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Methods and Rationale of a Multi-Centre Cross Sectional Costing Study of Elective Percutaneous Coronary Intervention: A Study Design based on Malaysia, a Middle-income Country

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Complete List of Authors:	Lee, Kun Yun; University of Malaya, Department of Social and Preventive Medicine Ong, Tiong Kiam; Sarawak General Hospital Heart Centre, Division of Cardiology Low, Ee Vien; Bahagian Perkhidmatan Farmasi Kementerian Kesihatan Malaysia Liau, Siow Yen; Queen Elizabeth 2 Hospital, Department of Pharmacy Anchah, Lawrence; Sarawak General Hospital Heart Centre, Department of Pharmacy Hamzah, Syuhada; Penang General Hospital , Administrative Office Mohd Ali, Rosli; National Heart Institute Liew, Huong Bang; Queen Elizabeth 2 Hospital, Division of Cardiology Ismail, Omar; Penang General Hospital , Division of Cardiology Wan Ahmad, Wan Azman; University Malaya Medical Centre, Medicine Said, Mas Ayu; University of Malaya, Department of Social and Preventive Medicine Dahlui, Maznah; University of Malaya, Department of Social and Preventive Medicine
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TITLE

Methods and Rationale of a Multi-Centre Cross Sectional Costing Study of Elective Percutaneous Coronary Intervention: A Study Design based on Malaysia, a Middle-income Country.

AUTHORS

Lee Kun Yun ^{a*}, Ong Tiong Kiam ^b, Low Ee Vien ^c, Liau Siow Yen ^d, Lawrence Anchah ^e, Syuhada Hamzah ^f, Liew Huong Bang ^g, Rosli Mohd Ali ^h, Omar Ismail ⁱ, Wan Azman Wan Ahmad ^j, Mas Ayu Said ^a, Maznah Dahlui ^a

^a Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya, Malaysia.

^b Division of Cardiology, Sarawak General Hospital Heart Centre, Malaysia.

^c Pharmaceutical Services Division, Ministry of Health, Malaysia.

^d Department of Pharmacy, Queen Elizabeth 2 Hospital, Sabah, Malaysia.

^e Department of Pharmacy Sarawak General Hospital Heart Centre, Malaysia.

^f Administrative Office, Penang General Hospital, Malaysia.

^g Division of Cardiology, Queen Elizabeth 2 Hospital, Sabah, Malaysia.

^h National Heart Institute, Kuala Lumpur, Malaysia

ⁱ Division of Cardiology, Penang General Hospital, Penang, Malaysia.

^j Department of Medicine, Faculty of Medicine, Kuala Lumpur, Malaysia.

***Corresponding Author**

Email address: leekunyun@gmail.com Telephone number: + 603-7967 4756

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Costing approach, research methods, coronary intervention, low- and middle-income countries

ABSTRACT

Objectives:

Limitations in the quality and access of cost data from low- and middle-income countries constrain the implementation of economic evaluations. With the increasing prevalence of coronary artery disease in Malaysia, local cost information are vital for cardiac service expansion. We aim to describe a modified costing data collection method tailored to our country setting, and to present the preliminary result. Percutaneous coronary intervention (PCI) was chosen for this purpose.

Design:

This is a cross-sectional costing study from the perspective of healthcare providers, using top-down approach, from January-June 2014. Cost items under each unit of analysis involved in the provision of PCI service were identified, valued and calculated to produce unit cost estimates.

Setting:

Five public cardiac centres participated. All the centres provide full-fledged cardiology services. They are also the tertiary referral centres of their respective regions.

Participants:

We included only patients who undergo PCI as an elective procedure. Patients with urgent/emergent indication for PCI, or with shock and hemodynamic instability were excluded.

Primary and secondary outcome measures:

The outcome measures of interest were the unit costs of admission to cardiac ward and cardiac catheterization utilization, which made up the PCI hospitalization cost.

Results:

Preliminary results from a single centre showed the total hospitalization cost per patient for elective PCI to be RM 14,309.01 (USD 3974.73). PCI consumables were the dominant cost item.

Conclusions:

Comprehensive results from all centres enable comparison from the levels of cost items, unit costs to total costs. Standardized costing approach in a multi-centre study generates important information on cost variations between centres, thus providing valuable guidance for service planning. In the setting of limited data availability like many LMIC, a modified costing method can be used for the purpose of economic evaluations.

Registration:

Malaysian MOH Medical Research and Ethics Committee (ID: NMRR-13-1403-18234 IIR)

ARTICLE SUMMARY

Strengths and limitations of this study

- Based on limitations in local settings, modified costing approach can be applied in LMIC to enhance the uptake of economic evaluation for healthcare services.
- Cost estimates from standardized collection methods can lead to between-centre comparison at multiple levels from individual cost items to overall hospitalization cost.
- The non-participation of private cardiac centres may limit the generalizability of the results.

INTRODUCTION

Economic evaluation is an important component of modern healthcare delivery. With the increasing prevalence of diseases and advancement of medical technologies, healthcare costs continue to escalate. In many developed countries, there are well-established guidelines for healthcare economic evaluation.[1] Most of the guidelines available were established in the backdrop of an easy access to high quality and freely available data, based on the setting in high-income countries. Therefore, costing analysis of healthcare services are commonly applied to assess the impact of investments in disease prevention and treatment, and to guide decision-making in future budget allocation and service planning.[2] In contrast, the lack of infrastructure and financial support for evidentiary data capture in low and middle-income countries (LMIC) results in a paucity of easily accessible and reliable cost data. This becomes a huge challenge to the healthcare providers in these countries towards the uptake of research and application of economic evaluation in their daily practice.[3-6]

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4 As with many other LMIC, the total health expenditure in Malaysia has been steadily increasing
5 from 3.0% in 2000, 4.0% in 2013 to 4.2% of national gross domestic product in 2014[7]. Public and
6 private healthcare sector expenditures were almost equal at 52.3% and 47.4%.[7, 8] However, the
7 expenditure pattern is not a good reflection of the difference in utilization rate between the public
8 and private sectors. Public healthcare service in Malaysia recorded higher utilization because it is
9 provided free or at a highly subsidized rate. This was reflected in the number of admission that was
10 twice as higher to public hospitals compared to private hospitals.[9]
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17 Among the various disease burdens in Malaysia, cardiovascular disease (CVD) is a leading cause of
18 morbidity and mortality. While the CVD mortality rate is declining in developed nations, the drastic
19 urbanization and lifestyle changes brought on by epidemiological transition has led to higher
20 prevalence of non-communicable diseases in LMIC, with CVD topping the list.[10] As a chronic
21 condition requiring frequent follow-ups and hospitalization, CVD places a huge economic burden on
22 the healthcare system. Hospitalizations and cost burden attributed to CVD have shown an increasing
23 trend in the European countries.[11-13] Malaysia is not spared of the same CVD epidemic. In 2013,
24 CVD accounted to 24.71% of total mortality in Malaysia and one of the top five causes of
25 hospitalization.[9]
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33 CVD encompasses a range of medical conditions such as coronary artery disease (CAD),
34 cerebrovascular disease, peripheral artery disease, and heart failure. Among all, CAD accounts for
35 the highest prevalence and mortality. CAD can present as mild angina attack to potentially fatal
36 acute coronary syndrome, a spectrum ranging from unstable angina to myocardial infarction.
37 Percutaneous coronary intervention (PCI) is a common treatment modality for CAD due to its safety
38 profile in terms of lower mortality and complications.[14, 15] In many countries, the availability of
39 coronary catheterization facilities and access to PCI is a key performance indicator of the cardiology
40 service. However, the need for sophisticated laboratory facilities, highly skilled clinical staff and
41 costly consumables such as cardiac stents often drive up the cost of PCI. This can be a constraining
42 factor towards its service establishment and delivery in resource-limited countries.
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51 With the increasing incidence of CAD, expansion of PCI services across Malaysia is underway.
52 More than 60 public, private and teaching institutions are performing approximately 12000 PCIs
53 annually in Malaysia, majority being elective PCI. In the public healthcare system, cardiology
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3 services are mainly provided by Ministry of Health teaching hospitals and state-level hospitals. In
4 addition, Malaysia has a highly specialized cardiac centre, which was established as a corporatized
5 entity, and given autonomy in terms of financial and staff autonomy, even though it is fully owned by
6 the government.
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10 Cost of PCI provision will continue to escalate with the advancement in medical technologies, as
11 with many other cardiac services. The scarcity of health resources necessitates cost-saving
12 mechanisms to be put in place. Policy makers and healthcare professionals will be interested to gain
13 more insight into the cost variation of performing cardiac procedures such as PCI in different
14 centres. In order to do that, reliable cost data from different cardiac centres are needed. However,
15 local evidence especially among public hospitals are lacking; as the development of health
16 economics is still in its infancy stage in Malaysia and efforts to conduct economic evaluations are
17 hampered by limited access to financial data and non-computerized patient clinical data.
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25 **OBJECTIVES**

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28 With these in mind, we describe a simple, standardized data collection method for a multi-centre
29 costing study of cardiac service in Malaysia. Elective PCI is the chosen procedure as it is among the
30 most commonly conducted procedure with the least heterogeneity among the patients and providers.
31 We aim to outline the modifications made to existing guidelines that were developed and
32 implemented in HIC. By presenting the preliminary result from one of the participating centre, we
33 hope to illustrate that it is feasible to conduct a comprehensive costing analysis in a LMIC setting
34 using modified costing approach.
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41 **METHODS**

42 **Study Design**

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45 This costing analysis was designed as a hospital-based cross-sectional study, from the perspective of
46 healthcare providers. Cost data collection was conducted from January 1st 2014 to June 30th 2014;
47 using a top-down costing approach. All cost estimates were presented in the local currency,
48 Malaysian Ringgit (RM), whereby USD 1=RM 3.60 at the time of study.
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Patient Population and Clinical Data Collection

PCI can be conducted as an emergency or elective procedure. Patients who undergo emergency PCI often have more severe comorbidities and disease presentation, leading to higher resource consumption and hospitalization cost. They often develop complications post PCI thus requiring admission to an intensive care unit. On the contrary, patients who undergo elective PCI have lower risk profile and likely have fewer complications. As a relatively homogenous group, patients who had elective PCI would be a better proxy to analyze hospital-level cost. As such, we restricted our analysis to patients who undergone PCI as an elective procedure, and excluding all patients with urgent/emergent indication for PCI, or with shock and hemodynamic instability. This definition is compatible with the definition of elective PCI adopted by other studies in the literature.[16, 17]

Study Sites

For the cost data collection, all the public and private cardiac centres that provided PCI service were invited to collaborate in this study. However, only five public cardiac centres agreed to participate. All five are the tertiary referral hospitals of their respective regions and they provide full-fledged cardiology and cardiothoracic services. Each was staffed by at least one interventional cardiologist. Three of the study sites (Centre II, III, and IV) are government public hospitals whereas Centre I is a semi-corporatized university teaching hospital. Centre V is a specialized heart centre established as a corporatized entity. The range of centres was able to represent variations across the different cost components stemming from the heterogeneity in hospital characteristics, treatment preferences and geographical locations. Table 1 outlines the main description of each centre.

Table 1 Background Information of Study Centres.

Centre	I	II	III	IV	V
Ownership Type	Semi-corporatized	Public	Public	Public	Corporatized
Start of PCI operation	1987	1994	2011	2010	1992
Interventional Cardiologist	5	3	1	1	15
Fellow Cardiologists	12	8	7	0	12
*Total Hospital Admission	34414	29336	1744	9340	8485
*Total Procedures in Cardiac Catheterization Laboratory	1084	1118	1485	940	2709
*Total PCI Procedures	580	257	282	251	1558

*During the study period of January-June 2014

Cost Data Collection

Due to the inherent characteristics of financial and medical record keeping in each healthcare system, there is no pre-existing data collection tool suitable for use by all. International guidelines recommended the design of a standardized cost collection tool that should be universally accessible and user-friendly for all involved parties.[18, 19] Thus, the health economists and interventional cardiologists in our study created a data collection tool using MS Excel. Improvements were made based on the feedbacks from the pilot study at one of the centres. A training workshop was organized for the data enumerators and study coordinators, covering topics such as the purpose of the study, introduction of the data collection tool, definitions of each of the cost categories, instructions on how to use the tool, and troubleshooting. Cost data collected were assessed for consistency and validity. Any queries on incomplete data were clarified with the respective centre.

Costing Pathway (Figure 1)

Step 1. Identification of unit of analysis

To achieve the most accurate estimate of PCI cost, it is important to identify all the resources consumed by the patients during hospital admission. Many HIC used Diagnosis Related Group (DRG), a system which classifies acute inpatient episodes based on the main clinical condition, as unit of analysis for illness-specific costing.[20] However, DRG is not practiced in any of the study centres. As an alternative, we outlined the event pathway for the provision of care for PCI patients from admission to discharge. Two main units of analysis were identified, namely cardiac ward (CW) and cardiac catheterization laboratory (CL). All the cost items under each unit of analysis were categorized under direct medical cost or overhead cost.

Step 2. Identification of Cost Items

For CW, the four cost items included under direct medical costs were labor, capital, consumables and medications; whereas overhead costs included utility, dietary, ancillary service and hospital support service. There were less cost items under CL, the second unit of analysis. Medications were prescribed and served at CW, thus not taken as a cost item under CL. Dietary and ancillary support service were also provided only once under CW.

Step 3. Valuation of Cost Items

In HIC, reference cost from national database or pre-set cost-to-charge ratios are used for cost item valuation in economic evaluation, such as the NHS reference cost in the United Kingdom,[21] and standard cost in the Australian costing guide.[22] However, reference cost is still under development in Malaysia. Thus, actual calculation of unit cost for all the cost items was conducted using a top-down approach. The subsequent sections discussed the valuation of each cost item.

Labour

This referred to the sum of full salary inclusive of wages and employers social contributions paid for the staff. A list of all the clinical staff and their respective grades involved in the provision of PCI service were used to obtain their respective payroll register from the hospital finance department. The average salary of each position was calculated from the maximum and minimum monthly salaries.

For labour cost of clinical staff stationed full time in the same unit, their salaries were summed up in total as all of their productivity were assumed to be contributed to the units they were stationed in. This included nurses and attendants in CW, laboratory technicians and radiographers in CL.

As for doctors, their work scope may spread across several units; including conducting interventions in the CL, treating patients in the specialist clinic, and leading the clinical ward rounds. Therefore, expert opinion from the interventional cardiologists at each centre was sought on the portion of time spent on different activities by doctors at each cardiac centre. The apportioned labour cost of doctors based on working hours assumed that all doctors were equally productive in delivering patient-related care and no idle time was spent.

Capital

This included fixed, one-time expenses incurred on the purchase of land, building, construction, and equipment. As the main intention of this study was to obtain the operational cost of PCI procedure, land and building costs were not taken into account. Only equipment such as machine, furniture and medical instrument with cost higher than RM 1000 and economic useful life exceeded 1 year were included.

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3 The complete list of asset in CW and CL, together with their purchase price and year of purchase
4 were obtained from the inventory list. The equivalent annual cost (EAC) was calculated by
5 annuitizing the capital outlay using a discount rate with their respective useful life years. Using the
6 straight-line depreciation approach, it was assumed that the services from the capital items were
7 divided equally over the useful life of the asset. A discount rate of 3% was chosen in conformity with
8 most economic evaluation studies conducted. Based on expert opinion and literature review, a useful
9 life of 5 years was used for equipment.[23] The discounted cost of all capital assets was summed up
10 to produce the capital costs.
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16 17 *Consumables*

18 This included items or goods that are disposable in nature and require regular replacement, such as
19 syringes, cotton swabs and needles used during hospitalization. The total costs of general
20 consumables were obtained from the central procurement section, under the purview of pharmacy
21 department.
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27 For the purpose of PCI costing, specific consumables referred to those items used in PCI procedure
28 such as cardiac stents, catheters, wires and balloons. All the centres have an up-to-date database of
29 the quantity and cost of purchase of these items.
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33 *Utility*

34 Utility cost referred to expenses incurred on electricity, water, telephone and Internet service. The
35 total bill was obtained from the annual financial account. Hospital floor plan from the engineering
36 department was obtained to calculate the space ratio, i.e. the percentage of square metres of physical
37 space occupied by the unit of analysis (CW or CL) in comparison to the total hospital indoors area.
38 Space ratio was the allocation basis to derive the utility cost of CW and CL respectively.
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44 *Hospital Support Service*

45 For all the participating centres, cost items under the hospital support service such as housekeeping,
46 laundry and linen, waste management, building, and equipment maintenance were outsourced as an
47 annual contract to a private company. The annual contract cost for all these services were obtained
48 from the finance department. Similar to utility cost, space ratio was used as the allocation basis to
49 derive the hospital support service cost for CW and CL.
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Dietary

This is the cost of meal preparation by the in-house dietary unit. The total dietary cost was obtained from the dietary unit and allocated to CW based on inpatient bed days.

Ancillary Service

Ancillary services from pharmacy, radiology, laboratory, and rehabilitation departments are usually provided to all hospital users. Due to the constraints in time and budget, separate costing analysis was not conducted to assign the cost of each ancillary department to the individual patients. Instead, we followed the recommendation by Hendriks et al. and grouped these four ancillary departments as a context-specific overhead category.[24] Its total cost would be the summation of the cost of general consumables supplied, the full salary pay-out for all the staff from the four departments, and the utility and hospital support cost calculated in the same manner as mentioned above.

Based on a report in Malaysia, 60% of clinical support services such as those provided by the ancillary departments can be attributed to the inpatient use, whereas the remaining 40% would be attributed to outpatient use.[25] Therefore, the same 60:40 proportion was applied in this study for the cost of ancillary services. Using the ratio of CW inpatient to total hospital inpatient bed days as allocation basis, the cost of ancillary service for CW was calculated.

Step 4 Calculation of Unit Cost

Upon valuation of each cost item, the summation of costs gave rise to the total direct medical and overhead costs at each unit of analysis. This in turn led to the total cost incurred by all patients in CW and CL. However, to delineate the cost incurred by patients who underwent elective PCI, suitable denominators must be applied. For CW, the inpatient bed day was deemed as an objective indicator for the workload. By dividing the total cost of all cost items in with the number of CW inpatient bed days during the study period, we were able to produce the cost of CW per bed day. The cost per bed day was multiplied by an average length of stay to produce the cost of CW admission per elective PCI. The average length of stay (ALOS) for an elective PCI was decided to be 3 days via consensus by all the interventional cardiologists in the study.

For CL, the second unit of analysis, the number of all CL procedures conducted was used as the denominator to derive the cost per CL utilization. As PCI consumables were not shared by all procedures conducted in CL, we applied a separate denominator i.e. the total number of PCI

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3 procedures, to calculate the PCI consumables cost per procedure. Together, this gave rise to cost per
4 PCI procedure in CL.
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8 The summation of cost per CW admission and cost of PCI procedures in the CL led to the total
9 hospitalization cost of a patient who underwent PCI. It is important to note that the cost produced is
10 via a top-down approach and it represented the average cost estimates for a patient admitted for an
11 elective PCI procedure, assuming average length of stay of 3 days, with no complications post PCI
12 that required intensive care. This cost also did not reflect any difference in the type and number of
13 stents used for each patient.
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18 19 **RESULTS**

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22 Based on the methods described, a range of results can be generated from this study. In this paper,
23 we presented the preliminary results from a single centre (Table 2). The ratio of cost incurred at CW
24 to CL was 1:4. By using ALOS of 3 days, the cost per admission in Centre I was RM 2,720. This
25 accounted for 19.0% of the total hospitalization cost. Of the CL cost, CL utilization cost per
26 procedure was RM 3,821. PCI consumables contributed more than half of the total hospitalization
27 cost. From the breakdown, direct medical cost items were more expensive if compared to overhead
28 cost items in both CW and CL. For CW admission cost, medication and labour costs were the
29 highest. On the contrary, capital cost ranked the highest under CL utilization, attributed by the high
30 cost of the cardiac angiography machine.
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39 By conducting the same process in the remaining centres, the cost of elective PCI between the
40 centres can be produced. These average cost estimates provide a reflection of the resource utilization
41 and cost consumption at the five centres. Comparisons can be made at the cost item level, CW or CL
42 level, up to the overall hospitalization cost. Hospital managers and policy makers will find this
43 information beneficial for resource distribution and budget allocation. Furthermore, The unit cost
44 estimates generated at cost item level would facilitate any future economic evaluation such as cost
45 effectiveness analysis. It could also be applied for costing of other services in the study centres.
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Table 2 Preliminary Cost Results from Centre I

Cost Items Of Each Unit Of Analysis	Unit Cost
Cardiac Ward Admission (CW)	
<i>Direct Medical</i>	
Labour	212.87
Capital	122.18
Consumable	37.08
Medication	337.47
	<i>Subtotal</i> 709.60
<i>Overhead</i>	
Utility	27.85
Dietary	8.33
Hospital Support	26.54
Ancillary support	134.36
	<i>Subtotal</i> 197.08
Average Cost per Cardiac Ward Bed Day	906.68
Average Cost per Admission (ALOS 3 days), A	2,720.04 (19.0%)
Cardiac Catheterization Laboratory Utilization (CL)	
<i>Direct Medical</i>	
Labour	810.63
Capital	2,619.31
Consumable	185.8
	<i>Subtotal</i> 3,615.74
<i>Overhead</i>	
Utility	105.6
Hospital support	100.64
	<i>Subtotal</i> 206.25
Average Cost per CL utilization, B	3,821.99 (26.7%)
PCI Consumables	
Stents	6,267.07
Others	1,499.91
Average Cost of PCI Consumables per PCI, C	7,766.98 (54.3%)
Average Cost of PCI procedure in CL, B+C	11,588.97 (81.0%)
TOTAL HOSPITALIZATION COST, A+B+C	14,309.01 (100%)

DISCUSSION

As the leading cause of mortality and morbidity in LMIC, service expansion of the cardiology service is inevitable. However, many such countries lack reliable evidence to guide the budget and resource planning. Majority of the LMIC do not have any official health economic evaluation guidelines in place, and the international guidelines are not a good fit for LMIC. There is also a lack of infrastructure support to sustain a comprehensive health informatics data. These are indispensable components to produce reliable cost-related outcome evidence towards better policy-making. In Malaysia specifically, there is a lack of easily accessible information such as accurate unit costs, up-to-date financial account and complete patient records, all of which are vital to conduct health economic evaluation. In this paper, we outlined the study design of a modified costing analysis for elective PCI in 5 cardiac centres in Malaysia, based on the limitations in our local setting. We also included the preliminary cost results from one of the centres.

We made some modifications to previously published health economics guidelines to adapt them to local setting. Firstly, like many LMIC, casemix system such as DRG is not a common practice in our local hospitals. To overcome this, we used an event pathway from admission to discharge to identify the cost items under the respective units of analysis. The lack of DRG and reference cost indirectly mandated us to narrow our inclusion criteria to limit the units of analysis. As such, we included only patients who had elective PCI, as they were unlikely to develop post-procedural complications that require admission to intensive care unit.

Furthermore, reference cost is also not readily available unlike most of the high-income countries. To reflect the actual cost, certain literature proposed the application of cost-to-charge ratio.[26] This method would be relatively simpler and less time consuming. However, it would be a suboptimal cost estimates as public healthcare is highly subsidized in Malaysia and the charges would be a poor proxy for the actual cost incurred in the provision of healthcare services. As a result, we conducted actual calculation of unit cost for all the cost items with top-down approach. Between top-down and bottom-up approaches, there is no consensus as to which is the gold standard. Typically, top-down approach is more straightforward to undertake but the trade-off is a lack of sensitivity especially for cost items that originated from a less homogenous production. On the contrary, bottom-up approach is able to produce a more accurate cost estimate, but the main limitation lies within the complexity and cost of its implementation, especially across different study centres.[27] Several authors advocated bottom-up approach but acknowledged that such data may not be easily available

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3 especially in resource-limited setting in LMIC.[3, 28, 29] As this costing study involved five centres,
4 a full top-down approach was applied to standardize the cost data collection in order to produce
5 reliable cost estimates for comparison between the centres.
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9 There were several limitations. Selection bias existed, as only public cardiac centres were included.
10 Due to the sensitive nature of the financial data required, private for-profit healthcare centres were
11 reluctant to participate. Despite this, the cost output from public cardiac centres would be of
12 tremendous value for policy makers as the major bulk of CVD cost and workload burden in Malaysia
13 fell on the public healthcare system. This is reflected in a national survey that showed 65.0% of the
14 Malaysian population sought treatment at public healthcare facilities and 52.4% of the total health
15 expenditure was incurred in the public sector.[8, 30] Moreover, potential bias due to inherent
16 differences in the financial record keeping between the centres may not be completely eliminated
17 despite our best effort to standardize the data collection process. Despite the shortcomings, this
18 costing study across five cardiac centres with different ownership and administration characteristics
19 will generate basic cost data that can lead to comprehensive costing analysis. In addition to
20 producing unit cost estimates per output along the clinical pathway, multiple cost components
21 involved in the PCI service can be aggregated to identify the dominant cost drivers, both within and
22 across the centres.
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33 Preliminary results from one centre showed the cost incurred in the cardiac catheterization laboratory
34 was four times that of the cost of cardiac ward admission. However, closer scrutiny revealed that
35 more than half of the total hospitalization cost could be attributed to PCI consumable. Based on this,
36 cost-saving strategy should be focused on the purchasing mechanism of PCI consumable, especially
37 the cardiac stents. To the best of our knowledge, this would be the first multi-centre costing analysis
38 of cardiac service in Malaysia. More comprehensive findings can be elicited after consolidating the
39 cost outputs from all centres. Furthermore, the results generated from this costing analysis can be
40 incorporated with appropriate clinical data to facilitate individual-level patient analysis, such as the
41 identification of cost predictors via regression analysis. The unit cost at multiple level of the care
42 pathway can also be applied to economic evaluation such as cost effectiveness analysis and
43 economic modeling purposes in relevant cardiology research. All these will provide valuable
44 information to the cardiac centres and policy makers for proper resource and budget allocation.
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CONCLUSION

The CVD epidemic in LMIC calls for targeted interventions from all aspects of healthcare delivery. Given the scarcity of healthcare resources, economic evaluations are needed to identify and implement the most cost effective intervention. Currently, the application of outcomes from economic evaluation to health policy decision-making in Malaysia is very limited due to the many obstacles in conducting costing studies. As such, we shared the alternative pathways we devised to overcome barriers in conducting a costing study for elective PCI in a LMIC setting. Future studies can be built on our efforts and like-minded researchers in other LMIC who wish to conduct similar studies can adapt this method to their respective country-specific settings.

FOOTNOTES

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Contributors

OI, MD, LHB, OTK, RMA, WAWA, LSY, LEV and KYL conceived the overall study. All authors are involved in the design of the study. WAWA, OI, LHB, OTK and RMA led the implementation of the study at each centre; while KYL, LEV, LSY, LA and SH coordinated the data collection. KYL drafted the manuscript. TKO and MD revised manuscript critically for intellectual content. All authors read and approved the final manuscript.

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Competing interests

All authors declared no competing interest.

Ethics approval

This study is approved by the Malaysian Ministry of Health Medical Research and Ethics Committee (ID: NMRR-13-1403-18234 IIR).

Provenance and peer review

Not commissioned; externally peer reviewed

Data sharing statement

No additional data are available

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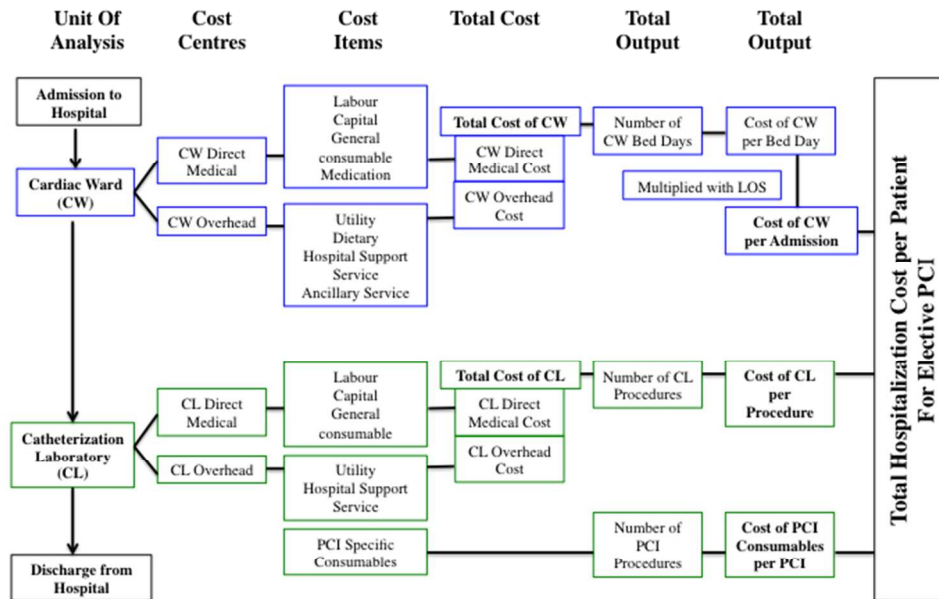


Figure 1 Pathway for the Costing Analysis of Elective PCI

Figure 1 Pathway for the Costing Analysis of Elective PCI

254x175mm (72 x 72 DPI)

STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

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

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA
		(b) Indicate number of participants with missing data for each variable of interest	NA
Outcome data	15*	Report numbers of outcome events or summary measures	NA
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	NA
		(b) Report category boundaries when continuous variables were categorized	NA
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	14
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	14-15
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	14-15
Generalisability	21	Discuss the generalisability (external validity) of the study results	15
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	16

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Methods and Rationale of a Multi-Centre Cross Sectional Costing Study of Elective Percutaneous Coronary Intervention: A Study Design based on Malaysia, a Middle-income Country

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Methods and Rationale of a Multi-Centre Cross Sectional Costing Study of Elective Percutaneous Coronary Intervention: A Study Design based on Malaysia, a Middle-income Country.

AUTHORS

Lee Kun Yun ^{a*}, Ong Tiong Kiam ^b, Low Ee Vien ^c, Liau Siow Yen ^d, Lawrence Anchah ^e, Syuhada Hamzah ^f, Liew Houng Bang ^g, Rosli Mohd Ali ^h, Omar Ismail ⁱ, Wan Azman Wan Ahmad ^j, Mas Ayu Said ^k, Maznah Dahlui ^a

^a Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya, Malaysia.

^b Department of Cardiology, Sarawak Heart Centre, Malaysia.

^c Pharmaceutical Services Division, Ministry of Health, Malaysia.

^d Department of Pharmacy, Clinical Research Centre, Queen Elizabeth 2 Hospital, Sabah, Malaysia.

^e Department of Pharmacy, Sarawak Heart Centre, Malaysia.

^f Administrative Office, Penang General Hospital, Malaysia.

^g Division of Cardiology, Clinical Research Centre, Queen Elizabeth 2 Hospital, Sabah, Malaysia.

^h Department of Cardiology, National Heart Institute, Kuala Lumpur, Malaysia

ⁱ Division of Cardiology, Penang General Hospital, Penang, Malaysia.

^j Division of Cardiology, Department of Medicine, Faculty of Medicine, University of Malaya, Malaysia.

^k Julius Centre University of Malaya, Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya, 50603 Kuala Lumpur, Malaysia

***Corresponding Author**

Email address: leekunyun@gmail.com Telephone number: + 6012-4281182

Postal address: Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya, Jalan Universtiti, 50603, Kuala Lumpur, Malaysia.

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ABSTRACT

Objectives:

Limitations in the quality and access of cost data from low- and middle-income countries constrain the implementation of economic evaluations. With the increasing prevalence of coronary artery disease in Malaysia, cost information is vital for cardiac service expansion. We aim to calculate the hospitalization cost of percutaneous coronary intervention (PCI), using a data collection method customized to local setting of limited data availability.

Design:

This is a cross-sectional costing study from the perspective of healthcare providers, using top-down approach, from January-June 2014. Cost items under each unit of analysis involved in the provision of PCI service were identified, valued and calculated to produce unit cost estimates.

Setting:

Five public cardiac centres participated. All the centres provide full-fledged cardiology services. They are also the tertiary referral centres of their respective regions.

Participants:

The cost was calculated for elective PCI procedure in each centre. PCI conducted for urgent/emergent indication or for patients with shock and hemodynamic instability were excluded.

Primary and secondary outcome measures:

The outcome measures of interest were the unit costs at the 2 units of analysis, namely cardiac ward admission and cardiac catheterization utilization, which made up the total hospitalization cost.

Results:

The average hospitalization cost ranged between RM11,471 (USD 3,186) and RM 14,465 (USD 4,018). PCI consumables were the dominant cost item at all centres. The centre with daycare establishment recorded the lowest admission cost and total hospitalization cost.

Conclusions:

Comprehensive results from all centres enable comparison at the levels of cost items, unit of analysis

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3 and total costs. This generates important information on cost variations between centres, thus
4 providing valuable guidance for service planning. Daycare establishment is a feasible cost-saving
5 option. For many LMIC with limited data availability, costing method tailored based on country
6 setting can be used for the purpose of economic evaluations.
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10 11 **KEYWORDS**

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14 Costing approach, top-down costing, research methods, hospitalization cost, cardiac centres, low-
15 and middle-income countries
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18 19 20 **Registration:**

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24 Malaysian MOH Medical Research and Ethics Committee (ID: NMRR-13-1403-18234 IIR)
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27 28 **ARTICLE SUMMARY**

29 30 31 **Strengths and limitations of this study**

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- 35 • A multi-centre costing analysis using standardized collection methods can lead to within- and
36 between-centre comparison at multiple levels, from cost items, units of analysis to overall
37 hospitalization cost.
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 - 39 • The non-participation of private cardiac centres may limit the generalizability of the results.
40
 - 41 • Top-down costing approach applied in this study produced an average estimate cost per
42 patient and enabled an objective comparison of resource consumption and hospitalization
43 cost between different centres.
44
 - 45 • However, this average cost estimates are insufficient for in-depth analysis at patient-level or
46 determination of cost predictors via regression analysis.
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 - 48 • This alternative costing methods we devised to overcome the data limitations in our setting
49 can be adapted by like-minded researchers in other low- and middle-income countries.
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56 57 **INTRODUCTION**

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3 Economic evaluation is an important component of healthcare delivery. With the increasing
4 prevalence of diseases and advancement of medical technologies, healthcare costs continue to
5 escalate. In high-income countries (HIC), there are well-established guidelines for healthcare
6 economic evaluation.[1] Most of these guidelines were established in the backdrop of an easy access
7 to high quality and freely available data. Therefore, costing analysis of healthcare services are
8 commonly applied in HIC to assess the impact of investments in disease prevention and treatment,
9 and to guide decision-making in budget allocation and service planning.[2] In contrast, the lack of
10 infrastructure and financial support for evidentiary data capture in low and middle-income countries
11 (LMIC) results in a paucity of easily accessible and reliable cost data. This becomes a huge
12 challenge to the healthcare providers in LMIC towards the uptake of research and application of
13 economic evaluation in their daily practice.[3-6]
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23 Among the various disease burdens in Malaysia, cardiovascular disease (CVD) is a leading cause of
24 morbidity and mortality. While the CVD mortality rate is declining in developed nations, the drastic
25 urbanization and lifestyle changes brought on by epidemiological transition has led to higher
26 prevalence of non-communicable diseases in LMIC, with CVD topping the list.[7] As a chronic
27 condition requiring frequent follow-ups and hospitalization, CVD places a huge economic burden on
28 the healthcare system and patients alike. Hospitalizations and cost burden attributed to CVD have
29 shown an increasing trend in the European countries.[8-10] Malaysia is not spared of the same CVD
30 epidemic. In 2013, CVD accounted to 24.71% of total mortality in Malaysia and was one of the top
31 five causes of hospitalization.[11]
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39 CVD encompasses a range of conditions including coronary artery disease (CAD), cerebrovascular
40 disease, peripheral artery disease, and heart failure. Among all, CAD accounts for the highest
41 prevalence and mortality. CAD can present as mild angina attack to potentially fatal acute coronary
42 syndrome, a spectrum ranging from unstable angina to myocardial infarction. Percutaneous coronary
43 intervention (PCI) is a common treatment modality for CAD due to its safety profile in terms of
44 lower mortality and complications.[12, 13] In many countries, the availability of coronary
45 catheterization facilities and access to PCI is a key performance indicator of the cardiology service.
46 However, the need for sophisticated laboratory facilities, highly skilled clinical staff, and costly
47 consumables such as cardiac stents often drive up the cost of PCI. This can be a constraining factor
48 towards its service establishment and delivery in resource-limited countries.
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56 With the increasing incidence of CAD, expansion of PCI services across Malaysia is underway.
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3 More than 60 public, private and teaching institutions, most of which are tertiary-level referral
4 hospitals located in urban areas, are performing approximately 12000 PCIs annually in Malaysia.
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6 This service is not available in district hospitals of lower tiers. In the public healthcare system,
7
8 cardiology services are provided by teaching hospitals and state-level Ministry of Health hospitals.
9
10 In addition, Malaysia has a highly specialized national heart institute, which was established as a
11 corporatized entity, and given autonomy in terms of financial and staff autonomy, even though it is
12 fully owned by the government. Cost of medical procedures and hospitalization often depend on the
13 type of hospitals. Studies have reported cost differences between public- or private-owned hospitals,
14 teaching or non-teaching institutions. Evans et al. reported that average cost of PCI in private
15 teaching hospitals in Japan was much higher than known published records from other hospitals.[14]
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17 Similar finding was observed between teaching and non-teaching hospitals in the state of New York,
18 United States for patients with myocardial infarction.[15] Policy makers and healthcare professionals
19 from other countries will also be interested to gain insight into the local cost variation.
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27 PCI and other CVD treatments will continue to evolve with the advancement in medical technology.
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29 The scarcity of health resources, together with competition for financial budget from other health
30 specialties, necessitate the identification of the most cost effective option via economic evaluation. In
31 order to do that, reliable cost data from cardiac centres are needed. However, local evidence are
32 lacking; as the development of health economics is still in its infancy stage in Malaysia, and efforts
33 to conduct economic evaluations are hampered by limited access to financial data and non-
34 computerized patient clinical data.
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41 **OBJECTIVES**

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44 With these in mind, we describe a simple, standardized data collection method for a multi-centre
45 costing study of cardiac service in Malaysia. Elective PCI is the chosen procedure as it is among the
46 most commonly conducted cardiac procedure with the least heterogeneity among the patients and
47 providers. We aim to outline the modifications made to existing guidelines. By presenting the cost
48 results from five cardiac centres, we hope to ascertain the cost variation between centres, and to
49 identify potential cost-saving options.
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55 **METHODS**

Study Design

This costing analysis was designed as a hospital-based cross-sectional study, from the perspective of healthcare providers. Cost data collection was conducted from January 1st 2014 to June 30th 2014; using a top-down costing approach. All cost estimates were presented in the local currency, Malaysian Ringgit (RM), whereby USD 1=RM 3.60 at the time of study.

Patient Population and Clinical Data Collection

PCI can be conducted as an emergency or elective procedure. Patients who undergo emergency PCI often have more severe comorbidities and disease presentation, leading to higher resource consumption and hospitalization cost. They might develop complications post PCI thus requiring admission to an intensive care unit. On the contrary, patients who undergo elective PCI have lower risk profile and likely fewer complications. As a relatively homogenous group, patients undergoing elective PCI would be a better proxy to analyze hospital-level cost. As such, we restricted our analysis to elective PCI, excluding patients with urgent/emergent indication for PCI, or with shock and hemodynamic instability. This definition is compatible with the definition of elective PCI adopted by other studies.[16, 17]

Study Sites

For the cost data collection, all the public and private cardiac centres were invited to collaborate in this study. However, only five public cardiac centres agreed to participate. Being the tertiary referral hospitals of their respective regions, all centres are located in the capital city and most urbanized area of each region. They provide full-fledged cardiology and cardiothoracic services and is staffed by at least one interventional cardiologist. Centre I is a semi-corporatized university teaching hospital while Centre II, III, and IV are government public hospitals. Centre V is a specialized heart centre established as a corporatized entity. The range of centres was able to represent possible cost variations stemming from the heterogeneity in hospital characteristics, treatment preferences and geographical locations. Table 1 outlines the main description of each centre.

Table 1 Background Information of Study Centres

Centre	I	II	III	IV	V
Ownership Type	Semi-corporatized	Public	Public	Public	Corporatized
Year of Initiation of PCI service	1987	1994	2011	2010	1992
*Interventional Cardiologist	5	3	1	1	15
*Fellow Cardiologists	12	8	7	0	12
*Total Hospital Admission	34414	29336	1744	9340	8485

*During the study period of January-June 2014

Cost Data Collection

Due to the inherent characteristics of financial and medical record keeping in each healthcare system, there is no pre-existing data collection tool suitable for use by all countries. For this study, our team of health economists and interventional cardiologists created a data collection tool using MS Excel, an easily available programme commonly used in local clinical and research facilities. Figure 1 outlines the steps of the cost data collection. For each centre, a data enumerator and a site coordinator were assigned. The data enumerator was in charge of the data collection from the respective departments. Site coordinators were senior personnel with vast knowledge on the daily clinical and financial operations of the centre, especially pertaining to cardiology department and PCI procedures.

Pilot study was conducted at Centre IV. Improvements were made based on shortcomings identified and feedbacks from data enumerator, site coordinator and data providers. Training workshops were organized, covering topics such as the purpose of the study, definitions of cost items, introduction of the data collection tool and instructions on how to use the tool. Upon completion of data collection by data enumerator, site coordinator would check the completeness of the data and conduct simple sense check to identify unjustifiable outliers. The compiled cost data was then forwarded to the primary investigator and assessed for its consistency and validity. All unit cost outliers (defined as less than one-tenth or more than 10 times the average unit cost at all centres) were flagged and queried with the site coordinators. All the cost data were subsequently reviewed in the presence of cardiologists and deemed accurate and justifiable before proceeding on with further calculation and analysis.

Costing Pathway (Figure 2)

Step 1. Identification of unit of analysis

To achieve the most accurate estimate of PCI cost, it is important to identify all the resources consumed by the patients during hospital admission. For this study, we outlined the event pathway for the provision of care for PCI patients from admission to discharge. Two main units of analysis were identified, namely cardiac ward (CW) and cardiac catheterization laboratory (CL). Based on guidelines in costing manual, health economists in our study team listed out various cost items that should ideally be included under each unit of analysis. The final list of cost items depended on general consensus of interventional cardiologists as they were the subject-matter experts. Under each

unit of analysis, cost items that can be directly attributed to patient care are categorized under direct medical cost, while resources that are used by more than one department/unit in the hospital are categorized as overhead cost items.

Step 2. Identification of Cost Items

For CW, direct medical cost items were labor, capital, consumables, and medication; whereas overhead costs included utility, dietary, ancillary service and hospital support service. There were less cost items under CL, the second unit of analysis. Medications were prescribed and served at CW, thus not taken as a cost item under CL. Dietary and ancillary support service were also provided only once under CW.

Step 3. Valuation of Cost Items (Table 2)

As reference cost is still under development for public hospitals in Malaysia, actual calculation of unit cost for all the cost items was conducted using a top-down approach in our study. The subsequent sections discussed the valuation of each cost item.

Labour

This referred to the full salary inclusive of wages and employers' social contributions paid for the staff. A list of all the clinical staff involved in the provision of PCI service were used to obtain their payroll register from the finance department. For clinical staff stationed full time in the same unit, for example nurses and attendants in CW, laboratory technicians and radiographers in CL, their salaries were summed up in total as all of their productivity were contributed to the units they were stationed in. As for doctors, their work scope may spread across several units; including conducting procedures in the CL, treating patients in the specialist clinic, and leading the ward rounds in CW. The interventional cardiologists in our study team were also the head of cardiology department of each centre. Therefore, their expert opinion was sought on the portion of time spent on various activities by doctors of different levels at their own respective centre. The apportioned labour cost of doctors based on working hours assumed that all doctors were equally productive in delivering patient-related care and no idle time was spent.

Capital

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3 This included fixed, one-time expenses incurred on the purchase of land, building, construction, and
4 equipment. As the main intention of this study was to obtain the operational cost of PCI procedure,
5 land and building costs were excluded. Only equipment such as machine, furniture and medical
6 instrument with cost higher than RM 1000 and economic useful life exceeding 1 year were included.
7
8 The complete list of asset in CW and CL, together with their purchase price and year of purchase
9 were obtained from the inventory list. Using the straight-line depreciation approach, it was assumed
10 that the services from the capital items were divided equally over the useful life of the asset. A
11 discount rate of 3% and a useful life of 5 years were used in conformity with most economic
12 evaluations.[18] The equivalent annual cost (EAC) of each asset was calculated by annuitizing the
13 capital outlay using a discount rate with their respective useful life years.
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20 21 *Consumables*

22 This included items that are disposable in nature and require regular replacement, such as syringes,
23 cotton swabs and needles. The costs of general consumables were obtained from the procurement
24 section of pharmacy department. For each of the cardiac centre, consumable provision may occur at
25 different levels, either at the level of individual wards or departments. Depending on the best
26 available cost information available, workload ratio from the corresponding unit was used as the
27 allocation basis to calculate the consumable cost. As for PCI-specific consumables such as cardiac
28 stents, catheters, wires and balloons, the quantity and cost of purchase were retrieved from the
29 purchase ledger of each cardiology department.
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36 37 *Medication*

38 Under the drug purchasing mechanism in public hospitals, general medication and cardiac-specific
39 medication were purchased by central pharmacy under separate budget. General medications are
40 often stored as floor stock in the ward whereas cardiac-specific medications would be distributed to
41 cardiology department. Appropriate workload ratio was used as the allocation basis to determine the
42 cost of general and cardiac-specific medication.
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48 49 *Utility*

50 Utility cost referred to expenses incurred on electricity, water, telephone and Internet service. The
51 total bill was obtained from the annual financial account. Hospital floor plan from the engineering
52 department was obtained to calculate the space ratio, i.e. the percentage of square metres of physical
53 space occupied by the unit of analysis (CW or CL) in comparison to the hospital indoors area. Space
54 ratio was the allocation basis to derive the utility cost of CW and CL.
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Hospital Support Service

For all the participating centres, hospital support services such as housekeeping, laundry, waste management, building, and equipment maintenance were outsourced as an annual contract to a private company. The annual contract cost were obtained from the finance department. Similar to utility cost, space ratio was used as the allocation basis to derive the hospital support service cost for CW and CL.

Dietary

Cost of meal preparation by the in-house dietary unit was derived by allocating the total dietary cost to CW based on inpatient bed days.

Ancillary Service

Services from pharmacy, radiology, laboratory, and rehabilitation departments are usually provided to all hospital users. Due to the constraints in time and budget, separate costing analysis was not conducted to assign the cost of each of these department to the individual patients. Instead, we followed the recommendation by Hendriks et al. and grouped them as a context-specific overhead category, labelled as ancillary service.[19] Its total cost would be the summation of the cost of general consumables supplied, the full salary pay-out for all the staff, the utility and hospital support services cost calculated in the same manner as mentioned above.

Based on a report in Malaysia, 60% of clinical support services such as those provided by the ancillary departments in our study can be attributed to the inpatient use, compared to 40% for outpatient use.[20] Therefore, the same 60:40 proportion was applied in this study for the cost of ancillary services. Using the workload ratio of CW to hospital inpatient bed days as allocation basis, the cost of ancillary service was calculated.

Step 4 Calculation of Unit Cost

Upon valuation of each cost item, the summation of costs gave rise to the total direct medical and overhead costs incurred by all patients at each unit of analysis. To delineate the cost incurred by patients who underwent elective PCI, suitable denominators were applied. For CW, the inpatient bed day was deemed as an objective indicator for the workload. By dividing the total cost of CW with the number of CW inpatient bed days during the study period, we were able to produce average cost

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3 per bed day. The cost per bed day was multiplied by an average length of stay (ALOS) to produce
4 the average cost per admission. The ALOS for an elective PCI patient was decided to be 3 days via
5 consensus by the interventional cardiologists in the study. For Centre III, the weighted admission
6 cost was calculated based on the ratio of elective PCI patients admitted to inpatient ward and
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For CL, the second unit of analysis, the number of CL procedures conducted was used as the denominator to derive the cost per CL utilization. As PCI consumables were not shared by all procedures conducted in CL, we applied a separate denominator i.e. the number of PCI procedures, to calculate the PCI consumables cost per procedure. Together, this gave rise to cost per PCI procedure in CL.

The summation of cost per admission and cost of per PCI procedures in CL led to the total hospitalization cost of a patient who underwent PCI.

Table 2 Data Required and Allocation Method for the Calculation of Cost Items

Cost Items	Cost Data Required for Valuation of Cost Items (<i>Source</i>)	Resource Output Data Required for Cost Item Calculation (<i>Source</i>)	Allocation Method for Calculation of Total Cost of Cost Items	
I labour	Doctor <i>(Human Resource, Finance)</i>	Salary payout for doctors of different grades <i>(Human Resource, Finance)</i>	Time spent for different work activities <i>(Head of Cardiology Department)</i>	Apportioned working hours * salary payout of doctors
	Others <i>(Human Resource, Finance)</i>	Salary payout for staffs other than doctors <i>(Human Resource, Finance)</i>	Not Applicable	Total salary of all staffs
Capital	Asset inventory, year of purchase, purchase price <i>(Engineering, Finance)</i>	Not Applicable	Total equivalent annual cost (EAC) of all assets	
C Consumables	General <i>(Procurement section of pharmacy department)</i>	Total cost of general consumable supplied to: (based on the availability of any of the below) i. CW/CL ii. Cardiology department iii. All Inpatient departments <i>(Procurement section of pharmacy department)</i>	Workload ratio in terms of inpatient bed days at: (based on the best cost data available) i. CW/CL ii. Cardiology department iii. All Inpatient departments <i>(Patient record office, CW census, CL procedure log)</i>	Allocation of total cost to CW or CL to corresponding workload ratio <i>Eg. For Centre I, allocated CW general consumable cost = Total inpatient consumable cost * ratio of CW bed days to total inpatient bed days</i>
	PCI-specific	Total cost of catheters, stents, balloons, and wires. <i>(Cardiology department purchase ledger)</i>	Total number of PCI procedures <i>(CL procedure logs)</i>	Average cost per procedure
Medication	Total cost of general medication supplied to: (based on the availability of any of the below) i. CW/CL ii. Cardiology department iii. All Inpatient departments <i>(Procurement section of pharmacy department)</i>	Workload Ratio in terms of inpatient bed days at: (based on the best cost data available) i. CW/CL ii. Cardiology department iii. All Inpatient departments <i>(Patient record office, CW census, CL procedure logs)</i>	For Centre III, IV and V, actual cost of general and cardiac-specific medication supplied to CW was available. No further allocation needed. Allocation of total cost to workload ratio for Centre I and II.	
Utility	Monthly utility bill <i>(Finance)</i>	Space area of hospital indoor area, CW and CL <i>(Engineering)</i>	Allocation of total utility bill to space ratio of CW or CL over total indoor area.	
Hospital Support	Annual contract cost <i>(Finance)</i>	Space area of hospital indoor area, CW and CL <i>(Engineering)</i>	Allocation of total contract cost to space ratio of CW or CL over total indoor area.	
Dietary	Total dietary cost <i>(Dietary)</i>	CW and hospital inpatient bed days <i>(Patient record office, CW census)</i>	Allocation of total cost to workload ratio of CW bed days over hospital inpatient bed days	
Ancillary	Labour cost for all personnel, consumables cost to all four departments, allocated hospital support and utility costs based on space ratio <i>(Finance, Human Resource, Pharmacy, Engineering)</i>	CW bed days Hospital inpatient bed days <i>(Patient record office, CW census)</i>	Assumption of 60:40 ratio of ancillary services by inpatient versus outpatient. Allocation of total inpatient ancillary services cost to workload ratio of CW bed days over hospital inpatient bed days.	

RESULTS

Based on the methods described, a range of results can be generated (Table 3). Comparisons can be made at the levels of cost item, unit of analysis (CW or CL), up to the total cost. It is important to note that the cost was produced via a top-down approach and it represented the average cost estimates for a patient admitted for an elective PCI procedure, assuming average length of stay of 3 days, with no complications post PCI that required intensive care. This cost also did not reflect any difference in the type and number of stents used for each patient.

The total hospitalization cost ranged from RM11,471 (USD 3,186) to RM 14,465 (USD 4,018). The admission cost accounted for one-fifth or less of the total hospitalization cost at all centres. On the contrary, cost incurred at CL was four times that of the admission cost. PCI consumables contributed to the biggest proportion among all the cost items, accounting for more than half of the total costs.

Total hospitalization cost was the highest at Centre II. Closer scrutiny revealed that average cost of PCI consumables of Centre II, and its proportion over the total hospitalization cost were highest across the 5 centres. In contrast, Centre III, the only centre with a daycare service for PCI patients, recorded the lowest cost of CW admission. This partly contributed to cheapest hospitalization cost in Centre III, at 12.3% to 26.1% lower compared to the other centres. Direct medical cost items were generally more expensive than overhead cost items in both CW and CL. For CW admission, medication and labour costs were the highest. As for CL utilization, capital cost ranked the highest at Centre I and V, the two corporatized hospitals.

Table 3 Cost Items of Each Unit of Analysis Contributing to Total Hospitalization Cost of Elective PCI at All Centres

Total Cost of Cost Item (Malaysian Ringgit)		Centre I	Centre II	Centre III	Centre IV	Centre V	
Cardiac Ward Admission (CW)							
				Inpatient	Daycare		
Direct Medical	Labour	666,064.92	1,333,604.78	874,136.64	1,340,625.80	345,683.73	1,244,978.02
	Capital	382,311.39	222,997.80	94,791.64	193,787.82	250,095.62	86,215.03
	Consumable	116,035.54	63,584.90	214,708.34	64,321.29	47,716.53	19,857.02
	Medication	1,055,939.18	12,697.27	287,242.14	558,577.96	62,189.01	575,258.55
Overhead	Utility	87,132.83	154,201.25	97,277.64	124,948.95	62,473.17	11,603.16
	Dietary	26,075.00	118,721.94	95,143.27	58,374.60	43,305.00	26,269.15
	Hospital Support	83,040.43	159,664.13	35,375.00	222,476.63	111,235.99	52,784.55
	Ancillary support	420,404.41	126,005.76	106,302.47	622,613.16	461,883.47	80,074.16
Total cost of CW		2,837,003.70	2,191,477.81	1,804,977.14	3,185,726.21	1,384,582.52	2,097,039.64
<i>Number of CW Bed Days</i>		3129	3682	2786	3892	2887	2526
Average Cost per Bed Day		906.68	595.19	647.87	818.53	479.59	830.18
Average Cost per Admission, A		2,720.04 (19.0%)	1,943.63 (13.4%)	*1,685.09 (14.7%)	2,490.54 (19.3%)	1,785.56 (12.6%)	
Cardiac Catheterization Laboratory Utilization (CL)							
Direct Medical	Labour	878,721.52	880,833.45		778,561.21	500,037.88	5,060,957.92
	Capital	2,839,335.96	614,370.96		687,789.25	782,479.78	7,238,726.57
	Consumable	201,404.15	359,953.93		398,523.57	334,733.31	10,261,691.59
Over-head	Utility	114,473.40	22,559.11		49,302.66	15,417.61	218,189.52
	Hospital Support	109,096.89	34,634.59		87,785.37	70,137.06	225,919.31
	Total Cost of CL	4,143,031.92	1,912,352.04		2,001,962.06	1,702,805.64	23,005,484.91
<i>Number of CL Procedures</i>		1084	1118		1485	940	5417
Average Cost per CL utilization, B		3,821.99 (26.7%)	1,710.51 (11.8%)		1,348.13 (11.8%)	1,811.5 (14.1%)	4,246.9 (29.9%)
Total Cost of PCI Consumables		4,504,850.00	2,778,554.00		2,379,464.50	2,152,343.50	12,743,046.50
<i>Number of PCI Procedures</i>		580	257		282	251	1558
Average Cost of PCI Consumables, C		7,766.98 (54.3%)	10,811.49 (74.7%)		8,437.82 (73.6%)	8,575.07 (66.6%)	8,179.11 (57.6%)
Average Cost of PCI procedure in CL, B+C		11,588.97 (81.0%)	12,522.00 (86.6%)		9,785.95 (85.3%)	10,386.57 (80.7%)	12,426.01 (87.4%)
Total Hospitalization Cost, A+B+C		14,309.01 (100%)	14,465.64 (100%)		11,471.04 (100%)	12,877.11 (100%)	14,211.82 (100%)

*Weighted admission cost was calculated for Centre III based on the ratio of elective PCI patients admitted to inpatient ward versus daycare.

DISCUSSION

As CVD represents the leading cause of mortality and morbidity in LMIC, service expansion of the cardiology service is inevitable. However, most LMIC lack reliable evidence to guide the budget and resource planning as they do not have any official economic evaluation guidelines in place, and the international guidelines are not a good fit for LMIC. There is also a lack of infrastructure support to sustain a comprehensive health informatics data. These are indispensable components to produce reliable cost-related outcome evidence towards better policy-making. In Malaysia, specifically, there is a lack of easily accessible information such as accurate unit costs, detailed financial account and complete patient records, all of which are vital to conduct economic evaluation. In this paper, we outlined the study design of a multi-centre costing analysis for elective PCI, based on the limitations in our local setting, before presenting the cost output. Overall, the results demonstrated substantial costs associated with the provision of PCI, with PCI consumables being the dominant cost item across all centres.

In the course of designing the costing analysis, we made some modifications to previously published guidelines. International guidelines recommended the design of a standardized cost collection tool that is universally available and easy to use for all involved parties.[21, 22] Thus, we chose MS Excel over other more sophisticated costing software, in view of its wide accessibility and user-friendliness. Many HIC used Diagnosis Related Group (DRG), a system which classifies acute inpatient episodes based on the main clinical condition, as unit of analysis for illness-specific costing.[23] However, casemix system such as DRG is not a common practice in our local hospitals. To overcome this, we used an event pathway from admission to discharge to identify cost items under the respective units of analysis. Furthermore, in HIC, reference cost from national database are used for cost item valuation, such as in the United Kingdom and Australia.[24, 25] In the absence of reference cost, certain literature proposed the application of cost-to-charge ratio, which is a relatively simpler and less time consuming method to reflect the actual cost.[26] However, it would be a suboptimal cost estimate as public healthcare is highly subsidized in Malaysia and the charges would be a poor proxy for the actual cost incurred. As a result, we conducted actual calculation of unit cost with top-down approach. Between top-down and bottom-up approaches, there is no consensus as to which is the gold standard. Typically, top-down approach is more straightforward to undertake but the trade-off is a lack of sensitivity especially for cost items that originated from a less homogenous production. On the contrary, bottom-up approach is able to produce a more accurate cost estimate, but the main limitation lies within the complexity of its implementation, especially across different

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3 study centres.[27] Several authors advocated bottom-up approach but acknowledged that such data
4 may not be easily available in resource-limited LMIC setting.[3, 28, 29] As this costing study
5 involved five centres, a full top-down approach was applied to standardize the cost data collection in
6 order to produce reliable cost estimates for comparison between the centres.
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11 The application of economic evaluation in routine clinical practice is not widespread in Malaysia.
12 The lack of familiarity among the staff in healthcare facilities towards the conduct of costing analysis
13 was a major barrier in our study. All private hospitals cited confidentiality issue of financial data
14 sharing as reason of non-participation. During the course of data collection, there were also
15 circumstances of bureaucratic resistance towards parting with cost data of sensitive nature.
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17 Misperception of the costing exercise as a performance audit by data providers at some hospital
18 departments was another reason behind their reluctance to cooperate. As a result, the relationship
19 between the enumerators and other hospital staff proved to be a vital factor towards a successful data
20 collection. In several instances, site coordinators had to step in and used their discretion to ensure
21 that the staff provided complete data. This highlighted the importance of ensuring access of
22 transparent and quality cost data towards the successful implementation of a costing analysis.
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31 There were several limitations. Selection bias existed, as only public cardiac centres were included
32 and there was no input from private for-profit healthcare centres. Despite this, the cost output would
33 be of tremendous value for policy makers as the major bulk of care burden in Malaysia fell on the
34 public healthcare system. This is reflected in a national survey that showed 65.0% of the Malaysian
35 population sought treatment at public healthcare facilities and 52.4% of the total health expenditure
36 was incurred in the public sector.[30, 31] The exclusion of land and building costs may reduce the
37 applicability of capital cost findings to rural, district hospitals. However, this has less impact towards
38 costing of highly specialized medical procedures such as PCI, as the provision of such services in
39 Malaysia will likely remain in tertiary-level hospitals in urban locations. Another limitation being the
40 potential bias arising from inherent differences in the financial record keeping between the centres.
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42 This may not be completely eliminated despite our best effort to standardize the data collection
43 process, as shown in the derivation of consumable and medication costs. Despite the shortcomings,
44 the key strengths of this study lie in the practical applications of its methodological contribution and
45 cost findings. We shared the alternative pathways we devised to overcome barriers in conducting a
46 costing analysis in a LMIC setting. To the best of our knowledge, this is the first multi-centre costing
47 analysis of cardiac service in Malaysia. Average cost estimates derived from five cardiac centres
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3 with different ownership and administration characteristics enabled us to compare the resource
4 utilization and cost output at various levels of the costing pathway.
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8 While direct cost comparison with other published literatures would not be completely feasible
9 owing to the heterogeneous study populations, different perspectives used in cost estimation, varying
10 cost calculation methods and vastly different healthcare systems, our finding of PCI consumables
11 being the dominant cost items strikes a similar chord with many studies.[32-34] This shows the
12 importance of an efficient consumable purchasing mechanism, especially for cardiac stents. Policy
13 makers should review the current procurement practice of PCI consumables by individual cardiac
14 centres. Vigorous negotiation via competitive bidding processes, ideally handled via a central
15 purchasing agency, may lead to potential cost reduction. Furthermore, our results showed that
16 daycare establishment can be an attractive cost-saving strategy. The general consensus among
17 studies that looked at the safety of same-day discharge for PCI patients found that low-risk patients
18 were good candidates for same-day discharge after uncomplicated PCI.[35, 36] Nevertheless, further
19 research in more hospitals need to be carried out to study the feasibility of establishing large-scale
20 daycare service for cardiac patients.
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31 Overall, the corporatization and teaching status of hospitals in this study appear to have minor
32 influence to the eventual cost. However, the cost differences may also be due to the casemix of
33 patients treated, and the outcomes of procedures at each centre. It would be interesting if further
34 casemix-adjusted analysis could be conducted to analyze if any of these contributes to the difference
35 in the cost output. Furthermore, results from this study can be incorporated with clinical data to
36 facilitate individual-level patient analysis, such as the identification of cost predictors via regression
37 analysis. The unit cost derived from the various levels of the care pathway can also be applied to
38 economic evaluation such as cost effectiveness analysis or economic modeling in relevant research.
39 All these will provide valuable information to the cardiac centres and policy makers for proper
40 resource and budget allocation. Lastly, while in-hospital treatment may account for a substantial
41 portion of overall cost of CAD care, pre- and post-PCI cost to the healthcare providers, patients and
42 society may represent hidden economic burden. This is an important area for future research.
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56 CONCLUSION

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4 The CVD epidemic in LMIC calls for targeted interventions from all aspects of healthcare delivery.
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6 Currently, the application of evidence from economic evaluation for health policy decision-making
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8 in Malaysia is very limited due to the obstacles in conducting costing studies. We devised alternative
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10 costing pathways to overcome the barriers and conducted a multi-centre costing analysis for elective
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12 PCI. The findings highlighted the need for effective procurement practice in view of the high cost of
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14 PCI consumables. Shorter hospitalization stay via daycare establishment represents another potential
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16 cost-saving mechanism. Future studies can be built on our efforts for other medical procedures or
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18 healthcare service. Recommendations from this study would also be useful for like-minded
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20 researchers who wish to conduct similar costing studies in LMIC.

21 FOOTNOTES

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27 collection.
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33 OI, MD, LHB, OTK, RMA, WAWA, LSY, LEV and KYL conceived the overall study. All authors
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35 are involved in the design of the study. WAWA, OI, LHB, OTK and RMA led the implementation of
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37 the study at each centre; while KYL, LEV, LSY, LA and SH coordinated the data collection. KYL
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39 drafted the manuscript. TKO and MD revised manuscript critically for intellectual content. All
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41 authors read and approved the final manuscript.

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52 Competing interests

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55 All authors declared no competing interest.
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Ethics approval

This study is approved by the Malaysian Ministry of Health Medical Research and Ethics Committee (ID: NMRR-13-1403-18234 IIR).

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No additional data are available

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16 Figure 1 Pathway for the Costing Analysis of Elective PCI
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19 Figure 2 Flow Chart of Task and Person-In-Charge Involved at Each Step of Data Collection Process
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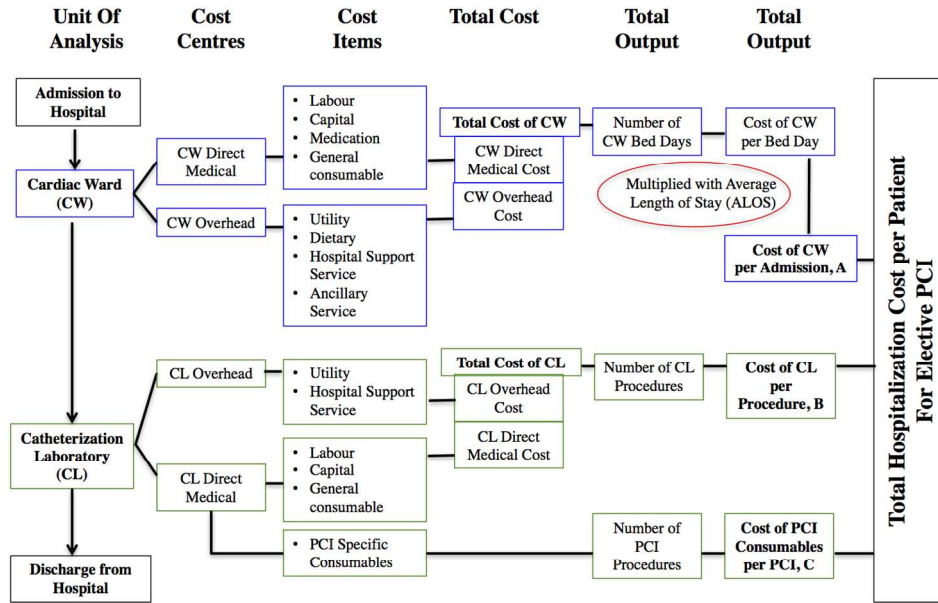


Figure 1 Pathway for the Costing Analysis of Elective PCI

Figure 1 Pathway for the Costing Analysis of Elective PCI

137x95mm (300 x 300 DPI)

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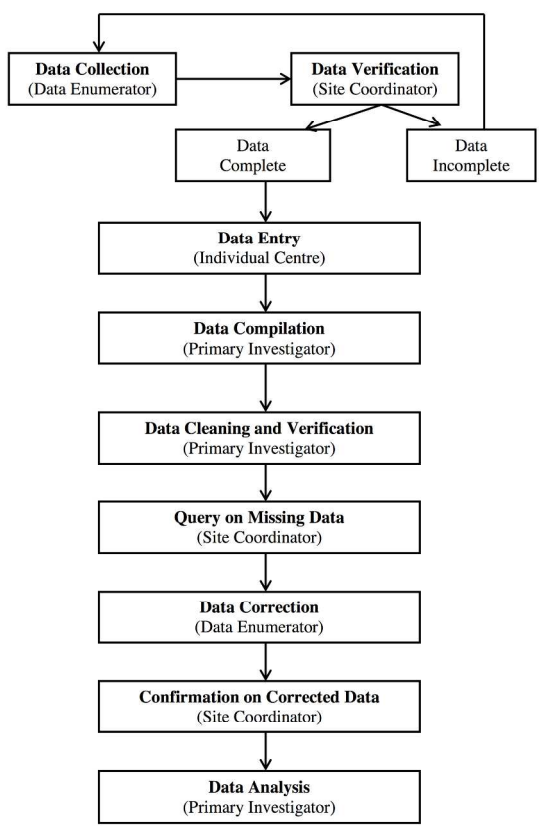


Figure 2 Flow Chart of Task and Person-In-Charge Involved at Each Step of Data Collection Process

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Figure 2 Flow Chart of Task and Person-In-Charge Involved at Each Step of Data Collection Process

296x419mm (300 x 300 DPI)

	Study Sections	Additional remarks
Study design		
(1) The research question is stated	Introduction	
(2) The economic importance of the research question is stated	Introduction, Discussion	
(3) The viewpoint(s) of the analysis are clearly stated and justified	Introduction, Methods	
(4) The rationale for choosing the alternative programmes or interventions compared is stated	Not relevant	
(5) The alternatives being compared are clearly described	Not relevant	
(6) The form of economic evaluation used is stated	Introduction, Methods	
(7) The choice of form of economic evaluation is justified in relation to the questions addressed	Introduction, Methods	
Data collection		
(8) The source(s) of effectiveness estimates used are stated	Not applicable	
(9) Details of the design and results of effectiveness study are given (if based on single study)	Not applicable	
(10) Details of the method of synthesis or meta- analysis of estimates are given (if based on an overview of a number of effectiveness studies)	Methods	
(11) The primary outcome measure(s) for the economic evaluation are	Methods-Costing	

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clearly stated	Pathway	
(12) Methods to value health states and other benefits are stated	Methods-Costing Pathway	
(13) Details of the subjects from whom valuations were obtained are given	Methods-Costing Pathway	
(14) Productivity changes (if included) are reported separately	Not Applicable	
(15) The relevance of productivity changes to the study question is discussed	Not Applicable	
(16) Quantities of resources are reported separately from their unit costs	Methods-Cost Data Collection-Table 2 and 3	
(17) Methods for the estimation of quantities and unit costs are described	Methods-Cost Data Collection-Table 2	
(18) Currency and price data are recorded	Methods-Study Design	
(19) Details of currency of price adjustments for inflation or currency conversion are given	Not applicable	
(20) Details of any model used are given	Not applicable	
(21) The choice of model used and the key parameters on which it is based are justified	Not applicable	
Analysis and interpretation of results		

(22) Time horizon of costs and benefits is stated	Methods-Study Design	
(23) The discount rate(s) is stated	Methods-Cost Data Collection-Labour	Only for calculation of Asset under Labour Cost
(24) The choice of rate(s) is justified	Methods-Cost Data Collection-Labour	Only for calculation of Asset under Labour Cost
(25) An explanation is given if costs or benefits are not discounted	Methods-Cost Data Collection-Labour	Only for calculation of Asset under Labour Cost
(26) Details of statistical tests and confidence intervals are given for stochastic data	Results	
(27) The approach to sensitivity analysis is given	Not applicable	
(28) The choice of variables for sensitivity analysis is justified	Not applicable	
(29) The ranges over which the variables are varied are stated	Not applicable	
(30) Relevant alternatives are compared	Not applicable	
(31) Incremental analysis is reported	Not applicable	
(32) Major outcomes are presented in a disaggregated as well as aggregated form	Results, Table 3	
(33) The answer to the study question is given	Results, Discussion	
(34) Conclusions follow from the data reported	Discussion, Conclusion	
(35) Conclusions are accompanied by the appropriate caveats	Conclusion	

BMJ Open

Cost of Elective Percutaneous Coronary Intervention in Malaysia, a Multi-Centre Cross Sectional Costing Study

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TITLE

Cost of Elective Percutaneous Coronary Intervention in Malaysia, a Multi-Centre Cross Sectional Costing Study

AUTHORS

Lee Kun Yun ^{a*}, Ong Tiong Kiam ^b, Low Ee Vien ^c, Liau Siow Yen ^d, Lawrence Anchah ^e, Syuhada Hamzah ^f, Liew Houng Bang ^g, Rosli Mohd Ali ^h, Omar Ismail ⁱ, Wan Azman Wan Ahmad ^j, Mas Ayu Said ^k, Maznah Dahlui ^a

^a Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya, Malaysia.

^b Department of Cardiology, Sarawak Heart Centre, Malaysia.

^c Pharmaceutical Services Division, Ministry of Health, Malaysia.

^d Department of Pharmacy, Clinical Research Centre, Queen Elizabeth 2 Hospital, Sabah, Malaysia.

^e Department of Pharmacy, Sarawak Heart Centre, Malaysia.

^f Administrative Office, Penang General Hospital, Malaysia.

^g Division of Cardiology, Clinical Research Centre, Queen Elizabeth 2 Hospital, Sabah, Malaysia.

^h Department of Cardiology, National Heart Institute, Kuala Lumpur, Malaysia

ⁱ Division of Cardiology, Penang General Hospital, Penang, Malaysia.

^j Division of Cardiology, Department of Medicine, Faculty of Medicine, University of Malaya, Malaysia.

^k Julius Centre University of Malaya, Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya, 50603 Kuala Lumpur, Malaysia

***Corresponding Author**

Email address: leekunyun@gmail.com Telephone number: + 6012-4281182

Postal address: Department of Social and Preventive Medicine, Faculty of Medicine, University of Malaya, Jalan Universtiti, 50603, Kuala Lumpur, Malaysia.

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ABSTRACT

Objectives:

Limitations in the quality and access of cost data from low- and middle-income countries constrain the implementation of economic evaluations. With the increasing prevalence of coronary artery disease in Malaysia, cost information is vital for cardiac service expansion. We aim to calculate the hospitalization cost of percutaneous coronary intervention (PCI), using a data collection method customized to local setting of limited data availability.

Design:

This is a cross-sectional costing study from the perspective of healthcare providers, using top-down approach, from January-June 2014. Cost items under each unit of analysis involved in the provision of PCI service were identified, valued and calculated to produce unit cost estimates.

Setting:

Five public cardiac centres participated. All the centres provide full-fledged cardiology services. They are also the tertiary referral centres of their respective regions.

Participants:

The cost was calculated for elective PCI procedure in each centre. PCI conducted for urgent/emergent indication or for patients with shock and hemodynamic instability were excluded.

Primary and secondary outcome measures:

The outcome measures of interest were the unit costs at the 2 units of analysis, namely cardiac ward admission and cardiac catheterization utilization, which made up the total hospitalization cost.

Results:

The average hospitalization cost ranged between RM11,471 (USD 3,186) and RM 14,465 (USD 4,018). PCI consumables were the dominant cost item at all centres. The centre with daycare establishment recorded the lowest admission cost and total hospitalization cost.

Conclusions:

Comprehensive results from all centres enable comparison at the levels of cost items, unit of analysis

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3 and total costs. This generates important information on cost variations between centres, thus
4 providing valuable guidance for service planning. Alternative procurement practices for PCI
5 consumables may deliver cost reduction. For countries with limited data availability, costing method
6 tailored based on country setting can be used for the purpose of economic evaluations.
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10 11 **KEYWORDS**

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14 Costing approach, top-down costing, research methods, hospitalization cost, cardiac centres, low-
15 and middle-income countries
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18 19 20 **Registration:**

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24 Malaysian MOH Medical Research and Ethics Committee (ID: NMRR-13-1403-18234 IIR)
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27 28 **ARTICLE SUMMARY**

29 30 31 **Strengths and limitations of this study**

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- 35 • A multi-centre costing analysis using standardized collection methods can lead to within- and
36 between-centre comparison at multiple levels, from cost items, units of analysis to overall
37 hospitalization cost.
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 - 39 • The non-participation of private cardiac centres may limit the generalizability of the results.
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 - 41 • Top-down costing approach applied in this study produced an average estimate cost per
42 patient and enabled an objective comparison of resource consumption and hospitalization
43 cost between different centres.
44
 - 45 • However, this average cost estimates are insufficient for in-depth analysis at patient-level or
46 determination of cost predictors via regression analysis.
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 - 48 • This alternative costing methods we devised to overcome the data limitations in our setting
49 can be adapted by like-minded researchers in other low- and middle-income countries.
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56 57 **INTRODUCTION**

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3 Economic evaluation is an important component of healthcare delivery. With the increasing
4 prevalence of diseases and advancement of medical technologies, healthcare costs continue to
5 escalate. In high-income countries (HIC) with an easy access to high quality and freely available
6 data, there are well-established guidelines for healthcare economic evaluation.[1] Therefore, costing
7 analysis of healthcare services are commonly applied to assess the impact of investments in disease
8 prevention and treatment, and to guide decision-making in budget allocation and service planning.[2]
9 In contrast, the lack of infrastructure and financial support for evidentiary data capture in low and
10 middle-income countries (LMIC) results in a paucity of easily accessible and reliable cost data. This
11 becomes a huge challenge to the healthcare providers in LMIC towards the uptake of research and
12 application of economic evaluation.[3-6]
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21 Cardiovascular disease (CVD) is a leading cause of morbidity and mortality in Malaysia. In 2013,
22 CVD accounted for 24.71% of total mortality and was one of the top five causes of
23 hospitalization.[7] CVD encompasses a range of conditions including coronary artery disease
24 (CAD), cerebrovascular disease, peripheral artery disease, and heart failure. Among all, CAD
25 accounts for the highest prevalence and mortality. Percutaneous coronary intervention (PCI) is a
26 common treatment modality for CAD due to its safety profile in terms of lower mortality and
27 complications.[8, 9] In many countries, the availability of coronary catheterization facilities and
28 access to PCI is a key performance indicator of the healthcare service. However, the need for
29 sophisticated laboratory, highly skilled clinical staff, and costly consumables such as cardiac stents
30 often drive up the cost of PCI. This can be a constraining factor towards its service establishment and
31 delivery in resource-limited countries.
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40 Currently, more than 60 public, private and teaching institutions, most of which are tertiary-level
41 referral hospitals located in urban areas, are performing approximately 12000 PCIs annually in
42 Malaysia. This service is not available in district hospitals of lower tiers. In the public healthcare
43 system, cardiology services are provided by teaching hospitals and state-level Ministry of Health
44 hospitals. In addition, Malaysia has a highly specialized national heart institute, which was
45 established as a corporatized entity, and given autonomy in terms of financial and staff autonomy,
46 even though it is fully owned by the government. Cost of medical procedures and hospitalization
47 often depend on the type of hospitals. International studies have reported cost differences between
48 public- or private-owned hospitals, teaching or non-teaching institutions.[10, 11] However, local
49 evidence are lacking; as the development of health economics is still in its infancy stage in Malaysia,
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3 and efforts to conduct economic evaluations are hampered by limited access to financial data and
4 non-computerized patient clinical data. Policy makers and healthcare professionals will be interested
5 to gain insight into the local cost variation. In order to do so, reliable cost data from cardiac centres
6 are needed.
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10 11 12 **OBJECTIVES**

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15 With these in mind, we describe a simple, standardized data collection method for a multi-centre
16 costing study of cardiac service in Malaysia. Elective PCI is the chosen procedure as it is among the
17 most commonly conducted cardiac procedure with the least heterogeneity among the patients and
18 providers. We aim to outline the modifications made to existing guidelines. By presenting the cost
19 results from five cardiac centres, we hope to ascertain the cost variation between centres, and to
20 identify potential cost-saving options.
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25 26 **METHODS**

27 28 29 **Study Design**

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33 This costing analysis was designed as a hospital-based cross-sectional study, from the perspective of
34 healthcare providers. Cost data collection was conducted from January 1st 2014 to June 30th 2014;
35 using a top-down costing approach. All cost estimates were presented in the local currency,
36 Malaysian Ringgit (RM), whereby USD 1=RM 3.60 at the time of study.
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41 **Patient Population and Clinical Data Collection**

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44 PCI can be conducted as an emergency or elective procedure. Patients who undergo emergency PCI
45 often have more severe comorbidities and disease presentation, leading to higher resource
46 consumption and hospitalization cost. They might develop complications post PCI thus requiring
47 admission to an intensive care unit. On the contrary, patients who undergo elective PCI have lower
48 risk profile and likely fewer complications. As a relatively homogenous group, patients undergoing
49 elective PCI would be a better proxy to analyze hospital-level cost. As such, we restricted our
50 analysis to elective PCI, excluding patients with urgent/emergent indication for PCI, or with shock
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3 and hemodynamic instability. This definition is compatible with the definition of elective PCI
4 adopted by other studies.[12, 13]
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7 8 **Study Sites** 9

10 For the cost data collection, 13 public and private cardiac centres were invited to collaborate in this
11 study. However, only five public cardiac centres agreed to participate. Being the tertiary referral
12 hospitals, all centres are located in the most urbanized area of their respective region. They provide
13 full-fledged cardiology services and is staffed by at least one interventional cardiologist. Centre I is a
14 semi-corporatized university teaching hospital while Centre II, III, and IV are government public
15 hospitals. Centre V is a specialized heart centre established as a corporatized entity. The range of
16 centres was able to represent possible cost variations stemming from the heterogeneity in hospital
17 characteristics, treatment preferences and geographical locations. Table 1 outlines the main
18 description of each centre.
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Table 1 Background Information of Study Centres

Centre	I	II	III	IV	V
Ownership Type	Semi-corporatized	Public	Public	Public	Corporatized
Year of Initiation of PCI service	1987	1994	2011	2010	1992
*Interventional Cardiologist	5	3	1	1	15
*Fellow Cardiologists	12	8	7	0	12
*Total Hospital Admission	34414	29336	1744	9340	8485

*During the study period of January-June 2014

Cost Data Collection

Due to the inherent characteristics of financial and medical record keeping in each healthcare system, there is no pre-existing data collection tool suitable for use by all countries. For this study, our team of health economists and interventional cardiologists created a data collection tool using MS Excel, a programme commonly used in local clinical and research facilities. Figure 1 outlines the steps of the cost data collection. For each centre, a data enumerator and a site coordinator were assigned. The data enumerator was in charge of the data collection from the respective departments. Site coordinators were senior personnel with vast knowledge on the daily clinical and financial operations of the centre, especially pertaining to cardiology department and PCI procedures.

Pilot study was conducted at Centre IV. Improvements were made based on shortcomings identified and feedbacks from data enumerator, site coordinator and data providers. Training workshops were organized to deliver topics such as the purpose of the study, definitions of cost items, introduction of the data collection tool and instructions on how to use the tool. Upon completion of data collection by data enumerator, site coordinator would check the completeness of the data and conduct face validity check to identify unjustifiable outliers. The compiled cost data was then forwarded to the primary investigator and assessed for its consistency and validity. Any unit cost outliers (defined as less than one-tenth or more than 10 times the average unit cost at all centres) were flagged and queried with the site coordinators. All the cost data were subsequently reviewed in the presence of cardiologists and deemed accurate and justifiable before further calculation and analysis.

Costing Pathway (Figure 2)

Step 1. Identification of unit of analysis

To achieve the most accurate estimate of PCI cost, it is important to identify all the resources consumed by the patients. For this study, we outlined the event pathway for the provision of care for PCI patients from admission to discharge. Two main units of analysis were identified, namely cardiac ward (CW) and cardiac catheterization laboratory (CL). Based on guidelines in costing manual, health economists in our study team listed out various cost items that should ideally be included under each unit of analysis. The final list of cost items depended on general consensus of interventional cardiologists as they were the subject-matter experts. Under each unit of analysis, cost items that can be directly attributed to patient care are categorized under direct medical cost, while resources that are used by more than one department/unit in the hospital are categorized as overhead

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3 cost items.
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6 Step 2. Identification of Cost Items 7

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9 For CW, direct medical cost items were labor, capital, consumables, and medication; whereas
10 overhead costs included utility, dietary, ancillary service and hospital support service. There were
11 less cost items under CL, the second unit of analysis. Medications were prescribed and served at
12 CW, thus not taken as a cost item under CL. Dietary and ancillary support service were also provided
13 only once under CW.
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17 Step 3. Valuation of Cost Items (Table 2) 18

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20 As reference cost is still under development for public hospitals in Malaysia, actual calculation of
21 unit cost for all the cost items was conducted using a top-down approach. The subsequent sections
22 discussed the valuation of each cost item.
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26 *Labour* 27

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29 This referred to the full salary inclusive of wages and employers' social contributions paid for the
30 staff. A list of all the clinical staff involved in the provision of PCI service were used to obtain their
31 payroll register from the finance department. For clinical staff stationed full time in the same unit,
32 for example nurses and attendants in CW or laboratory technicians and radiographers in CL, their
33 salaries were summed up in total as all of their productivity were contributed to their respective
34 units. As for doctors, their work scope may spread across several units; including conducting
35 procedures in the CL, treating patients in the specialist clinic, and leading the ward rounds in CW.
36 The interventional cardiologists in our study team were also the head of cardiology department at
37 each centre. Therefore, their expert opinion was sought on the portion of time spent on various
38 activities by doctors of different levels at their centre. The apportioned labour cost of doctors based
39 on working hours assumed that all doctors were equally productive in delivering patient-related care
40 and no idle time was spent.
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50 *Capital* 51

52 This included fixed, one-time expenses incurred on the purchase of land, building, construction, and
53 equipment. As the main intention of this study was to obtain the operational cost of PCI procedure,
54 land and building costs were excluded. Only equipment such as machine, furniture and medical
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3 instrument with cost higher than RM 1000 and economic useful life exceeding 1 year were included.
4 The complete list of asset in CW and CL, together with their price and year of purchase were
5 obtained from the inventory list. Using the straight-line depreciation approach, it was assumed that
6 the services from the asset were divided equally over the useful life. A discount rate of 3% and a
7 useful life of 5 years were used in conformity with most economic evaluations.[14] The equivalent
8 annual cost (EAC) of each asset was calculated by annuitizing the capital outlay using a discount rate
9 with their respective useful life years.
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14 15 16 *Consumables*

17 This included items that are disposable in nature and require regular replacement, such as syringes,
18 cotton swabs and needles. The costs of general consumables were obtained from the procurement
19 section of pharmacy department. For each of the cardiac centre, consumable provision may occur at
20 different levels such as individual wards or departments. Depending on the best available cost
21 information, workload ratio from the corresponding unit was used as the allocation basis to calculate
22 the consumable cost. As for PCI-specific consumables such as cardiac stents, catheters, wires and
23 balloons, the quantity and cost of purchase were retrieved from the purchase ledger.
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30 31 *Medication*

32 Under the drug purchasing mechanism in public hospitals, general medication and cardiac-specific
33 medication were purchased by central pharmacy under separate budget. General medications are
34 often stored as floor stock in the ward whereas cardiac-specific medications would be distributed to
35 cardiology department. Appropriate workload ratio was used as the allocation basis to determine the
36 cost of general and cardiac-specific medication.
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41 42 *Utility*

43 Utility cost referred to expenses incurred on electricity, water, telephone and Internet service. The
44 total bill was obtained from the annual financial account. Hospital floor plan from the engineering
45 department was obtained to calculate the space ratio, i.e. the percentage of square metres of physical
46 space occupied by the unit of analysis (CW or CL) in comparison to the hospital indoors area. Space
47 ratio was the allocation basis to derive the utility cost of CW and CL.
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53 54 *Hospital Support Service*

55 For all the participating centres, hospital support services such as housekeeping, laundry, waste
56 management, building, and equipment maintenance were outsourced as an annual contract to a
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private company. The annual contract cost was obtained from the finance department. Similar to utility cost, space ratio was used as the allocation basis.

Dietary

Cost of meal preparation by the in-house dietary unit was derived by allocating the total dietary cost to CW based on inpatient bed days.

Ancillary Service

Services from pharmacy, radiology, laboratory, and rehabilitation departments are usually provided to all hospital users. Due to time and budget constraints in this study, separate costing analysis was not conducted to assign the cost of each of these department to the individual patients. Instead, we followed the recommendation by Hendriks et al. and grouped them as a context-specific overhead category, labelled as ancillary service.[15] Its total cost would be the summation of the cost of general consumables supplied, the full salary pay-out for all the staff, the utility and hospital support services cost calculated in the same manner as mentioned above.

Based on a report in Malaysia, 60% of clinical support services such as those provided by the ancillary departments in our study can be attributed to the inpatient use, compared to 40% for outpatient use.[16] Therefore, the same 60:40 proportion was applied in this study for the cost of ancillary services. Using the workload ratio of CW to hospital inpatient bed days as allocation basis, the cost of ancillary service was calculated.

Step 4 Calculation of Unit Cost

Upon valuation, the summation of all cost items gave rise to the total direct medical and overhead costs incurred at each unit of analysis. To delineate the cost incurred by patients who underwent elective PCI, suitable denominators were applied. For CW, the inpatient bed day was deemed as an objective indicator for the workload. By dividing the total cost of CW with the number of CW inpatient bed days during the study period, we were able to produce average cost per bed day. The cost per bed day was further multiplied by an average length of stay (ALOS), giving rise to the average cost per admission. The ALOS for an elective PCI patient was decided to be 3 days via consensus of all the interventional cardiologists in the study. For Centre III, the weighted admission cost was calculated based on the ratio of elective PCI patients admitted to inpatient ward and daycare.

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4 For CL, the second unit of analysis, the number of CL procedures conducted was used as the
5 denominator to derive the cost per CL utilization. As PCI consumables were not shared by all
6 procedures conducted in CL, we applied a separate denominator i.e. the number of PCI procedures,
7 to calculate the PCI consumables cost per procedure. Together, this gave rise to cost per PCI
8 procedure in CL.
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14 The summation of cost per admission and cost of per PCI procedures in CL led to the total
15 hospitalization cost of a patient who underwent elective PCI.
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Table 2 Data Required and Allocation Method for the Calculation of Cost Items

Cost Items	Cost Data Required for Valuation of Cost Items (<i>Source of Data</i>)	Resource Output Data Required for Cost Item Calculation (<i>Source of Data</i>)	Allocation Method for Calculation of Total Cost of Cost Items	
I labour	Doctor <i>(Human Resource, Finance)</i>	Salary payout for doctors of different grades <i>(Human Resource, Finance)</i>	Time spent for different work activities <i>(Head of Cardiology Department)</i>	Apportioned working hours * salary payout of doctors
	Others <i>(Human Resource, Finance)</i>	Salary payout for staffs other than doctors <i>(Human Resource, Finance)</i>	Not Applicable	Total salary of all staffs
Capital	Asset inventory, year and price of purchase <i>(Engineering, Finance)</i>	Not Applicable	Total equivalent annual cost (EAC) of all assets	
C Consumables	General <i>(Procurement section of pharmacy department)</i>	Total cost of general consumable supplied to: (based on the availability of any of the below) i. CW/CL ii. Cardiology department iii. All Inpatient departments <i>(Procurement section of pharmacy department)</i>	Workload ratio in terms of inpatient bed days at: (based on the best cost data available) i. CW/CL ii. Cardiology department iii. All Inpatient departments <i>(Patient record office, CW census, CL procedure log)</i>	Allocation of total cost to CW or CL to corresponding workload ratio <i>Eg. For Centre I, allocated CW general consumable cost = Total inpatient consumable cost * ratio of CW bed days to total inpatient bed days</i>
	PCI-specific	Total cost of catheters, stents, balloons, and wires. <i>(Cardiology department purchase ledger)</i>	Total number of PCI procedures <i>(CL procedure logs)</i>	Average cost per procedure
	Medication	Total cost of general medication supplied to: (based on the availability of any of the below) i. CW/CL ii. Cardiology department iii. All Inpatient departments <i>(Procurement section of pharmacy department)</i>	Workload Ratio in terms of inpatient bed days at: (based on the best cost data available) i. CW/CL ii. Cardiology department iii. All Inpatient departments <i>(Patient record office, CW census, CL procedure logs)</i>	For Centre III, IV and V, actual cost of general and cardiac-specific medication supplied to CW was available. No further allocation needed. Allocation of total cost to workload ratio for Centre I and II.
Utility	Monthly utility bill <i>(Finance)</i>	Space area of hospital indoor area, CW and CL <i>(Engineering)</i>	Allocation of total utility bill to space ratio of CW or CL over total indoor area.	
Hospital Support	Annual contract cost <i>(Finance)</i>	Space area of hospital indoor area, CW and CL <i>(Engineering)</i>	Allocation of total contract cost to space ratio of CW or CL over total indoor area.	
Dietary	Total dietary cost <i>(Dietary)</i>	CW and hospital inpatient bed days <i>(Patient record office, CW census)</i>	Allocation of total cost to workload ratio of CW bed days over hospital inpatient bed days	
Ancillary	Labour cost for all personnel, consumables cost to all four departments, allocated hospital support and utility costs based on space ratio <i>(Finance, Human Resource, Pharmacy, Engineering)</i>	CW bed days Hospital inpatient bed days <i>(Patient record office, CW census)</i>	Assumption of 60:40 ratio of utilization by inpatient versus outpatient departments. Allocation of total inpatient ancillary services cost to workload ratio of CW bed days over hospital inpatient bed days.	

RESULTS

Based on the methods described, a range of results can be generated (Table 3). Comparisons can be made at the levels of cost item, unit of analysis (CW or CL), up to the total cost. It is important to note that the cost was produced via a top-down approach and it represented the average cost estimates for a patient admitted for an elective PCI procedure, assuming average length of stay of 3 days, with no complications post PCI that required intensive care. This cost also did not reflect any difference in the type and number of stents used for each patient.

The total hospitalization cost ranged from RM11,471 (USD 3,186) to RM 14,465 (USD 4,018). The CW admission cost accounted for one-fifth or less of the total hospitalization cost at all centres. On the contrary, cost incurred at CL was four times that of the admission cost. PCI consumables contributed to the biggest proportion among all the cost items, accounting for more than half of the total costs.

Total hospitalization cost was the highest at Centre II. Closer scrutiny revealed that average cost of PCI consumables of Centre II, and its proportion over the total hospitalization cost were highest across the 5 centres. In contrast, Centre III, the centre with a daycare service for PCI patients, recorded the lowest cost of CW admission. This partly contributed to cheapest hospitalization cost in Centre III, at 12.3% to 26.1% lower compared to the other centres. Direct medical cost items were generally more expensive than overhead cost items in both CW and CL. For CW admission, medication and labour costs were the highest. As for CL utilization, capital cost ranked the highest at Centre I and V, the two corporatized hospitals.

Table 3 Cost Items of Each Unit of Analysis Contributing to Total Hospitalization Cost of Elective PCI at All Centres

Total Cost of Cost Item (Malaysian Ringgit)		Centre I	Centre II	Centre III	Centre IV	Centre V	
Cardiac Ward Admission (CW)							
				Inpatient	Daycare		
Direct Medical	Labour	666,064.92	874,136.64	1,340,625.80	345,683.73	1,244,978.02	1,333,604.78
	Capital	382,311.39	94,791.64	193,787.82	250,095.62	86,215.03	222,997.80
	Consumable	116,035.54	214,708.34	64,321.29	47,716.53	19,857.02	63,584.90
	Medication	1,055,939.18	287,242.14	558,577.96	62,189.01	575,258.55	12,697.27
Overhead	Utility	87,132.83	97,277.64	124,948.95	62,473.17	11,603.16	154,201.25
	Dietary	26,075.00	95,143.27	58,374.60	43,305.00	26,269.15	118,721.94
	Hospital Support	83,040.43	35,375.00	222,476.63	111,235.99	52,784.55	159,664.13
	Ancillary support	420,404.41	106,302.47	622,613.16	461,883.47	80,074.16	126,005.76
Total cost of CW		2,837,003.70	1,804,977.14	3,185,726.21	1,384,582.52	2,097,039.64	2,191,477.81
<i>Number of CW Bed Days</i>		3129	2786	3892	2887	2526	3682
Average Cost per Bed Day		906.68	647.87	818.53	479.59	830.18	595.19
Average Cost per Admission, A		2,720.04 (19.0%)	1,943.62 (13.4%)	1,685.09 (14.7%)	2,490.55 (19.3%)	1,785.56 (12.6%)	
Cardiac Catheterization Laboratory Utilization (CL)							
Direct Medical	Labour	878,721.52	880,833.45		778,561.21	500,037.88	2,530,478.96
	Capital	2,839,335.96	614,370.96		687,789.25	782,479.78	3,619,363.29
	Consumable	201,404.15	359,953.93		398,523.57	334,733.31	5,130,845.80
Over-head	Utility	114,473.40	22,559.11		49,302.66	15,417.61	109,094.76
	Hospital Support	109,096.89	34,634.59		87,785.37	70,137.06	112,959.66
Total Cost of CL		4,143,031.92	1,912,352.04		2,001,962.06	1,702,805.64	11,502,742.46
<i>Number of CL Procedures</i>		1084	1118		1485	940	2709
Average Cost per CL utilization, B		3,821.99 (26.7%)	1,710.51 (11.8%)		1,348.13 (11.8%)	1,811.50 (14.1%)	4,246.12 (29.9%)
Total Cost of PCI Consumables		4,504,850.00	2,778,554.00		2,379,464.50	2,152,343.50	12,743,046.50
<i>Number of PCI Procedures</i>		580	257		282	251	1558
Average Cost of PCI Consumables, C		7,766.98 (54.3%)	10,811.49 (74.7%)		8,437.82 (73.6%)	8,575.07 (66.6%)	8,179.11 (57.6%)
Average Cost of PCI procedure in CL, B+C		11,588.97 (81.0%)	12,522.00 (86.6%)		9,785.95 (85.3%)	10,386.57 (80.7%)	12,425.23 (87.4%)
Total Hospitalization Cost, A+B+C		14,309.01 (100%)	14,465.64 (100%)		11,471.04 (100%)	12,877.11 (100%)	14,210.79 (100%)

*Weighted admission cost was calculated for Centre III based on the ratio of elective PCI patients admitted to inpatient ward versus daycare.

DISCUSSION

As CVD represents the leading cause of mortality and morbidity in LMIC, expansion of the cardiology service is inevitable. However, most LMIC lack guidance for budget and resource planning as they do not have any official economic evaluation guidelines, and the international guidelines are not a good fit for LMIC. There is also a lack of infrastructure support to sustain a comprehensive health informatics data. These are indispensable components to produce reliable cost-related outcome evidence towards better policy-making. In Malaysia, there is a lack of easily accessible information such as accurate unit costs, detailed financial account and complete patient records, all of which are vital to conduct economic evaluation. In this paper, we outlined the study design of a multi-centre costing analysis for elective PCI, based on the limitations in our local setting, before presenting the cost output. Overall, the results demonstrated substantial costs associated with the provision of PCI, with PCI consumables being the dominant cost item across all centres.

In the course of designing the costing analysis, we made some modifications to previously published guidelines. International guidelines recommended the design of a standardized cost collection tool that is universally available and easy to use for all involved parties.[17, 18] Thus, we chose MS Excel over other more sophisticated costing software, in view of its wide accessibility and user-friendliness. Many HIC used Diagnosis Related Group (DRG), a system which classifies acute inpatient episodes based on the main clinical condition, as unit of analysis for illness-specific costing.[19] However, this is not a common practice in our local hospitals. To overcome this, we used an event pathway from admission to discharge to identify cost items under the respective units of analysis. Furthermore, reference cost from national database of HIC are available for cost item valuation, such as in the United Kingdom and Australia.[20, 21] In the absence of reference cost, certain literature proposed the application of cost-to-charge ratio, which is a relatively simpler and less time consuming method to reflect the actual cost.[22] However, it would be a suboptimal cost estimate as public healthcare is highly subsidized in Malaysia and the charges would be a poor proxy for the actual cost incurred. As a result, we conducted actual calculation of unit cost with top-down approach. Between top-down and bottom-up approaches, there is no consensus as to which is the gold standard. Typically, top-down approach is more straightforward but the trade-off is a lack of sensitivity, especially for cost items that originated from a less homogenous production. On the contrary, bottom-up approach is able to produce a more accurate cost estimate, but the main limitation lies within the complexity of its implementation, especially across different study

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3 centres.[23] Several authors advocated bottom-up approach but acknowledged that such data may
4 not be easily available in LMIC.[3, 24, 25] As this costing study involved five centres, a full top-
5 down approach was applied to standardize the cost data collection in order to produce reliable cost
6 estimates for comparison between the centres.
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11 The application of economic evaluation in routine clinical practice is not widespread in Malaysia.
12 The lack of familiarity among the staff in healthcare facilities towards the conduct of costing analysis
13 was a major barrier in our study. All private hospitals cited confidentiality issue of financial data
14 sharing as reason of non-participation. During data collection, there were circumstances of
15 bureaucratic resistance towards parting with cost data of sensitive nature. Misperception of the
16 costing exercise as a performance audit was another reason behind some of the staff reluctance to
17 cooperate. As a result, the relationship between the enumerators and other hospital staff proved to be
18 a vital factor towards a successful data collection. In several instances, site coordinators had to step
19 in and used their discretion to ensure that complete data was provided. This highlighted the
20 importance of ensuring access of transparent and quality cost data towards the successful
21 implementation of a costing analysis.
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31 There were several limitations. Selection bias existed, as there was no input from private for-profit
32 healthcare centres. Despite this, the cost output from this study would be of tremendous value as the
33 major bulk of care burden in Malaysia fell on the public healthcare system. This is reflected in a
34 national survey that showed 65.0% of the Malaysian population sought treatment at public healthcare
35 facilities and 52.4% of the total health expenditure was incurred in the public sector.[26, 27] The
36 exclusion of land and building costs may reduce the applicability of capital cost findings to rural,
37 district hospitals. However, this has less impact towards costing of highly specialized medical
38 procedures such as PCI, as the provision of such services in Malaysia will likely remain in tertiary-
39 level hospitals in urban locations. Another limitation being the potential bias arising from inherent
40 differences in the financial record keeping between the centres. This may not be completely
41 eliminated despite our best effort to standardize the data collection process, as shown in the
42 derivation of consumable and medication costs. Despite the shortcomings, the key strengths of this
43 study lie in the practical applications of its methodological contribution and cost findings. We shared
44 the alternative pathways we devised to overcome barriers in conducting a costing analysis in a LMIC
45 setting. To the best of our knowledge, this is the first multi-centre costing analysis of cardiac service
46 in Malaysia. Average cost estimates derived from five cardiac centres with different ownership and
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3 administration characteristics enabled us to compare the resource utilization and cost output at
4 various levels of the costing pathway.
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8 While direct cost comparison with other published literatures would not be completely feasible
9 owing to the heterogeneous study populations, different perspectives used in cost estimation, varying
10 cost calculation methods and vastly different healthcare systems, our finding of PCI consumables
11 being the dominant cost item strikes a similar chord with many studies.[28-30] This shows the
12 importance of an efficient consumable purchasing mechanism, especially for cardiac stents. Policy
13 makers should review the current procurement practice of PCI consumables by individual cardiac
14 centres. Vigorous negotiation via competitive bidding processes, ideally handled via a central
15 purchasing agency, may lead to potential cost reduction. Furthermore, results from one of the study
16 centres showed that daycare establishment can be an attractive cost-saving strategy. The general
17 consensus among relevant studies found that low-risk patients were good candidates for same-day
18 discharge after uncomplicated PCI.[31, 32] Nevertheless, further research in more Malaysian
19 hospitals are warranted to study the feasibility of establishing large-scale daycare service for cardiac
20 patients.
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31 Overall, the corporatization and teaching status of hospitals in this study appear to have minor
32 influence to the eventual cost. However, the cost differences may also be due to the casemix and
33 outcome of patients at each centre. Further casemix-adjusted analysis could be conducted to analyze
34 the factors that contribute to the difference in the cost output. In addition, results from this study can
35 be incorporated with clinical data to facilitate individual-level patient analysis, such as the
36 identification of cost predictors via regression analysis. The unit cost derived from the various levels
37 of the care pathway can also be applied to economic evaluation such as cost effectiveness analysis or
38 economic modeling in relevant research. All these will provide valuable information to the cardiac
39 centres and policy makers for proper resource and budget allocation. Lastly, while in-hospital
40 treatment may account for a substantial portion of overall cost of CAD care, pre- and post-PCI cost
41 to the healthcare providers, patients and society may represent hidden economic burden. This is an
42 important area for future research.
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56 CONCLUSION

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4 The CVD epidemic in LMIC calls for targeted interventions from all aspects of healthcare delivery.
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6 Currently, the application of evidence from economic evaluation for health policy decision-making
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8 in Malaysia is very limited due to the obstacles in conducting costing studies. We devised alternative
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10 costing pathways to overcome the barriers and conducted a multi-centre costing analysis for elective
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12 PCI. The findings highlighted the need for effective procurement practice in view of the high cost of
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14 PCI consumables. Shorter hospitalization stay via daycare establishment represents another potential
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16 cost-saving mechanism. Future studies can be built on our efforts for other medical procedures or
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18 healthcare service. Recommendations from this study would also be useful for like-minded
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20 researchers who wish to conduct similar costing studies in LMIC.

21 FOOTNOTES

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25 The authors thank all cardiologists and nurses at each participating centres for their effort in data
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27 collection.
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30 Contributors

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32
33 OI, MD, LHB, OTK, RMA, WAWA, LSY, LEV and KYL conceived the overall study. All authors
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35 are involved in the design of the study. WAWA, OI, LHB, OTK and RMA led the implementation of
36
37 the study at each centre; while KYL, LEV, LSY, LA and SH coordinated the data collection. KYL
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39 drafted the manuscript. TKO and MD revised manuscript critically for intellectual content. All
40
41 authors read and approved the final manuscript.

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49 MOH-2014-02).
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52 Competing interests

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55 All authors declared no competing interest.
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Ethics approval

This study is approved by the Malaysian Ministry of Health Medical Research and Ethics Committee (ID: NMRR-13-1403-18234 IIR).

Provenance and peer review

Not commissioned; externally peer reviewed

Data sharing statement

No additional data are available

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Figure 1 Pathway for the Costing Analysis of Elective PCI

Figure 2 Flow Chart of Task and Person-In-Charge Involved at Each Step of Data Collection Process

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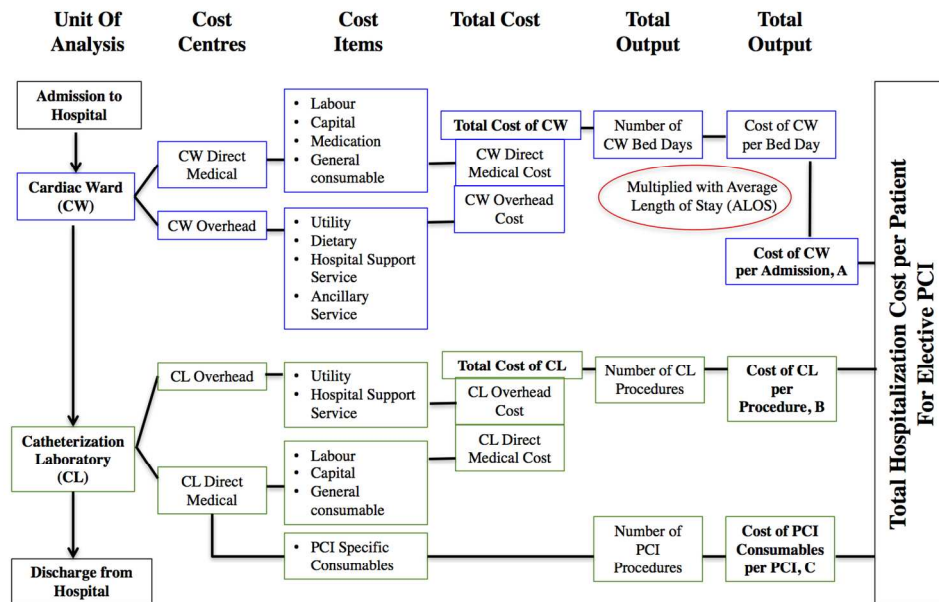


Figure 1 Pathway for the Costing Analysis of Elective PCI

Figure 1 Pathway for the Costing Analysis of Elective PCI

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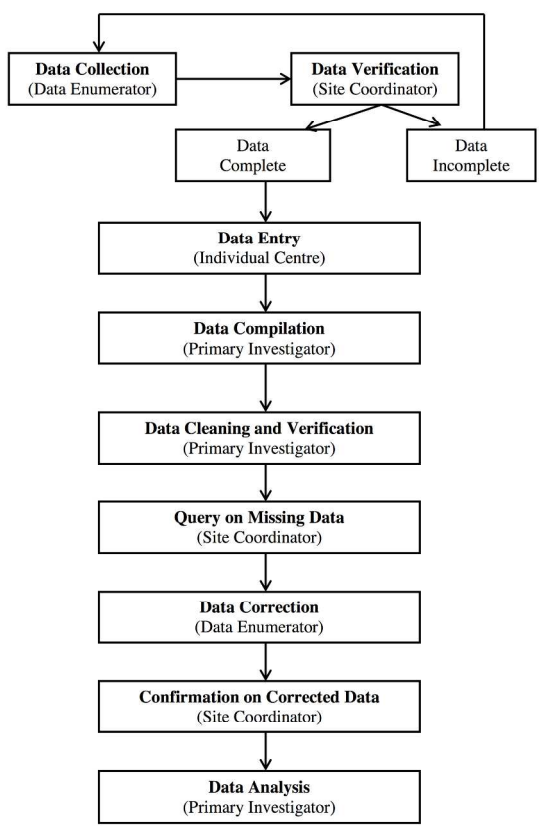


Figure 2 Flow Chart of Task and Person-In-Charge Involved at Each Step of Data Collection Process

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Figure 2 Flow Chart of Task and Person-In-Charge Involved at Each Step of Data Collection Process

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STROBE 2007 (v4) Statement—Checklist of items that should be included in reports of *cross-sectional studies*

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

Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	NA
		(b) Give reasons for non-participation at each stage	NA
		(c) Consider use of a flow diagram	NA
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	NA
		(b) Indicate number of participants with missing data for each variable of interest	NA
Outcome data	15*	Report numbers of outcome events or summary measures	15
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	15 (only unadjusted estimates are relevant here)
		(b) Report category boundaries when continuous variables were categorized	NA
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	NA
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	NA
Discussion			
Key results	18	Summarise key results with reference to study objectives	16
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	17
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	17-18
Generalisability	21	Discuss the generalisability (external validity) of the study results	18
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	19

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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