Authors:
Ms. Atikah Shaharudin
Ms. Gan Yan Nee
Dr. Izzuna Mudla Mohamed Ghazali

External Reviewer:
Dr. Mohamed Hirman Abdullah
Ms. Puan Salbiah Yaakop
Mr. Fezri Aziz
Ministry of Health Malaysia

For further information, please contact:

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
Level 4, Block E1, Precinct 1
Government Office Complex
62590 Putrajaya.

htamalaysia@moh.gov.my
Tel: 603 8883 1229

Available at the following website:
http://www.moh.gov.my

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Background

Medical devices play a significant role in the delivery of healthcare services. The increasing costs of medical devices over the years have contributed to significant economic burden on healthcare organisations. Therefore, an efficient use of health care resources is vital in achieving sustainable healthcare system. One of the methods introduced to reduce cost of the healthcare equipment is refurbishment of medical device which also bring about social benefits by reducing waste and conserving resources.

The used of refurbished medical devices has been on the rise in many countries due to reported beneficial effect especially from costing aspect of refurbished medical effect. When a device can be refurbished, it is a more economical alternative to purchasing a new one; however, not every medical device can be refurbished, and careful assessment and selection criteria must be used. In 2019, North America was the largest regional market for refurbished medical equipment, which was primarily attributed to the presence of a large number of private healthcare facilities, increasing aging population, high prevalence of various diseases, ongoing reimbursement cuts and favourable regulatory scenario for the sale and use of refurbished medical devices in the United State of America (US). Refurbishment of medical device is also favourable in developing countries without full medical coverage. For example the original pacemaker implantation may be delayed because the patient cannot afford to pay for the device, hence the refurbished pacemaker which is less costly might be the good choice for this situation. However, the effectiveness and safety of refurbished devices are still a matter of debate.

According to the Strategic framework of the Medical Programme, Ministry of Health, Malaysia (MOH) 2020-2025, one of the strategies proposed is to optimise resource management including facility, equipment and financing. Hence, this review was requested by the Director of Medical Development Division to assess whether refurbished medical devices are effective, safe and conform to acceptable standards for the benefits of the public.

Objective

To ensure the refurbished medical device is effective, safe and conforms to acceptable standards for the benefits of the public, before implementing it in MOH facilities.

Methods

The following electronic databases were searched through the Ovid interface: Ovid MEDLINE® In-process and other Non-indexed citations and Ovid MEDLINE® 1946 to present, EBM Reviews - Cochrane Central Register of Controlled Trials – March 2020, EBM Reviews - Cochrane Database of Systematic Reviews - 2005 to March 2020, EBM Reviews - Health Technology Assessment – 4th Quarter 2016 and EBM Reviews – NHS Economic Evaluation Database 1st Quarter 2016. PubMed and Google Scholar were used to search for additional web-based materials and information.
The references of retrieved articles were scrutinised for additional articles. No limits were applied. The last search was conducted on 25th May 2020.

Results and conclusion:
A total of 384 records were identified through several databases and other sources. Thirteen studies included in this review: seven cohort studies on effectiveness and six cost analysis studies.

Efficacy/Safety
The seven cohort studies retrieved involved pacemaker, defibrillator, implantable cardioverter defibrillators (ICD), cardiac rhythm management device (CRM) and cardiac resynchronisation device (CRD) which are grouped as cardiac implantable electronic devices (CIEDs) in this review. Outcome measures include battery depletion, infection rate, and device malfunction/dysfunction.

Cardiac Implantable Electronic Devices (CIEDs)
a. Battery depletion-Good level of evidence showed that there was no significant difference between refurbished CIEDs and new devices in term of battery depletion for average three years' follow-up [Odds Ratio (OR): 2.30, 95% CI: 0.84, 6.33; p=0.74, I^2=0%].
b. Infection rate-Good level of evidence showed that there was no significant difference in infection rate between refurbished CIEDs and new devices [OR: 0.81, 95% CI: 0.49, 1.36; p=0.66, I^2=0%].
c. Device malfunction/ dysfunction-Fair level of evidence showed that there was no significant difference on the malfunction risk between refurbished CIEDs and new devices [OR: 1.21, 95% CI: 0.53, 2.78;p=0.86, I^2=0%].
d. Mortality (all-cause mortality)-There was no death related to device implantation reported. The pooled data from cohort studies showed that there was no significant difference for all-cause mortality in both groups [Risk Ratio (RR): 0.89, 95% CI: 0.61, 1.31; p=0.25, I^2=24%].

Adverse events
There was no retrievable evidence on the adverse events of refurbished medical device. However, the establishment of refurbished medical devices shall comply with the Medical Device Act 2012 (Act 737), Medical Device Regulations 2012 and 2019 and Circular Letter 1/2016 Refurbishment of Medical Device (Revision 2).

Cost-effectiveness/Economic implication
There was no retrievable evidence on the cost-effectiveness of refurbished medical device. However, six cost analysis studies were retrieved.

Based on several cost analysis studies from the physician and company perspective, the costs of reused devices or equipment are generally preferred than the new devices or equipment. A cost-benefit analysis study concluded that implantation of reused pacemakers would lead to a national saving of USD $919 300.
Another cost-minimisation study also reported that if the gastrointestinal endoscopy unit utilised reusable biopsy forceps, it would save costs about 1.5 to 2.3 times less compared to using disposable devices. One study concluded that the cost reduction was about 41.3% by utilising reused wheelchairs. While another study estimated that using single-use anaesthetic equipment would cost more than using reusable equipment from approximately AUD$10,000 to AUD$90,000. Also, one study stated that the refurbished devices can save up to 28% when compared with new device. However, the cost parameters included varied among the

reused devices or equipment and the analysis has not been taken into account the re-implantation and complications cost that might be occurred as well as the cheaper price is due to the shortened battery life of the CIED.

Organisational issues

There was no retrievable evidence on the organisational, societal, ethical or legal issues of refurbished medical device. However, companies undertaking refurbishment activities should comply with the requirements stipulated in the guidelines by WHO, FDA and MDA on good refurbishment practice of medical device. Implantable pacemaker pulse generator has been classified under class III. Based on Malaysian's societal legal and ethical perspective, it may raise issues on acceptability of the patient, relatives and society as from their perception, it was not appropriate to take device or anything from dead body. In some religions, it is considered taboo.