaning for the four other health clinics (KK Bandar Botanic, KK Meru, KK Pulau Indah and KK Pulau Ketam) were not available. Estimations were made for these clinics taking into account that all clinics would have cleaning costs as part of the maintenance cost. The cleaning costs were estimated by taking the equivalent replacement value based on the market value in 2011 and also based on the floor area of the building. i.e KK Botanic/ Klang was similar to KK Pandamaran or Bukit Kuda. KK

Meru is similar to KK Kapar. KK Pulau Indah is about half of KK Kapar while KK Pulau Ketam is about half the building area of KK Pulau Indah. The building areas are as shown in Appendix L. As for the costs of security, data were only available for health clinics that had security services. The cost for security services were collected for three out of eight health clinics which were KK Pandamaran, KK Bukit Kuda and KK Kapar. Table 4.7 showed the cost of cleaning and security for 2011, and the annual cost of operation and maintenance for 2011.

Table 4.7: Cost of operation and maintenance of health clinics in Klang district for the year 2011 (RM 2011)

	Annual cost of operation and maintenance for 2011		
Name of facilities	**Cleaning**	**Security**	**Total costs**
a) KK Pandamaran	49,980.00	27,780.48	77,760.48
b) KK Bukit Kuda	49,920.00	39,528.00	89,448.00
c) KK Bandar Botanic/Klang	49,980.00		49,980.00
d) KK Kapar	38,400.00	39,528.00	77,928.00
e) KK Meru	38,400.00		38,400.00
f) KK Pulau Indah	19,200.00		19,200.00
g) KK Pulau Ketam	9,600.00		9,600.00
h) KK Pelabuhan Klang	49,920.00		49,920.00
Total	305,400.00	106,836.48	412,236.48

The operation and maintenance costs for the year 2010 and 2009 were not available for data collection. Therefore, the operation and maintenance costs for the year 2010 and 2009 were estimated using the 2011 operation and maintenance costs by assuming that the operation and maintenance costs for 2009 and 2010 were the same as that obtained for 2011.

Similar to the 2011 cost of utilities and communication, the 2011 cost of operation and maintenance was also prorated taking into account for the 9 months study period and not one year. This was because the data for 2011 collected ended in September

2011. Therefore, the annual cost and the total number of patients (both in the MCH and the OPD) for 2011 were apportioned for 9 months by dividing the value with 12 months and multiplied with 9 months of study period (as shown in Appendix K1 to K8, in line ‘p’ and ‘q” for the year 2011).

The cost of operation and maintenance per patient (as shown in Appendix K1 to K8, line ‘s’) was calculated by dividing the total cost of operation and maintenance (as shown in Appendix K1 to K8, line ‘r’) with the total patients (in MCH and OPD units) in the health clinics (as shown in Appendix K1 to K8, line ‘f’). The calculation for the cost of operation and communication per patient was calculated for each health clinic for the respective years (2009 to 2011) as shown in Appendix K1 to K8 for the eight health clinics under the section recurrent indirect cost for maintenance (line ‘p’ to ‘s’).

The average cost of operation and maintenance per patient for each health clinic, and the average cost per patient for the eight health clinics were then calculated by averaging the cost per patient for 2009 to 2011 in each health clinic and averaging the costs among the eight health clinics respectively. The overall average cost of operation and maintenance for the eight health clinics was RM0.703 (±RM0.205). Table 4.8 shows the obtained average cost of operation and maintenance per patient.

Table 4.8: Average cost of operation and maintenance per patient in health clinics in Klang for the year 2009 to 2011 (expressed in 2011 RM)

Health clinics	Cost of operation & maintenance per patient		
	Mean	SD	Range
a) KK Pandamaran	0.56	0.051	0.50-0.60
b) KK Bukit Kuda	0.90	0.084	0.80-0.97
c) KK Bandar Botanic/Klang	0.24	0.018	0.22-0.26
d) KK Kapar	1.29	0.615	0.88-2.00
e) KK Meru	0.50	0.036	0.46-0.53
f) KK Pulau Indah	0.78	0.037	0.75-0.82
g) KK Pulau Ketam	0.75	0.028	0.72-0.78
h) KK Pelabuhan Klang	0.61	0.015	0.59-0.62
Average cost	0.703	0.205	0.22-2.00

4.2.4 Cost of staff salary

The total costs of staff salary were calculated based on the total annual salary of staffs that were directly involved in the CBE activity according to their job grades for all the health clinics. As for CBE activity, the staffs that were directly involved in running the Pap smear and clinical breast examination (CBE) were the staff nurses (grades 29) and community nurses (either grade 19 or 24), whereby the grade 24 community nurses were those whom were promoted after serving for a number years. Usually, there were two nurses on duty to run the Pap smear and the clinical breast examination clinic. One of which was a staff nurse and another was a community nurse. According to the Ministry of Health policy, Pap smear examination should be done by a staff nurse whereas CBE can be done by either a staff nurse or a community nurse. However, the nurses that were on duty for Pap smear and CBE on a particular day also did other tasks in the Maternal and Child Health clinic such as assisting in the child health clinic and children immunization services when there was no client.

To calculate the cost of salary for the CBE activity, a time motion survey was carried out in the Pap smear and CBE room in two out of eight health clinics which were KK Kapar and KK Bandar Botanic. The purpose of which was to measure the contact time for each staff nurse and community nurse with the patient during the Pap smear or CBE activity. The CBE activity was divided into five small job steps. These were registration, patient preparation for examination, CBE activity, Pap smear activity and setting next appointment all of which happen in the Pap smear room. Patient who came for Pap smear were offered clinical breast examination at the same time.

Upon arrival, this patient was directed to the Pap smear room where the registration took place by the community nurse. The patient was screened for vital signs such as taking the patient’s blood pressure and weight and also taking a short history related to

Pap smear screening and breast screening. CBE was either done by the community nurse or the staff nurse, while the Pap smear screening was done by the staff nurse as according to the standard operating procedure. Setting up next appointment and recording was done by either the community nurse or the staff nurse. Although at any job step, either a community nurse or a staff nurse can carry out the task, an assumption was made that for certain job steps only the staff nurse will be on duty. As for the registration, the community nurse usually did the task while at other times both nurses were on duty to do the Pap smear and the CBE activity. The mean time taken for each job step is shown in the table 4.9 below, while table 4.10 shows the total patient contact time by staff category.

Table 4.9: Staffs contact time per patient for Pap smear and clinical breast examination activity in health clinics in Klang district

Patient contact time (minutes)	Mean	SD	Range
Registration time	7.1	±5.0	(1-24)
Patient preparation time	3.0	±3.2	(1-15)
CBE time	2.1	±1.0	(1-8)
Pap smear examination	4.6	±2.0	(2-16)
Setting appointment time	3.1	±2.4	(1-12)

Table 4.10: Staffs contact time per patient for Pap smear and clinical breast examination activity in health clinics in Klang district by staff category

Patient contact time (in minutes)	Staff Nurse	Community Nurse
Registration time	NA	7.1
Patient preparation time	3.0	3.0
CBE activity	2.1	2.1
Pap smear examination	4.6	4.6
Setting next appointment	3.1	3.1
Total (minutes)	8.1	15.2
Total (hours)	0.14	0.25

The monthly salary and salary per hour were calculated for both categories of nurses based on their working hours (Table 4.11 and 4.12). This included monthly basic salary and their monthly allowances. The nurses worked 8 hours per day for 5 days in a week. On average, the nurses worked 22 days in a month taking weekends as off days for each week. An average staff cost for community nurse was calculated as there were two grades of community nurse (these are grades 19 and 24). As there were 72 community nurses (11 of grades 24 and 61 of grades 19), the total salary per month for these staffs were divided by 72 to get an average to represent the monthly salary for the community nurse category. This is shown in table 4.11.

Table 4.11: Average salary for community nurse staff category for 2011

Job title and grades	No. of staff	Total salary per month (1 staff)	Total salary per month	Average monthly salary per staff
Community nurses (U24)	11	2,756.87	30,325.57	1,731.95
Community nurses (U19)	61	1,547.13	94,374.93	

The total salary per hour was obtained by dividing the total salary per month with the total working hours in a month that was 176 hours (ie. 22 working days multiplied by 8 hours of working per day). The calculation for staff cost per patient for 2011 is as shown in table 4.12 based on their total contact time with patient. Therefore, the staff cost per patient was RM1.59 for staff nurse and RM2.49 for community nurses. The total cost of staff per patient was RM4.08 for the year 2011.

Table 4.12: Costs of salary per patient for women who attended clinical breast examination in health clinics in Klang for the year 2011

<table>
<tr><th>Category of staff</th><th>Total salary per month</th><th>Average total salary per month</th><th>Average total salary per hour</th><th>Average contact time (hours)</th><th>Total salary per patient</th><th>Cost of salary per patient</th></tr>
<tr><td>Staff Nurses</td><td>2,067.75</td><td>2,067.75</td><td>11.75</td><td>0.14</td><td>1.59</td><td rowspan="3">4.08</td></tr>
<tr><td>Community nurses U24</td><td>2,756.87</td><td rowspan="2">1,731.95</td><td rowspan="2">9.84</td><td rowspan="2">0.25</td><td rowspan="2">2.49</td></tr>
<tr><td>Community nurses U19</td><td>1,547.13</td></tr>
</table>

The staff salaries for these two nurses were only available for the year 2011 which included the annual salary and the annual allowances. Therefore, the costs of staff salary for the year 2010 and 2009 were estimated using the 2011 costs of staff salary by assuming that the costs of staff salary for 2009 and 2010 were the same as that obtained for 2011. The cost of salary per patient for 2009 and 2010 were calculated the same way as in 2011 by applying the estimated costs of salary for 2009 and 2010. The calculations of costs of staff in each health clinics are shown in Appendix K1 to K8 in the direct cost section under salary (line‘t’ to ‘v’).

The average cost of salary per patient for each health clinic and the average cost of salary per patient for the eight health clinics were then calculated by averaging the cost per patient for 2009 to 2011 in each health clinic and averaging the costs among the eight health clinics respectively. The overall average cost of salary for the eight health clinics were RM4.08. This cost was similar in all clinics as they have the same staff categories and contact times that were applied.

4.2.5 Total cost per patient for clinical breast examination

Total costs of CBE per patient were calculated for each health clinic for the respective years (2009 to 2011). This was done by adding the cost per patient for the different cost items which were the cost of equipment and furniture per patient, cost of utilities and communication per patient, cost of operation and maintenance per patient and the cost of salary per patient according to the respective years. The calculations are as shown in Appendix K1 to K8 for each health clinics (line 'w').

The average cost of CBE per patient for each health clinic and the average cost of CBE per patient for the eight health clinics were then calculated by averaging the cost of CBE per patient for 2009 to 2011 in each health clinic and averaging the costs among the eight health clinics respectively. The overall average cost of CBE for the eight health clinics was RM6.677 (±RM0.203). Table 4.13 shows the obtained average cost of CBE per patient.

Table 4.13: Average cost of CBE per patient in health clinics in Klang for the year 2009 to 2011 (expressed in 2011 RM)

	Cost of CBE per patient		
Name of facilities	**Mean**	**SD**	**Range**
a) KK Pandamaran	5.93	0.159	5.75-6.04
b) KK Bukit Kuda	7.06	0.267	6.77-7.29
c) KK Bandar Botanic/Klang	7.19	0.218	6.94-7.34
d) KK Kapar	7.22	0.647	6.7-7.94
e) KK Meru	5.71	0.110	5.58-5.79
f) KK Pulau Indah	6.50	0.094	6.43-6.60
g) KK Pulau Ketam	8.06	0.002	8.06-8.06
h) KK Pelabuhan Klang	5.76	0.046	5.71-5.79
Average cost	6.677	0.203	5.58-8.06

Total cost for the clinical breast examination activities in the eight health clinics can be calculated by multiplying each cost items with the number of women screened in the year 2009 to 2011 which was 15,279 cases. Therefore, the calculated total cost is as shown in table 4.14 below.

Table 4.14: Total costs (RM2011) of clinical breast examination among women screened in health clinics in Klang district for the year 2009 to 2011

Cost items	**Average cost per patient (RM)**	**Total cost for CBE for 15,279 women RM, (%)**
i) Costs of equipment and furniture	0.553	RM8,449.29 (8.28)
ii) Costs of utilities and communication	1.342	RM20,504.42 (20.10)
iii) Cost of maintenance	0.703	RM10,741.14 (10.53)
iv) Cost of salary per patient	4.079	RM62,323.04 (61.09)
Total cost per patient	**6.677**	**RM102,017.89 (100.00)**
Total cost per patient*	**6.68**	**RM102,063.72 (100.00)**

*rounded to 2 decimal points

The calculated total cost of clinical breast examination per patient for a women screened in the government health clinic was RM6.68 (rounded to 2 decimal points) while the total cost calculated from 15,279 women screened was RM102,063.72. Majority of the cost is attributed to the cost of salary (61.09%), followed by cost of utilities and communication (20.10%), cost of operation and maintenance (10.53%) and cost of equipment and furniture (8.28%).

4.2.5.1 Cost per CBE screening and cost per mammography screening

For cost analysis, cost per CBE and cost per mammography screening were calculated as explained in the methodology section. Table 4.15 showed the average cost per CBE screening that was done in health clinics in Klang according to the different cost items. The average cost of CBE per patient was RM 6.68 (SD 0.203, Range 5.58-8.06). Cost per CBE was largely contributed by cost of staff salary followed by cost of utilities and communication, cost of operation and maintenance and cost of equipment and furniture.

Table 4.15 : Average cost per CBE according to different cost items in health clinics in Klang for the year 2009 to 2011 (expressed in 2011 RM)

Cost items	Average cost per CBE		
	Mean	**SD**	**Range**
Cost of equipment and furniture	0.553	0.026	0.19-1.73
Cost of utilities and communication	1.342	0.061	0.75-2.8
Cost of operation and maintenance	0.703	0.205	0.22-0.97
Cost of staff salary	4.079	0.000	4.08-4.08
Average cost per CBE	**6.68***	**0.203**	**5.58-8.06**

*rounded to 2 decimal points

4.2.5.2 Total cost of CBE followed by mammography when breast abnormality is detected

The total cost to screen 15,279 women by CBE was RM 102,063.72. Out of 15, 279 women screened by CBE, 84 women were found to have abnormal breast findings which needed mammography examination. The cost for the mammography examination for these 84 women was RM 16,573.20. This was obtained by multiplying cost per mammography examination (RM 197.30) with 84 women (cost per mammography examination will be detailed later in section 4.3). Therefore, the total cost to screen 15,279 women by CBE followed by mammography when breast abnormality is detected was calculated by adding the total cost to screen 15,279 women by CBE with the total cost of mammography examinations for 84 women with abnormal breast findings which gave a value of RM 118, 636.92.

4.2.6 Cost per breast cancer detected by CBE followed by mammography when breast abnormality detected

The cost per breast cancer detected by clinical breast examination followed by mammography when breast abnormality is detected was calculated by dividing the total cost to screen 15,279 women by this method that was RM 118,636.92 with the number of breast cancer cases detected that was 10 cases. Therefore, the cost per breast cancer detected by CBE followed by mammography when abnormality is detected was RM 11,864.

4.2.7 Factors affecting the clinical breast examination cost and outcome

There are two factors that affect the cost of clinical breast examination and cost per breast cancer detected by CBE followed by mammography if breast abnormality is detected. These are cost of labour and breast cancer detection rates. Calculations were done by varying the labour costs and the breast cancer detection rates to determine their relationship with cost per clinical breast examination and cost per breast cancer detected. This was done by applying the labour costs either a community nurse grade 19 or a community nurse grade 24 as the person who does the clinical breast examination and also by applying the various breast cancer detection rates from other countries.

4.2.7.1 Labour cost of CBE

There are four cost items for CBE that were included in the cost calculation. These are cost of equipment and furniture, cost of utilities and communication, cost of operation and maintenance, and cost of staff salary.

The relationships of the costs of labour in clinical breast examination (CBE) activity were calculated by varying the cost of staff salary in the CBE activity. In the clinical breast examination activity, CBE can either be done by a community nurse grade U24 or by a community nurse grade U19. The cost of staff salary per hour when the patient was seen by either a community nurse grade U24 was RM 15.66 and by a community nurse grade U19 was RM 8.79.

The cost of staff salary per patient examined by a community nurse grade U24 and community nurse grade U19 were obtained by multiplying its cost of staff salary per hour (RM15.66 and RM8.79, respectively) by the average patient contact hour (0.25) which gave a value of RM3.92 and RM2.20, respectively. These were then added to the average cost of staff salary per patient seen by a staff nurse grade U29 that was RM1.69 respectively (as there were always 1 staff nurse and 1 community nurse on duty at any one time for Pap smear and CBE screening activities). The costs of staff salary per CBE was (RM3.92+RM1.69) RM 5.61 when patient was seen by a community nurse grade 24 and a staff nurse, while the costs of staff salary per CBE was (RM2.20+RM 1.69) RM 3.89 when patient was seen by a community nurse grade 24 and a staff nurse. Therefore, the cost per clinical breast examination were calculated by adding the respective cost of staff salary per CBE to the other cost items which were maintained as shown in table 4.16.

Table 4.16: Relationship of labour cost on the cost per CBE

CBE	**If patient seen by SN & CN (Grade 24)**	**If patient seen by SN & CN (Grade 19)**
Cost items	**Cost per CBE (RM)**	**Cost per CBE (RM)**
Equipment & Furniture	0.55	0.55
Utilities & Communication	1.38	1.38
Operation & Maintenance	0.68	0.68
Staff salary	5.61	3.89
Costs for CBE (RM)	**8.22**	**6.50**

The results showed that cost per clinical breast examination was higher when a community nurse grade U24 is on duty as compared to a community nurse grade U19. Cost of CBE could be reduced further if only community nurse grade U19 were used to conduct CBE among patients. If we were to calculate for 10,000 women screened, costs needed are RM 82,200 if CBE were to be done by a community nurse grade U24, and

RM 65,000 if CBE were to done by a community nurse grade U19. Using only community nurse grade U19 for CBE screening could reduce total costs by 20.1%.

4.2.7.2 Breast cancer detection rate

The other factor that can affect the costs of clinical breast examination activities is the breast cancer detection rate. Different breast cancer detection rates determine whether the cost per breast cancer detected by CBE activity to be higher or lower. In order to demonstrate this relationship, breast cancer detection rates by CBE obtained from previous studies were applied into the calculation for cost per breast cancer detected by CBE. For the purpose of calculation, the minimum and maximum breast cancer detections rates obtained from previous literatures were applied and the costs were calculated for 10,000 women. This is shown in table 4.17.

The minimum and maximum breast cancer detection rates by clinical breast examination were extracted from previous literatures. The range of breast cancer detection rates by CBE that were reported by previous literatures was 0.02% to 0.8% (as shown in table 2.2 in chapter 2. The minimum breast cancer detected by CBE was reported by Feigin et al. (2006) where 14 cancers (0.02%) were detected from 60,027 women screened (Feigin et al., 2006). However, 23% of women needing conversion to diagnostic examination were lost to follow up. Therefore, the minimum breast cancer detection rate by CBE was taken from another study reported by a large observational study by Bancej et al. (2003) involving 300,303 women screened by CBE, 0.3 per 1000 women screened or 0.03% had breast cancers (C Bancej, 2003). The maximum breast cancer detection rate was abstracted from a pilot study in Cairo reported by Boulos et al. (2005), whereby there were 20 breast cancer that were diagnosed from 2481 women screened by CBE giving a rate of 0.8% (20/2481) (S Boulos, 2005).

The estimated minimum and maximum number of breast cancer detected by CBE was calculated by multiplying the minimum and maximum breast cancer detection rates with the total number of women screened (n=10,000) respectively. This gave a minimum number of breast cancers of 3 persons and a maximum number of breast cancers of 50 persons. The respective minimum and maximum abnormality detection rates by CBE from these two studies were 3.5% and 11.7%. When applied to the number of women screened by CBE (10,000 women), those with abnormal CBE findings that needed mammography examinations were 350 women and 1170 women respectively. Therefore, the mammography costs needed for these women were obtained by multiplying the expected number of women with abnormal mammography examinations with the cost per mammography (RM197.30). The minimum and maximum total costs to screen 10,000 women by CBE followed by mammography when breast abnormality is detected, were calculated by adding the respective minimum and maximum costs for CBE screening and to the cost of mammography examinations for women estimated to have abnormal CBE findings, respectively. These calculations are shown in table 4.17.

Table 4.17: The minimum and maximum breast cancer detection rates and the calculated cost per breast cancer detected for CBE followed by mammography when breast abnormality is detected

CBE followed by mammography when breast abnormality is detected	Minimum	Maximum
Cancer detection rate (%) by CBE	**0.03**	**0.8**
Total number of cancers	3	80
Breast abnormality detection rate (%)	3.5	11.7
Number of breast abnormality detected by CBE	350	1170
Total cost of CBE followed by mammography when breast abnormality is detected (RM)	66,800.00 +69,055.00 =135,855.00	66,800.00 +230,841.00 =297,641.00
Cost per breast cancer detected	**45,285.00**	**3,720.51**

Note: Total cost calculated for 10,000 women screened by CBE followed by mammography when breast abnormality is detected.

The cost per breast cancer detected was higher (RM 45,285) at minimum breast cancer detection rate for CBE followed by mammography when breast abnormality is detected. In contrast, a much lower (RM 3,721) cost per breast cancer detected was calculated at maximum breast cancer detection rate. This suggests that by increasing breast cancer detection rates by clinical breast examination followed by mammography when breast abnormality detected would reduce the total costs of breast cancer screening by this approach. Increasing breast cancer detection rate can be done by improving the quality of breast cancer screening and also increasing the coverage of breast cancer screening especially those in the targeted or high risk groups.

4.3 Cost Analysis of Mammography

The total costs for mammography examination comprised of the capital costs and the recurrent costs. The capital cost included the cost of equipment and furniture while the recurrent costs comprised of utilities and communication, operation and maintenance, cost of consumables and cost for staff salary. The actual expenditures incurred were collected for the year 2008, 2009, 2010 and 2011. The calculation for each of these cost items will be explained further in the sections below.

4.3.1 Cost of Equipment and Furniture

The equipment and furniture that were used in the mammography activity were identified. The purchased price and the year of purchase of the equipment and furniture were obtained. For instances where information regarding the purchasing of the equipment and furniture were unavailable, the costs were estimated from the 2011 market price for the items.

These costs were then annualized using the 3% discount rate by dividing the purchased price for each item by the respective annualization factor (Appendix I). The total annualized cost for equipment and furniture was then calculated by adding the annualized costs for both equipment and furniture. The list of equipment and furniture and the calculation of the costs is as shown in Appendix M (a) and L (b).

These costs were then adjusted for inflation using the calculated Inflation Correction Factor (ICF) taking the year 2011 as the base year. The annual Malaysian inflation rate that was reported by the Department of Statistics of Malaysia for the respective years, were used to adjust these costs. The total annualized cost for mammography equipment and furniture expressed in RM 2011 is as shown in table 4.18.

Table 4.18: Annualized cost of equipment and furniture in Mammography Unit, HTAR, Klang (in 2011 Ringgit Malaysia value)

	Annualized costs (RM)
Mammography unit equipment	454,590.23
Mammography unit furniture and fittings	1,648.47
Total cost	456,238.70

Cost of equipment and furniture per unit was reported as cost per examination as the hospital statistics for the radiology department were reported as the number of examinations or procedures performed and not the number of patients. This allowed more accurate calculation for cost per procedure done by the Radiology Department. The cost of equipment and furniture per examination for the year 2008 to 2011 was calculated by dividing the annualized cost of equipment and furniture with the number of examinations or procedures in the Mammography unit in HTAR for the respective years. This was because the mammography unit came in a set together with other equipment that also provided other services. Therefore, the denominator was the number of examinations or procedures in the mammography unit which included the mammography examinations, ultrasound examinations, ultrasound breast biopsies and stereotactic biopsies. The mammography unit statistics for the number of examinations or procedures by activities is as shown Appendix O (line ‘h’). However, magnetic resonance imaging (MRI) of the breast was excluded from the denominator as MRI imaging was done in a separate unit that was the MRI unit.

The number of radiological examinations or procedures in the mammography unit for the year 2011 was averaged according to the study period (which was six months) as the data collection for 2011 ends on the 30th June 2011. This means that the total procedures done for the year 2011 that was 4674 procedures were divided by 12 months and multiplied by six months in order to calculate for the six months period of data collection for 2011 that gave a value of 2337 (Appendix O, line ‘h’ for 2011). As for 2008 to 2010, the denominators were the total number of radiological examinations in the mammography unit for the respective years excluding MRI examinations or procedures. The total number of radiological examinations or procedures in the mammography unit according to the respective years (2008 to 2011) is as shown in table 4.19 below. The calculation for the cost of equipment and furniture per patient in the mammography unit for 2008 to 2011 is shown in Appendix O under the capital cost section (line ‘k (i)’ to ‘l’).

Table 4.19: Total number of radiological examinations or procedures in the mammography unit in HTAR for the year 2008 to 2011

	2008	2009	2010	2011	Average
Total examinations /procedures in MMG unit	3454	3877	4456	4674	4115

The mean cost of equipment and furniture per patient for the mammography unit per year was calculated by averaging the annualized costs of equipment for the year 2008 to 2011. The mean cost of equipment and furniture for the mammography unit was RM 112.44 (±RM 15.647). Table 4.20 shows the obtained mean cost of equipment and furniture per patient in the mammography unit.

Table 4.20: Cost of equipment and furniture per patient in the mammography unit, HTAR for the year 2008 to 2011 and the mean cost of equipment and furniture (expressed in 2011 RM)

	2008	2009	2010	2011	Mean (±SD)
Equipment & Furniture	132.09	117.68	102.39	97.61	112.44 (±15.647)

4.3.2 Cost of Utilities and communication

The annual costs of utilities were obtained from the Finance Unit of the administrative office of HTAR, Klang for the year 2008 to 2011 (Appendix P). Cost of utilities comprised of electricity bills, water bills and telephone bills for the respective years. The nominal costs of the utilities for the year 2008 to 2010 were adjusted for inflation rate by applying the calculated Inflation Correction Factor (ICF) taking 2011 as the base year. The respective actual inflation rates for Malaysia were used to calculate the ICF.

The actual expenditures for utilities and communication (for the year 2008 to 2010) were expressed in 2011 Ringgit Malaysia by adjusting for inflation (taking 2011 as the base year) by multiplying the nominal cost with the inflation correction factor. The calculation for the adjusted cost of utilities and communication is as illustrated in table 4.21. However, the total utility costs for the year 2011 was prorated for six months period by apportioning it based on the study period of six months as data collection in 2011 ends on the 30th June 2011. This was done by dividing the 2011 annual utility and communication costs by twelve and multiplying it with six months.

Table 4.21: Total utility costs (in RM2011) for HTAR for the year 2008 to 2011 adjusted for inflation rate taking 2011 as the base year

	2008	2009	2010	2011
Inflation Rate (%)*	5.4	0.6	1.70	3.20
Inflation Correction Factor (ICF)	1.056	1.050	1.032	1.000
Electricity	5,678,172.21	7,196,866.65	7,613,660.76	6,280,295.22
Water	1,310,945.47	1,115,038.76	1,016,872.73	896,255.60
Telephone	321,567.03	324,604.10	370,060.08	303,909.53
Total utilities	**7,310,684.71**	**8,636,509.51**	**9,000,593.57**	**7,480,460.35**

*Source of inflation rate: International Monetary Fund-2011 World Economic Outlook.

The total cost of utility and communication provided were the expenditure for the whole hospital. Therefore, the total cost of utilities for the whole hospital was apportioned according to the space ratio of the mammography unit to the hospital space area. The space area of the mammography unit was 54.21m^2, while the total space area for the hospital was 42,666 m^2. Therefore, the space ratio of the mammography unit to the hospital space area was 0.13% (Appendix O, line 'g'). This ratio was applied to the utility and communication costs of the respective years to obtain the estimated utility and communication cost of the mammography unit.

As for the denominator, the hospital statistics for patient attendance and radiological examinations were obtained from the Medical Records office of Hospital Tengku Ampuan Rahimah (HTAR), Klang and also the Radiology Department of HTAR for the year 2008 to 2011. These included the total number of out-patients and in-patients for the year 2008 to 2011.

The statistics provided for the radiology department were expressed as the total number of examinations and procedures instead of the total number of patients. This implies that one patient may undergo more than one radiological examination at any one time. These statistics is as shown in table 4.22. For the purpose of calculation, an assumption has to be made that the number of examinations done in the radiology department represents the number of patients using the services in order to obtain the cost per patient.

Table 4.22: Total number of patients in HTAR and total number of examinations done in Radiology Department, HTAR for the year 2008 to 2011

		2008	**2009**	**2010**	**2011**
A	Total HTAR in-patients (A)	83251	86473	88352	90225
B	Total HTAR out patients (B)	381183	395166	427491	469374
C	Total HTAR patients (A+B)	464,434	481639	515843	559599
D	Total examinations at radiology department (D)	148276	159466	172792	177037
E	Total mammography examinations (E)	1448	1391	1504	1508
F	Total USG examinations at Mammography Unit (F)	1760	2166	2597	2750
G	Other procedures in Mammography Unit(G)	246	320	355	416
H	Total examinations/ procedures in mammography unit (E+F+G)	3454	3877	4456	4674

Source: Medical Records Office, Hospital Tengku Ampuan Rahimah (HTAR), Klang and Radiology Department HTAR, Klang.

The cost of utility and communication per patient in the mammography unit for each year (Appendix O, line 'o') was obtained by dividing the apportioned utility and communication cost of mammography unit with the number of examinations done in the mammography unit (Appendix O, line 'h') for the respective years.

The average cost of utilities and communication per patient for the mammography unit was calculated by averaging the costs of utilities and communication per patient for the year 2008 to 2011. The overall average cost of utilities and communication per examination or procedure for the mammography unit was RM 2.59 (±RM 0.36). Table 4.23 shows the obtained average cost of utilities and communications per examination or procedures in the mammography unit. The calculation for cost of utilities and communication per patient for the respective years (2008 to 2011) is illustrated in Appendix O, line 'o'.

Table 4.23: Cost of utilities and communication per examination in the mammography unit, HTAR for the year 2008 to 2011 (expressed in 2011 RM)

	2008	2009	2010	2011	Mean (±SD)
Utilities and communication	2.75	2.90	2.63	2.08	2.59 (±0.36)

4.3.3 Cost of operation and maintenance:

Majority of the operation and maintenance services for Hospital Tengku Ampuan Rahimah (HTAR), Klang were done by the Radicare Sdn. Bhd. This is an outsourced company to cater the non-clinical hospital support services. It provides 5 main services which covers the whole hospital. These are the Facilities Engineering Maintenance Services (FEMS), Biomedical Engineering Maintenance Services (BEMS), Linen And Laundry Services (LLS), Cleansing Services (CLS) and the Clinical Waste Management Services (CWMS) (Radicare (M) Sdn. Bhd, 2013). Other than services covered by the Radicare the cost of operation and maintenance also included cost of security service.

Cost of operation and maintenance for the year 2008 to 2011 were obtained from the Finance Unit in the administration office of HTAR. The costs were the actual expenditure of the six services mentioned above (Appendix Q). For the purpose of calculation and comparison, these costs were adjusted for the inflation rate for the respective years using the calculated Inflation Correction Factor (ICF) taking 2011 as the base year. All costs will be expressed in Ringgit Malaysia 2011 currency as shown in table 4.24. The adjusted costs were obtained by multiplying the operation and maintenance costs with the ICF.

Table 4.24: Costs of Operation and Maintenance (RM2011) in Hospital Tengku Ampuan Rahimah (HTAR), Klang for the year 2008 to 2011 adjusted for inflation (RM 2011)

Year	2008	2009	2010	2011
Inflation Rate (%)	5.4	0.6	1.70	3.20
Inflation Correction Factor (ICF)	1.056	1.050	1.032	1.000
Services				
FEMS	6,329,742.93	7,647,816.37	7,734,079.39	7,474,615.11
BEMS	9,609,562.41	9,935,914.75	10,086,033.63	10,389,228.52
CLS	3,380,715.34	3,373,970.57	3,282,926.36	3,150,570.13
CWMS	1,916,292.46	2,187,168.44	2,233,088.21	3,336,616.87
LLS	4,864,654.12	5,385,966.05	5,759,473.05	4,792,248.73
Security	1,076,908.54	1,625,862.63	2,213,029.68	3,397,041.31
TOTAL	27,177,875.79	30,156,698.81	31,308,630.30	32,540,320.67

The total operation and maintenance costs for HTAR for the year 2011 was apportioned for six months based on the study period of six months as data collection in 2011 ends on the 30th June 2011. This was done by dividing the 2011 annual operation and maintenance costs for HTAR by twelve (months) and multiplying it with six (months). As for the year 2008 to 2010, annual costs of operation and maintenance for HTAR were used for the next calculation.

These costs are shown in Appendix O under the recurrent indirect costs for maintenance in line ‘p.i’ and ‘p.ii’. The total costs of operation and maintenance for mammography examinations were calculated by adding the cost of FEM, BEMS, CLS, CWMS, LLS and security (as shown in Appendix O, line ‘q’).

Next, the cost of operation and maintenance for the whole hospital was apportioned in order to calculate the cost of operation and maintenance for the Mammography Unit. This was done by apportioning the space area of the mammography unit (in square meters, m^2) to the hospital space area (in square meters, m^2) which was 0.13% (Appendix O, line ‘g’). Therefore, the cost of operation and maintenance for Mammography Unit was obtained by multiplying the cost of operation and maintenance for the whole hospital with the apportioned space area (0.13%) for the respective years.

In order to obtain the cost of operation and maintenance per patient, the apportioned costs for operation and maintenance for mammography unit was then divided by the total examinations in the mammography unit (as shown in Appendix O, line ‘h’). This calculation was repeated for the different years using their respective numerators and denominators which represent the cost of operation and maintenance per mammography examination for the year 2008 to 2011.

The average cost of operation and maintenance per mammography examination for the mammography unit was calculated by averaging the costs of operation and maintenance per mammography examination for the year 2008 to 2011. The overall average cost of operation and maintenance per examinations for the mammography unit was RM 9.63 (±RM 0.63). Table 4.25 shows the obtained average cost of operation and maintenance per mammography examination in the mammography unit. The calculation for cost of operation and maintenance per mammography examination according to the respective years (2008 to 2011) is illustrated in Appendix O in line ‘r’.

Table 4.25: Cost of operation and maintenance per mammography examination in the mammography unit, HTAR for the year 2008 to 2011 (expressed in 2011 RM)

	2008	2009	2010	2011	Mean (±SD)
Operation and maintenance	10.23	10.11	9.13	9.05	9.63 (±0.63)

4.3.4 Cost of consumables

The cost analysis of consumables included consumable items that were directly related to mammography examination up to establishing the BI-RADS classification for each mammogram result. This included breast ultrasonography to complement mammogram findings. However, biopsy procedures performed were not included in this analysis. There were three consumable items identified that were mammography films, ultrasound films and ultrasound gel. Stationeries were not included in the cost of consumables as they are considered negligible. Mammogram and ultrasound reports were printed on the same request form most of the time and the mammogram or ultrasound envelopes were recycled in most cases.

4.3.4.1 Cost of mammogram films

There were two sizes of mammography films that were Konica Dry Imaging Film SD-P 10”x12” and Konica Dry Imaging Film SD-P 10x8". The former was the medium to large mammogram film (24cmx30cm) and the latter was the small to medium size mammogram films (18cmx24cm). The usage of these films depended on the size of the women’s breasts. Here in this mammography suite, ultrasound thermal papers were not used to print ultrasound imaging. Instead, the ultrasound imaging was printed on the smaller size mammography films. Ultrasound gel was used as lubricating agent during the ultrasound procedure.

In order to calculate the cost of consumables, the number of mammogram films usage (and also the proportion for each sizes used) and ultrasound gel usage were estimated. The total number of items used for a certain period of time was obtained. From the stock keeping records, between 1st of April 2012 to 31st December 2012 (9 months) the number of mammogram films indented by the mammogram unit were 85 boxes for medium to large films and 80 boxes for small to medium films. However, the small to medium films were used to print both mammography and ultrasound imaging whereas the larger films were used for mammogram only.

From the 2011 mammography registry, the median number of films used for each patient was 4 films which comprised of 75% of the total population who underwent the mammography examination. An assumption was made that in most cases each patient needed 4 films (either sizes) for the two view mammography examination that were cranio-caudal and medio-lateral oblique, while 1 film (small to medium size films) was needed for the ultrasound imaging.

Therefore, for the small to medium films, the proportion of small films used according to the type of imaging namely mammogram imaging (4/5) and ultrasound imaging (1/5) were 0.8 and 0.2 respectively out of the total small to medium size films used. These allowed estimation of the number of boxes of small to medium films that were used for mammography examination and the ultrasound. From the 80 boxes of small to medium films indented (for the period of 9 months) at the radiology department, the estimated number of boxes used for mammography examinations were 64 boxes (0.8x 80 boxes) while for ultrasound the estimated number of boxes used were 16 boxes (0.2x 80 boxes).

The proportion of films used for mammography examination either medium to large or small to medium can be calculated based on the number of boxes used. For the period of 9 months, total boxes used for medium to large films are 85 boxes whereas 64 boxes were used for the small to medium films. Therefore, the proportions of mammogram films usage according to the size were 0.57 and 0.43 for medium to large films and small to medium films respectively for the period of 9 months.

Each box of films contained 125 sheets. Each box costs RM450 and RM350 for medium to large and small to medium size films respectively (costs were reported for the year 2011). Thus, the cost per film was RM3.60 for medium to large films and RM2.80 for small to medium films. Cost of films used for mammogram for the 9 months, was calculated by multiplying the number of boxes for medium to large films with the price of 1 box (85 boxes x RM 450) which was RM 38,250.00. As for the small to medium size films that were used for mammography examination, the cost was RM 22,400.00 (64 boxes x RM 350) for the same time period. The cost was then estimated for one year by calculating the cost that would be incurred for 12 months. The calculated cost was RM 51,000 for medium to large films (RM 38,250/9x12) while for small to medium films, the calculated cost was RM 29,866.67 (RM 22,400/9x12). The limitation was that this cost included the films that were void, damaged or rejected and also additional imaging.

The costs of mammogram films were calculated by applying the proportion of films used for mammography examination according to their sizes to their respective price per unit. An assumption was made that average patient needed four films for mammography examination. The cost per unit film for each size was multiplied by four giving the cost of mammogram films per patient. This cost was then multiplied by the respective number of mammography patients that used either small to medium size or medium to large size films. The number of patients was obtained by multiplying the proportion of women using either size for mammography films that is 0.57 (medium to large size) and 0.43 (small to medium size) with the number of mammography patients in 2011 that was 1508, which gave a value of 860 and 648 respectively.

The total cost of mammography films used by each film size per year was obtained by multiplying the total number of patients that used the films according to the size with the cost of 4 mammography films per examination. This means for medium to large size mammogram films, the total cost per year was obtained by multiplying 860 patients with cost per mammography examination RM 14.40 which gave a value of RM12, 377.66. Similarly, for small to medium size films, total number of patients that was 648, was multiplied by RM11.20 which gave a value of RM7, 262.53 for the total cost of mammogram films per year. The calculation is as shown below in table 4.26. The cost of mammogram films per mammography examination was calculated by dividing the total costs of mammogram films (RM19,640.19) by the average number of mammography examinations done in 2011 (n=1508) which gave a value of RM13.02 per mammography examination.

Table 4.26: Calculation of costs of mammography films (in RM2011) for mammography examination in HTAR, Klang for the year 2011

Type of film	Size of films	Proportion	Cost per unit (RM)	Cost per screening (4 films)	Total cost per year (RM)
Konica Dry Imaging Film SD-P 10x12"	medium to large	0.57	3.60	14.40	12,377.66
Konica Dry Imaging Film SD-P 10x8"	small to medium	0.43	2.80	11.20	7,262.53
Total cost of films/ year					19,640.19
Number of mammography examinations in 2011					1508
Cost of mammography films per mammography examination					**13.02**

The costs of mammography films were not available for the year 2008 to 2010. Therefore, the mammography films costs for the year 2010 and 2009 were estimated using the 2011 mammography films costs by assuming that the mammography films costs for 2009 and 2010 were the same as that obtained for 2011.

Total cost of mammography films per mammography examination was calculated by multiplying the adjusted cost of mammogram film per mammography examination by the total number of mammography examinations for the respective years (2008 to 2011). This is shown in Appendix O, line 's'.

4.3.4.2 Cost of ultrasound (USG) films

In the Radiology Department HTAR, Klang, ultrasound examinations were either done in the main ultrasound room or in the mammography suite. The former usually included mainly the non-breast ultrasounds while in the latter in most of the cases were the breast ultrasounds. The Radiology Department statistics on the number of ultrasound examinations done in the year 2008 to 2011 were obtained as shown in table 4.27 below. The total ultrasound examinations in the radiology department included all ultrasound examinations done in the radiology unit including those done in the main ultrasound room and the mammography suite while the total ultrasound done in mammography unit included only those that were done in the mammography unit.

Not all mammography patients end up having had ultrasound (USG) examinations as a complementary examination to their mammography examination. The number of women who needed breast ultrasound was calculated by apportioning the number of mammography cases per year who needed additional ultrasound examination. From the statistics collected 84.1% (2729) women out of 3245 women who had mammography also had ultrasound examination. In other words, the proportion of women who needed additional ultrasound examination on top of mammography examination was 0.84. This means, if the annual mammography patient for 2011 was 1508, applying 0.84 to 1508 estimated the number of women who had ultrasound which was 1267. Similarly, the total mammography examinations with complementary USG for 2008 to 2010 were calculated as shown in table 4.27 in row (d).

Table 4.27: Number of patients attended the mammography and the ultrasound services in the Mammography Suite HTAR, Klang for the year 2008 to 2011

	2008	**2009**	**2010**	**2011**
a)Total mammography patients	1448	1391	1504	1508
b)Total USG patients (Radiology Department)	8054	9600	12224	12087
c)Total USG patients at mammography unit	1760	2166	2597	2750
d)Total mammography patients with USG	1218	1170	1265	1267

In the Mammogram Suite, HTAR Klang, the small and medium size mammogram films were also used to print ultrasound imaging of the breast. The calculated cost per mammogram film was RM2.80 for this film size. It was assumed that for each breast ultrasound done, one film per ultrasound was used to print the image. Therefore, cost of film per ultrasound examination was RM2.80.

The costs of ultrasound films per mammography examination were not available for the year 2008 to 2010. Therefore, the costs of ultrasound films per mammography examination for the year 2008, 2009 and 2010 were estimated using the 2011 costs of ultrasound films per mammography examination by assuming that the costs of ultrasound films per mammography examination for 2008, 2009 and 2010 were the same as that obtained for 2011.

The estimated total cost of films for ultrasound per year was then calculated by multiplying the costs of small to medium mammogram film adjusted for inflation by the total number of mammography examinations with complementary ultrasound (according to the respective years) as shown in Appendix O in line 'j'. The calculated costs of consumables for Ultrasound films for the year 2008 to 2011 are as shown in Appendix O in line 't'.

4.3.4.3 Cost for ultrasound gel

Ultrasound gel was used as lubricating agent during the ultrasound examination. The stock counts and movements were documented in a systematic way in stock cards starting from end of March 2012 onwards by the stock officer of the Radiology Department. Information on stock counts and movements was insufficient for periods before that. Therefore, for the purpose of calculation, the stock counts in 2012 were adapted to 2011 patient statistics and costs.

The usage of ultrasound gel from 1st April 2012 to 31st December 2012 (9 months) was 30 cubitainers for all ultrasound examinations which included those that were done both in the main ultrasound room and in the mammography unit. The price for one cubitainer was RM55 (cost in RM2011). Therefore the price of ultrasound gel for the 9 months (RM55.00 x 30 cubitainers) was RM495.00. Annual estimation for ultrasound gel expenditure was calculated for 12 months by dividing RM495.00 with 9 months and multiplying with 12 months. This gave an annual estimation for ultrasound gel expenditure of RM 660.00 in 2012. This annual estimation of cost of ultrasound gel for 2012 was then used to estimate the cost for 2011 by deflating (reverse inflation, 1.7%) the 2012 cost to the year 2011. This was done by dividing the cost of ultrasound gel in 2012 with the inflation correction factor (1.017). This gave an estimation value of RM 648.97 for 2011.

Therefore, the calculation of cost of ultrasound (USG) gel per ultrasound examination for 2011 was done by dividing the total costs of ultrasound gel per year (RM648.97) with the number of ultrasound examinations done in the radiology department for 2011 (n=12,087) which gave a value of RM0.05. This is shown in table 4.28.

Table 4.28: Calculation of costs of ultrasound gel per ultrasound (USG) examination in the radiology department, HTAR for the year 2012 and 2011

	Type of item	**Cost per unit**	**Cost for 9 months**	**Cost per year**	**Cost per year**
		(2012)			**(estimated for 2011)**
USG gel	KONIX (5 Litres)	RM55/cubitainer	RM495	RM660	RM 648.97
Cost of ultrasound gel per ultrasound examination				**RM 0.05**	**RM 0.05**

The costs of USG gel per mammography examination were not available for the year 2008 to 2010. Therefore, the cost of USG gel per mammography examination for the year 2008, 2009 and 2010 were estimated using the 2011 cost of USG gel per mammography examination by assuming that the cost of USG gel per mammography examination for 2008, 2009 and 2010 were the same as that obtained for 2011.

The estimated total cost of USG gel per year was calculated by multiplying the adjusted costs of USG gel per mammography examination by the total number of mammography examinations with complementary ultrasound (according to the respective years). The calculations for the costs of USG gel for the year 2008 to 2011 are as shown in Appendix O in line ‘u’.

4.3.4.4 Total costs of consumables

Total costs of consumables were calculated by adding the total costs of mammogram films, ultrasound films and ultrasound gel per mammography examination for the respective years (2008 to 2011).

The costs of consumables per mammography examination (Appendix O, line ‘w’) were calculated for the year 2008 to 2011 by dividing the total costs of consumables (Appendix O, line ‘v’) with the number of mammography examinations (Appendix O, line ‘e’) according to the respective years. The cost of consumables per mammography examination for the year 2008 to 2011 is illustrated in table 4.29 below. The mean cost of consumables per mammography examination for a year was calculated by taking the average cost of consumables per mammography examination which gave a value of RM 15.42 (±0.001).

Table 4.29: Costs of consumables per mammography examination in the mammography unit, HTAR for the year 2008 to 2011 (expressed in 2011 RM)

	2008	2009	2010	2011	Mean (±SD)
Consumables	15.42	15.42	15.42	15.41	15.42 (±0.001)

4.3.5 Cost of staff salary

The mammography suite operated on a daily basis for five days in a week. The usual team that runs the mammography services at any one time comprised of either a consultant radiologist or a specialist radiologist, a medical officer, a staff nurse, two radiographers and an attendant. However, there were days that there might be an extra radiographer on duty although this seldom happen. These staffs were put on duty in the mammography suite on a rotational basis. There was one consultant, five radiologist specialists, seven medical officers, eight radiographers, three staff nurses whom were rotated to be on duty in the mammography suite. As for the attendants, their job covered the whole Radiology Department during the working hours. The staffs were divided into 5 job categories which were the specialists (may be a consultant or a specialist radiologist), medical officers, staff nurses, radiographers and attendants. Each staff category had different grades and their annual salary depended on their grades. All staff on duty each day worked according to the usual working hour that was 8 hours a day from 8 am to 5 pm with a one hour break between 1 pm and 2 pm. The average number of working days in a month was 22 days.

The total cost of staff were calculated based on the total contact hours that each staff spent with each patient except for the attendants whereby the salary cost were calculated based on the working hours that was 8 hours for 5 days in a week. The patient contact hours with staff were measured by a time motion study to obtain the total time spent directly with patient (Appendix D). This measured the time from when the patient arrived at the Mammography Suite until the end of the mammography session when the patient left the facility as shown in Appendix E. However, as for the attendants, they covered the whole of the Radiology Department. Therefore the cost of salary for attendant per examination was measured by dividing the average annual salary for one attendant (RM 22,477.12) with the average number of radiological examinations (164,393) which costs RM0.68 per radiology examination.

The annual salaries were obtained for the consultant, specialists, doctors, staff nurses, radiographers and attendants according to their grades for the year 2008, 2009, 2010 and 2011 (Appendix R) . This included annual salary and allowances. Salaries were adjusted for inflation by using inflation rate correction factor (ICF) taking 2011 as the base year which allowed comparison of monetary value over the four years. An average monthly salary was calculated for each staff category for each year. Salary per hour was then calculated for each staff category by dividing the monthly salary by 22 working days and eight working hours a day. The calculation for salary per hour for each staff category was done for each year.

Cost of salary per patient for each category was calculated by multiplying the salary per hour of staff by the total patient contact hours of the respective staff category. This calculation was repeated for the year 2008 to 2011.

At any one time, a patient was seen by either a consultant or by a specialist radiologist depending on the rotation schedule for that particular day. Therefore, to calculate the salary per hour for this job category (consultant or a specialist radiologist) an average of cost of salary per hour was calculated to represent the specialist group. There was one consultant and five radiologists that were rotated to be on duty at the mammography unit at any one time. Therefore, the ratio of consultant to specialist was

1/6 and 5/6 respectively. This was then applied to the salary per hour for the consultant/ specialist job category.

Therefore, to average the salary for these two staff categories, an example using 2008 staff salary will be demonstrated. For example, for the year 2008 (expressed in 2011 RM) the salary per hour for a consultant (RM 107.44) was multiplied by the ratio of the consultant to the specialist group that was 1/6 which gave a value of RM 17.91. As for the specialist, the salary per hour (RM 45.83) was multiplied by the ratio of the specialist that was 5/6 which gave a value of RM 38.19. The salary per hour that represents the two staff categories (consultant and specialists) in the mammography unit was obtained by adding RM 17.91 and RM 38.19 which gave a value of RM56.10. An example of the calculation for cost of staff per patient for the year 2008 is as shown in table 4.30 below.

Table 4.30: Cost of staff salary by staff category in Mammography Unit HTAR for the year 2008 (expressed in RM2011)

Staff Category	Contact Hour (a)	Salary per hour (b)	No. of Staff (c)	Cost Per Patient (d)
Consultant/ Specialist*	0.35	56.10	1	19.63
Medical Officers	0.35	27.31	1	9.56
Staff Nurses	0.30	18.58	1	5.57
Radiographers	0.65	13.55	2	17.62
Attendants	NA	0.68	1	0.68
Salary per patient				**53.06**

*Salary per hour for consultant and specialist were moderated to represent the specialist group.

Similarly, the cost of salary were then calculated for the year 2009 to 2011 as shown in Appendix O, in the salary section in line ‘x (i)’ to ‘x (v)’. The total salary per patient for the respective years was obtained by adding the cost of staffs for the different job categories according to their contact hours respectively, as shown in Appendix O in line 'y'. An example of the calculated total cost of salary per patient for the year 2008 is as shown in table 4.41. The average total cost of salary per patient were calculated for the year 2008 to 2011 by adding the cost of salary per patient for the respective years and divided by the four years which gave a value of RM57.22 (±3.52).

4.3.6 Total cost per patient for mammography examination

The mean cost per patient for a mammography examination was obtained by adding the mean costs per patient for all cost items which were cost of equipment and furniture, cost of utilities and communication, cost of operation and maintenance, cost of consumables and cost of staff salaries as shown in table 4.31. The mean total cost of mammography screening per patient was RM 197.30 (±RM13.01).

Table 4.31: Mean cost of mammography screening per patient in HTAR, Klang for the year 2008 to 2011 adjusted for inflation (in 2011 RM value)

Cost items	Mean	SD	Range
Equipment and Furniture	112.44	15.647	(97.62-132.10)
Utilities and Communication	2.59	0.356	(2.08-2.89)
Operation and Maintenance	9.63	0.624	(9.05-10.23)
Consumables	15.42	0.001	(15.41—15.42)
Salary	57.22	3.524	(53.06-61.06)
Cost per MG	**197.30**	**13.005**	**(185.21-213.55)**

4.3.6.1 Total cost for mammography screening of women with risk factors

Total cost for screening mammography in Hospital Tengku Ampuan Rahimah, Klang for 1427 women for the year 2008 to 2011 were calculated by multiplying the cost per patient for each cost item with the total number of women who underwent screening mammography. The calculated total cost is as shown in table 4.32. The majority of the total costs were attributed to the costs of equipment and furniture (56.99%), followed by costs of staff salary (29.00%), costs of consumables (7.82%), costs of operation and maintenance (4.88%) and costs of utilities and communication (1.31%). The total cost calculated for 1427 women who went for screening mammography was RM 281,547.10.

Table 4.32: Cost per mammography and the total cost for mammography (RM2011) in HTAR, Klang for the year 2008 to 2011 for 1427 women

Cost items	Cost per patient (RM)	Total cost for 1427 women (RM)	Percentage (%)
Equipment & Furniture	112.44	160,451.88	56.99
Salary	57.22	81,652.94	29.00
Consumables	15.42	22,004.34	7.82
Operation and Maintenance	9.63	13,742.01	4.88
Utilities and Communication	2.59	3,695.93	1.31
Total	**197.30**	**281,547.10**	**100.00**

4.3.7 Cost per breast cancer detected by mammography of women with risk factors

The cost per breast cancer detected by mammography screening among women with risk factors were obtained by multiplying the total cost to screen 1,427 women that was RM 281,547.10 with the number of breast cancer detected that was 29 breast cancers. Therefore, the cost per breast cancer detected was RM 9,709.

4.3.8 Factors affecting cost of mammography screening

4.3.8.1 Labour cost of mammography

There are five cost items for mammography screenings that were included in the cost calculation. These are cost of equipment and furniture, cost of utilities and communication, cost of operation and maintenance, cost of consumables and cost of staff salary. The largest portion of cost of mammography screening per patient (RM

197.30) was contributed by the cost of equipment which contributed about 57.0%, followed by cost of staff salary which contributed about 29.0%.

The relationships of the costs of labour in mammography screening activities were calculated by varying the cost of staff salary. This can be done by applying the minimum and maximum cost of staff salary into the calculation of cost per mammography screening. The average costs for other cost items used were maintained.

Among the staffs involved in the mammography screening, the largest cost of staff salary was contributed by the salary of the radiologist. Radiologists can either be a consultant or a specialist. Therefore, the minimum and the maximum cost of staff salary for radiologist were identified. The cost of staff salary was at its minimum if a specialist was involved (with the minimum cost of salary per hour of RM45.83 for a specialist), while it was at its maximum if a consultant was involved (with the maximum cost of salary per hour of RM109.54 for a consultant). The cost of staff salary per patient for a specialist and a consultant was calculated by multiplying the respective salary per hour by the patient contact time that was 0.35 per hour for a specialist or a consultant. These were then added to the costs of salary of other staff categories. The minimum or maximum costs of staff salary per patient for each staff category were calculated. This is as shown in table 4.33.

Table 4.33 : The minimum and maximum cost of staff salary for mammography

Staff Category	Contact hour (a)	No. of staff (b)	Minimum salary per hour (c)	Maximum salary per hour (d)	Minimum cost per patient (e)	Maximum cost per patient (f)
Consultant/ Specialist*	0.35	1	45.83	109.54	16.04	38.34
Medical Officers	0.35	1	27.31	36.00	9.56	12.60
Staff Nurses	0.30	1	18.58	19.06	5.57	5.72
Radiographers	0.65	2	12.83	13.55	16.68	17.62
Attendants	NA	1	0.68	0.68	0.68	0.68
Salary per patient					**48.53**	**74.96**

The minimum and maximum cost per screening mammogram were calculated by adding the minimum and maximum costs of staff salary respectively to the average cost of the other cost items which was kept similar. The findings of these calculations are as shown in table 4.34. The minimum and the maximum costs of mammography screening were RM 188.62 and RM 215.05, respectively.

Table 4.34: Minimum and maximum costs per mammogram

MG	**Minimum**	**Maximum**
Cost items	**Cost per MMG (RM)**	**Cost per MMG (RM)**
Equipment & Furniture	112.44	112.44
Utilities & Communication	2.59	2.59
Operation & Maintenance	9.63	9.63
Consumables	15.42	15.42
Staff	48.53	74.96
Costs for MG (RM)	**188.61**	**215.04**

4.3.8.2 Breast cancer detection rate

The other factor that can affect the costs of mammography screening activities is the breast cancer detection rate. Different breast cancer detection rates determine whether the cost per breast cancer detected by mammography screening activity to be higher or lower. In order to demonstrate this relationship, breast cancer detection rates by mammography screening were obtained from previous studies and applied into the calculation for cost per breast cancer detected by mammography screening. For the purpose of calculation, the minimum and maximum breast cancer detections rates obtained from previous literatures were applied and the costs were calculated for 10,000 women.

The minimum and maximum breast cancer detection rates for mammography screening of women in the general population was obtained by identifying and applying the lowest and the highest breast cancer detection rates. The minimum breast cancer detection by mammography was abstracted from an observational study reported in Japan by Honjo et al. (2007) which involved 3,435 women. Out of the 3,435 women screened by mammography alone, 10 breast cancer cases were detected giving a detection rate of 0.29% (Honjo et al., 2007). The maximum breast cancer detection rate was chosen from an observational study by Lui et al. (2007), where 46, 637 women were screened by opportunistic mammography screening in a local Well Women Clinic in Hong Kong. Out of 46,637 women screened, 232 women were diagnosed with breast cancer giving a rate of 0.5% (5 in 1,000 women screened) (Lui et al., 2007). Similar breast cancer detection rate was also reported by Yen et al. (2016), where 594,345 women were screened by universal biennial mammography in Taiwan. Out of those screened, 2891 women were diagnosed with breast cancer giving a rate of 4.86 per 1000 women screened (0.49%) (Yen et al., 2016).

The minimum (0.29%) and maximum (0.5%) detection rates were then applied to 10,000 women screened in order to obtain the minimum and maximum number of breast cancer detected. Table 4.35 shows the calculation of the cost per breast cancer detected by mammography screening of women in the general population using the minimum and the maximum breast cancer detection rates. This was done by dividing the total cost of mammography screening for 10,000 women with the minimum and maximum number of breast cancer cases, respectively.

Table 4.35: The minimum and maximum breast cancer detection rates and the calculated cost per breast cancer detected for by mammography screening

MMG screening	Minimum	Maximum
Cancer detection rates (%)	0.29	0.5
Total number of cancers	29	50
Cost per MMG	197.30	197.30
Cost per breast cancer detected	**68,034.48**	**39,460.00**

The cost per breast cancer detected was higher (RM 68,034.48) at minimum breast cancer detection rate for mammography screening among women in the general population. In contrast, a lower (RM 39,460) cost per breast cancer detected was calculated at maximum breast cancer detection rate. This suggests that by increasing breast cancer detection rates by mammography screening would reduce the cost per breast cancer detected by this approach. Increasing breast cancer detection rate can be done by improving the quality of breast cancer screening and also increasing the coverage of breast cancer screening especially those in the targeted or high risk groups.

4.4 Comparison of cost per CBE and cost per mammography

When comparisons were made between cost per CBE and cost per mammography screening, it was found that, the total cost for CBE was contributed largely by the cost of salary for CBE (61.6%), followed by utilities and communication (20.1%), operation and maintenance (10.5%) and equipment and furniture (8.3%). On the other hand, most of the cost for mammography screening was contributed majority by the cost of equipment and furniture (57.0%). This was followed by cost of staff salary (29.0%), cost of consumables (7.8%), operation and maintenance (4.9%), and lastly cost of utilities and communications (1.3%). As for CBE, the recurrent costs contributed a larger percentage to the total cost compared to the capital costs. On the other hand, for mammography screening, the capital cost contributed a larger portion of the total cost of screening. These figures are as shown in table 4.36.

Table 4.36: Cost per breast screening activity (RM 2011) for clinical breast examination and mammography screening

	Cost per CBE (RM, %)	Cost per MMG (RM, %)
Capital cost		
Equipment and furniture	0.553 (8.3)	112.44 (57.0))
Subtotal, Capital	0.553 (8.3)	112.44 (57.0)
Recurrent cost		
Utilities and communication	1.342 (20.1)	2.59 (1.3)
Operation and Maintenance	0.703 (10.5)	9.63 (4.9)
Staff salary	4.079 (61.1)	57.22 (29.0)
Consumables	-	15.42 (7.8)
Subtotal, Recurrent	6.124 (91.7)	84.86 (43.0)
Total*	6.68 (100.0)	197.30 (100.0)

*rounded to 2 decimal points

4.5 Discussion on Cost Analysis

This economic analysis and outcome assessment study aims to determine the cost and outcome of the current breast cancer screening approaches that are CBE followed by mammography when breast abnormality is detected, and mammography screening only among women with risk factors for breast cancer. The costs per breast cancer detected by both approaches were also calculated. This study was carried out in Klang district in Selangor which involved women who participated in the Pap smear screening programme and had CBE done in health clinics, and also women with breast cancer risk factors who attended the mammography screening in a general hospital (Hospital Tengku Ampuan Rahimah, Klang).

4.5.1 Costs analysis for breast cancer screening

The costing for each screening method included all costs involved in the breast screening activity from the registration of the patient until the outcome of the screening activities were obtained. The costs incurred for further investigation or other diagnostic tests involved in the diagnosis of breast cancer were not included in the cost calculation. For the purpose of comparison of costs in the study findings with other countries, all costs in 2011 Ringgit Malaysia will be converted to 2011 US Dollars for the same base year that was 2011. The exchange rate used was 1 RM equivalent to RM 0.31556, using the average rate for Malaysian Ringgit to US Dollar on the 31st December 2011.

4.5.1.1 Cost of CBE and mammography

The calculated cost of screening per patient by CBE was RM6.68 (USD2.11) and by screening mammography was RM197.30 (USD62.26). The major cost for mammography screening was contributed by the capital cost (57.0%), followed by cost of staff salary (29.0%) and cost of consumables (7.8%). Meanwhile, as for CBE screening, most of the cost was contributed by the cost of staff salary (61.1%), followed by utilities and communication cost (20.1%) and operation and maintenance cost (10.5%). The higher cost of mammography screening was contributed by the high cost of equipment and mammography machine and cost of staff salary. Therefore, in order to implement screening mammography, a huge amount of investment is needed. In contrary, CBE screening only needed very minimal cost in terms of equipment as no special machine was involved in its activity. In addition to that, CBE used existing labour resources with minimum cost and less time required for training compared to mammography screening activity.

This study showed that the cost of mammography screening was RM 197.30 (USD 62.26) per screening. In Kuala Lumpur, the market price for screening mammography alone in the private facilities as updated in January 2014 ranged from RM110 (USD31.44 in 2014 USD) to RM250 (USD71.45 in 2014 USD), for breast ultrasound only ranged from RM100 (USD28.58) to RM205 (USD58.59), while for mammography and breast ultrasound package ranged from RM160 (USD45.73) to RM 290 (USD82.88) depending on the type of mammography screening (either analogue or digital mammography screening), the type of ultrasound machine used, and the type of facility which offers the service (Appendix S). The exchange rate used was 1 RM equivalent to 0.28580 USD using the average rate for Malaysian Ringgit to US Dollar on the 31st December 2014. If these private facility costs were expressed in the same base year that is 2011 (by dividing the 2014 RM value with the inflation correction factor for 2014 that is 1.074; and converted to 2011 USD (1RM = 0.31556USD)) to allow comparison of price in public and private facilities, the price in private facilities for screening mammography alone ranged from RM102.42 (USD32.32 in 2011 USD) to RM232.77 (USD73.45 in 2011 USD), for breast ultrasound only ranged from RM93.11 (USD29.38) to RM190.88 (USD60.23), while for mammography and breast ultrasound package ranged from RM148.98 (USD47.01) to RM 270.02 (USD85.21). With the assumption that the costs of mammography and breast ultrasound in Kuala Lumpur and Selangor (including Klang district) were similar, this suggests that cost per mammography screening among women with risk factors obtained from this study (RM197.30 (USD 62.26)) was comparable to the price of mammography and breast ultrasound in the private facilities especially for the package service (ranged from RM148.98 (USD47.01) to RM 270.02 (USD85.21)). However, the cost for mammography and breast ultrasound would be higher in most private facilities if both of these services were purchased separately (ranged RM195.53 (61.7USD) to RM423.65 (133.68USD)), considering that most mammography screening for women with risk factors would need breast ultrasound in order for the Breast Imaging-Reporting and Data System (BI-RADS) classification to be made. This study showed that about 84.1% of women with risk factors for breast cancer that were screened by mammography needed breast ultrasound as a complementary examination in order to be classified using the BI-RADS classification.

The mammography unit in the public facilities catered mostly diagnostic mammography procedures and other diagnostic imaging procedures and also biopsies apart from screening asymptomatic women. Therefore, there was limited numbers of women that were seen either for diagnostic mammography or screening mammography in a day (more cases for diagnostic mammography as compared to screening mammography). This cost (cost per mammography) could be reduced if the efficiency of the machine was increased in terms of number of women screened per day. However, in a referral hospital like HTAR as in this study, the higher number of diagnostic procedures limited the number of asymptomatic women that can be screened by mammography in a day. Having dedicated mammography screening centres would allow the number of women screened to be higher and therefore reduces the cost per mammography screening.

Compared to a study done by Neha Reddy et al. (2012), in Andhra Pradesh, India, showed that the average cost for breast cancer screening activity per patient was USD$30 (which included CBE, mammogram, ultrasound and fine needle aspiration), where mammogram and ultrasound being the major cost. Cost of each mammogram was USD$12. Other cost items included in the total cost were cost of advertisement, training of ASHA (Accredited Social Health Activist) workers, team transportation, lunch and other expenditure (Reddy et al., 2012). This showed that the cost of breast cancer screening camp (which included CBE, mammography, ultrasound and fine needle aspiration) in Andhra Pradesh was cheaper compared to those found in this study that was RM197.30 (USD 62.26). Cost of mammography screening in Malaysia can be further reduced if the number of patients that utilizes the mammogram services increases. This will therefore reduce the average cost of mammography screening per patient.

The study by Neha Reddy et al. (2012) also showed that this average cost of USD$30 per patient in the breast screening camp can be reduced to USD$16 for simple clinical breast examination only without mammogram, ultrasound and fine needle aspiration (Reddy et al., 2012). This showed that the cost for CBE was far more expensive in the camp in India compared to the cost of CBE done in this study which only cost RM6.68 (USD 2.11). The difference of the cost of CBE may be contributed by the difference in the examiners where in this study CBE was done by nurses while in the breast cancer screening camp in Andhra Pradesh it was done by physicians whom were medical oncologist, a radiation oncologist and a surgical oncologist. In addition to that, the camp also carried other costs that were contributed by the activities involved in running the breast cancer screening camp. However, the overall cost per patient for the screening camp can be further reduced if the number of participant was increased therefore reducing the average cost per person.

Overall, cost per CBE that was RM6.68 (USD 2.11) found in this study was comparatively low due to the fact that this activity was done using existing health facilities and staff. However, opportunity cost lost due to this activity has to be taken into account where other services in the Maternal and Child Health clinic activities were foregone in exchange for the CBE activity because the staffs involved were from the same pool of staff.

4.5.2 Cost per breast cancer detected

This study found that the cost per breast cancer detected was RM 11,864 (USD 3,744) for CBE followed by mammography when breast abnormality is detected, while for mammography screening among women with risk factors for breast cancer, the cost per breast cancer detected was RM 9,709 (USD 3,064). This means that the cost to detect one breast cancer by CBE followed by mammography when breast abnormality is detected was RM 11,864 (USD 3,744), while for mammography of women with risk factors was RM 9,709 (USD 3,064). Although the difference of costs per breast cancer detected between the two breast cancer screening approaches were not very large, there are other additional costs that were not included in this calculation as this study only included screening costs.

Other costs that should be considered before implementing mammography screening in the population are capital outlay costs, costs for human resource and trainings of staffs including radiologist, costs for treatment of breast cancer detected from screening activities, and costs for rehabilitation and palliative care services.

Comparing the findings of cost per breast cancer detected by clinical breast examination in this study (RM6.68 (USD2.11) to a study by Feigin et al. in 2006, showed that the cost of CBE per cancer detected solely with positive CBE finding was USD$122 598 per cancer detected (Feigin et al., 2006). However, this finding was not comparable to the findings found in this study. The big difference of cost per cancer detected from the study by Feigin et al. (2006) and this study was caused by few factors.

Firstly, the cost calculation in the study by Feigin et al. (2006), included all additional diagnostic tests including diagnostic mammography, ultrasound, ductography, fine needle aspiration biopsy, core biopsy and excisional biopsy, and associated image-guidance and pathologic costs in which the calculated cost used the Medicare reimbursement rates. (Feigin et al., 2006). In comparison to this study, only the screening cost was included into the cost calculation but not the cost of diagnostic investigation of breast cancer due to the lack of data on cost of diagnostic investigation for breast cancer in Malaysia. Secondly, study by Feigin et al. (2006) has higher percentage of abnormal breast findings by CBE that was 0.79% compared to 0.5% found in this study (Feigin et al., 2006). Thirdly, it may be due to the difference in the qualification of the examiner whereby the nurse practitioner who did the CBE has higher qualification with master's degrees as compared to diploma certificate for nurses in this study.

In another study by Denewer et al. (2010), where women received CBE-based screening with selective mammography showed that the cost of screening per cancer detected was approximately USD $415 (excluding treatment cost) (Denewer et al., 2010). However, the cost items included in the cost calculation for cost of screening were not mentioned in detail. The smaller cost of screening per cancer detected in rural Egypt study compared to this study could be contributed by the difference in the breast cancer detection rate in rural Egypt, where it is very high as compared to other countries where 18 breast cancers were detected among 5,900 women screened (0.3%) by CBE-based screening with selective mammography (Denewer et al., 2010). Comparatively, the breast cancer detection rates by clinical breast examination followed by mammography obtained in this study was 0.07%.

This study also showed that the cost per breast cancer detected for mammography among women with risk factors was RM 9,709 (USD 3,064). This was found to be lower than that found in a population-based mammography screening in a middle-income country like Poland where the cost was USD 3,665 per cancer found (Szynglarewicz & Matkowski, 2011). These differences may be contributed by many factors such as the costs involved in the cancer screening programme and also other known factors that affect the breast cancer detection rate such as the sensitivity of the screening methods used, incidence of breast cancer and also the population coverage of the breast cancer screening programme (de Koning, 2000). However, the cost involved in the calculation for the study in Poland was not stated in detail in the literature which did not allow comparison to be made in terms of cost items involved.

There are other studies that were done that measures cost-effectiveness of breast cancer screening methods involving clinical breast examination and mammography screening. However, currently there is limited evidence for breast cancer screening strategies in low- and middle-income countries that are of good quality (Zelle & Baltussen, 2013). Most cost-effectiveness analysis studies were model based and the reported effectiveness outcome measures were different.

CHAPTER 5: RESULTS ON OUTCOME ASSESSMENT

5.1 Introduction

This chapter shall cover the discussion on the findings of the outcomes of the two breast cancer screening approaches that are CBE followed by mammography when breast abnormality is detected, and mammography among women with risk factors.

5.2 Outcome of CBE followed by mammography when breast abnormality is detected

This study population was among women who participated in the Pap smear screening and had CBE done during their visit. There were 16,078 women registered in the Pap smear registry books in 8 health clinics in the Klang district. Eleven (11) cases cancelled their Pap smear examinations therefore were not included in the analysis. There were 776 cases with no documentation of the clinical breast examination (CBE) findings in the CBE column in the Pap smear registry books. There were two possible reasons why there was no documentation of the CBE findings such as the examiner had forgotten to record the CBE findings or the CBE was not done for some reasons. These cases were excluded as they did not have the outcome variables. After exclusion of cases that were not eligible, the total number of cases that were available for further analysis was 15,279 cases. Out of 16,078 cases, there were 96 cases with documentation of abnormal CBE findings of which 12 were excluded due to either known case breast cancer (6 cases) and those with known case of abnormal breast findings prior to the CBE (6 cases). This left about 84 cases with abnormal CBE findings. The flow chart of the clinical breast examination outcomes is as shown in Figure 5.1.

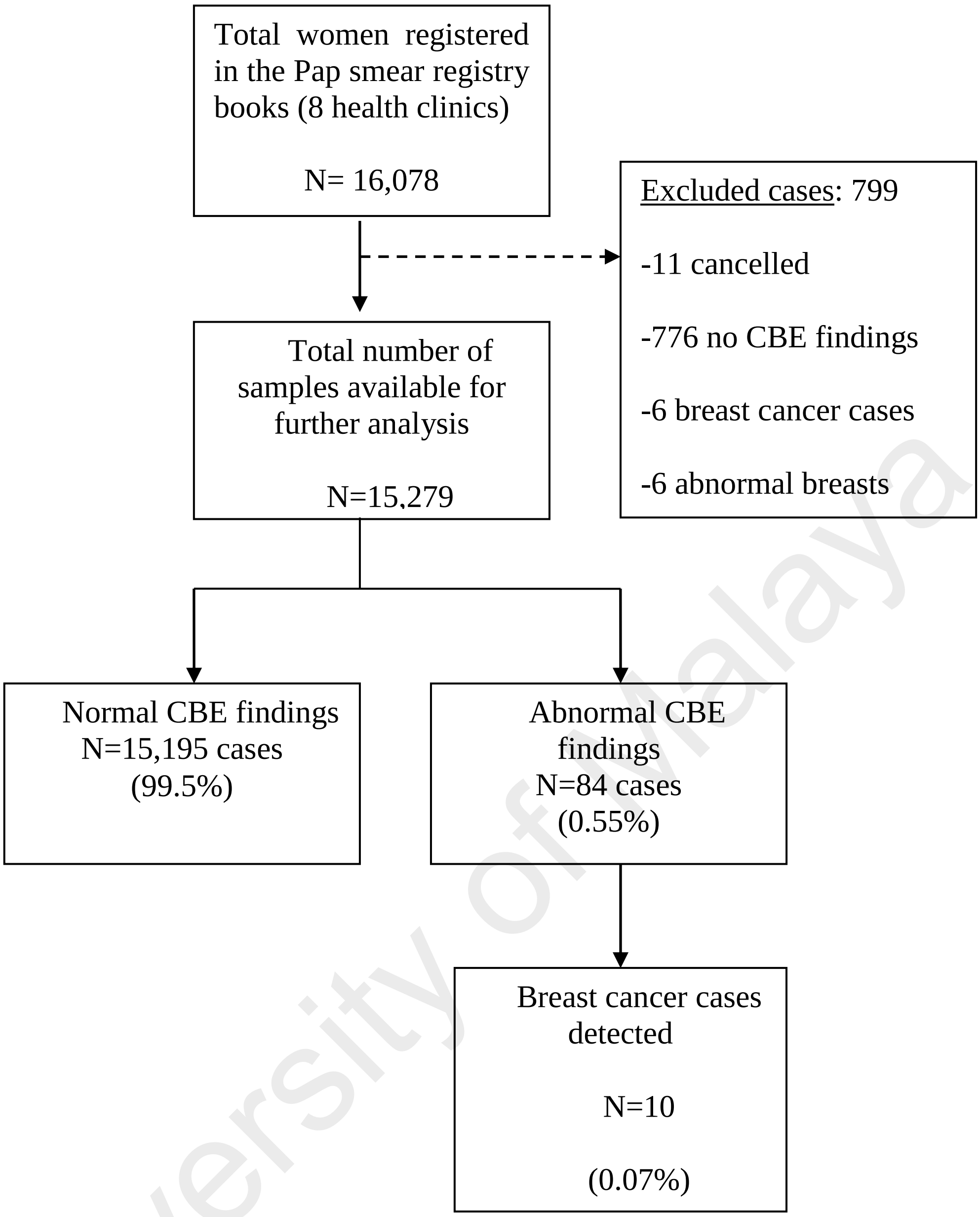

Figure 5.1: Flow chart of the outcome for clinical breast examination on the sample population from 8 health clinics in Klang district

5.2.1 Socio-demographic and reproductive characteristics for CBE participant

A total of 15,279 cases were registered in the Pap smear registry books that were eligible for analysis. These cases were analysed for socio-demographic characteristics, reproductive characteristics and clinical breast examination (CBE) findings. The socio-demographic characteristics were age groups, nationality and ethnic groups while the reproductive characteristics were the number of children, family planning methods used and whether they were family planning users or non-users. The socio-demographic and reproductive characteristics are shown in table 5.1 below.

Table 5.1: Socio-demographic and reproductive characteristics of women who had CBE done in 8 health clinics from the year 2009 to 2011

Characteristics	n, (%) n=15,279
Age	
Mean age (±SD)	42.39 (±11.396)
Range	15-82
Age group	
<=24 years	632 (4.1)
25-29 years	1563 (10.2)
30-39 years	4335 (28.4)
40-49 years	4323 (28.3)
50-59 years	3197 (20.9)
>= 60 years	1212 (7.9)
Nationality	
Malaysian	14961 (97.9)
Non-citizen	318 (2.1)
Ethnic groups	
Malay	6327 (41.4)
Chinese	4750 (31.1)
Indian	3738 (24.5)
Others	464 (3.0)
Number of children	
Nulliparous (0)	718 (4.7)
Parous (>= 1 child)	13666 (89.4)
Unknown	895 (5.9)
Family Planning Methods	
Condom	147 (1.0)
IUC	489 (3.2)
OCP	1109 (7.3)
Injections	842 (5.5)
Implants	30 (0.2)
BTL	271 (1.8)
Others	41 (0.3)
Family Planning Users	
Users	2929 (19.2)
Non-users	10784 (70.6)
Unknown	1566 (10.2)

Characteristics	n, (%) n=15,279
Health clinics	
Bukit Kuda (BKD)	2684 (17.6)
Bandar Botanic (BTN)	3405 (22.3)
Kapar (KPR)	1413 (9.2)
Meru (MRU)	2302 (15.1)
Pandamaran (PDM)	3173 (20.8)
Pulau Indah (PID)	404 (2.6)
Pelabuhan Klang (PKG)	1622 (10.6)
Pulau Ketam (PKM)	276 (1.8)

The mean age of women who participated in the clinical breast examination screening in the eight health clinics was 42.39 (SD 11.396) years old. Majority of the women screened by CBE were in the 30-39 years age group (28.4%), followed by the 40-49 years (28.3%) and the 50-59 years (20.9%). This suggest that majority of the women screened were below the age of 50 years old.

According to the ethnicity distribution, Malays formed the majority of the group with 41.4% followed by the Chinese (31.1%) and the Indians (24.5%). There were only 2.1% who were non-Malaysians. Analysis of the reproductive characteristics showed that only 4.7% of the women were nulliparous, while about 19.2% were users of any type of family planning method. However analysis according to whether a family planning method was hormonal or non-hormonal could not be carried out due to the incomplete documentation regarding the type of Intra Uterine Contraceptive Device used. Only 0.3% used other contraceptive methods which included either natural family planning or using traditional methods.

5.2.2 CBE abnormality detection and breast cancer detection

The mean age of women with abnormal clinical breast examination (CBE) and those who were identified as having breast cancer were almost similar where the mean age were 41.29 (SD9.977) and 46.30 (SD9.557) respectively. Majority of those women found to have abnormal CBE findings were in the 30 to 49 age group (65%) whereas eight out of the 10 breast cancer cases or 80% of breast cancer cases identified were in the slightly older age group that was 40 to 59 years.

There were similarities in the ethnic group distribution for both abnormal CBE findings and breast cancer cases identified by CBE whereby the majority were from the Malay ethnic group (38.1% and 40.0%, respectively), followed by the Chinese (29.8% and 40.0%, respectively) and Indians (26.2% and 20.0%, respectively). As for reproductive characteristics, more than 80% of the women with abnormal CBE findings or breast cancer cases at least had one child and about 60% were users of any family planning method. The characteristics of women with abnormal CBE findings and those identified having breast cancer is as illustrated in table 5.2.

Table 5.2: Characteristics of abnormal Clinical Breast Examination (CBE) findings and breast cancer cases among women whom were screened in eight health clinics in Klang district in the year 2009 to 2011

	Abnormal CBE (n, %) n=84	**Breast cancer cases (n, %) n=10**
Age		
Mean age (±SD)	41.29 (±9.977)	46.30 (±9.557)
Range	15-82	29-57
Age group		
<=24 years	2 (2.4)	0 (0)
25-29 years	11 (13.1)	1 (10)
30-39 years	25 (29.8)	1 (10)
40-49 years	30 (35.7)	4 (40)
50-59 years	12 (14.3)	4 (40)
>= 60 years	4 (4.8)	0 (0)
Nationality		
Malaysian	1 (1.2)	0 (0)
Non-citizen	83 (98.8)	10 (100)
Ethnic groups		
Malay	32 (38.1)	4 (40)
Chinese	25 (29.8)	4 (40)
Indian	22 (26.2)	2 (20)
Others	5 (6.0)	0 (0)

	Abnormal CBE (n, %) n=84	Breast cancer cases (n, %) n=10
Number of children		
Nulliparous (0)	5 (6.0)	1 (10)
Parous (>= 1 child)	73 (86.9)	9 (90)
Unknown	6 (7.1)	0 (0)
Family Planning Users		
Users	56 (66.7)	6 (60)
Non-users	17 (20.2)	2 (20)
Unknown	11 (13.1)	2 (20)
Health clinics [a,b]		
Bukit Kuda (BKD)	8 (9.5)	1 (10)
Bandar Botanic (BTN)	23 (27.4)	3 (30)
Kapar (KPR)	19 (22.6)	2 (20)
Meru (MRU)	9 (10.7)	0 (0)
Pandamaran (PDM)	12 (14.3)	2 (20)
Pulau Indah (PID)	0 (0)	0 (0)
Pelabuhan Klang (PKG)	6 (7.1)	0 (0)
Pulau Ketam (PKM)	7 (8.3)	2 (20)
Stage of Breast Cancer		
Stage 1	na	1 (10)
Stage 2	na	2 (20)
Stage 3	na	5 (50)
Stage 4	na	2 (20)
Breast cancer stage group		
Early stage	na	3 (30)
Late stage	na	7 (70)

Notes:
[a] Chi square test (p <0.001) for abnormal CBE
[b] Fisher Exact test (p <0.005) for breast cancer cases detected
na =not applicable

Most of the abnormal CBE findings were detected in Klinik Kesihatan (KK) Botanic (27.4%) whereby three were identified as having breast cancer followed by KK Kapar (22.6%) and KK Pandamaran (14.3%) whereby two breast cancer cases were identified in each clinic. The other clinic with breast cancer cases were KK Pulau Ketam (two cases) and Bukit Kuda (one case). However, there were significant difference in the rate of abnormal CBE findings in the eight health clinics with the highest being KK Pulau Ketam (2.5%) followed by KK Kapar (1.3%), (p=0.03, 95%CI 0.08-1.42). Interestingly, the total number of cases screened for CBE in these two clinics was among the least, 276 women and 1413 women respectively (as shown in table 5.3).

Table 5.3: Breast abnormality and breast cancer detection rate among women who had clinical breast examination (CBE) in eight health clinics in Klang district in the year 2009 to 2011

	Breast abnormality detection rates (%)	p-value (95%CI)	Breast cancer detection rates (%)	p-value (95%CI)
District level				
Klang district	0.5	NA	0.07	NA
Health clinics[a,b]				
Bukit Kuda (BKD)	0.3	0.03 (0.08-1.42)	0.04	0.17 (-0.07-0.33)
Bandar Botanic (BTN)	0.7		0.09	
Kapar (KPR)	1.3		0.14	
Meru (MRU)	0.4		0	
Pandamaran (PDM)	0.4		0.06	
Pulau Indah (PID)	0		0	
Pelabuhan Klang (PKG)	0.4		0	
Pulau Ketam (PKM)	2.5		0.72	

Note:
[a]Chi square test, p<0.005 for abnormal CBE findings
[b]Fisher exact test, p>0.005 for breast cancer cases

5.2.3 Stage of breast cancer

Among the 15,279 women screened by CBE, there were ten cases of breast cancer identified. The study showed that among the ten breast cancer cases, three (30%) were in the early stage (stage 1 and stage 2) while another seven (70%) were in the late stage (stage 3 and stage 4). Among the three early stage breast cancer cases, two were Chinese while one was an Indian lady. In contrast, four out of seven (57.1%) late stage breast cancer cases were among the Malay ethnic group, two (28.6%) were Chinese and one (14.3%) was an Indian lady. Majority of the women in both early and late stage had more than one child and used any family planning method as shown in Table 5.4.

Table 5.4: Characteristics of women diagnosed with breast cancer following abnormal clinical breast examination (CBE) in health clinics in Klang for the year 2009 to 2011 according to stage of breast cancer

	Early stage n(%), n=3	Late stage n(%), n=7
Age[a]		
Age group		
25-29 years	0	1 (14.3)
30-39 years	0	1 (14.3)
40-49 years	1 (33.3)	3 (42.9)
50-59 years	2 (66.7)	2 (28.6)
Ethnic groups[a]		
Malay	0	4 (57.1)
Chinese	2 (66.7)	2 (28.6)
Indian	1 (33.3)	1 (14.3)
Number of children[a]		
Nulliparous (0)	0	1 (14.3)
Parous (>= 1 child)	3 (100)	6 (85.7)
Family Planning Users[a]		
Yes	2 (66.7)	4 (57.1)
No	1 (33.3)	1 (14.3)
Unknown	0	2 (28.6)

[a]Fisher Exact Test, p>0.005

5.3 Outcome of mammography only for women with risk factors

There were a total of 5,133 cases that were registered in the mammography registry of the Mammography Suite, Hospital Tengku Ampuan Rahimah Klang. Out of these 5,133 cases, 1,884 (36.6%) cases that were excluded for various reasons according to the eligibility criteria. The cases that were excluded were 1,016 (19.8%) known case of breast cancer, 45 (0.9%) cases with cancer at other sites other than breast, 16 (0.3%) cases who cancelled their mammography examination for various reasons, 12 (0.2%)

cases with incomplete mammography report, 12 (0.2%) cases were male patients, 370 (7.2%) cases undergo other procedures other than bilateral mammography such as unilateral mammography, spot magnification mammography, cone compression mammography, hook wire localization and others. In addition to that, 413 (8.0%) cases were excluded due to missing mammogram report. Four cases with mammography classification of BI-RADS 0 were excluded due to missing final BI-RADS classification after 18 months from the time of the mammography examination done. After exclusion of these cases that were not eligible, there were a total of 3,245 cases that were left. However, out of 3,245 mammography cases, further exclusions were made for 1,796 diagnostic mammography cases and 22 cases that were unable to be classified as screening or diagnostic due to missing data on signs and symptoms of breast cancer. Therefore, there were 1,427 cases that were available for further analysis. These were women without any symptoms or signs of breast cancer. The study flow chart for mammography outcome is as shown in Figure 5.2.

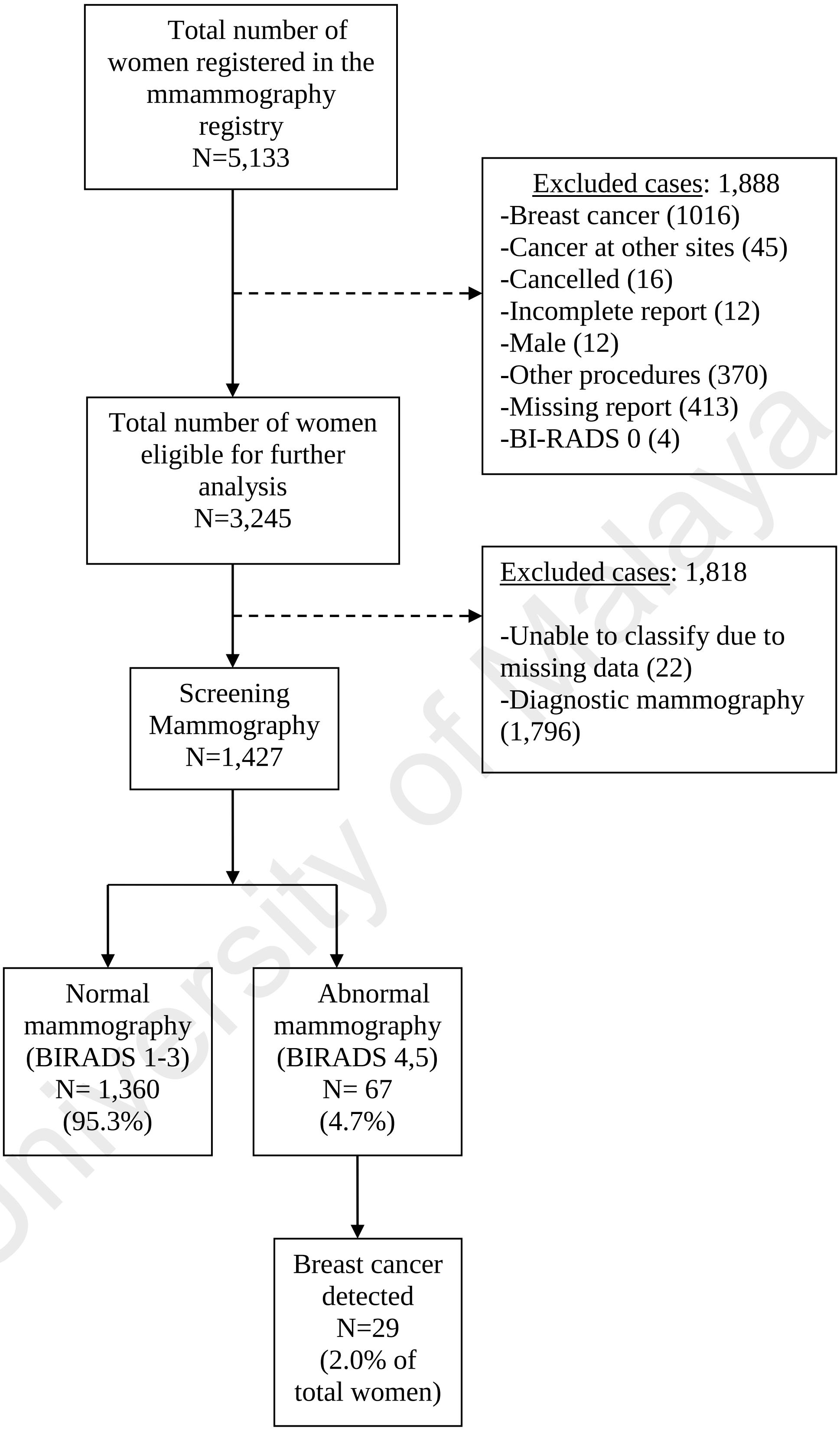

Figure 5.2: Flow chart of the outcome of mammography screening in HTAR, Klang for the year 2008 to 2011

5.3.1 Socio-demographic characteristics of mammography only among women with risk factors

Further analysis was done for the 1427 eligible women who went for the screening mammography examinations to look at the socio-demographic characteristics and also other clinically related characteristics such as the breast cancer risk factors and past medical and surgical history. Table 5.5 shows the characteristics of women attended the screening mammography examination in HTAR. The next section discussed the four characteristics of the subcategories starting with the socio-demographic characteristics followed by the breast cancer risk factors and past medical and surgical history.

Table 5.5: Characteristics of women who attended the screening mammography examinations in Hospital Tengku Ampuan Rahimah, Klang in the year 2008 to 2011

	n (%) **n=1427**
Socio-demographics	
Age	
Mean age (±SD)	51.17 (±6.928)
Range	34-82
Age groups	
25-39	23 (1.6)
40-49	536 (37.6)
50-59	716 (50.2)
60 and above	152 (10.7)
Ethnic groups	
Malay	716 (50.2)
Chinese	267 (18.7)
Indian	442 (31.0)
Others	2 (0.1)
Breast cancer risk factors	
Early menarche[a]	
Yes	460 (32.2)
No	807 (56.6)
Menopausal status	
Yes	658 (46.1)
No	769 (53.9)
Late menopause (>55 years old) [a]	
Yes	47 (3.3)
No	675 (47.3)
Non menopause	658 (46.1)
Parity[a]	
Nulliparous	143 (10.0)

	n (%) n=1427
Parous	1221 (85.6)
Ever Breastfed[a]	
Yes	874 (61.2)
No	265 (18.6)
Family History of Breast Cancer	
Yes	328 (23.0)
No	1099 (77.0)
Ever on OCP	
Yes	77 (5.4)
No	1350 (94.6)
Ever on HRT	
Yes	423 (29.6)
No	1004 (70.4)
Other clinical characteristics	
Past surgery	
Breast surgery	144 (10.1)
Others	95 (6.7)
Unknown	28 (2.0)
No past surgery	1160 (81.3)
Previous MMG/USG	
Yes	668 (46.8)
No	759 (53.2)
Previous biopsy	
Yes	155 (10.9)
No	1272 (89.1)
Past Medical / Surgical History	
Yes	133 (9.3)
No	1294 (90.7)
Previous benign breast disease	
Yes	352 (24.7)
No	1075 (75.3)

Note:
[a] Percentages did not add up to 100% due to missing data.

There were two socio-demographic factors that were analysed which were the age and the ethnic group of women screened by mammography. The mean age for women who participated in the mammography screening was 51.17 (±SD6.928) years old. About half of the women were in the 50-59 years age group, followed by 40-49 years age group (37.6%) and 60 and above years age group (10.7%). Overall, three quarters of the participants were in the 40-59 age groups.

The Malays were the main ethnic group among the participants which comprised of about 50.2% of those who participated in the mammography screening. This was followed by the Indians (31.0%) and the Chinese ethnic groups (18.7%).

5.3.2 Breast cancer risk factors and other related factors of mammography among women with risk factors

On analysing the breast cancer risk factors among women screened by mammography, more than half of them ever breastfed their children (61.2%) and about 32.2% had their menarche before the age of 12 years old. Following this, about 29.6% of them was ever on hormone replacement therapy (HRT). Nearly a quarter of these women (23%), had a family history of cancer. These included breast cancers among first-degree, second-degree and other relatives. Only about 10% were nulliparous and a small percentage was ever on oral contraceptive pills (OCP) (3.3%) and had late menopause (5.4%).

The other clinically related characteristics of the study population that were analysed were history of previous surgery, history of previous mammography or ultrasonography of the breast, past medical or surgical history and presence of previous benign breast disease. About 16.8% of women screened by mammography had surgical procedure prior to their mammography examination whereby 10.1% of them were breast related surgery. Almost half of them (46.8%) had previous mammogram or ultrasound of the breast. About 10.9% of them had previous biopsy of the breast, 9.3% had one or more past medical or surgical history. About nearly a quarter had previous benign breast disease (24.7%) such as fibroadenoma, fibrocystic disease or other benign breast disorder.

5.3.3 Abnormality detection and breast cancer detection by mammography among women with risk factors

From the 1427 cases eligible for analysis, majority of the mammography screening results were normal whereby 95.3% had BI-RADS classification of B1 to B3. There were 67 cases (4.7%) with BI-RADS classification 4 and 5 which were classified as abnormal mammography results as shown in table 5.6. These cases when matched to the Selangor State Breast Cancer Registry indicated that there were 29 cases listed in the cancer registry as having breast cancer. These cases were those with suspicious and highly suspicious of breast malignancy needing biopsy.

Table 5.6: Mammogram findings among women who had mammography screening in Hospital Tengku Ampuan Rahimah (HTAR), Klang for the year 2008 to 2011

Mammogram findings n=1427	n (%)
BI-RADS classifications	
B1	707 (49.5)
B2	410 (28.7)
B3	243 (17.0)
B4	61 (4.3)
B5	6 (0.4)
Mammogram results classification	
Normal (B1- B3)	1360 (95.3)
Abnormal (B4 - B5)	67 (4.7)
Breast cancer	
Yes	29 (2.0)
No	1398 (98.0)

Among the 67 cases with abnormal mammogram findings, majority of cases were reported as BI-RADS 4 (89.7%) while only 10.3% were classified as BI-RADS 5. Among these abnormal mammogram cases, about two thirds (65.5%) were in late stage, whereby 11 cases (37.9%) were in stage 3 and eight cases (27.6%) were in stage 4 of breast cancer. The stage of breast cancer cases is as shown in table 5.7 below.

Table 5.7: Number of breast cancer cases diagnosed among mammography screenings done in the year 2008 to 2011 in HTAR, Klang according to the BI-RADS classification and the stage of breast cancer

Breast cancer characteristics n=29	No of cancer cases n (%)
BI-RADS classification	
B4	26 (89.7)
B5	3 (10.3)
Breast cancer stage	
Stage 1	4 (13.8)
Stage 2	6 (20.7)
Stage 3	11 (37.9)
Stage 4	8 (27.6)
Breast cancer stage group	
Early stage	10 (34.5)
Late stage	19 (65.5)

5.4 Comparison of the outcome of CBE and mammography screening of women with risk factors

Comparisons were made for some of the variables that can be compared for the two breast cancer screening approaches that are being practiced currently in Malaysia that is CBE and mammography screening among women with risk factors. This included the characteristics of women who participated in the CBE and the mammography screening of women with risk factors in terms of their age, ethnicity and parity as shown in section 5.4.1 below.

5.4.1 Comparison of the characteristics of participants

Characteristics of women who participated in each breast cancer screening programme were compared for characteristics that were common in both screening methods. Women who attended the CBE screening were women who came to the health clinics for Pap smear screening and had their CBE done at the same time. As for screening mammography, women who participated were women whom were asymptomatic for breast cancer and were referred for mammography at the general hospital. This analysis was done for some characteristics that were available for comparison which included participant's age, ethnicity and parity.

The age of women who participated in the CBE screening was younger as compared to those who participated in screening mammography where the mean age was 42.39 (±SD11.396) years old and 51.17 (±SD6.928) years old respectively. The range of age for CBE screening showed younger age group in the lower end of the age range as compared to screening mammography group. This was because CBE is the method of choice for breast cancer screening for younger age group. Majority of the women in the CBE screened group were from the 25 to 49 years of age, whereas the majority of women screened by mammography were in the 40 to 59 years age group.

In both breast cancer screening approaches, the majority of women who participated were from the Malay ethnic group. As for CBE, about 38.1% were from the Malay ethnic group, followed by the Chinese (29.8%) and the Indians (26.2%). However, in the screening mammography activities, the majority of participants were from the Malay ethnic group (50.2%), followed by the Indians (31.0%) and the Chinese (18.7%). For both breast screening modalities, more than 80% of women were non-nulliparous. The characteristics of women who participated in both CBE and screening mammography is as illustrated in table 5.8.

Table 5.8: Comparisons of the characteristics of CBE and mammography screening among women with risk factors in Klang district

	CBE n (%) n=15,279	Mammography screening n (%) n=1427
Socio-demographic		
Age		
Mean (±SD)	42.39 (±11.396)	51.17 (±6.928)
Range	15-82	34-82
Age groups		
<=24	2 (2.4)	0
25-39	36 (42.9)	23 (1.6)
40-49	30 (35.7)	536 (37.6)
50-59	12 (14.3)	716 (50.2)
>= 60	4 (4.8)	152 (10.7)
Ethnic		
Malay	32 (38.1)	716 (50.2)
Chinese	25 (29.8)	267 (18.7)
Indian	22 (26.2)	442 (31.0)
Others	5 (6.0)	2 (0.1)
Parity[a]		
Nulliparous (0)	718 (4.7)	143 (10.0)
Parous (>= 1 child)	13666 (89.4)	1221 (85.6)

[a]Total number does not add up to respective analysed number due to missing data

5.5 Discussion on Outcome Assessment of Clinical Breast Examination and Mammography screening

The outcomes of breast cancer screening activities were obtained from health records for two breast cancer screening approaches that were being practiced in Malaysia which were CBE followed by mammography when breast abnormality is detected, and mammography only for women with risk factors.

This chapter covers the discussion on the outcomes for both breast cancer screening approaches which included the characteristics of women who participated in breast cancer screening activities, the detection rates for abnormal breast findings and breast cancers detected. Finally, the strengths and limitations of the study were discussed at the end of the chapter.

5.5.1 Age group distribution of women screened by CBE

In this study, majority (71.0%) of women whom were screened by CBE in the health clinics were women from the reproductive age group that was 15 to 49 years old. Most of these women screened were 25 to 39 years old (38.6%), followed by 40 to 49 years old (28.3%) and 50 to 59 years old (20.9%) age groups. This was not consistent with the peak age-standardised rate (ASR) for breast cancer in Malaysia for 2007 that was 50-59 years age group (Omar; & Tamin, 2011). This showed that, women at younger age groups utilized the Pap smear and CBE screening offered in health clinics more than the older age groups. This was because women in this younger age group utilized the health clinic more frequently for other health services. These services included the maternal and child health services and also family planning services. As compared to a study in Philippines by Pisani et al. (2006), women who participated in the population based CBE screening were majority aged 40 to 49 years old (38.6%) which was slightly older age group to the majority found in this study. This was followed by those aged less than 40 years old (33.9%) and those aged 50 to 59 years old (20.6%) while only 6.9% were aged 60 years old or more (Paola Pisani, 2006). However, recently in a cross-sectional study in rural areas in Malaysia (2014), showed that about 53.3% of women ever had CBE done, and among these women, those in the 36 to 50 and 51 to 64 age groups had the highest frequency of having CBE done by either a doctor or a nurse. (Nik Farid, Abdul Aziz, Al-Sadat, Jamaludin, & Dahlui, 2014). This may be contributed by the study design which involved household survey where more women in these age groups were captured in the study.

In comparison to another study in Rural Egypt, about 77% of the participants of CBE screening were between the ages of 25 to 50 years old. In addition to that, compared to the Malaysian population, most (48%) of these women in Rural Egypt were in the older age group (40 to 50 years age group), followed by 50 to 65 years (33%) age group and 25 to 40 years (29%) age group (Denewer et al., 2010). This suggested that the targeted population in Malaysia for breast cancer screening was not met and more effort is needed to encourage more Malaysian women in the older age group to participate in cancer screening activities as they are at higher risk to develop breast cancer.

An unpublished data of the SIPPS Programme (by the Family Health Development Department of the Ministry of Health Malaysia) showed that only 12.8% of women in Klang responded (overall) to the Pap Smear call recall programme in the year 2008 to 2011 (17,597 women responded out of 137,603 women invited). Furthermore, the response rate for Pap smear uptake for Klang district was very low that was 11.3% (15,575 women). Therefore, efforts to increase the response and uptake rates of Pap smear could improve the CBE participants as these women were screened opportunistically when they had their Pap smear done. The SIPPS data (unpublished) had also shown that the respondents were from the older age group where the majority were from the 40 to 49 years old (32.4%) and the 50 to 59 years old (30.4%). This suggests that the older age groups seemed to respond better to invitation for Pap smear. In addition to that, a study by Rima et al. (2013) had shown that the most cost-effective recall method for cervical cancer screening was by phone call (CER RM 69.18 (SD 0.14) as compared to SMS, registered letter and letter (Rashid, Ramli, John, & Dahlui, 2014).

5.5.2 Age group distribution of mammography among women with risk factors

As for screening mammography, this study showed that about three quarters of the participants were in the 40-59 age groups. This showed that most of the mammography screening done covered the targeted age group that was high risk for breast cancer. This may be contributed by the fact that these women were referred by their doctors for screening mammography taking into account their risk of getting breast cancer as according to the Ministry of Health Malaysia (2010) Clinical Practice Guideline on the Management of Breast Cancer. The breast cancer recommendation suggested that mammography screening should be offered to women aged 40 years old and above and also those who are at risk of getting breast cancer. However, the recommended age group for mammography screening and the frequency of mammography screening varies across countries depending on their local policies. In a population based mammographic screening trial in Singapore by Ng et al. (1998), the targeted group were slightly older age group that was 50 to 64 years age group (Ng et al., 1998).

5.5.3 Ethnic distribution of women screened for breast cancer

This study also found that the Malay ethnic group was the majority who participated in both CBE and mammography screening groups. For CBE screening, the Malays comprised of 41.4% of the women screened, followed by the Chinese (31.1%), the Indians (24.5%) and others (3.0%). However, for screening mammography, majority were Malays (50.2%) followed by the Indians (31.0%) and then the Chinese (18.7%). Both groups were inconsistent with the incidence of breast cancer in Malaysia according to the different ethnic groups whereby the Chinese formed the majority of women diagnosed with breast cancer, followed by the Indians and Malays where the age-standardized rate for breast cancer in Malaysia were 38.1 per 100,000 population, 33.7 per 100,000 population and 25.4 per 100,000 population, respectively (Omar; & Tamin, 2011). The different ethnic proportions among women who utilized the government health facilities may suggest that more of the Chinese women utilize private health facilities for breast cancer screening than other ethnic groups. However, having the Malays as the majority ethnic group who participated in both breast screening activities would give an advantage to them to be screened early and regularly thereafter as they were the majority of cases who presented at a later stage of breast cancer compared to other ethnic groups (Cheng Har Yip et al., 2006). Presenting at an earlier stage of breast cancer would give better prognosis and survival. Previous literatures also showed that the overall breast cancer survival rate for Malaysian women was lower than in the western countries. Therefore, the health providers need to plan to target high risk groups for breast cancer screening in order to detect breast cancer as early as possible and to ensure better survival (Ibrahim et al., 2012; Taib et al., 2008).

5.5.4 Reproductive characteristics of women screened by CBE

Results showed that only 4.7% of the women screened by CBE were nulliparous, while about 19.2% of them were users of various types of family planning methods which include condom, intrauterine contraceptive device, oral contraceptive pills, injections, implants and bilateral tubal ligations. Only about 0.3% of these women used other contraceptive methods which included either natural family planning or the traditional methods. In Malaysia, all women whom were registered under the family planning health clinic were routinely screened by CBE at least annually or 6 monthly. This also suggested that, family planning clinic is one of the entry points for Pap smear screening. Currently, there are other entry points for Pap smear and CBE screening such as from the postnatal clinics, attendees from the outpatient departments and community health camps. There are also outreach cervical cancer screening services that were done in other government and non-governmental organizations to increase the Pap smear screening coverage. These Pap smear and CBE data were entered into the Pap smear registry books in the respective health clinics.

5.5.5 Breast abnormality and breast cancer detection rates by CBE

The abnormal CBE finding from the sample population was 0.55% of the total 15,279 women screened. This finding was similar to two other studies by Indraneel Mitra et al. (2010) in a cluster randomised trial in Mumbai, India, where the abnormal CBE was 0.46% from 75,360 women screened (Mittra et al., 2010). Another study by Feigin et al. (2006) in U.S also recorded a slightly higher abnormal CBE finding that was 0.8% (Feigin et al., 2006). The difference was that, in Mumbai, the study used trained primary health workers, while the study by Feigin et al. (2006) used nurse practitioners. However, higher abnormal CBE findings were reported in other studies both from observational or randomised controlled trials such as in Philippines (2.5%), Egypt (3.2%), Canada (3.5%), Japan (4.6%), Kerala in India (5.7%), U.S (6.9%), Canada (11.2%) and Cairo (11.7%) (C Bancej, 2003; Denewer et al., 2010; Honjo et al., 2007; Janet K Bobo, 2000; Miller et al., 1992; Paola Pisani, 2006; S Boulos, 2005; Sankaranarayanan et al., 2011). Generally, higher abnormal CBE finding were found in developed countries compared to other countries except for Cairo.

As for the breast cancer detection by CBE, this study showed that the breast cancer detection rate done by nurses in the government health clinics was 0.07%. When compared to other counterparts, this was found to be higher than in a population based studies in Philippines by Pisani et al. (2006) where the detection rates were 0.04% (by trained nurses and midwives) and in another observational study done using the Canadian Breast Cancer Screening Database (CBCSD) by Bancej et al. (2003) where the detection rate was 0.03% by nurses or technologist (C Bancej, 2003; Paola Pisani, 2006). However, breast cancer detection rate in a study done in Cairo were higher (0.8%) (S Boulos, 2005). The difference in this study compared to the previous ones that may contribute to the high detection rate was that the examiners were female doctors and that the target women were invited using direct approach (person to person basis) through social workers. In addition to that, another large observational study in a community based setting in the U.S by Bobo et al. (2000) also showed high cancer detection rate of 0.5% from 752,081 women screened, however the examiner were not specified (Janet K Bobo, 2000). However, the accuracy of any CBE was found to be dependent on many factors which include examiner factors such as the duration of the examination, the technique used, the examiner's experience and also patient factors like patient's age, breast characteristics and cancer characteristics (Barton et al., 1999).

This study also found that the average duration of CBE for both breasts that was done by nurses were 2.1 minutes (SD 1.0) which was low as compared to the recommended duration of CBE. Previous literatures suggest that two factors are associated with the accuracy of CBE which are longer duration of CBE and higher frequency of specific techniques. The recommended technique for CBE include proper patient positioning, thoroughness of search, use of vertical-strip search pattern, proper finger position and movement during CBE, and duration of CBE of 3 minutes per breast (Barton et al., 1999). Therefore, the CBE technique and duration practiced in the health clinics should be strengthen in order to further increase the detection rate of breast cancer.

5.5.6 Breast abnormality and breast cancer detection rate by mammography of women with risk factors

This study also showed that the abnormality and breast cancer detection rates for mammography among women with breast cancer risk factors were 4.7% and 2.0%, respectively. In this study, the sample population was asymptomatic women with risk factors for breast cancer whom were referred for mammography screening. Therefore, these women were among those who have higher risk for breast cancer as compared to those in the community. Despite this study having had higher cancer detection rate for mammography among women with risk factors as compared to detection rate for mammography of women in the general population generally, a recent study in Taiwan showed otherwise. The breast cancer detection rates (prevalent screenings and subsequent screenings per 1000 population) showed that it was highest for universal biennial mammography (4.6% and 2.98% respectively) followed by risk-based biennial mammography (2.80% and 2.77% respectively) (Yen et al., 2016). In the risk-based biennial mammography screening, women were screened using a questionnaire at the first stage to identify their risk score and at the second stage women with risk score of more than the median value of the underlying population were referred for biennial mammography screening (Yen et al., 2016). However, compared to other studies from the developed countries showed that the mammography detection rate among women at high risk for breast cancer was 0.3 % (95% CI, 0.01-1.5%) (Lehman et al., 2005).

Previous literature had also shown that other factors that can influence the outcome of a breast cancer screening programme in any country such as the quality of the screening programme, the epidemiology of breast cancer of that country and also the coverage of breast cancer screening programme in the population (de Koning, 2000).

5.5.7 Breast abnormality and breast cancer detection rate by mammography screening of women in the general population

This study assessed the outcome of two breast cancer screening approaches that are clinical breast examination followed by mammography when breast abnormality is detected, and also mammography screening among women with risk factors for breast cancer. However, as comparison to these two breast cancer screening approaches, this section shall discuss about the outcome of mammography screening among women in the general population that were obtained from other studies done previously.

A randomised controlled trial for mammography screening for women aged 50 to 64 years old done in Singapore by Ng et al. (1998), found that the breast cancer detection rate was 0.48% (Ng et al., 1998). This finding was similar to an observational study in Hong Kong by Lui et al. (2007) which showed that the breast cancer detection rate for screening mammography was 0.5% (Lui et al., 2007). However, another study on mass breast cancer screening programmes by universal biennial mammography screening in Taiwan, showed that the recall rates (number of cases of BI-RADS score of 0, 4 or 5) were 10.21%, and the breast cancer detection rates were 4.86% (Yen et al., 2016). The higher breast cancer detection rates may be contributed by the higher incidence of breast cancer in Taiwan for the year 2003 to 2007 where the age standardised rate (ASR) for breast cancer among females was 45.4 per 100,000 (Taiwan Cancer Registry, 2008). Compared to two other observational studies that was done previously in Canada by Bancej et al. (2003) and Japan by Honjo et al. (2007), the abnormality detection rates for mammography screening were lower than in Taiwan whereby by the rates were 7.4% and 8.1% respectively, while even lower breast cancer detection rates were reported for these countries (0.41% and 0.29% respectively) (C Bancej, 2003; Honjo et al., 2007). A lower breast cancer detection rate (0.05%) was reported in an observational study in New York by Feigin et al. (2006) (Feigin et al., 2006; Lui et al., 2007; Ng et al., 1998). It was reported that the low detection rate could be contributed by the high number of women who required further diagnostic examination that were loss to follow up (23%) (Feigin et al., 2006).

5.5.8 Strengths and limitations of the study

5.5.8.1 Strengths of the study

This study will provide the baseline information and knowledge on the currently practiced breast cancer screening activities in Malaysia. With the escalating healthcare costs, it is important and timely to conduct economic analysis of the current breast cancer screening practices in Malaysia and to plan for breast cancer screening activities using evidence based medicine.

To our knowledge, there is lack of local data on economic analysis and outcome of breast cancer screening approaches in Malaysia. Therefore, this study was conducted to add new knowledge and evidence on economic analysis and outcome assessment of two breast cancer screening approaches in Malaysia that are clinical breast examination followed by mammography screening when breast abnormality is detected, and mammography screening among women with risk factors. The findings on costs and outcome of these breast cancer screening approaches can be used for allocation of resources, planning and projections on the needed investment for breast cancer screening programme in Malaysia. Therefore, the evidence from this study will help health providers and the policy makers involved in decision making for breast cancer screening initiatives in Malaysia, and will also become the stepping stone for further research to be conducted with regards to breast cancer screening.

The cost analysis used activity based costing (ABC) approach by taking into account the actual usage of equipment and materials used in the breast cancer screening programme and therefore provided more accurate data on cost calculation. This study also provided information on the cost breakdown in breast cancer screening activities.

This study used secondary data from the government health facilities for the outcomes of the current breast cancer screening programmes for CBE followed by mammography when breast abnormality is detected, and mammography screening of women with risk factors. Therefore, it provided baseline data on breast cancer screening approaches locally which can be used to plan and improve the breast cancer screening programme and also breast cancer screening research in Malaysia.

This study also described the characteristics of women who utilized the breast cancer screening services offered. Although limited by the numbers of variables that were looked into for clinical breast examination, the four variables that were used to describe the characteristics which are ethnicities, age, parity and family planning methods used are important as it is known that breast cancer presentation and prognosis differs with regards to these characteristics.

The time motion study of the job steps involved in each of the breast screening activity provided new evidence on the CBE and mammography services that is currently delivered to the community which enable comparisons to be made with other standards in other countries. The findings of the outcome of the study could also contribute to improve the quality of breast screening activities in terms of detecting breast cancers. This gives an opportunity to improve breast cancer detection among women utilizing the health facility in Malaysia particularly in the government healthcare services setting.

5.5.8.2 Limitations of the study

There were limitations in the sample population for both CBE followed by mammography when breast abnormality is detected, and mammography screening of women with risk factors. For CBE screening, the study population were among women who participated in the Pap smear screening activity which represents a portion of eligible women in the population, among which were responders to the Pap smear invitation at the government health clinics. However, the participation rate for Pap smear uptake was low whereby only about 12.8% of women in Klang responded to the invitation (unpublished data). However, this may represent the real scenario on participation rate if there were population-based mass screening that combined Pap smear screening and clinical breast examination. This also limited the generalizability of the results as it may not represent the real outcome for the whole population. Therefore, the cancer screening programme should also focus on increasing health education among women to participate in cancer screening activities. This will encourage more women to participate in the breast cancer screening activities especially those who are in the high risk group for breast cancer.

Another limitation of the sample population for CBE was that, this study only focused on women who participated in Pap smear screening and had CBE done opportunistically. This was because that the outcome data for CBE among women who came for Pap smear were well documented in the Pap smear registry book, whereas CBE that was done in other setting in the health clinics were not well documented. Therefore, this may contribute to potential selection bias. However, the scope of this study was set to only focus on the outcome of CBE among women who had Pap smear done. This also limits the generalizability of the results to other population settings.

The sample populations for this study were taken from women who utilize government health facilities. There are also woman who utilizes the private health care facilities for breast cancer screening. This contributes to selection bias. However, the scope of this study was limited to breast cancer screening services offered in the government health facilities. Therefore, the results should be interpreted carefully and cannot be generalized for the whole population.

Due to the sample population was among women who utilized the government healthcare facilities. These women are usually more health conscious and tend to be healthier as compared to the rest of the general population. As for mammography screening among women with risk factors, the sample population were also of those women who utilized the health facilities. They were asymptomatic and opportunistically screened for breast cancer. Therefore, again there was selection bias as these women although asymptomatic may have one or more risk factors for breast cancer. Therefore, the interpretation of the results of this study should be done by taking into account all this limitations.

Data collections for CBE followed by mammography when breast abnormality is detected were done by extracting data retrospectively from the Pap smear registries and medical records. The data that were collected were recorded by different nurses. They were either a staff nurse or community nurse of different grades and working experiences. However, the details of the staffs that did the CBE and recorded findings were not documented and were not able to be traced. Therefore, this could lead to source for information bias. However, these staffs were trained to perform CBE and document the findings according to the standardized CBE manual.

Another limitation in this study was measurement bias in measuring the outcome whereby the breast cancer screening activities were done by different operators. Successful clinical breast examination (CBE) is very much operator dependent. The rate of detection of abnormality and breast cancer detection by CBE depends on the experience and trainings gained by the examiner. However, an assumption was made that there is no difference in CBE abnormality detection among the nurses as the nurses were trained to do CBE according to the standardized CBE manual by the Ministry of Health, and majority went for refresher courses that were done annually together with other courses related to women's health activities.

CHAPTER 6: PROJECTIONS OF COSTS

6.1 Introduction

This chapter shall discuss about the calculation of cost projections for breast cancer screening programmes for women in Malaysia using either clinical breast examination followed by mammography when breast abnormality is detected, or mammography screening for women in the general population. The cost projections include the total costs of screening, but excludes the costs of treatment as there is no published data on the cost to treat breast cancer in Malaysia as of now.

Costs data obtained from this study (cost per CBE and cost per mammography) were used to calculate the cost projections for ten years period from the year 2015 to the year 2024. The total costs needed to screen 25% of eligible women population in Malaysia as targeted by the Ministry of Health using these breast cancer screening approaches were projected for the period of ten years. The findings of these cost projections help us to estimate the budget needed for the different breast screening modalities if they were chosen as the screening modalities for women in the general population in Malaysia. The findings can also be used in the decision making of health programmes and health budget allocation by the policy makers.

6.2 Cost calculation for 2015

Cost were calculated for the two breast cancer screening approaches that were CBE followed by mammography when abnormality is detected, and mammography only for women in the general population using women population for the year 2015. Costs were calculated from the perspective of the provider that is the Ministry of Health (MOH), Malaysia with regards to the Ministry of Health's budget.

According to the National Guideline for CBE screening, it is recommended that for women aged 20 to 39 years old should be screened by clinical breast examination

(CBE) every three years while those above 40 years old should be screened every year. Therefore, the total cost of CBE per year was obtained by adding the costs to screen one third of eligible women aged 20-39 years old by CBE to the cost to screen all eligible women aged 40-64 years old women by CBE. The estimated number of women for CBE screening in Malaysia for the year 2015 was estimated from the 2013 data by taking into account the average annual female growth rate in Malaysia (for the year 2009 to 2011) that was 1.6% and also the average crude death rate for female that was 4.15 per 1000 population for the year 2009 and 2010 (Department of Statistics Malaysia). The estimated number of women targeted for CBE screening in Malaysia for 2013 by state is as shown in Appendix T.

In order to calculate the cost projection for women in Malaysia for the year 2015, the estimated total numbers of population for 2015 that were eligible to be screened for each age group were then multiplied with the cost per CBE expressed in 2015 RM value. This means that the cost per CBE in 2011 RM value was expressed in 2015 RM value by multiplying with the inflation correction factor (ICF). The inflation correction factor was calculated by applying 3% average inflation rate for Malaysia according to the Central Bank of Malaysia.

The inflation correction factor (ICF) for the chosen base year, in this case was 2015 was given a value of 1.000. To calculate the ICF for year 2014, the ICF for 2015 that was 1.000 was added to the Malaysia inflation rate for the year 2015 that was set by the Central Bank of Malaysia as 3.00 percent or 0.03 which gave a value of 1.030 [(1.000 + (1.000 x 3.0/100) = 1.030)].

To obtain the ICF for the year 2013, the ICF value for 2014 that was 1.030 was added to the product of 1.030 and the 2014 inflation rate that was 3.143 percent or 0.031, which gave an inflation correction factor for 2013 as 1.063 (1.030 + (1.030

x3.143/100) = 1.062). This method was continued for the calculation of ICF for 2012 and 2011 using the respective inflation rates. Therefore, cost per CBE in Ringgit Malaysia 2015 value was calculated by multiplying RM6.68 with 2015 ICF which was 1.103 which gave a value of RM 7.37.

The total costs calculated for CBE screening per year in 2015 was calculated by multiplying the cost per CBE (in RM 2015 value) that was RM7.37 with the total number of estimated women population screened (5,225,203 women). This gave the estimated total cost for CBE screening per year for 2015 as RM 38,509,746.11.

As for mammography screening only among women in the general population, the estimated total women aged 40 to 64 years old in Malaysia for the year 2015 was 1,781,738. The total cost for mammography screening only in a year were calculated for half of the women aged 40 to 64 years old with the assumption that women were offered mammography screening every two years. Cost per screening mammography expressed in 2015 Ringgit Malaysia value was RM 217.62 (RM 197.30 x ICF 1.103). The total estimated mammography screening cost for the year 2015 was RM 387,741,823.56 which was obtained by multiplying cost per mammography (RM217.62) with number of women screened (1,781,738 women). The projected cost of clinical breast examination and mammography only of women in the general population in Malaysia for the year 2015, is as shown in table 6.1.

Table 6.1: Cost projection for clinical breast examination and mammography only for women in the general population for the year 2015 (in RM2015)

Clinical breast examination			Mammography only for women in the general population		
Total population	Cost per CBE (RM)	Total cost (RM)	Total population	Cost per MMG (RM)	Total cost (RM)
5,225,203	7.37	38,509,746.11	1,781,738	217.62	387,741,823.56

6.3 Ten years cost projection for Clinical Breast Examination (CBE)

In order to calculate the ten years cost projection for CBE, from the year 2015 to 2024, the numbers of women to be screened for the respective years were estimated taking into account the average annual population growth rate for female in Malaysia for the year 2009 to 2011 (1.6%), and the average crude death rate for females in Malaysia for the year 2009 to 2010 (4.15 per 1000 population) as obtained from the Department of Statistics, Malaysia.

The estimated population for CBE screening for women in Malaysia for the year 2016 and subsequent years until the year 2024 were calculated by multiplying the previous year's estimated number of women for CBE screening with the average annual population growth rate for females in Malaysia that was 1.6%, and were then added back to the previous year's estimated population to give the total estimated population for the respective years. This was then subtracted with the average crude death rate for females in Malaysia that was 4.15 per 1000 population.

For example, the estimated population for CBE screening for 2016 was obtained by multiplying the 2015 estimated population (5,225,203) with 1.6% which gave a total of 83,603 women. This was then added back to the 2015 estimated population (5,225,203) which gave a value of 5,308,806 women. This was then subtracted by the average crude death rate for females which was 4.15 per 1000 population (21,684). Therefore, the calculated estimated population for CBE screening for the year 2016 is 5,287,122. The same method of calculation was applied for the year 2017 to 2024 using the same average annual growth rate for females and the average crude death rate for females in Malaysia. This is illustrated in table 6.2 in column (a).

Cost per CBE screening (in RM2015 value) for the year 2015 to 2024 (as in table 6.2 in column (c)) was calculated by multiplying cost per CBE in 2015 that was RM7.37 with the respective Inflation Correction Factor (in table 6.2 in column (b)).

The total cost of screening for all eligible women in Malaysia by CBE (as in table 6.2 column (d)) was calculated by multiplying the cost of CBE for the year 2015 to 2024 (as in table 6.2 column (c)) by the estimated population for CBE screening in Malaysia (as in table 6.2 in column (a)) for the respective years.

Table 6.2: Cost projection for CBE screening for Ten Years from 2015 to 2024

Year	Estimated population for CBE screening in Malaysia* (a)	Inflation Correction Factor (ICF)** (b)	Cost per CBE screening in RM2015 value (RM7.37*ICF) (c)	Total cost for CBE screening (RM2015 value) [(d)=(a)*(c)]
2015	5,225,203	1.000	7.37	38,509,746.11
2016	5,287,122	1.030	7.59	40,129,255.98
2017	5,349,774	1.061	7.82	41,835,232.68
2018	5,413,169	1.093	8.05	43,576,010.45
2019	5,477,315	1.126	8.29	45,406,941.35
2020	5,542,222	1.159	8.54	47,330,575.88
2021	5,607,897	1.194	8.80	49,349,493.60
2022	5,674,350	1.230	9.06	51,409,611.00
2023	5,741,591	1.267	9.33	53,569,044.03
2024	5,809,629	1.305	9.61	55,830,534.69
Total	55,128,272			466,946,445.77

*Estimated number of women for CBE screening per year in Malaysia. Only 25% of eligible women were targeted for CBE screening. This was calculated by applying average annual population growth rate for females in Malaysia that was 1.6% and average crude death rate for females in Malaysia that was 4.15 per 1000 population (Department of Statistics, Malaysia).

**ICF is calculated by using the Malaysian interest rate at 3% set by the Central Bank of Malaysia.

In order to calculate the total costs of CBE followed by mammography when breast abnormality is detected for each year, the cost of CBE screening for each year was added to the estimated costs of mammography needed for women with abnormal CBE findings estimated for the respective years. The number of abnormal CBE cases was estimated by applying the abnormal CBE detection rates obtained from this study that was 0.55% to the number of women screened for the respective years. This was used in view of lack of other local data on breast cancer detection rates for CBE followed by mammography when breast abnormality is detected. Therefore, the interpretation of the cost projections should take into account of this limitation.

The total costs for mammography needed for women with abnormal CBE findings for the respective years were calculated by multiplying the number of women with abnormal CBE for the respective years with the cost of mammography screening adjusted for ICF for the respective years. This is as shown below in table 6.3.

Table 6.3: Cost projection for CBE followed by mammography when breast abnormality is detected for the year 2015 to 2024

Year	Estimated population with abnormal CBE findings* (e)	Cost per MG in RM2015 value (RM217.62 *ICF) (f)	Cost of mammography for women with abnormal CBE findings (RM) [(g)=(e)*(f)]	Total cost (CBE + MG when abnormality is detected) (RM) [(h)=(d)+(e)]
2015	28739	217.62	6,254,181.18	44,763,927.29
2016	29079	224.15	6,518,017.14	46,647,273.12
2017	29424	230.87	6,793,208.86	48,628,441.54
2018	29772	237.80	7,079,759.26	50,655,769.71
2019	30125	244.93	7,378,613.47	52,785,554.82
2020	30482	252.28	7,690,036.27	55,020,612.15
2021	30843	259.85	8,014,543.09	57,364,036.69
2022	31209	267.65	8,352,937.50	59,762,548.50
2023	31579	275.67	8,705,525.20	62,274,569.23
2024	31953	283.94	9,072,886.29	64,903,420.98
Total				542,806,154.03

6.4 Ten years cost projection for mammography only for women in the general population

To calculate the ten years cost projection for mammography screening only among Malaysian women in the general population, the number of women eligible for mammography screening for the ten respective years from 2015 to 2024 were estimated.

The estimated population for mammography screening for women in Malaysia for the year 2015 was estimated using the data on number of women targeted for mammography screening for the year 2013 obtained from the Ministry of Health. As for screening mammography, the estimated total women aged 40 to 64 years old in Malaysia for the year 2015 was 1,781,738 as shown in table 6.1 above. The total cost for screening mammography for each year were calculated for half of the women aged 40 to 64 years old with the assumption that women were offered mammography screening every two years.

As for the year 2016 to 2024 the estimated number of women targeted for mammography screening were calculated by multiplying the previous year's estimated number of women for mammography screening with the average annual population growth rate for females in Malaysia for the period of 2009 to 2011 that was 1.6%, and was then added back to the previous year's estimated population to give the total estimated population for the respective years. This was then subtracted with the average crude death rate for females in Malaysia that was 4.15 per 1000 population.

For example, the estimated population for mammography screening for 2016 was obtained by applying the 1.6% growth rate to the 2015 estimated population (1,781,738), and was then subtracted by the annual death rate (calculated by applying annual death probability of 4.15 per 1,000 to the estimated women to be screened by mammography for the year 2015). Therefore, the calculated estimated number of women for the year 2016 was 1,802,852. The same method of calculation was applied for the year 2017 to 2024. This is illustrated in table 6.4 in column (a).

Cost per mammography screening (in RM2015 value) for the year 2015 to 2024 (as in table 6.4 in column (c)) were calculated by multiplying cost per mammography screening in 2015 that is RM 217.62 with the Inflation Correction Factor (ICF) for the respective years (as in table 6.4 in column (b)).

The total cost for mammography screening for women in the general population in Malaysia (as in table 6.4 in column (d)) was calculated by multiplying the cost of mammography for the respective years from 2015 to 2024 (as in table 6.4 in column (c)) by the estimated population for mammography screening in Malaysia (as in table 6.4 in column (a)) for the respective years. These calculations are as illustrated in table 6.4. The comparison of total cost of screening by CBE followed by mammography when abnormality is detected and mammography only for women in the general population for ten years period is shown in table 6.5.

Table 6.4: Cost projection for mammography screening among women in the general population in Malaysia from 2015 to 2024

Year	Estimated population for MMG screening in Malaysia*	Inflation Correction Factor (ICF)**	Cost per MMG screening in RM2015 value (RM217.62* ICF)	Total cost for MMG screening (RM2015 value)
	(a)	(b)	(c)	[(d)=(a)*(c)]
2015	1,781,738	1.000	217.62	387,741,823.56
2016	1,802,852	1.030	224.15	404,109,275.80
2017	1,824,216	1.061	230.87	421,156,747.92
2018	1,845,833	1.093	237.80	438,939,087.40
2019	1,867,706	1.126	244.93	457,457,230.58
2020	1,889,838	1.159	252.28	476,768,330.64
2021	1,912,233	1.194	259.85	496,893,745.05
2022	1,934,893	1.230	267.65	517,874,111.45
2023	1,957,821	1.267	275.67	539,712,515.07
2024	1,981,021	1.305	283.94	562,491,102.74
Total	18,798,151			4,703,143,970.21

*Estimated number of women for mammography screening per year in Malaysia. Only 25% of eligible were targeted for mammography screening.
This was calculated by applying average annual population growth rate for females in Malaysia that was 1.6% and average crude death rate for females in Malaysia that was 4.15 per 1000 population (Department of Statistics, Malaysia).
**ICF is calculated by using the Malaysian interest rate at 3% set by the Central Bank of Malaysia.

Table 6.5: Comparison of the total cost of screening by clinical breast examination followed by mammography when abnormality is detected and mammography only among women in Malaysia

	Total cost of screening	
Year	**CBE followed by MMG when abnormality is detected**	**MMG screening**
2015	44,763,927.29	387,741,823.56
2016	46,647,273.12	404,109,275.80
2017	48,628,441.54	421,156,747.92
2018	50,655,769.71	438,939,087.40
2019	52,785,554.82	457,457,230.58
2020	55,020,612.15	476,768,330.64
2021	57,364,036.69	496,893,745.05
2022	59,762,548.50	517,874,111.45
2023	62,274,569.23	539,712,515.07
2024	64,903,420.98	562,491,102.74
Total	542,806,154.03	4,703,143,970.21
Mean	54,280,615.40	470,314,397.02

The following table 6.6 shows the total cost of breast cancer screening by clinical breast examination followed by mammography screening when abnormality is detected among women in the general population for the next ten years, and its percentage from the government health expenditure. The latest data on the government health expenditure (GHE) was for 2011 that was RM 19,797 million or RM 21,836 million in 2015 RM value (calculated by multiplying with the respective Inflation Correction Factor (ICF) that was 1.103). It was shown that the General Government

Health Expenditure for the year 1997 to 2011 showed an average increase of about 12% annually (Malaysia National Health Accounts Unit, 2013). This average annual 12% increase in GHE was then applied to the 2011 GHE that was RM 21,836 (in 2015 RM value) to estimate the GHE for the year 2015 to 2024.

Then the percentages of the total costs of CBE screening from the government health expenditures for the respective years were calculated. The percentage of the total cost of screening by CBE from the government health expenditure ranged from 0.07% to 0.13% and showed a decreasing trend over the ten years period from 2015 to 2024 as shown in table 6.6 below.

Table 6.6: Total costs of screening by CBE followed by mammography when abnormality is detected and the percentages from the government health expenditure

Year	Total cost of screening by CBE followed by mammography when abnormality is detected (RM)	Government health expenditure (RM millions)	Percentage of the government health expenditure (%)
2015	44,763,927.29	34,359	0.13
2016	46,647,273.12	38,482	0.12
2017	48,628,441.54	43,100	0.11
2018	50,655,769.71	48,272	0.10
2019	52,785,554.82	54,065	0.10
2020	55,020,612.15	60,553	0.09
2021	57,364,036.69	67,819	0.08
2022	59,762,548.50	75,958	0.08
2023	62,274,569.23	85,073	0.07
2024	64,903,420.98	95,281	0.07

The following table 6.7 shows similar calculation for the total cost of screening by mammography among women in the general population for the next ten years, and its percentage from the government health expenditure. The average annual 12% increase in Government Health Expenditure (GHE) for Malaysia for the year 1997 to 2011 was then applied to the 2011 GHE that was RM 21,836 (in 2015 RM value) to estimate the GHE for the year 2015 to 2024. Then the percentages of the total costs of mammography screening from the government health expenditures for the respective years were calculated. The percentage of the total cost of screening by mammography among women in the general population from the government health expenditure ranged from 0.59% to 1.13% and showed a decreasing trend over the ten years period from 2015 to 2024 as shown in table 6.7 below.

Table 6.7: Total costs of screening by mammography only among women in the general population, and the percentages from the government health expenditure

Year	Total cost of screening by mammography only (RM)	Government health expenditure (RM millions)	Percentage of the government health expenditure (%)
2015	387,741,823.56	34,359	1.13
2016	404,109,275.80	38,482	1.05
2017	421,156,747.92	43,100	0.98
2018	438,939,087.40	48,272	0.91
2019	457,457,230.58	54,065	0.85
2020	476,768,330.64	60,553	0.79
2021	496,893,745.05	67,819	0.73
2022	517,874,111.45	75,958	0.68
2023	539,712,515.07	85,073	0.63
2024	562,491,102.74	95,281	0.59

6.5 Discussion on Cost Projections for Ten Years

This study found that the cost per CBE screening in 2011 was RM 6.68 (USD 2.11) while cost per screening mammography was RM 197.30 (USD62.26). When expressed in RM 2015 (USD2015), the cost per CBE screening was RM7.37 (USD 1.72), while the cost per mammography was RM 217.62 (USD 50.71). For the purpose of discussion in this section, all costs will be in RM 2015 and also converted to 2015 US Dollars for the same base year that was 2015. The exchange rate used was 1 RM equivalent to 0.2330 USD using the average rate for Malaysian Ringgit to US Dollar on the 31st December 2015.

Further projection showed that for the next ten years period (2015 to 2024) the estimated total cost to screen 25% of women targeted in Malaysia for ten years is RM 542,806,154.03 (USD 126,473,833.89) by clinical breast examination (CBE) followed by mammography when breast abnormality is detected. The frequency of CBE screening is as according to the current recommendation by the Clinical Practice Guideline for Breast Cancer that is three yearly CBE for women aged 20 to 39 years old and yearly for those above 40 years old. The percentage of the estimated cost of screening by CBE from the government health expenditure for the year 2015 to 2024 ranged from 0.07% to 0.13%. This percentage showed a downward trend as the number of years increased. However, these results should be interpreted with caution as it assumes that the average annual growth rate for General Health Expenditure (GHE) was constant at 12%.

As for mammography screening among women in the general population, the total cost to screen 25% of women in Malaysia for the next ten years period (2015 to 2024) is RM 4,703,143,970.21 (USD$ 1,095,832,545.06) with the assumption that women aged 40 to 65 years old were screened every 2 years by mammography. The percentage of the estimated cost of screening by mammography from the government health expenditure for the year 2015 to 2024 ranged from 0.59% to 1.13% with a decreasing trend over the ten years period. However, similar to CBE as mentioned above, these results assumes that the average annual growth rate for General Health Expenditure (GHE) was constant at 12%. In addition, the results also showed a large amount of funding is needed to support the breast cancer screening programme if mammography screening among women in the general population is chosen as the population based screening method.

The current growing burden of communicable and non-communicable diseases including cancers in Malaysia makes health budget allocation more challenging and difficult. However, other issues need to be considered before a mass screening programme is implemented. This includes ensuring not only quality screening services but also adequate and appropriate diagnostic services, breast cancer treatment and palliative services are available. Preparation of adequate and well trained human resources should also be put in place before a mass population screening is implemented.

In addition, the five elements that a screening programme needs to have in order for it to be successful should be well thought and prepared. These are an identifiable target group or population, implementation measures available to guarantee high coverage and participation, access to high quality screening, an effective referral system in place for diagnosis and treatment and measures in place to monitor and evaluate a program (C. H. Yip et al., 2008). Therefore, the challenge for Malaysian policy makers is to ensure that these elements are met to a certain extent. These will definitely incur more cost to the health provider in Malaysia and to ensure women in Malaysia are appropriately screened and managed accordingly.

CHAPTER 7: CONCLUSION AND RECOMMENDATIONS

7.1 Introduction

Breast cancer is the leading cause of death among Malaysian women. Currently, the approach used in Malaysia for breast cancer screening in the government health facilities is mainly by two methods that are clinical breast examination followed by mammography when breast abnormality is detected, and mammography screening of women with risk factors for breast cancer.

Currently, mammography screening is regarded as the only breast cancer screening method that has proved to be effective in organized population-based screening programmes (World Health Organization, 2014) However, its implementation for population screening in a developing country like Malaysia is still very challenging. This is because of several factors such as the escalation of healthcare costs, scarce healthcare resources and increasing demand of healthcare resources and funding of other disease burdens and health priorities in Malaysia such as the prevention and control programmes of infectious diseases including emerging and re-emerging diseases, disaster preparedness activities and other non- communicable diseases programmes. Therefore, this leads to limited allocation of funds for breast cancer screening programmes.

Thus, this study aimed to determine and compare the costs and outcomes of the current breast cancer screening programmes that are clinical breast examination (CBE) followed by mammography when abnormality is detected, and mammography screening among women with risk factors.

7.2 Conclusion on the findings

7.2.1 Economic Analysis

This is the first study of economic analysis and outcome assessment of clinical breast examination followed by mammography when breast abnormality is detected, and mammography screening among women with risk factor in the government health facilities in Malaysia which used top down and activity based costing approach. The calculated cost per screening for CBE and mammography showed that the cost per CBE screening was RM 6.68 (USD2.11), while for cost per mammography was RM 197.30 (USD 62.26). In general, the cost for CBE was cheaper in the public facilities compared to the cost in the private facilities. As for mammography screening, the cost per mammography found in this study (RM 197.30 (USD62.26)) was comparable to the price of mammography and breast ultrasound services in the private facilities especially for the package services in the private facilities in Malaysia (ranged from RM148.98 (USD47.01) to RM 270.02 (USD85.21)). However, the cost for mammography and breast ultrasound would be higher in most private facilities if both of these services were purchased separately. The mammography unit in the public hospital caters screening mammography and diagnostic mammography as well as other procedures for breast cancer diagnostic purposes. Therefore, numbers of women for mammography screenings were limited. More studies are needed to look at the potential of developing breast cancer screening centres or women health screening centres whereby the latter combines other cancer screening services for women (like cervical cancer screening) as well as breast cancer screening.

The largest portion of the cost per mammography screening is contributed by the capital cost which is mainly costs of equipment and furniture (57.0%), followed by cost of staff salary (29.0%). This suggests that to implement or expand breast cancer screening programme by mammography screening would need substantial amount of funding that need to be considered. This includes the capital outlay costs and human resource and trainings. As for CBE, the majority of the cost is contributed by the cost of staff salary (61.1%), followed by costs of utilities and communication (20.1%). However, in practice, CBE screening uses existing human resource to run the breast screening activities.

The cost per breast cancer detected by CBE followed by mammography when breast abnormality is detected, and mammography screening of women with risk factors for breast cancer were RM 11,864 (USD 3,744) and RM 9,709 (USD 3,064), respectively. Cost per breast cancer detected was lower for mammography screening only among women with risk factors as compared to CBE followed by mammography when breast abnormality is detected. These results suggests that the current breast cancer screening approach by mammography screening among women with risk factors should be promoted and strengthened as recommended in the Ministry of Health (2010) Clinical Practice Guideline on the Management of Breast Cancer. However, expanding mammography screening to a larger population may not be currently feasible as it would need substantial amount of funding, for capital outlay cost, human resources and training due to the current constraint on health budget. The current mammography screening among women with risk factors should be optimized and strengthened in terms of improving the quality of services given to the patients.

On the other hand, although cost per breast cancer detected is slightly higher for CBE followed by mammography when breast abnormality is detected, compared to mammography screening of women with risk factors, CBE activity is more feasible and practical to be implemented at this point of time because of the lack of financial resources. Therefore, in a budget constrained situation, CBE should also be promoted and strengthened as it uses existing resources especially health staff and does not need any special equipment for its activity. Moreover, CBE activity in health clinics covers both women with and without risk factors for breast cancer, and is able to reach more women in terms of numbers of women screened. CBE can be considered as a simple, cheap and easily accessible for women to undergo breast cancer screening. Furthermore, Maznah et. al (2012) had showed that CBE is still relevant since breast education and BSE could be demonstrated to women and thus encourages women to perform routine examination to detect breast abnormality earliest possible.

7.2.2 Outcome of breast cancer screening

In terms of characteristics of women screened, women who participated in the CBE screening were among the younger age group, 42.7% were below 40 years old. However, for screening mammography among women with risk factors for breast cancer, although majority of the women screened (50.2%) were among the target group who are at higher risk of getting breast cancer, younger women with risk factor such as family history or on hormonal contraceptive or treatment would highly benefit from mammogram. More efforts on strategies to increase breast cancer screening uptake including mammogram among women with risk of breast cancer should be undertaken. Further studies are needed to look at issues on the barriers of women to come forward for breast cancer screening, and interventions in order to increase the participation rate of women in particular those with risk factors for breast cancer.

This study also showed that breast cancer detection rate for CBE followed by mammography when breast abnormality is detected was 0.07%, which was comparable to other countries in the Asian region. On the other hand, breast cancer detection rate by mammography among women with risk factors in this study was found to be higher at 2.0% and was comparable to a risk–based biennial mammography screening in Taiwan. Therefore, both programmes that are currently being practiced should be strengthened at all levels and targets more of high risks women. Health education and awareness on importance of early detection of breast cancer should be promoted to the public to get more women to come forward for breast cancer screening.

7.2.3 Cost projections

The cost projections for the two breast cancer screening approaches showed that the total cost to screen 25% of targeted women (as set by the Ministry of Health, Malaysia) for the ten years period (2015 to 2024) by CBE followed by mammography when breast abnormality is detected amounts to RM 542.8 million (USD 126.5 million), which represents about 0.07% to 0.13% of the government health budget annually. On the other hand, the total cost to screen 25% of women in the general population by mammography only for the ten years period (2015 to 2024) would cost about RM 4,703.1 million (USD 1,095.8 million) which represents about 0.59% to 1.13% from the government health expenditure. This shows that a substantial amount of funding is needed if health policy planners are to plan for a population based breast cancer screening programme using mammography compared to CBE followed by mammography when breast abnormality is detected.

7.3 Application of findings and recommendations

This study provides information regarding the economic analysis and outcome assessment of the currently practiced CBE followed by mammography when breast abnormality is detected, and mammography among women with risk factors in Malaysia particularly in the Klang district. This study suggests that both currently practiced breast cancer screening approaches should be continued concurrently as they serve different groups of women. CBE followed by mammography screening when breast abnormality is detected were offered to women attending Pap smear screening, while mammography were done among women with risk factors of breast cancer that was referred for mammography screening in the hospital.

The planning on optimizing and strengthening the current breast cancer screening programme in Malaysia in the government health setting would be the first step before a more costly population based breast cancer screening programme is planned. This includes expanding the population coverage for breast cancer screening and getting more women especially those in the targeted group including those with risk factors of breast cancer to be screened, improving the quality of screening and breast cancer detection rate, diagnosing and treatment of breast cancer as well as ensuring patient's compliance to follow up given by health care providers.

The government as the main health care provider and funder would have to plan for both CBE and mammography screening programme in the population taking into account the other factors that are essential for a screening programme to be successful. Not only by providing the breast cancer screening programme but also ensuring that correct diagnosis can be made, appropriate and adequate treatment facilities and that the continuity of care are available and accessible for patients. Continuous monitoring and evaluation of the breast cancer programme are also essential in ensuring quality services are given to the clients.

The preparation of infrastructure and human resources by the health care provider are also important as one of the preparation to implement or expand the breast cancer screening programme. Expanding the coverage of a breast screening programme would mean that more breast cancers will be detected and the whole spectrum of breast cancer screening, diagnosis, treatment and palliative care services should be well prepared and ready before implementing population based screening programme. Human resource training at the primary and at the secondary health care facilities should be carried out from time to time as shortage of health care staff has always been an issue in the government health facilities.

In addition to that, good and integrated data collection and management of breast cancer screening activities, diagnosis and treatment are also important in order to obtain a reliable and useful data. This may act as a good monitoring and evaluation tool for breast cancer screening programme. However, unfortunately current data on breast cancer screening are all kept in the respective health facilities and are not linked between the primary and the secondary care and also inter-departments. Integrated data management would make the data collected more meaningful and easy to be accessed and analysed.

Future research is needed to further study the implementation issues on the ground for breast cancer screening. In addition to that, the government as the main health care provider also needs to consider other factors that affect breast cancer screening programmes such as the epidemiology of the disease, the health care system, healthcare costs, the quality of the screening programme and the attendance rate of the targeted population. Future research on possibilities of collaboration with private sectors for breast cancer screening services should be carried out using the existing mammography centres. However, the challenges on competing with other health programmes for health funding especially the emerging and re-emerging infectious diseases which are currently the main highlight in the public health sector will remain as a big challenge as for now. Therefore, a timely economic analysis and assessment of health programme outcome is important for healthcare providers and policy makers for making decision in healthcare services delivery.

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List of Publication and Papers Presented

Publication:

	Title	Journal
1.	Breast cancer prevention and control programs in Malaysia. Dahlui, M.[1,2], Ramli, S.[2], & Bulgiba, A. M.[1] *[1]Centre of Population Health, [2]Department of Social and Preventive Medicine, Faculty of Medicine, [3]Julius Centre, University of Malaya, Kuala Lumpur, Malaysia*	*Asian Pacific Journal of Cancer Prevention, 12*(6), 1631-1634. (2011)

Papers presented:

	Title	Event
1.	Cost-effectiveness Analysis of Clinical Breast Examination and Mammography Screening in Breast Cancer Detection in Klang District, Selangor- Intermediate Findings	The 2ND UK-SEA-ME Psychosocial Cancer Research Network Symposium (Psychosocial and Community Research in Breast Cancer) – 1st December 2011
2.	Abstract title: Outcomes of Clinical Breast Examination (CBE) screening among women in Malaysia: a Pilot Study	The Second International Public Health Conference & 19th National Public Health Colloquium (2012).