

APPENDIX B: STATISTICAL METHODS

The analysis described below was conducted on data collected in the NCVD-PCI registry for 2013 and 2014. Inclusion criteria were all patients who had PCI procedures performed in 2013 or 2014 and were aged 20 years and above. In general, the unit of analysis was PCI procedures performed or treated lesions. However, for some results, a patient level analysis was conducted.

Regarding the CRFs used for data collection: Data on some of the patients with PCI procedure in 2013 was collected using an earlier version of the CRF (version 1.4). Whereas other patient data was collected using the new CRF (version 1.5). In the new CRF, certain variables such as IABP, PCI status for STEMI, functional ischaemia, were collected in a different format and categorisation. Therefore, in the data preparation process, we combined the information for these variables in order that the data could be analysed appropriately.

Statistical methods used mainly descriptive analysis. For discrete data, we calculated frequency and percentages; while for continuous data, the mean, standard deviation (SD), median, minimum and maximum values were calculated. The only exception to this was regression analysis performed to evaluate prognostic factors for in-hospital mortality and 30-day mortality.

Missing data was reported for both discrete and continuous data. No statistical imputation was applied to replace any missing data. Acceptable ranges for different characteristics are presented in the table below:-

Name of the field	Acceptable range
Age	≥ 20 years old
Height	130 – 250 cm
Weight	40 – 200 kg
Body mass index (BMI)	14 – 50 kgm ⁻²
Heart rate	25 – 200 beats/min
Systolic blood pressure	60 – 230 mmHg
Diastolic blood pressure	10 – 120 mmHg
Creatinine	44 – 2000 micromol/L
Total cholesterol (TC)	2.0 – 5.0 mmol/L
Low-density lipoprotein (LDL)	0.7 – 20.0 mmol/L
Ejection fraction status	10 – 80 %
Fluoroscopy time	2.0 – 180.0 minutes
Contrast volume	15.0 – 500.0 mL
Pre-stenosis	0 – 100 %
Post-stenosis	0 – 100 %
Estimated lesion length	1.0 – 150.0 mm
Stent length	8.0 – 80.0 mm
Stent diameter	2.0 – 7.0 mm
Maximum balloon size used	1.0 – 6.0 mm
Maximum stent/balloon deploy pressure	1.0 – 40.0 mm
HbA1c	4.0 – 32.0 %

Analysis performed for each report chapter is described below:

1. Chapter 1: Patient characteristics

Patient characteristics were summarised in Chapter 1. Numbers of patients in each year were determined based on their PCI procedure year. The results presented the patients' age, gender, ethnicity, coronary risk factors, comorbidities, lab investigations, previous interventions, and other variables contained in the CRF.

2. Chapter 2: Clinical presentations and investigations

Chapter 2 included an analysis of clinical presentation, baseline investigations, cardiac status such as NYHA and Killip class, Canadian Cardiovascular Score and IABP use at PCI procedure. An analysis of STEMI time-to-treatment was performed in which we excluded any illogical values for time-to-treatment (such as negative values for symptom-to-door and door-to-balloon time).

3. Chapter 3: Procedural setting

Chapter 3 included an analysis of the procedural details and treatment received by the patients. This chapter includes results for PCI procedure characteristics, duration of thienopyridine use, PCI and access site.

4. Chapter 4: Lesion characteristics

Lesion characteristics were summarised in Chapter 4. This chapter included location of lesion, types of lesion, types of stent, types of intracoronary devices used, stent diameter, stent length and TIMI flow. Sub-group analyses were performed for PCI to left main stem, in-stent restenosis and graft lesion and CTO. In this chapter, numbers of lesions in each year were used as the denominator in the results. This was unlike other chapters where numbers of patients was the denominator.

5. Chapter 5: Outcome

The overall in-hospital mortality, all-cause mortality, post-procedural complications, medications and patient outcome at discharge and follow-up (30-days, six months, and one year) are presented in Chapter 5. In order to evaluate the status of patients (whether alive or deceased), individual patients were matched against the status provided by the Malaysian National Registration Department (NRD). Patients were considered as alive at the time of follow-up if the death date was not provided in the NRD dataset.