TECHNOLOGY REVIEW (MINI-HTA)

REFURBISHED MEDICAL DEVICE

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
009/2020

IPT Mark
Mini-HTA
INAHTA

Malaysian Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia
Level 4, Block E1, Precinct 1
Government Office Complex
62590, Putrajaya
Tel: 603 8883 1229

Available online via the official Ministry of Health Malaysia website: http://www.moh.gov.my

e-ISBN: 978-967-19299-7-1

SUGGESTED CITATION: Atikah S, Yan Nee G and Izzuna MMG. Refurbished Medical Device. Technology Review. Ministry of Health Malaysia: Malaysian Health Technology Assessment Section (MaHTAS); 2020. 67 p. Report No.: 009/2020. e-ISBN: 978-967-19299-7-1

DISCLOSURE: The author of this report has no competing interest in this subject and the preparation of this report is entirely funded by the Ministry of Health Malaysia.

AUTHORS

Ms. Atikah Shaharudin (AS)
Pharmacist
Senior Principal Assistant Director
Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia

Ms. Gan Yan Nee (GYN)
Pharmacist
Senior Principal Assistant Director
Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia

Information Specialist:
Ms. Zamilah Mat Jusoh@Yusof (ZMJ)
Nursing sister
Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia

REVIEWERS

Dr. Izzuna Mudla Mohamed Ghazali
Public Health Physician
Deputy Director
Health Technology Assessment Section (MaHTAS)
Medical Development Division
Ministry of Health Malaysia

EXTERNAL REVIEWERS (alphabetical order)

Dr. Mohamed Hirman Abdullah
Head of Medical Resources Unit
Medical Development Division
Ministry of Health Malaysia

Mr. Fezri Aziz
Deputy Director
Basic, Code & Standard Division
Medical Device Authority
Ministry of Health Malaysia

Puan Salbiah Yaakop
Director
Basic, Code & Standard Division
Medical Device Authority
Ministry of Health Malaysia

EXECUTIVE SUMMARY

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.

Analyses by marketing companies found that refurbishment of medical device benefited in reducing health-care costs regardless of the product type. However, issues on safety and effectiveness of the original device have been raised such as whether the medical devices can be restored to their original safety, effectiveness and who is ultimately responsible for ensuring the safety of such devices.

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/aim

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.

Results and conclusions

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%].

Organisational/Societal/Ethical/Legal 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.

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).

Economic evaluation

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.

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.

TABLE OF CONTENTS

ABBREVIATIONS

AEs	**Adverse events or adverse effects**
AV	**Atrioventricular**
CASP	**Critical Appraisal Skills Programme**
CI	**Confidence interval**
CIEDs	**Cardiac Implantable Electronic Devices**
CT	**Computed tomography**
CRD	**Cardiac resynchronisation device**
CRMD	**Cardiac rhythm management device**
EMI	**Electromagnetic interference**
FDARA	**Food and Drug Administration Reauthorization Act**
HTA	**Health Technology Assessment**
ICD	**Implantable cardioverter defibrillators**
ICER	**Incremental cost-effectiveness ratio**
MA	**Meta-analysis**
MaHTAS	**Malaysian Health Technology Assessment Section**
MDA	**Medical Device Authority**
MOH	**Ministry of Health**
MRI	**Magnetic resonance imaging**
OR	**Odds ratio**
QALY	**Quality adjusted life year**
QoL	**Quality of life**
RR	**Relative risk**
RCT	**Randomised controlled trial**
SR	**Systematic Review**
USA	**United State of America**
US FDA	**United States Food and Drug Administration**
WHO	**World Health Organization**

1.0 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.[1] Therefore, an efficient use of health care resources is vital in achieving sustainable healthcare system.[1-2] 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.[1] In the United State of America, about 4.6 million reprocesses refurbished devices had eliminated approximately 945 tons of medical waste in 2004.[3]

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.[1] 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.[1] However, the effectiveness and safety of refurbished devices are still a matter of debate.[3] The three major manufacturers of medical equipment in the market include Siemens Healthineers (Germany), Koninklijke Philips NV (Netherlands) and GE Healthcare (US) have implemented the refurbished process and sell their refurbished medical equipment with full warranty under distinct brand name.[4-6] Medical devices that are mostly refurbished are high-complexity, high-cost equipment such as operating room and surgical equipment, imaging equipment, neurology equipment, endoscopy equipment and others.[7-8] In 2017, European Commission published a report that focus on the longer-term of refurbished medical equipment market specifically on capital imaging devices such as computed tomography (CT) scanners, magnetic resonance imaging (MRI) and other diagnostic imaging equipment.[8] Many firms are also restoring used disposable devices, such as catheters and surgical cutting instruments and accessories.[8]

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 US.[9]

Analyses by marketing companies found that refurbishment of medical device benefited in reducing health-care costs regardless of the product type. However, issues on safety and effectiveness of the original device have been raised such as whether the medical devices can be restored to their original safety, effectiveness and who is ultimately responsible for ensuring the safety of such devices.[10-11]

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.[12] 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.

2.0 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.

3.0 TECHNICAL FEATURES

3.1 Definition of refurbished

According to Medical Device Authority (MDA), Malaysia and Food and Drug Administration Reauthorization Act (FDARA), refurbished was defined as to restore a used medical device or medical device to manufacturer defined safety and performance standards, which include actions such as repair, recondition, rework, software updates, replacement of worn parts with original parts. All actions shall be performed in a manner consistent with product specifications and service procedures defined by the manufacturer without changing its intended use or purpose.[10-11]

The objective was to specially processed and refurbished the devices that has been taken out of service, went through a set of standard operating procedure and quality requirements to ensure it is safe and effective as when it was new.[11]

Refurbished applies mainly to reusable medical devices that are designed to be used on more than one patient, where not all medical devices are appropriate for refurbished.[1] Thus, it differ from service/maintenance or repair of medical devices. Usually the devices being put back into service at different location.[10]

3.2 Process of refurbished medical device

The steps in refurbishing depend on the validated instructions provided by the manufacturer and the risk of infection posed by the devices.[1,11] Test validation

protocol and validation report shall be ensured by the manufacturer with no compromises of quality and safety at any level of refurbished process.[1,11] The details of the refurbished process could be accessed from the guidance prepared by MDA.[11] Below is the summarisation of the five steps of refurbished process based on Medical Device Authority (MDA) guidance document on 'Good Refurbishment Practice for Medical Device' MDA/GD/0029, January 2016 version:

Table 1. Brief explanation on the steps of Refurbished Process

Process	Activity	Information/Resources needed
1. Selection of medical device for refurbished	❖ Evaluate type, age and the configuration, condition of a medical device, upgradeability of software and hardware status, availability of original spare parts and service	❖ Product service history, data of the Installed Medical devices database, service records of the relevant equipment, service instructions by the manufacturer; equipment condition, device upgradeability documentation of the original manufacture, original manufacturer spare parts and service availability
2. Dismantling, packaging and shipment	❖ Medical device check at customer's site, preliminary decontamination/disinfection, professional disassembly	❖ Instructions of the manufacturer for medical device check and the tools needed, preliminary decontamination instructions, original manufacturer instructions for medical device disassembly, appropriate tools needed, appropriate tools for transportation lock, trained personnel performing the disassembly
3. Refurbished	❖ Decontamination / disinfection / sterilisation, planning, cosmetic refurbished, mechanical, electrical and device configuration, medical device testing, declaration of conformity, packaging and shipment	❖ Requirements for decontamination / disinfection / sterilisation as part of a validated refurbisheding process, technical documentation for the planning of refurbished, original paint tested and approved by the original manufacturer, instructions for replacing worn parts, medical device and system check procedure, refurbished labelling, packaging materials, tools and transportation instructions.
4. Reinstallation of refurbished medical device	❖ Installation, performance check-up, training, hand-over documentation, updating device history record (DHR)	❖ Trained employees, user documentation, DHR of medical device
5. Professional services	❖ Warranty, spare parts availability, maintenance contract, application training, financing solution and service contract, qualified contact partner	❖ Warranty card, suppliers contact, documentation about refurbished medical device

Customer could consider these steps in considering procurement of any refurbished medical device.[13]

3.3 Types of refurbished medical device

Currently, the types of medical devices which are most commonly refurbished are high-complexity, high-cost equipment such as medical imaging equipment (X-rays, MRI machines), patient monitors and anaesthesia machines.[14] Small, medium-complexity equipment are also refurbished (such as replacing staples or sharpening blades), though these tend to be performed as part of a hygienic recovery process.[14-15]

3.3.1 Cardiac Implantable Electronic Devices (CIEDs)

Cardiac implantable electronic device is used for management of bradyarrhythmia, ventricular tachyarrhythmia, and advanced systolic heart failure.[16] Pacemaker was patented in 1959 and implanted in 1960 by Greatbatch. The technology has evolved with more technology advancements being introduced throughout the years.[17]

Originally, pacemakers aimed to provide lifesaving fixed rate pacing during bradycardia and generally indicated for the management of sinus node dysfunction and second and third degree atrioventricular (AV) block. However, significant advanced technologies have produced devices (CIEDs) that can stimulate the heart's normal automaticity and AV activation patterns.[16] CIEDs become smaller in size with longer battery longevity and improved diagnostic capabilities.[16] The three main classes of CIEDs that include[16]:

a. Pacemakers
b. Implantable cardioverter defibrillators (ICD)
c. Cardiac resynchronisation device (CRD)

Primarily, ICD were implanted for the secondary prevention of sudden cardiac arrest in patients who survived cardiac arrest from a nonreversible cause. However, now the indications for ICD have been expanded as the device has been modified to fit patient who do not have indication for pacing especially in younger patient population at risk of sudden death.[16] Nevertheless, the core function of an ICD is to appropriately treat ventricular arrythmias.[16]

CRD is aimed to electrically resynchronize the left and right side of the heart to improve mechanical dyssynchrony that exists between the ventricular septum and the left ventricular lateral wall.[16] It has been associated with improvement of systolic heart failure.[16]

The estimated prevalence of cardiac arrhythmias in the US was 14.4 million patients which account for approximately 40,700 deaths annually.[18] As the indications for device placement continue to expand and evidence supporting

device placement compared to medical therapy well established, CIEDs are becoming common among US population.[19] Approximately one million patients worldwide receive a pacemaker or ICD each year; therefore, it is imperative that all anaesthesiologists and anaesthesia professionals understand the perioperative implications of these devices.[19]

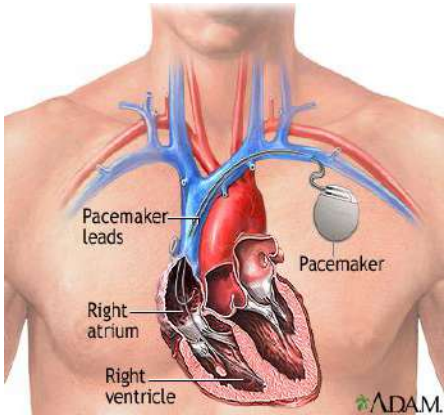

Figure 1. Pacemaker

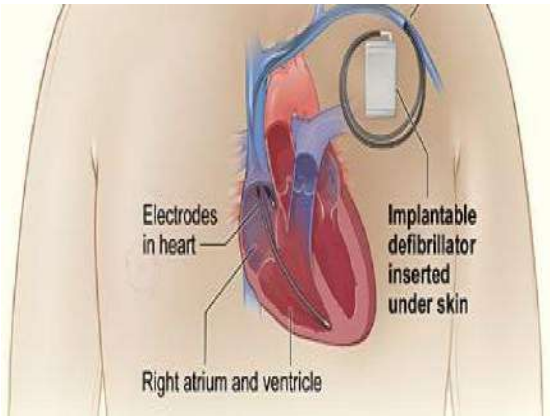

Figure 2. Implantable cardioverter defibrillator

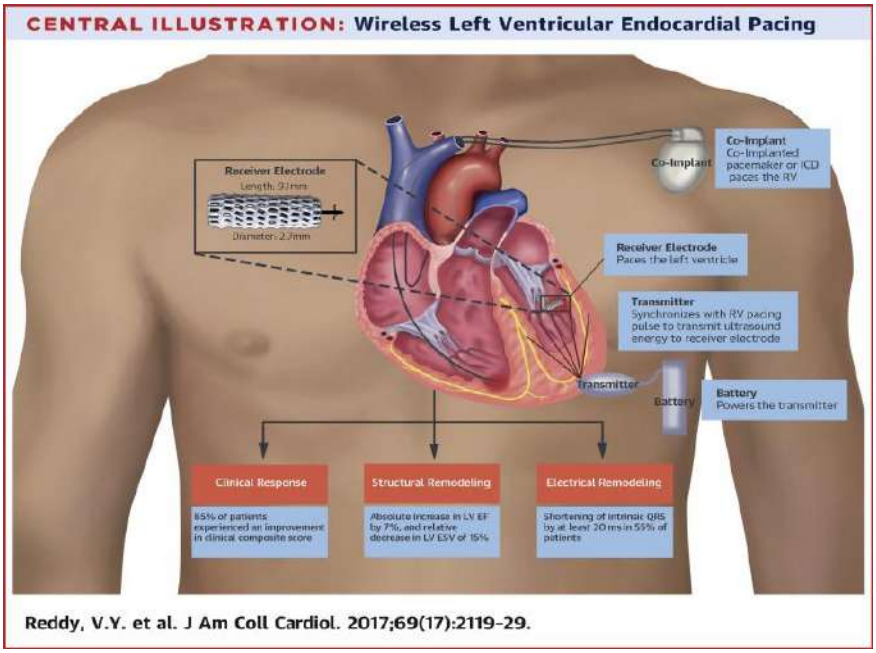

Figure 3. Cardiac resynchronisation device (CRD)

3.4 Challenges related to refurbished medical device

The motivation to use refurbished medical devices is the presumed that they are less costly. However, even experienced companies also faced challenges in balancing the cost of refurbished equipment since the design requirements sometimes in conflict. For instance, making an outer product covering with an irreversible snap-fit design decreases time and costs on the new product assembly line, but greatly increases costs when that product is later refurbished.[20] Another challenge to refurbish medical equipment which may decrease the rate of potential recovery is the supply chain. New equipment is manufactured at a certain quantity in response to market demands; however refurbished equipment vendors are also dependent on the number of machines coming out of commission for their supply.[21] Vendors therefore need to employ some unique strategies such as bundling selections of different refurbished products together and selling to hospitals as a package in order to keep inventory low.[21]

4. METHODS

4.1. Searching

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
- EBM Reviews – NHS Economic Evaluation Database 1st Quarter 2016.

PubMed and Google Scholar were used to search for additional literatures from the references of the retrieved articles. No limits were applied. The last search was conducted on 25th May 2020. Appendix 1 showed the detailed search strategies.

4.2. Selection

Two reviewers (AS and GYN) independently screened the titles and abstracts against the inclusion and exclusion criteria as shown below and evaluated the selected full-text articles for final article selection:

Inclusion criteria:

Population	Medical devices, equipment
Interventions	Refurbished, recondition, reuse
Comparators	New devices
Outcomes	a. Efficacy/ effectiveness: battery depletion, infection rate, device malfunction/dysfunctional, mortality b. Safety c. Organizational and Societal issue d. Cost-effectiveness
Study design	Systematic review (SR) of non-randomised controlled trials (non-RCTs) and meta-analysis (MA), cohort and cost-analysis

Exclusion criteria:

i. Animal / laboratory / case series / case report
ii. Narrative review

Relevant articles were critically appraised using Critical Appraisal Skills Programme (CASP)[24] and were graded according to US/Canadian preventive services task force (Appendix 2). Data were extracted and summarised in evidence table as in Appendix 3.

4.3 Analysis and Synthesis of the Evidence

Data extraction strategy

The following data was extracted:

i. Details of study and types of medical device.
ii. Details of intervention and comparators.
iii. Details of outcomes measures

Data was extracted from selected studies by one reviewer using a pre-designed data extraction form and checked by another reviewer. Disagreements will be resolved by discussion.

Statistical analysis

Meta-analysis was conducted for the cohort studies that compared refurbished device with new device. The data were pooled using Review Manager (Revman) 5.3 if heterogeneity, I^2 is less than 80%. Odds Ratio (OR) were calculated using fixed–effect method for dichotomous data and the results were reported as OR with 95% Confidence Interval (CI). Statistical significance was set at $p<0.05$ for all outcomes.

5. RESULTS

5.1 Selection of the included studies

A total of 371 records were identified through the databases mentioned above and 13 records were identified from other sources (references of retrieved articles). After removal of 180 duplicates, 204 records were screened and 122 records were excluded. Of these, 82 relevant abstracts were retrieved in full text. After applying inclusion and exclusion criteria, 69 articles were excluded with reasons (Figure 4).

There were 13 studies included in this review: Seven cohort (effectiveness) and six cost analysis studies. The studies were conducted in USA, UK, China, Africa, Romania, Australia, France, Spain, Sweden and Middle-East. The selection of the studies was shown in Figure 4.

Thirteen studies were included for qualitative analysis while only seven studies included in quantitative analysis (meta-analysis). However, in this report, studies that fulfilled the inclusion criteria were related to cardiac devices only. All of these studies were observational studies and the types of device used were pacemakers, implantable cardioverter defibrillators (ICD), cardiac rhythm management (CRM) and cardiac resynchronisation device (CRD). Details about the included studies were described in Table 2.

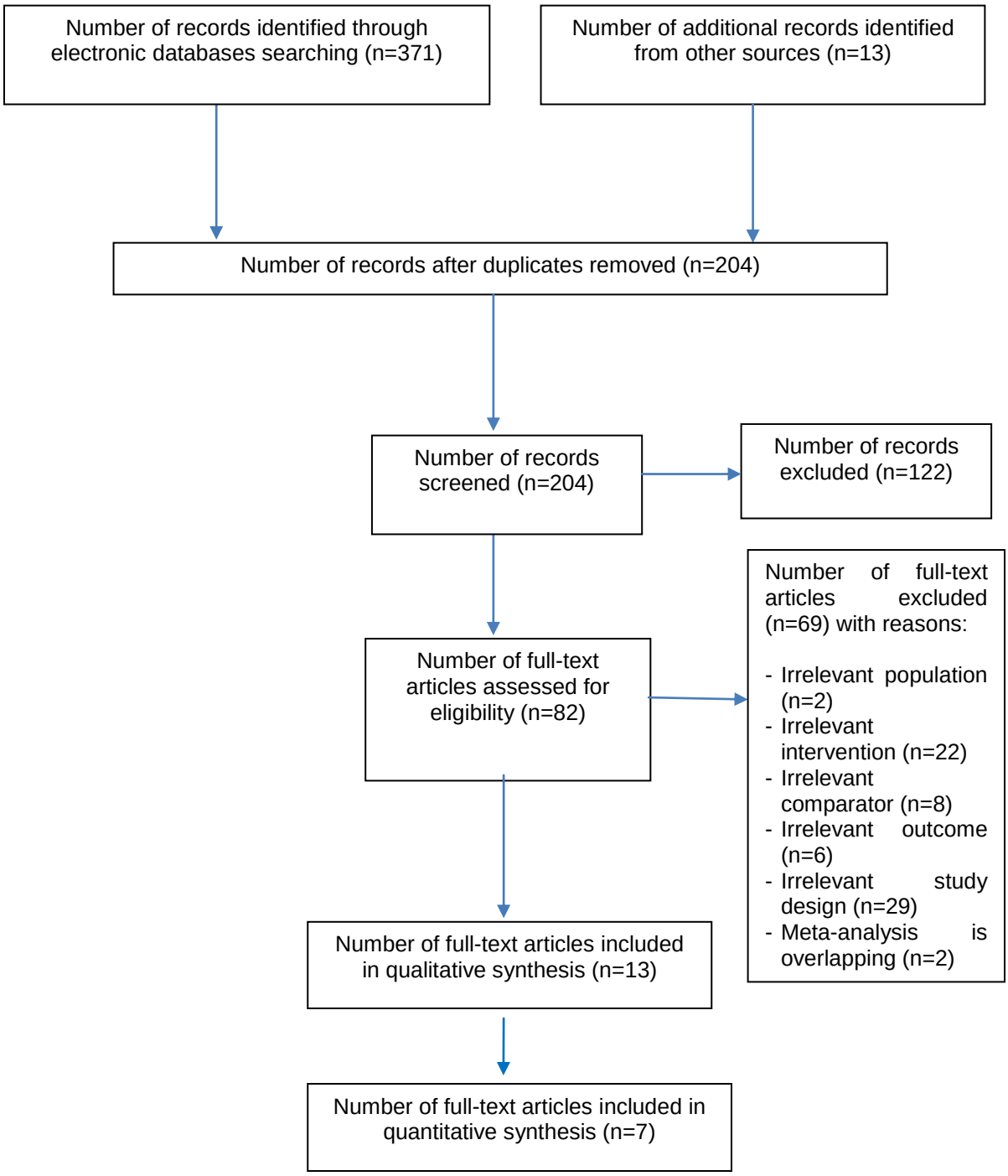

Figure 4. Flow chart of study selection

Table 2. Description of the included studies: intervention and comparison, duration of follow-up and outcome measures

Study	Intervention & Comparator (number of devices/patients)	Duration of follow-up	Outcome measures
Cohort studies:			
Linde et al. (1998)[32]	Re-used pacemaker (n=100) New pacemaker (n=100)	11 & 32 months	• Battery depletion • Infection rate • Device malfunction/dysfunction
Pescariu et al. (2003)[33]	Re-used pacemaker (n=365) New pacemaker (n=358)	Average 35 months	• Infection rate • Device dysfunction • Battery depletion • Mortality • Cost benefits analysis
Nava et al. (2013)[22]	Refurbished pacemaker (n=307) New pacemaker (n=296)	48 months	• Battery depletion • Infection rate • Device malfunction/dysfunction • Mortality
Ze et al. (2014)[23]	Refurbished Cardiac Rhythm Management Devices CRMD (n=99) New CRMD (n=113)	42 months	• Battery depletion • Infection rate • Device malfunction/dysfunction • Mortality
Jama et al. (2015)[25]	Refurbished pacemaker (n=51), implantable cardioverter defibrillators (ICD) (n=12), New pacemaker (n=51), New ICD (n=12)	3, 12 & 15 months	• Battery depletion • Infection rate • Device malfunction/dysfunction
Sosdean et al. (2015)[34]	Refurbished Biventricular devices (Bd)/pacemaker (n=115) New Bd/pacemaker (n=146)	12 months	• Battery depletion • Infection rate • Device malfunction/dysfunction

Table 2. Description of the included studies: continued

Study	Intervention & Comparator (number of patients)	Duration of follow-up	Outcome measures
Cohort studies:			
Selvaraj et al. (2017)[26]	Pacemaker, defibrillator (n=225), cardiac resynchronisation devices (CRD) (n=35) New pacemaker, defibrillator (n=535),CRD (n=92)	6 months	• Infection rate • Device malfunction • Mortality
Cost studies:			
Mancuso et al. (1995)[40]	Orthopaedic reamer reusable Orthopaedic reamer disposable	48 months	• Cost analysis • Cost saving
Bourguignon et al. (2003)[39]	Biopsy forceps reusable Biopsy forceps disposable	48 months	• Cost-minimization
Sloan et al. (2007)[38]	Refurbished and new: Orthopaedic blades, Cardiac catheter, Compression sleeve, Trocar	NA	• Markov model having several parameters
Shan et al. (2012)[37]	Refurbished wheelchair (n=49) New wheelchair (n=49)	5 years	• Cost analysis • Cost saving
Bejandi et al. (2015)[36]	Refurbished (n=20) New device (n=20) Remanufacturing (n=20)	12 months	• Cost analysis
McGain et al. (2017)[35]	Re-used anaesthetic equipment Single use anaesthetic equipment	12 months	• Cost analysis

5.2 Critical appraisal of the included studies

Both reviewers (AS and GYN) independently appraised relevant articles using the Critical Appraisal Skills Programme (CASP) checklist.[24] Review authors' judgements involved answering "yes", "no" and "can't tell" to specific questions and discrepancies were resolved by consensus.

The critical appraisal of included studies are summarised as below. For the cost analysis studies, the articles were not appraised as the studies did not assess and compare costs and consequences which would require the use of appraisal checklist for full economic evaluation.

Assessment for Cohort Study Using Critical Appraisal Skills Programme (CASP) Checklist

The cohort studies were assessed using the CASP checklist. Seven articles were included in this appraisal (Figure 5). Three articles were of good quality where all criteria were judged 'yes'.[22,23,34] Another four articles were of moderate quality.[25,26,32,33] Jama et al. (2015), Selvaraj et al. (2017), Linde et al. (1998), and Pescariu et al. (2003) were judged 'no' for the confounding analysis criterion as they did not provide the analysis of confounding factors (comorbidities) between both groups.[25,26,32,33]

Jama et al. (2015) stated the duration of follow-up was 15 months. However, only 57% and 37% of participants were followed-up at three and 12 months, respectively. There were no details on the rest of participants missing from the follow-up which led to the judgement of 'can't tell' for the follow-up criterion.[25] As for Selvaraj et al. (2017) the length of follow-up was only six months which was deemed not long enough and warranted the judgment of 'no' for the follow-up criterion.[26]

Criteria assessed	Selection of cohort	Exposure accurately measured	Outcome accurately measured	Confounding factors	Follow-up of subjects
Linde et al. (1998)[32]	yes	yes	yes	no	yes
Pescariu et al. (2003)[33]	yes	yes	yes	no	yes
Nava et al. (2013)[22]	yes	yes	yes	yes	yes
Ze et al. (2014)[23]	yes	yes	yes	yes	yes
Jama et al. (2015)[25]	yes	yes	yes	no	can't tell
Şoşdean et al. (2015)[34]	yes	yes	yes	yes	yes
Selvaraj et al. (2017)[26]	yes	yes	yes	no	no

Figure 5: Critical appraisal for Cohort study

5.3 Efficacy/Safety

A total of seven studies were retrieved for the effectiveness of the refurbished medical devices where six were retrospective (Linde et al., Pescariu et al., Nava et al., Jama et al., Sosdean et al. and Selvaraj et al.) and one (Ze et al.) was a cohort study. As all seven cohort studies involved pacemaker, defibrillator, ICD, CRM and CRD, they were pooled under meta-analysis of CIEDs. The outcome measures included battery depletion, infection rate, device malfunction/dysfunction, and all-cause mortality.

The differences between the meta-analysis in this review and previous meta-analysis were: (i) this meta-analysis was performed for each outcome (battery depletion, infection rate, device malfunction/dysfunction, and all-cause mortality) instead of composite outcome;[28] (ii) an additional article was included which were not pooled in previous meta-analyses.[27 ,28]

5.3.1 Cardiac Implantable Electronic Devices (CIEDs)

A. Battery depletion

Pooled data from seven cohort studies which included 1309 refurbished devices and 1703 new devices for the outcome of unexpected battery depletion showed no significant difference between refurbished and new devices [OR: 2.30, 95% CI: 0.84, 6.33; p=0.74, I^2=0%] (Figure 6).[22-23,25-26,30,32-34, level II-2] However, the confidence interval was wide and only two out of seven studies had events reported for either arm.[22,34]

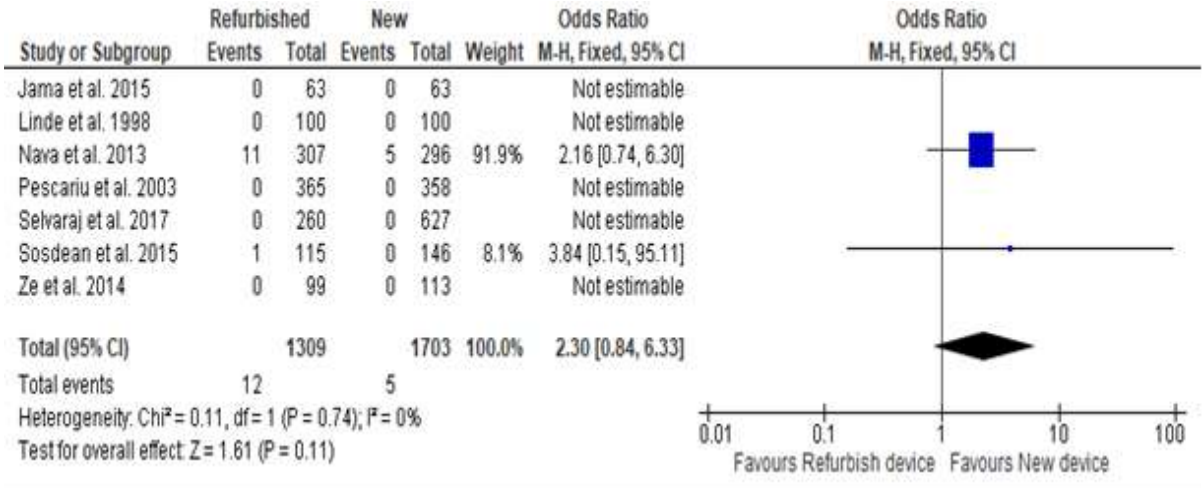

Figure 6. Refurbished device versus New device; Outcome: Battery depletion

B. Infection rate

Pooled data from six cohort studies (1246 refurbished devices versus 1640 new devices), showed that, there was no significant difference for the outcome of infection rate between both groups [OR: 0.81, 95% CI: 0.49, 1.36; p=0.66, I^2=0%] (Figure 7). One study (63 refurbished CIEDs versus 63 new CIEDs) had no event reported for both. [22-23,25-26,30,32-34, level II-2]

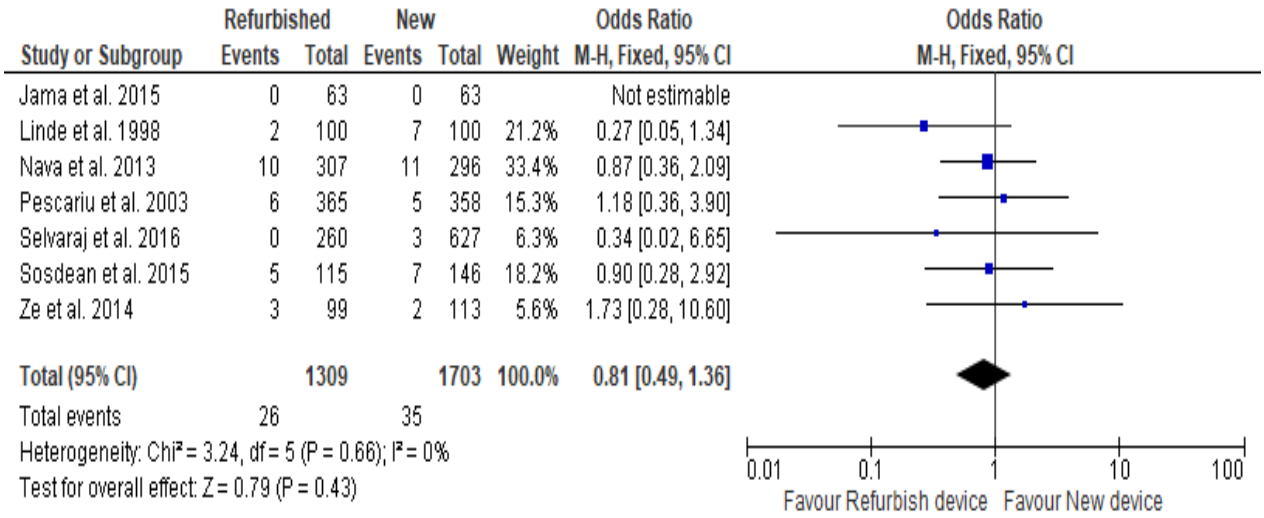

Figure 7. Refurbished device versus New device; Outcome: Infection rate

C. Device malfunction/ dysfunction

Pooled data from seven cohort studies that included 1309 refurbished devices and 1703 new devices showed no significant difference between the refurbished devices and new devices for the device malfunction/dysfunction outcome [OR: 1.21, 95% CI: 0.53, 2.78; p=0.86, I^2=0%] (Figure 8). [22-23,25,30,32-33, level II-2] Two studies had no event reported for both arms.[26,34]

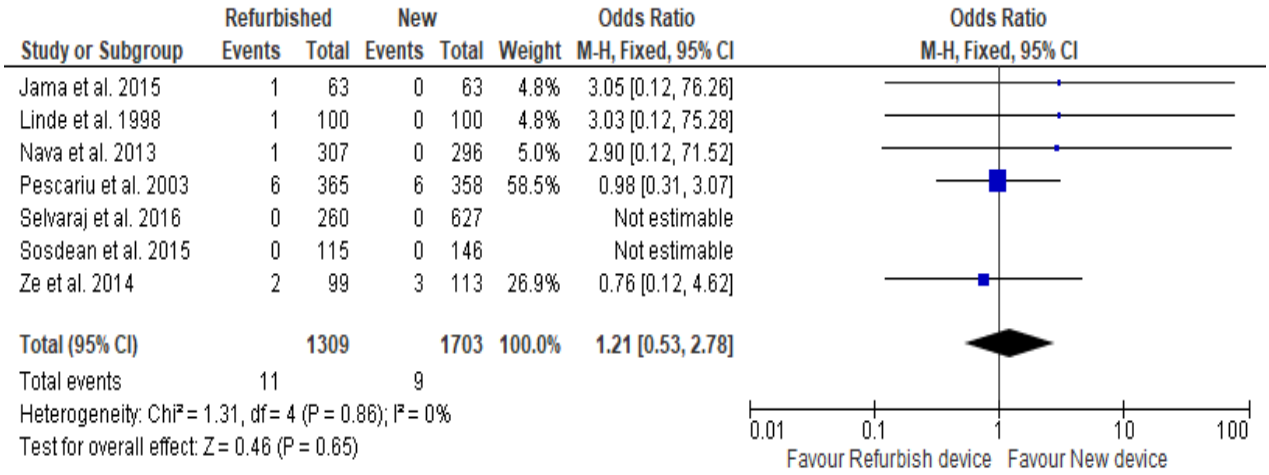

Figure 8. Refurbished device versus New device; Outcome: Device malfunction/dysfunction

D. Mortality (all-cause mortality)

There was no device-related mortality reported in three cohort studies conducted by Ze et al, Selvaraj et al., and Pescariu et al. [23,26,33, level II-2] Nava et al. stated the total number of death during the follow-up, however the underlying causes of the death were not explained. Hence, they could not divide whether the deaths were related to the device or not.[22, level II-2] The other three cohort studies did not report on the death outcome.[25,32,34, level II-2]

The six deaths reported by Ze et al. (2014) during follow-up were due to cancer (n = 1) and heart failure (n = 1) in the new device group; and peripheral arterial disease (n=1), renal failure (n = 1), myocardial infarction (n = 1), and stroke (n=1) in the refurbished group (p=0.32).[23, level II-2]

As for Selvaraj et al. (2016), the three deaths reported were due to heart failure: two in patients with an Automatic Implantable Cardioverter Defibrillator (AICD) and one in a patient with a CRT device.[26, level II-2] Pescariu et al. (2003) reported no deaths during follow-up.[33, level II-2] Nava et al. (2013) reported the total number of deaths during follow-up, however, the deaths could not be attributed to the devices as underlying causes were not explained.[22, level II-2] Mortality was not assessed in the other three cohort studies.[25,32,34, level II-2]

Pooled results from four studies that included 1031 patients from refurbished group and 1394 patients from new device group for all-cause mortality showed that there was no significant difference between both groups [Risk Ratio (RR):

0.89, 95% CI: 0.61, 1.31; p=0.25, I^2=24%]. Two studies had no event reported for both arms (Figure 9).[22-23,26,33, level II-2]

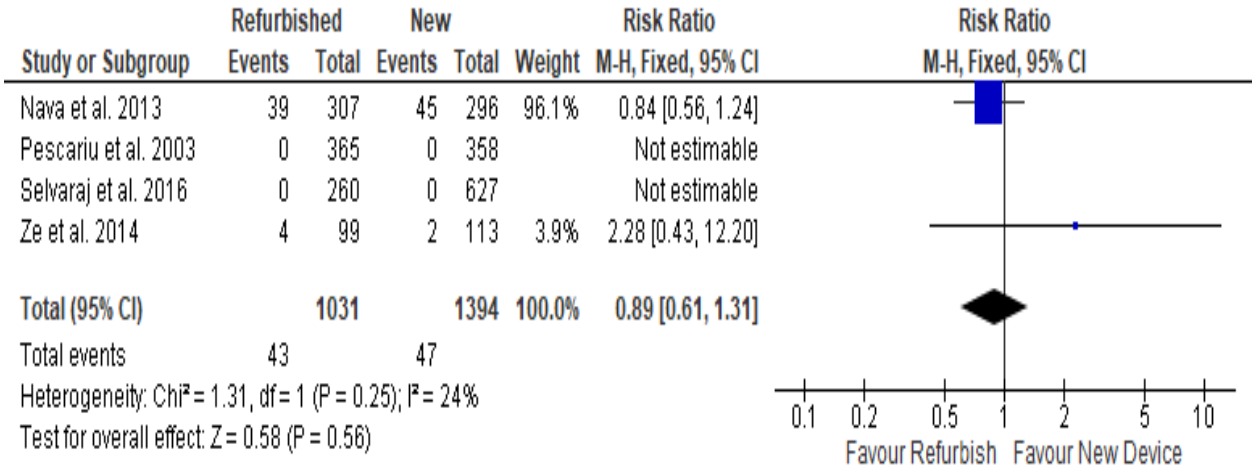

Figure 9. Refurbished device versus New device; Outcome: All-cause mortality

5.4 ORGANISATIONAL ISSUES

There was no retrievable evidence on the organisational issue for refurbished medical devices. However, companies undertaking refurbishment activities should comply with the requirements stipulated in the guidelines produced by WHO[1], FDA[10] and MDA[11] on good refurbished practice of medical device. Based on the medical device classification from FDA, implantable pacemaker pulse generator has been classified under class III which *"any other implantable pacemaker pulse generator device shall have an approved premarket approval or declared completed product development protocol in effect before being placed in commercial distribution."*[10]

5.5 SOCIETAL/ ETHICAL/LEGAL ISSUES

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. However, there was no retrievable evidence from the scientific databases.

5.6 ADVERSE EVENTS

There was no retrievable evidence from included articles on the adverse effects related to the used of refurbished medical devices.

Regulatory requirement
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).[11]

5.7 ECONOMIC EVALUATION

There was no retrievable evidence on the cost-effectiveness related to refurbished medical device. However, six cost analysis studies were retrieved on different medical devices comparison.

McGain et al. (2017) conducted a cost analysis to analyse the financial and environmental costs of reusable and single-use anaesthetic equipment by using life cycle assessment model (Monte Carlo analysis) of different scenarios from the healthcare provider perspective.[35] The financial and environmental costs included were labour costs, electricity, water costs for central sterile and supply department, number of washer loads excluding the washer and sterilizer maintenance as the costs were fixed annually regardless of the number of loads performed. In all five scenarios, the financial cost to process single-use anaesthetic equipment was AUD$32,033 more than for reusable anaesthetic equipment (AUD$69,018 versus AUD$36,985).[35] For total costs applied, the cost for using single-use anaesthetic equipment was approximately AUD$10,000 to almost AUD$90,000 more compared to using reusable equipment. The labour costs to process all reusable equipment were notably modest (AUD$14,560). Most environmental impacts of processing anaesthetic equipment were small, with only carbon dioxide emission and water consumption being relatively important.[35]

Bejandi et al. (2015) did a comparative cost study to evaluate the impact of choosing three strategies (remanufactured, refurbished and new devices) on warranty costs and profitability from the company perspective from 2012 to 2013 by choosing ten devices which had about similar in usage or functions.[36] The key parameters for costing involved item costs, related costs to compute profitability, warranty costs after upgrading actions and profitability of each item.[36] For only item costs included, the refurbished cost was the lowest ($5,750 for total cost; $7,000 for sale price) followed by remanufactured device ($6,120 for total cost; $8,500 for sale price) and new device ($7,400 for total

cost; $10,000 for sale price).[36] However, regardless of the strategy, the longer the duration of warranty period, the higher the warranty costs. Thus, it is crucial to select appropriate warranty period because it has a direct impact on total costs and profitability.[36] The warranty costs of refurbished products significantly increased past the age of three years.[36]

Shan et al. (2012) conducted a retrospective cost analysis using data from billing records and annual statistical reports from 2004 to 2009 to determine the cost of having a recycled wheelchair and seating compared with the newly purchased equipment.[37] The perspective of this study was from the physician of Physical Medicine and Rehabilitation. The cost of labour, utilities, and any modifications made to the wheelchair were included. While the other costs such as soap, cleaning agents and water were minimal and were not included. They reported the average cost of a used and new wheelchair was CAD$698.11 and CAD$2143.69, respectively, leading to an average savings of CAD$1445.58 per wheelchair.[37] With a total of 49 wheelchairs issued, this resulted in a total cost savings of CAD$85,393.97. When labour costs were taken into account (CAD$50,060.26), the savings amounted to CAD$35,333.71. Overall cost reduction was 41.3%.[37]

Sloan et al. (2007) developed a Markov decision process model to examine the choice between new and reprocessed medical devices which included orthopaedic blades, cardiac catheter, compression sleeve and trocar.[38] The key parameters included were device costs, device failure probabilities and failure penalty costs. For each of these parameters, expressions were developed where indifference point between using new and reprocessed devices were identified.[38] The results showed that reprocess orthopaedic blades, cardiac catheter, compression sleeve were preferred compared to new devices while new devices were preferred compared to reprocessed trocar.[38]

In 2003, Bourguignon et al. conducted a cost-minimisation analysis to compare the cost of reusable and disposable biopsy forceps in gastrointestinal endoscopy from the hospital perspective.[39] Direct costs from 1997 to 1999 such as purchase prices, chemicals, equipment, technician time and a fee for sterilization were included for reusable devices while acquisition costs and destruction costs were included for disposable devices.[39] The cost per use of reusable biopsy forceps was USD$6.85 and the mean number of uses was 90 per reusable forceps while the cost of disposable biopsy forceps ranged from USD$10.72 to USD$15.63. In other words, the additional cost of using disposable biopsy forceps ranged from USD$3.88 to USD$8.78 per use which was 1.5 to 2.3 times higher than using reusable biopsy forceps. Annually, using

disposable biopsy forceps might incur an additional cost of USD$6500 to USD$13000 for the gastrointestinal endoscopy unit.[39]

A simple cost-benefit analysis conducted by Linde et al. (1998) estimated the costs of reused and new pacemakers from the cardiologist and thoracic surgeon perspective.[32] Of 129 patients, 73 died after an average of 3.1 years following implantation; remaining 44 were implanted with reused pacemakers for a mean of 5.4 years; and only 12 patients underwent replacement for a mean time of 4.3 years. This resulted in 463.9 patients' years or 5567 pacing months with reused pacemaker. The estimated costs of new and reused pacemaker were USD$3000 per unit and USD$100 per unit, respectively. The National Swedish Pacemaker Registry reported an expenditure of USD$12.1 million for 4023 new pacemakers in 1995 and USD$31700 for 317 reused, yielding a national savings of USD $919 300.

Mancuso et al. (1995) conducted a cost analysis study to estimate the true costs of disposable and reusable orthopaedic reamer instruments used at one facility from the surgical services perspective over a 48-month period.[40] They compiled a list of related cost variables and data elements which were divided into six major categories; process and process equipment costs, product or equipment analysis, personnel education, safety, liability and outcomes, customer satisfaction and cost-effectiveness. The cost comparison yielded a minimum cost of USD$111.20 per reamer use for reusable instruments but the cost of handling, utilities, minor chemicals and sterilizer cycles were not included. The disposable instruments yielded USD$80.41 per reamer use (a minimum cost at USD$80 per use) or USD$100.41 per reamer use (a minimum cost at USD$100 per use) without including the cost of handling and utilities. Overall, a total of USD$213,513 for reusable devices and USD$192,779 for disposable devices over a 48-month period were reported, suggesting that reusable devices incurred an additional cost of $20,734.[40]

However, the re-implantation and complications of surgery costs have not been taken into the analysis as well as the cheaper price is due to the shortened battery life of the CIED.

5.8 STRENGTH AND LIMITATIONS

The strength of this review is the degree of rigour in the conduct of review, in particular the comprehensive and systematic search carried out in the initial stage of review. This technology review has several limitations. Few potential articles were excluded due to lack of control group to the refurbish medical

devices. Few other articles were also excluded due to lack of details in the process of reusing devices which presented uncertainty as to whether the process was similar to the refurbishment process defined in this review. A standard definition is yet to be developed for the evaluation of battery depletion and device malfunction outcomes which is crucial in order to organise a uniform outcome in setting the end points of any study as suggested by Nava et al.[22]

6.0 DISCUSSIONS AND CONCLUSION

6.1 Discussions on complications related to CIEDs

Several complications could occur due to implantation of CIEDs that include infections, lead failure, haematoma, cardiac perforation, pacing-induced cardiomyopathy, phrenic nerve stimulation.[16] Therefore, for the long-term device management, it is recommended to inspect the devices every three, six to 12 months.[16] In many of the articles that we retrieved, three main complications of CIEDs related to the outcomes were battery depletion, infection rate and device malfunction/dysfunction were measured.

A. Battery depletion

The result from this meta-analysis was in line with one SR and MA of non-randomised trials conducted by Sinha et al. which included 2429 devices. They examined the risk of reused pacemakers and defibrillators compared with the new devices. The data reported in meta-analysis that included three trials with 518 new devices and 497 reused devices with a median follow-up about 3.8 years (new devices) and 3.5 years (reused devices) revealed no significant difference between the new device group versus the reused device group [1.0% vs 2.6%, p= 0.084; (Odds Ratio (OR): 0.43, 95% Confidence Interval (CI): 0.16, 1.12)]. [28]

However, battery depletion is an obvious disadvantage for resterilised devices. Interestingly, even when the average duration for all refurbished devices was lower than new devices, it was only two and half years less (6.17±1.67 years versus 8.9±0.68 years in control subjects), so, the average duration for the resterilized pacemakers was actually longer than expected. Generally, only devices with two or more years of battery life remaining with no evidence of external damage were eligible for reused.[25]

Resterilised devices do have a shorter battery life, as should be expected, and there is a tendency to have higher rates of unexpected battery depletion than in new pacemakers. In addition, battery reading depends on the parameters

that are programmed at the time of interrogation.[22] Once the pacemaker is reprogrammed according to the new patient needs (such as voltage thresholds, impedance, percentage of pacing) it might change the actual life expectancy of the pacemaker.[22] This should be considered during the process of choosing refurbished pacemakers according to battery life.[22] Depending on patterns of use, most pacemakers can thus have sufficient battery left when patients die.[26]

Importantly, unlike the previous review, we did not include data for this outcome from Jama et al. as we decided that the data was for device malfunction (i.e.: inappropriate delivery of shocks for supraventricular tachycardia) and not battery depletion.

B. Infection rate

Our meta-analysis results showed that there was no difference in the infection rate between refurbished and new medical device. However, one of the important complications that could occur was a postoperative infection.[16] Usually it appears within two weeks of implant and the risk is higher during generator replacement procedure than with initial device implants. Oral antibiotics can be given for superficial infections while deep pocket infections require that the generator and leads be explanted in conjunction with intravenous antibiotic therapy.[16]

Procedure-related infections include right-sided endocarditis with lead involvement, sepsis with evidence of involvement of the lead and implantation pocket, involvement of the pacemaker implantation pocket and involvement of the lead or generator. Infections that occurred after a year of implantation were considered not to be related to the procedure.[25] Referring to our included trials, only Selvaraj et al. have a minimum duration of follow-up which was six months, while the rest were 12 months to five years of follow-up.

Our result was in line with the SR and MA conducted by Baman et al. which only include data regarding the safety of reused pacemaker compared with the new pacemaker. They found no significant difference in infection rate between 913 reused pacemakers and 6679 new devices [(OR: 1.31, 95% CI: 0.50, 3.40; p=0.58]; heterogeneity testing I^2=70.6% (25.4%; 88.5%; p=0.009)]. While the proportion of patients who had device infection after pacemaker reused was 1.97% (p=0.008). [27]

Unlike meta-analysis conducted by Sinha et al. reported only four trials with 1988 included devices, our meta-analysis have included seven trials. However, they also showed no significant difference between reused devices (n=793)

and new devices (n=1195) [1.9% vs 2.3%, p= 0.785, OR: 1.09 (95% CI: 0.58, 2.07)].[28]

C. Device malfunction/dysfunction

The pooled result from this review was in line with SR and MA conducted by Sinha et al. They found, the two trials included 815 devices showed no significant difference on the malfunction risk between reused pacemakers, defibrillators (n=406) and new devices (n=409) [0.0% vs 0.5%; p= 0.319; (OR: 0.32, 95% CI: 0.03, 3.05)]. [28] However, the results were contradicting with the study by Baman et al. (2011). In this study, four controlled trials included for outcome device malfunction with a total of 793 reused pacemakers were compared with 2200 new device pacemakers implant. They found a significant increased risk for device malfunction in the reused group [OR: 5.80, 95% CI: 1.93, 17.47; p=0.002; heterogeneity testing I^2=0%, CI: 0%, 62.9%; p=0.756]. [27] They also reported data for 2150 patients in 17 trials with the outcome of proportion of patients who had device malfunction was 0.68% (CI: 0.27, 1.28%; p=0.057) for reused pacemakers.

In other review regarding pacemaker, the device malfunction was defined as a defect in the structural or electric integrity of the pulse generator to accomplish the desired role such as set screw abnormalities, spontaneous reprogramming not able to sense ventricular tachycardia/fibrillation and inability to sense or pace when required.[25,27-28] Malfunction of pacemakers and defibrillators could also be due to the electromagnetic interference (EMI).[29-30] Several malfunctions related to EMI can cause pacing inhibition, damage the pulse generator and inappropriate tachycardia therapy depending on the type of CIED.[31]

6.2 Conclusions

In terms of efficacy or safety, the evidence showed that there was no significant difference between refurbished CIEDs and new devices for outcome battery depletion for average three years' follow-up, infection rate and device malfunction or dysfunction. The evidence also suggested that no death related to device implantation was reported and no significant difference for all-cause mortality in both groups.

In terms of organisational issues, companies that undertaking refurbishment activities should comply with the requirements stipulated in the guidelines by WHO and FDA on good refurbishment practice of medical device. Also, they should be complied with the Medical Device Act 2012 (Act 737) and Medical

Device Regulations 2012 and 2019 and Circular Letter 1/2016 Refurbishment of Medical Device (Revision 2).11, Malaysia.

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. Cost analysis studies shared that refurbished medical device may save up to 28% when compared to using a 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.

8.0 REFERENCES

1. World Health Organization (WHO). Decommissioning Medical Devices: WHO Medical device technical series. Department of Medicines and Health Product: WHO. Switzerland. 2019. ISBN 978-92-4-151704-1.

2. Baradaran M and Soltani-Neshan M. Service-oriented strategies and warranty management prospect by applying foresight method. 5th International conference on future oriented technology analysis-FTA. Brussel, Belgium. 2014.

3. Klein A. Hospitals save money, but safety is questioned. Washington Post. 2005. Available at: https://www.washingtonpost.com/archive/ business/2005/12/11/hospitals-save-money-but-safety-is-questioned/ ac112bb6-319c-4f90-b6b6-a294e461b8be/. Accessed on 8 July 2020.

4. Philips. Philips takes circular economy to healthcare and inaugurates a new imaging systems refurbished facility in Best, the Netherlands. Philips Media. Philips. November 13, 2014. http://www.philips.com/a-w/about/news/archive/standard/ news/press/2014/20141113-Philips-takes-circular-economy-to-healthcare-andinaugurates-a-new-imaging-systems-refurbished-facility-in-Best.html

5. GE Healthcare. “GoldSeal Brochure”. GE Healthcare. 2012. http://www3.gehealthcare. com/~/media/documents/us-global/products/goldseal-refurbished/brochures/ gehealthcare-brochure_goldseal_refurbished-imaging-systems.pdf

6. Siemens, 2016. EcoLine Brochure. Siemens Healthcare. https://static.healthcare.siemens. com/siemens_hwem-hwem_ssxa_websites-context-root/wcm/idc/groups/public/@ global/@refurb/@imaging/documents/download/mda2/mjcz/~edisp/rs_ document_ecoline_customerbrochure-03359363.pd

7. Dremed, 2015. Popular Refurbished Equipment. Retrieved 9 14, 2016, from. http:// www.dremed.com/catalog/index.php/cPath/45_674.

8. Srivatsav N, Dervojeda K, Lengton M et al. Refurbished of medical equipment: Report on promising KETs-based product nr. 4; European Union. 2017. 31 p. Contract nr EASME/COSME/2015/026.

9. Globe Newswire. Refurbished Medical Equipment Market by Product, Application, End User -Global Forecasts to 2025. 2020. 215 p.

10. Food and Drug Administration (FDA). FDA Report on the Quality, Safety, and Effectiveness of Servicing Medical Devices: In accordance with Section 710 of the Food and Drug Administration Reauthorization Act of 2017 (FDARA). US; 2018. 32 p.

11. Medical Device Authority (MDA). Good refurbished practice of medical device (GRPMD). Medical Device Guidance Document. Ministry of Health Malaysia; 2016. 16 p. Document No.: MDA/GD/0029

12. Hospital Management Unit. Strategic Framework of the Medical Programme Ministry of Health Malaysia 2021-2025. Medical Development Division; 2020. 132 p. MOH/P/PAK/438.20(BK)-e.

13. Green TG. Five Tips to Consider Before Buying Refurbished Equipment. Biomedical instrumentation & technology. 2004 Jul;38(4):291-292.

14. Kruger CM. Processing single-use medical devices for use in surgery-importance, status quo and potential. GMS Krakenhhyg Interdisziplinar. 2008;3(3):21

15. SterilMed, 2014. How We Reprocess Medical Devices. Retrieved September 25, 2016, from SterilMed: https://www.sterilmed.com/Our-Services/Reprocessing/Pages/ default.aspx.

16. Steffen MM, Osborn JS and Cutler MJ. Cardiac Implantable Electronic Device Therapy: Permanent Pacemakers, Implantable Cardioverter Defibrillators, and Cardiac Resynchronization Devices. Med Clin North Am. 2019;103(5):931-943.

17. Beck H, Boden WE, Patibandla S et al. 50th Anniversary of the first successful permanent pacemaker implantation in the United States: historical review and future directions. Am J Cardiol. 2010;106(6):810-818.

18. Roger VL, Go AS, Lloyd-Jones DM et al. American Heart Association Statistics Committee and Stroke Statistics Subcommittee. Heart disease and stroke statistics—2011 update: a report from the American Heart Association. Circulation 2011;123:e18-e209.

19. Neelankavil JP, Thompson A and Mahajan A. Managing cardiovascular implantable electronic devices (CIEDs) during perioperative care. Anesth Patient Saf Found Newsl. 2013;28(2):29-35.

20. Boorsma, N. E. (2016). A design tool for refurbished: Generating industry specific design rules.

21. Ross AD and Jayaraman V. Strategic Purchases of Bundled Products in a Health Care Supply Chain Environment. Journal of the Decision Sciences Institute. 2009; 40(2): 269-293.

22. Nava S, Morales JL, Márquez MF et al. Reuse of pacemakers: comparison of short and long-term performance. Circulation. 2013;127(11):1177-1183.

23. Ze F, Li X, Zhang P et al. Reuse of Infected Cardiac Rhythm Management Devices in the Same Patients: A Single-Center Experience. Pacing and Clinical Electrophysiology. 2014;37(8):940-946.

24. Critical Appraisal Skill Programme (CASP) checklist. Available at https://casp-uk.net/casp-tools-checklists/. Accessed on 15 June 2020.

25. Jama ZV, Chin A, Mayosi BM et al. Performance of re-used pacemakers and implantable cardioverter defibrillators compared with new devices at Groote Schuur Hospital in Cape Town, South Africa. Cardiovascular Journal of Africa. 2015;26(4):181-187.

26. Selvaraj RJ, Sakthivel R, Satheesh S et al. Reuse of pacemakers, defibrillators and cardiac resynchronisation devices. Heart Asia. 2017;9(1):59-62.

27. Baman TS, Meier P, Romero J et al. Safety of pacemaker reuse: a meta-analysis with implications for underserved nations. Circ Arrhythm Electrophysiol. 2011;4(3):318-323.

28. Sinha SK, Sivasambu B, Yenokya G et al. Worldwide pacemaker and defibrillator reuse: Systematic review and meta-analysis of contemporary trials. Pacing and Clinical Electrophysiology. 2018;41(11): 1500-1507.

29. Belott PH, Sands S and Warren J. Resetting of DDD pacemakers due to EMI. Pacing Clin Electrophysiol. 1984;7:169-172.

30. Godin JF and Petitot JC. STIMAREC report. Pacemaker failures due to electrocautery and external electric shock. Pacing Clin Electrophysiol 1989;12:1011.

31. Mangar D, Atlas GM and Kane PB. Electrocautery-induced pacemaker malfunction during surgery. Br J Anaesth 1991;38:616-618.

32. Linde CL, Bocray A, Jonsson H et al. Re-used pacemakers—as safe as new? A retrospective case-control study. European Heart Journal. 1998;19(1):154-157.

33. Pescariu S, Stiubel M, Cozma D et al. La réutilisation des pacemakers, une alternative pour les personnes âgées démunies: etude rétrospective. Stimucouer. 2003;31:186-189.

34. Şoşdean R, Mornoş C, Enache B et al. Safety and feasibility of biventricular devices reuse in general and elderly population- a single-center retrospective cohort study. Clinical interventions in aging. 2015;10:1311-1318.

35. McGain F, Story D, Lim T et al. Financial and environmental costs of reusable and single-use anaesthetic equipment. BJA: British Journal of Anaesthesia. 2017;118(6):862-869.

36. Bejandi JR, Soltani-Neshan M. Comparative Studies of Three Types of Product Policies (Remanufactured, Refurbished and New Products) on Warranty Cost and Profitability. International journal of Business and Technopreneurship. 2015; 5(3): 407-420.

37. Shan RS, Chrusch WM, Linassi AG et al. Reuse and Refurbished: A Cost Savings Delivery Model for Specialized Seating. Archives of physical medicine and rehabilitation. 2012;93(7):1286-1288.

38. Sloan TW. Safety-cost trade-offs in medical device reuse: a Markov decision process model. Health Care Management Science. 2007;10(1):81-93.

39. Bourguignon C, Destrumelle AS, Koch S et al. Disposable versus reusable biopsy forceps in GI endoscopy: a cost-minimization analysis. Gastrointestinal endoscopy. 2003;58(2):226-229.

40. Mancuso R Jr and Bickham MJ. Estimating the true costs of disposable and reusable instruments. AORN J. 1995;62(1):39-48.

9.0 APPENDICES

9.1 Appendix 1: SEARCH STRATEGY

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to March 24, 2020>

Search Strategy:

---

1 DIAGNOSTIC IMAGING/ (40570)
2 (diagnostic adj1 imaging).tw. (13862)
3 RADIOGRAPHY/ (317421)
4 x-ray machines.tw. (229)
5 ULTRASONOGRAPHY/ (178414)
6 Ultrasound System.tw. (1598)
7 MAGNETIC RESONANCE IMAGING/ (394981)
8 mri machines.tw. (70)
9 TOMOGRAPHY SCANNERS, X-RAY COMPUTED/ (3346)
10 (x-ray adj2 (cat scanner* or ct scanner*)).tw. (85)
11 TOMOGRAPHY, EMISSION-COMPUTED, SINGLE-PHOTON/ (30407)
12 nuclear imaging system*.tw. (12)
13 SURGICAL EQUIPMENT/ (5207)
14 (surgical adj1 equipment*).tw. (432)
15 MONITORING, INTRAOPERATIVE/ (18635)
16 (intraoperative adj1 monitoring).tw. (2232)
17 "EQUIPMENT AND SUPPLIES, HOSPITAL"/ (8894)
18 (hospital equipment adj3 suppl*).tw. (7)
19 hospital equipment.tw. (258)
20 hospital suppl*.tw. (256)
21 MONITORING, PHYSIOLOGIC/ (54123)
22 ((patient or physiologic*) adj1 monitoring).tw. (4609)
23 MICROSCOPY/ (42667)
24 ((optical or simple or compound or hand held or hand-held) adj1 microscopy).tw. (8125)
25 ELECTROCARDIOGRAPHY/ (188866)
26 MONITORING, AMBULATORY/ (8006)
27 MONITORING, AMBULATORY/ (8006)
28 multiparameter monitors.tw. (4)
29 WEARABLE ELECTRONIC DEVICES/ (2036)

30 (electronic adj1 skin).tw. (268)
31 (wearable adj1 device*).tw. (2148)
32 (wearable adj2 electronic device*).tw. (208)
33 (wearable adj1 technolog*).tw. (734)
34 ELECTROCARDIOGRAPHY, AMBULATORY/ (10724)
35 (holter adj1 monitoring).tw. (4531)
36 OXIMETRY/ (12799)
37 (pulse adj1 oximetr*).tw. (6518)
38 SIGNAL PROCESSING, COMPUTER-ASSISTED/ (46445)
39 (computer-assisted signal adj2 (interpretation* or processing)).tw. (1)
40 (digital signal adj2 processing).tw. (1002)
41 BLOOD PRESSURE MONITORS/ (2256)
42 (blood pressure adj2 monitor*).tw. (10766)
43 ECHOCARDIOGRAPHY/ (86985)
44 echocardiography.tw. (105717)
45 ELECTROENCEPHALOGRAPHY/ (143516)
46 eeg machine.tw. (40)
47 ELECTROCONVULSIVE THERAPY/ (12996)
48 ect machine.tw. (16)
49 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19 or 20 or 21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42 or 43 or 44 or 45 or 46 or 47 or 48 (1557036)
50 EQUIPMENT REUSE/ (2846)
51 (equipment adj1 (recycling or reusability or reuse)).tw. (27)
52 (product adj1 recycling).tw. (29)
53 50 or 51 or 52 (2897)
54 49 and 53 (191)

Database: Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to March 10, 2020>
Search Strategy:
---
1 "EQUIPMENT AND SUPPLIES"/ (23715)
2 device*.tw. (404141)
3 (instrument* adj3 apparatus).tw. (174)
4 (equipment adj3 suppl*).tw. (1707)
5 (medical adj1 device*).tw. (14195)

6 equipment.tw. (81517)
7 "EQUIPMENT AND SUPPLIES, HOSPITAL"/ (8888)
8 (hospital adj1 equipment).tw. (268)
9 (hospital equipment adj3 suppl*).tw. (7)
10 (hospital adj1 suppl*).tw. (292)
11 (medical adj1 equipment).tw. (2762)
12 AMBULANCES/ (6021)
13 ambulance*.tw. (10142)
14 (hospital adj1 ambulance).tw. (81)
15 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 (514332)
16 EQUIPMENT REUSE/ (2843)
17 (waste adj1 management).tw. (4493)
18 recondition.tw. (92)
19 rebuild.tw. (1421)
20 restore.tw. (63038)
21 reusable.tw. (5719)
22 16 or 17 or 18 or 19 or 20 or 21 (77004)
23 15 and 22 (4004)
24 reuse.tw. (9919)
25 15 and 24 (746)
26 limit 25 to (english language and humans) (371)

****

OTHER DATABASES	
EBM Reviews - Cochrane database of systematic reviews	Same MeSH, keywords, limits used as per MEDLINE search
EBM Reviews - Cochrane Central Register of Controlled Trials	
EBM Reviews - Health Technology Assessment	
EBM Reviews – NHS Economic Evaluation Database	

9.2 Appendix 2:

HIERARCHY OF EVIDENCE FOR EFFECTIVENESS

I Evidence obtained from at least one properly designed randomized controlled trial.

II-I Evidence obtained from well-designed controlled trials without randomization.

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one centre or research group.

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of the introduction of penicillin treatment in the 1940s) could also be regarded as this type of evidence.

III Opinions or respected authorities, based on clinical experience; descriptive studies and case reports; or reports of expert committees.

SOURCE: US/CANADIAN PREVENTIVE SERVICES TASK FORCE (Harris 2001)

9.3 Appendix 3: Evidence table

REFURBISHED MEDICAL DEVICE

Evidence Table : Effectiveness and Safety
Question : Is refurbished medical device **(pacemaker, defibrillator)** effective and safe?

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
1. Linde CL, Bocray A, Jonsson H et al. Re-used pacemakers—as safe as new? A retrospective case-control study. European Heart Journal. 1998;19(1): 154-157.	**Retrospective cohort study** **Aim** To investigate the safety of re-use of pacemakers **Methods:** a retrospective case-control study of consecutive 100 patients who between 1 January 1992 and 1 January 1994 received a re-used pacemaker at primary implantation or replacement. These patients were matched for date of implantation and stimulation mode (AAI, VVI, DDD) to 100 other patients who had received newly manufactured pacemakers. All files were reviewed for complications by two investigators (C.L., A.B.). The follow-up ended on 1 August 1996. Since 1 August 1993 all patients were administered cloxacillin sodium 2 g intravenously prior to implantation as part of a routine to prevent infection. Complications related to the re-use of pacemakers were defined as infections that required	II-2	200 patients Between Jan1992 and Jan 1994 *Table 2 Patients and follow up data* Parameter / Re-use / New / Statistical significance Age ± SD (years) / 79 ± 9 / 68 ± 21 / P<0·0001 Male/Female / 39/61 / 50/50 / ns Follow up ± SD (months) / 32 ± 11 / 32 ± 11 / ns Primary implantations (%) / 83 / 75 / ns Replacements (%) / 17 / 25 / ns	100 patients refurbished pacemakers	100 patients refurbished pacemakers	11 & 32 months	**Results** **Battery Depletion** There were no early replacements due to battery depletion during the 32&11 months follow up. **Infection rate** Re-used: 2 New: 7 **Complication rate** The complication rate was 3% in patients receiving re-used pacemakers and 7% in those given newly manufactured units. Eight of the complications occurred in connection with primary implants (re-used pacemakers n=1, newly manufactured n=7). There were slightly more infections in the group receiving newly manufactured pacemakers than in the group receiving re-used pacemakers. All but one of these nine infections occurred before the introduction of the routine to give prophylactic intravenous antibiotics prior to implantation. *Table 3 Number of complications (n) during follow up of re-used or newly manufactured pacemakers* Pacemaker / Infection / Malfunction / Total Re-used / 2 / 1 / 3 New / 7 / 0 / 7 **Malfunction/Device Dysfunction** Re-used: 1 (in a 92-year-old man who underwent a	

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
	antibiotics and/ or re-operations, suspicion of pacemaker-malfunction described in the file or causing replacement and replacements due to battery depletion. Lead-related complications as well as those associated with an inappropriate choice of pacing mode, i.e. pacemaker syndrome, were not defined as related to the choice of a re-used or newly manufactured pacemaker. Such problems were therefore excluded from this study. **Definitions:** **No definitions**						primary implant of VVIR pacemaker owing to high degree atrioventricular block) New: 0 **Cost benefit analysis** **They were analysed for survival and time to pacemaker replacement.** There were 55 women and 74 men in the study. Two patients were lost to follow up. Seventy-three of the 129 patients (56%) died after an average implantation time of 3·1 years and before a need of replacement. The 44 patients who are still alive have had the re-used pacemaker implanted for a mean of 5·4 years. Only 12/129 (9%) underwent replacement (mean time=4·3 years). This signifies a saving of 73 patients 3·1 years+44 patients 5·4=463·9 patient years, or 5567 pacing months with a re-used pacemaker. This corresponds to an average of 7 years per pacemaker. The estimated cost for a pacemaker is 3000 USD/unit (USD=United States dollars). The comparable cost for a re-used pacemaker is 100 USD/unit. Calculated from figures in the National Swedish Pacemaker Registry, the national expenditure of the 4023 pacemakers that were implanted in Sweden in 1995 was 12·1 million USD. The corresponding cost for the 317 re-used units was 31 700 USD. This amounts to an estimated national saving of 919 300 USD. **Conclusion** The re-use of pacemakers can be carried out without increased risk to the patients provided a proper routine for technical control and sterilization is followed.	

Evidence Table : Effectiveness and Safety
Question : Is refurbished medical device (**pacemakers**) effective and safe?

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
2. Pescariu S, Stiubel M, Cozma D et al. La réutilisation des pacemakers, une alternative pour les personnes âgées démunies: etude rétrospective. Stimucouer. 2003;31:186-189.	**Cohort group** **Aim** To evaluate the performance (safety and efficacy) of angioplasty catheters, restored under a strict manufacturing process, in patients with coronary artery disease. **Methods:** We analyzed 365 patients group 1) implanted between January 1993 and December 2001 with a PM refurbished after a first implantation or replacement. A small number of them were new but had passed the expiration date or had been accidentally de-sterilized. These patients were compared with regard to the duration of implantation and the mode of stimulation (AAI, VVI or DDD) with 358 patients (group 2) having received a new PM. All the patient files and all the data were analyzed for complications by two investigators, independently of each other and their conclusions were compared. Patient monitoring ended in December 2002 Patients in both groups received 2 g of intravenous sodium oxacillin for prophylaxis for infections within 30 minutes of implantation.	III	Pacemakers patients 723 365 patients group 1) implanted between January 1993 and December 2001 with a PM refurbished after a first implantation or replacement.	Re-used 365	New 358	Average 35 months	**Results** Six complications were retained: 1. Infections of the compartment requiring antibiotic therapy or re-intervention 2. Dysfunctions of PM having induced premature replacement: 3. Premature exhaustion 4. Endocarditis on probe 5. Reoperations for displacement of probe or elevation of threshold 6. PM-related complications **Infection** Re-used: 6 New: 5 **Device dysfunction** Re-used: 6 New: 6 The 6 cases of group 1 PM dysfunction are due to the displacement of the stimulation probes including 4 in the atrial position and are not related to the implantation of a refurbished box. The 6 group 2 dysfunctions are linked to displacements probes (n = 6) including 2 atrial probes, tamponade treated by puncture, and early probe fracture. **Battery depletion** No premature changes due to battery depletion were made during the 35± 21 months of follow-up. **Adverse events** No deaths attributable to implantation and no endocarditis of the right heart were detected. **Cost benefits**	

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
							A cost / benefit analysis was carried out for all patients **implanted with a refurbished** PM (365 patients). The parameters taken into account were survival and the number of box changes. 210 patients (58%) died after 3.3 years without needing a change of housing. n = 157 had a relocated PM for an average of 4.2 years Only 14/365 patients (3.8%) required a change of housing (after average time of 4.1 years). The savings can be estimated at 210 x years + 157 x 4.2 years = 1352.4 patient years or 16,228.8 months of stimulation. The estimated average cost of a stimulator is around € 2,000. a refurbished PM is around € 100 The cost of the refurbished 367 MPs represents only € 36,700 The budget represented by the 358 new PM implanted at the Institute of Cardiovascular Diseases of Timisoara therefore represents € 716,000. **Conclusion** Our study confirms that the reuse of PM, provided that certain rules are strictly observed, does not represent an additional danger for the patient. These conclusions are similar to other studies already published in Sweden, Linde et al. as well as Havia and Schuller reported few or no complications after re-use of PM.	

Evidence Table : Effectiveness and Safety
Question : Is refurbished medical device **(pacemaker, defibrillator**) effective and safe?

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
3. Nava S, Morales JL, Márquez MF et al. Reuse of pacemakers: comparison of short and long-term performance. Circulation. 2013;127(11):1177-83.	**Retro and prospective Cohort** **Aim** To provide more evidence that this practice is safe, a cohort of consecutive patients who received either a new or a refurbished pacemaker is studied considering a combined end point of 3 major determinants: unexpected battery depletion, infection, and device dysfunction. **Methods** A single-center cohort of consecutive patients from 2000 to 2010 was studied in an ambispective, noninferiority study. From 2000 to 2005, the analysis was made retrospectively; from 2005 to 2010, it was done prospectively. The percentage of patients with a primary outcome in desterilised. **Definitions:** **Expected battery depletion** occurred when the elective replacement indication on the device was reached after **8 years.** **Unexpected battery depletion** was defined according to the studied groups. For new pacemakers, **early battery depletion** was defined as depletion **before the sixth year** after implantation without relation to high pacing outputs or	II-2	603 consecutive patients from 2000 to 2010 Control group consisted of patients ≥18 years of age with Class I American Heart Association/American College of Cardiology/European Society of Cardiology indication for pacing who could afford a new pacing device. The study group consisted of patients who could not afford a new pacemaker, could not obtain a new one through donation within a waiting period defined by their attending physician according to their cardiac status, and were offered a resterilized device, 96% of them from cadaveric donation.	patients **(n=307)** received desterilised pacemakers 54 pacemakers had to be explanted in the study group (17.6%)	patients **(n=296)** received a new pacemaker 31 pacemakers had to be explanted in the control group (10.5%)	5 years	**Outcomes** 43 reached the primary end point, 16 in the control group (5.5%) and 27 in the study group (7.2%; relative risk, 1.3; 95% confidence interval, 0.70–2.45; P=0.794). **Results** **Battery Duration/Battery depletion** **Unexpected battery depletion** was observed in **5 devices in the control group** (1.7%) versus **11 in the study group**. In terms of individual outcomes, 5 new pacemakers (1.7%) and 11 desterilised pacemakers (3.6%) had unexpected battery depletion (relative risk, 2.12; 95% confidence interval, 0.75–6; P=0.116); **Early battery depletion was** observed in 5 devices in the study group (1.6%) versus 1 device in the control group (0.3%) with no statistical significance (P=0.198). **Premature battery depletion** was seen in 6 devices in the study group versus 4 devices in the control group (P=0.399). **Expected battery depletion** was observed in 15 devices in the control group (5%) versus 32 of the study group (10%; RR, 2.1; 95% CI, 1.1–3.75; P=0.031) **Average battery depletion** In devices with expected battery depletion, the average duration for new devices was 8.8±0.24 years compared with 6.3±0.3 years for the resterilised pacemakers (P=0.001). In devices with unexpected battery depletion, the duration was 6.31±0.79 years compared with 2.47±0.9 years in the study group (P=0.002). **Infection**	

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
	abnormal electrode impedances that would void the device warranty. **Premature battery depletion** was considered to have occurred when the elective replacement indication was reached **between the sixth and eighth years** after the initial implantation **For resterilized pacemakers,** as previously mentioned, at our institution, we consider for reuse only those devices that have at least 50% of their calculated battery life left. If we consider the expected battery depletion for new devices to occur at 8 years, then the **expected battery depletion in reuse devices would occurred after the fourth year, early battery depletion, before the second year,** and **premature battery depletion between the second and fourth years.** To define infection, used by Byrd in the classic textbook by Ellenbogen et al. that described 4 types of infection: I, right endocarditis with electrode involvement; II, sepsis without evidence of involvement of the circuit or pocket; III, infection of the pacemaker pocket; and IV, extrusion of wires or generator. early infection to occur in the first month after implantation and late infection to occur in the first year after implantation that could be						a total of 21 events were considered infections. 10 in the study group (3.2%) versus 11 in the control group (3.7%; P=0.46). 3.7% new pacemakers and 3.2% refurbished pacemakers had a procedure-related infection (relative risk, 0.87; 95% confidence interval, 0.38–2.03; P=0.46) **Malfunction** We found only 1 event associated with device malfunction (refurbished); it was also a screw malfunction. 1 pacemaker in the study group malfunctioned. Since that event, special attention to the existence and function of screws has been given during the refurbisheding process, and no other event has been detected. We agree that thorough inspection of screws is essential to guarantee pacemaker function. **Adverse Event** During follow-up, **45 patients died in the control** group (15.2%) versus **39 patients in the study group** (12.7%; RR, 0.83; 95% CI, 0.56–1.24; P=0.376). Because differences in follow-up times could influence results, cumulate survival analysis was performed for the primary event and for all explanted pacemakers and showed no difference between groups for the primary end point (P=0.340) and a significant difference between groups for all pacemakers explanted for any reason (P=0.048). This difference is evident only after the fifth year of follow-up, which is most likely explained by the difference in battery life for resterilized pacemakers. **Conclusion** Pacemaker reuse is feasible and safe and is a viable option for patient with bradyarrhythmias. Other than the expected shorter battery life, reuse of pacemaker generators is not inferior to the use of new devices.	

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
	considered to be related to the procedure. After the first year, infection is not considered to be related to the procedure							

Evidence Table : Effectiveness and Safety
Question : Is refurbished medical device **(pacemaker, defibrillator)** effective and safe?

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
4. Ze F, Li X, Zhang P et al. Reuse of Infected Cardiac Rhythm Management Devices in the Same Patients: A Single-Center Experience. Pacing and Clinical Electrophysiology. 2014;37(8):940-946.	**Retro and prospective Cohort** **Aim** To evaluate whether infected devices that have been carefully resterilized can be safely reimplanted in the same patients **Methods:** A single-center cohort of consecutive patients was included in a two-way noninferiority study. Patients referred to the Cardiovascular Center of The Peking University People's Hospital for extraction of an infected CRMD from 2007 to 2012 were included in the analysis. Patients treated from 2007 to 2009 were enrolled retrospectively, and patients treated from 2009 to 2012 were enrolled prospectively. The inclusion criteria were: (1) infected CRMD, with a Class I recommendation for removal (2) CRMD reimplantation required after careful reevaluation of the patient, and (3) CRMD reimplantation performed on the contralateral side. All patients who met these criteria and underwent device removal and reimplantation using endocardial leads were included in the study. Patients who underwent reimplantation using epicardial leads were not included.	II-2	a cohort of consecutive patients with infected CRMDs who had either a new CRMD implanted or the same CRMD reimplanted. The end point was the occurrence of infection, unexpected battery depletion, or device dysfunction. Four weeks after the procedure, patients were reviewed at our center and the CRMDs were reprogrammed. Patients were then **followed-up twice a year** at our center. For some patients who lived in remote areas, survival and functional status were determined by telephone.	**99 patients** in the study group (reimplantation of the same CRMD)	**113 patients** in the control group (implantation of a new CRMD)	3 years	The overall median follow-up time was 3.52 years (IQR: 2.1–4.7 years, total range: 0.5–5.2 years). The median follow-up time was 3.6 years (IQR: 1.1–4.6 years) in the study group and 3.3 years (IQR: 0.8–4.1 years) in the control group (P=0.175). The end point was the occurrence of infection, unexpected battery depletion, or device dysfunction. At the end of the follow-up period,10 patients had reached the end point, **including five in the study group and five in the control group (5% vs 4.3%, RR: 1.07, 95% CI: 0.57–2.03, P = 0.719).** **Results** **Unexpected battery depletion** There were no cases of unexpected battery depletion in either group **Infection** Recurrent infection occurred in **3 patients in the study** group and **2 patients in the control group** (3.0% vs 1.7%, RR:1.29, 95% CI:0.62–2.69, P=0.561) Recurrent endocarditis occurred in one patient with Brugada syndrome at 17 months after implantable cardioverter defibrillator reimplantation, and recurrent pocket infection occurred in one patient at 6 months after dual-chamber pacemaker (DDD) reimplantation and in one patient at 20 months after cardiac resynchronization therapy pacemaker reimplantation. In the control group, all patients underwent CRMD removal because of pocket infection. Recurrent pocket infection occurred in one patient with SSS at 12 months after reimplantation, and in one patient with type III atrioventricular block at 6 months after reimplantation. The same bacterial species was responsible for the recurrent infection in only one patient. The most	

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
	The indications for pacing were similar between the two groups (P=0.770). The most common reason for CRMD implantation was sick sinus syndrome (SSS), accounting for 44 patients (44.4%) in the study group and 42 patients (37.2%) in the control group. **Definitions:** **No definitions**						commonly cultured organism was Staphylococcus epidermidis, and 52% of cultures were negative. **Malfunction/Device Dysfunction** Device malfunction occurred in **2 patients in the study** group and **3 patients in the control** group (2.0% vs 2.6%, RR: 0.76, 95% CI: 0.21–3.03, P=0.642). There was no significant difference in the rate of malfunction between the two groups (2% vs 2.6%, P=0.642). The most common malfunction was an increased threshold and failure to sense with the atrial lead, which occurred in four patients (1.9%), including one patient (1.0%) in the study group at 2 months after reimplantation and three patients (2.6%) in the control groupat 44 months, 45 months, and 48 months, respectively, after reimplantation. All the atrial leads that malfunctioned were passive-fixation leads. One patient (1.0%) in the study group developed intermittent failure to capture and sense with the active ventricular lead at 21 months after DDD reimplantation. Because differences in follow-up times could affect the results, cumulative survival analyses were performed for the primary event (Fig. 1). These analyses showed no significant difference between the two groups (P=0.151). **Adverse Event** 6 patients died during the follow-up period, resulting in an overall mortality rate of 2.8%. The deaths were because of cancer (n = 1) and heart failure (n = 1) in the control group, and because of peripheral arterial disease (n=1), renal failure (n = 1), myocardial infarction (n = 1), and stroke (n=1) in the study group (P=0.32). **Conclusion** In our experience, re-implantation of infected CRMDs in the same patients is feasible.	

Evidence Table : Effectiveness and Safety
Question : Is refurbished medical device **(pacemaker, defibrillator)** effective and safe?

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
5. Jama ZV, Chin A, Mayosi BM et al. Performance of re-used pacemakers and implantable cardioverter defibrillators compared with new devices at Groote Schuur Hospital in Cape Town, South Africa. Cardiovascular Journal of Africa. 2015;26(4):181.	**Retrospective Cohort study** **Aim** To compare the risk of infection and the rate of malfunction of re-used pacemakers and ICDs with new devices implanted at Groote Schuur Hospital in Cape Town, South Africa. To investigate the performance of re-used pacemakers and ICDs at Groote Schuur Hospital, Cape Town, South Africa **Methods:** Patients with re-used devices (cases) were then matched by age, gender and date of implantation on a 1:1 basis to patients with new devices (controls). In the pacemaker group, cases and controls were matched to the same month of implantation, and for the ICD group, to the same year of implantation. Devices for re-use were obtained from cadaveric donors. They were inspected for external damage and tested for remaining battery life. Devices with less than two years of battery life remaining and/ or with external evidence of damage were not re-used. Only devices with two or more years of battery life remaining with no evidence of external damage were eligible for re-use. **Definitions:** **Procedure-related infection:** infections were classified into four types: (1) right-sided endocarditis with lead involvement; (2) sepsis with evidence of involvement of the lead and implantation pocket; (3) involvement of the pacemaker implantation pocket; and (4) involvement	II-2	126 devices implanted in 126 patients between 2003 and 2013 were analysed	63 patients pacemakers 51 re-used ICDs 12 re-used	63 patients pacemakers 51 new ICDs 12 new	3 months, 1-year	The outcomes were incidence of device infection, device malfunction, early battery depletion, and device removal due to infection, malfunction, or early battery depletion **Results** **Unexpected battery depletion** **There was no device infection, malfunction**, early battery depletion or device removal in either the re-used or new pacemaker groups over the median follow up of 15.1 months [interquartile range (IQR), 1.3–36.24 months] for the re-used pacemakers, and 55.8 months (IQR, 20.3–77.8 months) for the new pacemakers. **Infection** In both the pacemaker and ICD groups, there were no procedure-non-related infections documented for the respective follow-up periods. In the ICD group, no device infection occurred over a median follow up of 35.9 months (IQR, 17.0–70.9 months) for the re-used ICDs and 45.7 months (IQR, 37.6–53.7 months) for the new ICDs. **Malfunction/Device Dysfunction** One device delivered inappropriate shocks, which resolved without intervention and with no harm to the patient. This re-used ICD subsequently needed generator replacement 14 months later. **Conclusion** No significant differences were found in performance between re-used and new pacemakers and ICDs with regard to infection rates, device malfunction, battery life and device removal for complications. Pacemaker and ICD re-use is feasible and safe and is a viable option for patients	

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
	of the lead or generator. Infections were considered early if the onset of illness was within the first month of implantation, and late if the onset of illness was after the first month to a year after implantation. Infections that occurred after a year of implantation were considered not to be related to the procedure •**Device malfunction** was defined as failure of the device to accomplish the desired role, e.g. in the case of an ICD, not able to sense ventricular tachycardia/fibrillation and deliver appropriate treatment. In the case of a pacemaker, device malfunction was defined as inability to sense or pace when required. •**Early battery depletion** was defined as battery depletion **within six years of implantation for new devices.** For **re-used devices**, early battery depletion was defined as battery depletion **within one to two years of implantation** for those with two to four years of battery life remaining, and within two years of implantation for those with four years or more of battery life remaining at the time of implantation, provided this depletion was not explained by high pacing outputs or abnormal electrode impedance. •**Device explantation for infection**, malfunction and/or battery depletion involved removal of the pacemaker or ICD due to infection, malfunction or early battery depletion						with bradyarrhythmias and tachyarrthythmias.	

Evidence Table : Effectiveness and Safety
Question : Is refurbished medical device **(pacemaker, defibrillator**) effective and safe?

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
6. Şoşdean R, Mornoş C, Enache B et al. Safety and feasibility of biventricular devices reuse in general and elderly population- a single-center retrospective cohort study. Clinical interventions in aging. 2015;10:1311.	**Retrospective Cohort** **Aim** To analyze infection burden in the general and elderly population and also early battery depletion and generator malfunction of resterilized biventricular devices compared to new devices. **Methods:** A cohort of 261 CRT patients (286 devices), who underwent implantation between 2000 and 2014, was retrospectively analyzed. The study group included 115 patients and 127 resterilized devices, that was divided into a subgroup of 69 elderly patients (60 years) and 74 devices and a subgroup of 47 younger patients (60 years) and 53 devices, and the control group included 146 patients and 159 new devices. The groups were compared using a multivariate logistic regression model. **Definitions:** **No definitions**	II-2	261 patients receiving 286 devices:, between 2000 and 2014	a number of **115 patients** in the study group, who received 127 resterilized devices the subgroup of patients over 60 years of age included 69 patients who received 74 resterilized devices and the subgroup under 60 years of age included 47 patients who received 53 resterilized devices.,	a number of **146 patients** in the control group, who received 159 new devices.	1, 3 months and 1 year	**Results** Six patients/devices from the study group and seven patients/devices from the control group reached one of the primary outcomes in a similar median period of time of 13 months (interquartile range, 10–16 months) and 7 months (interquartile range, 5–8 months), respectively (P=0.22). **Unexpected battery depletion** 34 devices (in 32 patients) had to be explanted for battery depletion, 21 in the study group and 13 in the control group, after a median period of time of 40 months (interquartile range, 36–66 months) for the study group and 67 months (interquartile range, 56–74 months) for the control group (P=0.01). There was **only one case** of early battery depletion, after 17 months, in **one study** group patient. Regarding early battery depletion, one patient in the study group had to have his triple-chamber defibrillator replaced after 17 months (1 year and 5 months, second replacement), without any change in the device's parameters and without any shock delivery that might have led to an increase in battery consumption. There was no early battery depletion in the control group. **Infection** A number of 12 (4.2%) infectious complications were encountered, **five (3.9%) in the study group and seven (4.4%) in the control group** (odds ratio, 2.83 [0.59–13.44], P=0.189), one (1.3%) in the elderly and four (7.5%) in the younger subgroup (odds ratio, 3.80 [0.36–40.30], P=0.266), with no statistically significant difference between them. All infections were related to the device pocket without signs of lead involvement and/or endocarditis.	

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
							4 of these patients had device exteriorization, without proven infection (3 in the control group and 1 in the study group, eg, decubitus lesions), but the wound was considered and treated like an infection according to the current protocols. 7 patients had device exteriorization with proven infection (3 in the control group and 4 in the study group), and 1 patient in the study group had a chronic collection underneath the device, without external and/or systemic signs of infection. **Malfunction/Device Dysfunction** No generator malfunction was detected There were 9 cases of pacing malfunction, all due to lead displacement without electronic device/generator involvement. We encountered 6 cases of coronary sinus lead displacement and 3 cases of right ventricle lead displacement, along with lead fracture in one of them **Adverse Event** To the best of our knowledge, one single study evaluated 81 patients receiving 106 biventricular defibrillators for CRT, concluding that reuse of these devices is safe, without a raise in complication rate (infection, defibrillator malfunction), but necessitating further studies for validation and confirmation. The study also lacked a control group. Evaluating specific aspects of defibrillator malfunction (eg, inappropriate shock delivery) was beyond the purpose of our study. **Conclusion** Reuse of biventricular cardiac implantable electronics seems feasible and safe in both the general population and the elderly population, and it could be a promising alternative when new devices cannot be obtained in a safe period of time.	

Evidence Table : Effectiveness and Safety
Question : Is refurbished medical device **(pacemaker, defibrillator)** effective and safe?

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
7. Selvaraj RJ, Sakthivel R, Satheesh S et al. Reuse of pacemakers, defibrillators and cardiac resynchronisation devices. Heart Asia. 2017;9(1):59-62.	**Retrospective Cohort study** **Aim** To study early outcomes with implants using refurbished devices and compare them with those with implants using new devices. **Methods:** We studied all patients who underwent implantation of a new or refurbished pacemaker, cardiac resynchronisation therapy (CRT) device or implantable cardioverter defibrillator (ICD) in the last 5 years at a single institution. We analysed outcomes related to infection, device malfunction and device-related death within 6 months after initial implantation. **Definitions:** **Device-related infection:** Infection of the device in situ and its pocket usually requiring explantation of the device. Device-related infections were classified based on the timing of its occurrence from the date of implant as early infection when it occurs in the first month of the implant and late infection when it occurs in the first 6 months of the implant. **Device malfunction;** Failure of the device to perform its intended function (pacing, sensing or defibrillation) which is not due to	II-2	887 patients underwent implantation between Jan 2010 and Dec 2015	260 devices were refurbished **Pacemakers** n=760 (85.7%) AAI 14 VVI 132 VDD 8 DDD 71 **Total 225** (29.6%) **Complex devices** n=127 (14.3%) Single-chamber ICD 22 Dual-chamber ICD 1 CRT-P 11 CRT-D 1 **Total 35** (27.6%)	627 devices were new 77 275 33 150 **535(70.4%)** 46 8 34 4 **92 (72.4%)**	6 months	**Results** During the study period, 887 patients underwent device implant, including 127 CRT devices or ICDs. There were no infections among patients receiving a refurbished device. **Infection** **Three** device-related infections in implants using a new device. Three patients in the entire group developed pocket infection and required explantation of the pacing system. The second was a 29-year-old male who had no risk factors and underwent a dual chamber pacemaker implant for congenital atrioventricular block. Both presented as pocket infection within a month of implant with no bloodstream infection or endocarditis and were successfully managed with device explant and subsequent implantation of a new device. The third was a young male with dilated cardiomyopathy who underwent a CRT device implant for dilated cardiomyopathy, heart failure and left bundle branch block. He presented with a pocket infection 40 days after implantation of a new CRT device and was also treated by explanting the device and leads. No infections were seen in patients who received a refurbished device. **Malfunction/Device Dysfunction** There were no device malfunctions or device-related deaths in either group. **Mortality** No device-related mortality occurred in both group. **Three deaths occurred**, all due to heart failure: two in patients with an Automatic Implantable Cardioverter	

Bibliographic Citation	Study Type/Methods	LE	Number of Device/Patient & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
	lead-related problems and may be because of loss of mechanical or electric integrity during the extraction and/or sterilisation process. **Device-related death:** Mortality due to device infection or device malfunction within 6 months of the implant.						Defibrillator (AICD) and one in a patient with a CRT device. **Conclusion** The potential benefits of refurbished devices in cardiac electrophysiology should be explored to benefit many patients in need of them in low/middle-income countries across the globe. Legal restrictions to access such device therapy should be eased and standard protocols developed to ensure safe and ethical practice. In the light of evidence provided by this study, in addition to those from previous such studies, it is unethical and unscientific to deny this life-saving therapy to patients in need.	

Evidence Table : Cost analysis
Question : Is refurbished medical device cost-effective?

Bibliographic Citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
1. Mancuso R Jr, Bickham MJ. Estimating the true costs of disposable and reusable instruments. AORN J. 1995;62(1):39-48.	**Cost Analysis (comparison-case study)** **Aim** To establish a process for analyzing the true costs of disposable and reusable instruments (complex issues involved in determining true costs, cost-effectiveness, and efficacy of the reusable and disposable instruments). **Methods** For the purpose of the case study, we assumed that the sterile processing department (SPD) and OR suites were located in separate areas of the facility and that the processing of reusable power equipment was performed sequentially in the OR suites and in the SPD. We also assumed that the equipment was transported between the two areas by personnel and mechanical dumbwaiters.	I	§ perspective § year of cost reported § type of cost included. boleh guna untuk compare across the studies kalau similar § results: total costs/ cost comparison, net monetary benefit	Orthopaedic reamer reusable	Orthopaedic reamer disposable		**Overview of included studies** **Types of cost analysis** **Included tangible, intangible, direct, indirect, fixed, and variable costs jn the overall process**. These costs included salaries and benefits for all personnel involved in performing processing tasks, necessary equipment, and average personnel overtime costs associated with the process. **Included costs of internal and external communications** and development and maintenance of documentation, policies, and procedures. Also included contracts and warranties (ie, process costs of negotiating, developing, obtaining services; actual costs of services). **Included a third-party analysis of purchase** price, including actual subscription costs and internal facility process costs, and costs of repairs, preventive maintenance, service contracts, and support equipment. **Minimum expenses for use of reamers for 48 months** **Table 1** **ORTHOPEDIC REAMER COST COMPARISON** Reusable / Disposable Equipment acquisition: $77,760 / $192,000[b] Repairs: $65,520 / NA Preventive maintenance survey: $2,880 / NA Battery replacement: $43,200 / NA[c] Chargers: $6,000 / NA Processing personnel: $7,680 / NA Processing and supplies: $10,473 / NA Disposal: NA / $778[d] Totals: $213,513[e] / $192,779[e]	

Bibliographic Citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
							Cost Analysis Minimum expenses for use of reamers for 48 months. Assumption of $80 to $1 00 per use (ie, $1 53,600 at $80 per use; $1 92,000 at $1 00 per use). If battery operated, assume battery is included in purchase price. 1.5 pounds at 27 cents per pound. High expenses for use of reamers for 48 months. Procedure volume for 48 months = 1,920 Note: Handling costs (eg, vendor/distributor, internal ordering, receiving), utilities, minor chemicals, and sterilizer cycles not included. Expense+ by procedure volume = minimum cost per patient procedure. **Reusable calculation:** $213,513 / 1,920 = $1 11.20 minimum cost per reamer use. **Disposable calculation:** $154,378 /1,920 = $80.41 minimum cost at $80 per use. $192,779 /1,920 = $100.41 minimum cost at $100 per use. **Conclusion** Actual savings or cost-effectiveness, therefore, may be different than expressed in this analysis. Depending on the cost figures used, cost-effectiveness, efficacy of disposable and reusable instruments, and analysis outcomes will vary.	

Evidence Table : Cost-minimization analysis
Question : Is refurbished medical device cost-effective?

Bibliographic Citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
2. Bourguignon C, Destrumelle AS, Koch S, Grumblat A, Carayon P, Chopard C, Woronoff-Lemsi MC. Disposable versus reusable biopsy forceps in GI endoscopy: a cost-minimization analysis. Gastrointestinal endoscopy. 2003 Aug 1;58(2):226-9.	**Cost-minimization Analysis** **Aim** To compare the cost of reusable versus disposable biopsy forceps. **Methods** A retrospective cost-minimization analysis of the use of reusable versus disposable biopsy forceps was carried out from **the viewpoint of the hospital.** The cost-minimization analysis requires the assumption that the outcomes of the strategies are considered equivalent. Direct medical costs were included, related to the therapy and to specific health care services. Reusable biopsy forceps were used at our university hospital during this study. A sensitivity analysis was performed to evaluate the robustness of the results and to determine the degree to which several parameters (examined one at a time) could influence the conclusions of the economic impact of clini- cal decisions.	I	Hospital patient until year 2001	Reusable biopsy forceps in GI endoscopy	Disposable biopsy forceps in GI endoscopy		**Overview of included studies** The cost per use of the disposable biopsy forceps **included acquisition and destruction costs.** Acquisition cost was based on the price proposed by the **manufacturer in September 2000 for an annual procurement of 1500 biopsy forceps.** These medical devices are incinerated similar to contaminated waste ($568.68 per ton). The acquisition costs varied according to manufacturer and the type of product, whereas destruction cost varied according to weight. Minimum and maxi mum values of these costs were determined. The cost per use of the reusable forceps included the acquisition cost per biopsy and the reprocessing cost. The cost of disposable forceps included the acquisition cost and destruction costs. In total, 7666 upper and lower endoscopies were performed during 1998 and 1999. The purchase price of disposable biopsy forceps ranged from $10.70 to $15.60, depending on manufacturer, for an annual order of 1500 disposable biopsy forceps. The destruction cost ranged from $0.02 to $0.03 depending on the weight of the forceps. The cost per use of disposable biopsy forceps varied from $10.72 to $15.63 On average, approximately 17 new reusable biopsy forceps were purchased each year during this period. The purchase price was $326.00 per forceps in 1999. Each biopsy forceps was used for an average of	

Bibliographic Citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
							approximately 90 biopsy sessions before destruction. The acquisition cost per biopsy was then $3.60. **Thus, the total cost of a disposable forceps was 1.5 to 2.3 times higher than that for a reusable forceps. If a disposable biopsy forceps had been used, it would have led to an additional annual cost of $6500 to $13,000 to the GI endoscopy unit.** **Sensitivity analysis** A purchase price of $6.85 for a disposable biopsy forceps would have been needed for strict equivalence of cost between reusable and disposable biopsy forceps. At a purchase price of $455.00, the cost per use of a reusable biopsy forceps would have been $8.30. If a reusable biopsy forceps was used 20 or 45 times (instead of 90 times on average), the cost per biopsy would increase, respectively, to $19.50 and $10.56. In this situation, the disposable biopsy forceps would become cost-effective. **Conclusion** The present economic analysis favors reusable biopsy forceps. However, patient safety must be taken into account, particularly the potential risk of the spread of infection. The additional cost per use of disposable versus reusable biopsy forceps varied from $3.88 to $8.79 (depending on purchase price).	

Evidence Table : Cost analysis
Question : Is refurbished medical device cost-effective?

Bibliographic Citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
3. Sloan TW. Safety-cost trade-offs in medical device reuse: a Markov decision process model. Health Care Management Science. 2007;10(1):81-93	**Cost-Safety-cost trade-offs Markov model** **Aim** To determine a use/reuse policy that minimizes the long-run expected average cost. **Methods** A Markov model was developed for making decision process model examining the choice between using new and reprocessed medical devices.		Markov model	Reuse 1. Orthopedic blades 2. Cardiac catheter 3. Compression sleeve 4. Trocar	New device 1.Orthopedic blades 2.Cardiac catheter 3.Compression sleeve 4.Trocar	NA	**Key parameter** -device costs -device failure probabilities -failure penalty costs **Limitations** -no failure costs However, healthcare providers can use the model for rough-cut analysis of different scenarios, and it may be used to confirm intuition about different kinds of devices. Device reprocessing also involves important policy issues. Specifically, reimbursement to hospitals from Medicare and insurance companies is based on predetermined rates for different procedures. Thus, the reimbursement for a particular procedure is not tied directly to the actual cost. This creates an incentive for hospitals to pursue ways to save money on devices, because these savings go directly into their pockets. The model can also be used to study device reuse issues from the device makers' perspective. The OEMs obviously have an incentive to encourage healthcare providers to buy new devices. The device makers' primary use of the model would be to examine pricing questions: How much lower would the cost of a new device need to be in order to make it preferable to the reprocessed device?	

Bibliographic Citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
							Conclusion The model could also be used to study the impact of improved reliability, e.g., how much more reliable does the new device need to be as compared to a reprocessed device? The model also can be used to answer questions like: Given the failure probability trade-off point, what is the maximum failure probability such that it is still optimal to use a reprocessed device? The model could also provide guidance in terms of pricing for the reprocessed devices.	

Evidence Table : Cost analysis
Question : Is refurbished medical device cost-effective?

Bibliographic Citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
4. Shan RS, Chrusch WM, Linassi AG et al. Reuse and Refurbished: A Cost Savings Delivery Model for Specialized Seating. Archives of physical medicine and rehabilitation.2012;93(7):1286-1288.	**Retrospective cost analysis** **Aim** To determine the cost of having a wheelchair and seating recycling program compared with the estimated cost of the equipment had it been newly purchased. **Methods** A retrospective cost analysis using data from billing records and annual statistical reports of the specialized seating program, for the 2004 to 2009 billing period.		Pediatric patients (N=40) with physical disabilities (cerebral palsy, developmental delay, acquired brain injury, spinal cord injury, Down syndrome, other) who were referred, assessed, and met inclusion criteria. 40 patients, 49 wheelchairs, 9 patients required 2 wheelchairs	49 wheelchairs	49 wheelchairs	2004-2009	**Results** The average cost of a used wheelchair was Can $698.11. The average cost of a new chair was $2143.69, leading to an average savings per chair of $1445.58. Of the 49 chairs issued, this resulted in a total cost savings of $85,393.97. When labour costs were taken into account ($50,060.26), the savings amounted to $35,333.71. Overall cost reduction was 41.3%. **Limitations** Further analysis also revealed that the administrative cost of procuring a new unit was higher due to the multilevel involvement of ordering and payment processes. The recycled seating components were not catalogued. Therefore, no cost burden was incurred there either. In addition, costs regarding clerical support, committee approval time, and therapy costs were not included in this study. However, as the program is publicly funded, regardless of whether the program used new or refurbished wheelchairs, these would be fixed costs which would be incurred in either case. **Conclusion** A retrospective analysis shows evidence of cost containment. Long-term sustainability of the program requires ongoing analysis of the cost and environmental advantages of a recycling program and review of benefits provided in relation to the ability to meet patient needs. This delivery model does incorporate accountability and a policy framework, which could serve as a model for other centers.	

Evidence Table : Cost-analysis
Question : Is refurbished medical device cost-effective?

Bibliographic Citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
5. Bejandi JR, Soltani-Neshan M. Comparative Studies of Three Types of Product Policies (Remanufactured, Refurbished and New Products) on Warranty Cost and Profitability. International journal of Business and Technopreneurship. 2015; 5(3): 407-420.	**Comparing cost** **Aim** To evaluate quantitatively the impact of choosing three strategies on warranty costs, and the profitability of companies. We want to know if the profitability of remanufactured and refurbished products compared to new products for the organization. **Methods** The warranty cost has estimated by existing model in literature and all products considered under FRW warranty policy. The company that we selected is a leading firm in IRAN that works as a third party or importer. This helps us to assess all factors related to buying, reconditioning and selling products. For this purpose, the failure data of 60 medical devices of a leading company has analyzed from 2013 to 2014. For each strategy (remanufacturing, refurbished and new products), 20 devices were selected and monitored over a year. The selected products were similar in usage to minimal the impact of function differences. First step to calculate the profitability of each device is to compute costs before and after sales. The costs of new, refurbished and remanufactured products are different for Third Party		60 medical devices with failure data § perspective § year of cost reported § type of cost included. boleh guna untuk compare across the studies kalau similar § results: total costs/ cost comparison, net monetary benefit	20 refurbished	20 remanufacturing 20 new products	2013-2014	**Key Parameter for costing** **1) item costs related to remanufacturing and refurbished process** **2) related costs which provided by accounting department to compute profitability.** **3) result of warranty costs after upgrading actions calculated by applying Shafiee's model (2011)** **4) profitability of each item** **Results** Regardless of choosing the strategy, warranty costs increased by rising the warranty period. This indicates the importance of selecting warranty period wisely because it has a direct impact on total costs and profitability. The warranty costs of refurbished products have significant increase in products with age three. This displays that although warranty costs of refurbished products with the one-year past age increase about 20 percent, when the past age rise to three, we could observe increasing in cost about 60 percent. This emphasizes that in used products with higher past age; companies should imply stronger upgrade strategies such as remanufactured. Based on figure 2, the refurbished products have the least profitability. This is due to the higher costs of these products that increase by rising past	

<table>
<tr><th>Bibliographic Citation</th><th>Study Type/Methods</th><th>LE</th><th>Number of Patients & Patient Characteristic</th><th>Intervention</th><th>Comparison</th><th>Length of Follow Up (If Applicable)</th><th>Outcome Measures/Effect Size</th><th>General Comments</th></tr>
<tr><td></td><td>Company; however, all products have the same fixed costs.</td><td></td><td></td><td></td><td></td><td></td><td>age.

What needs to more discussion here is advertising costs. The current strategy of company is to perform more advertisement and promotion for used products, as we mentioned in section 1, some customers are uncertain about the quality and history of used products. Therefore, to enjoy the advantages of used products companies should spend more money on advertising of used products to attend customers and satisfied their needs.

Table 4. Other costs related to three options ($)
<table>
<tr><th>Item costs</th><th>1. New</th><th>2. Refurbished</th><th>3. Remanufactured</th></tr>
<tr><td>Fixed costs</td><td>800</td><td>800</td><td>800</td></tr>
<tr><td>Cost of advertising</td><td>500</td><td>700</td><td>700</td></tr>
<tr><td>Cost of buying products(new or used)</td><td>6100</td><td>4000</td><td>4000</td></tr>
<tr><td>cost of refurbishing process</td><td>0</td><td>250</td><td>250</td></tr>
<tr><td>Cost of remanufacturing process</td><td>0</td><td>0</td><td>370</td></tr>
<tr><td>Total cost</td><td>7400</td><td>5750</td><td>6120</td></tr>
<tr><td>Sale price</td><td>10000</td><td>7000</td><td>8500</td></tr>
</table></td><td></td></tr>
</table>

Evidence Table : Cost analysis
Question : Is refurbished medical device cost-effective?

Bibliographic Citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
6. McGain F, Story D, Lim T et al. Financial and environmental costs of reusable and single-use anaesthetic equipment. BJA: British Journal of Anaesthesia. 2017;118(6):862-869.	**Retrospective cost analysis** **Aim** To analyse the financial and environmental costs of reusable and single-use anaesthetic equipment **Methods** They performed an LCA using Monte Carlo analysis at two major hospitals in Melbourne, Victoria, Australia. They obtained data for breathing circuits, face masks, LMAs, and direct and video laryngoscopes. Data of anaesthetic equipment use were obtained for Hospital 1 (Scenario 1, reusable variants) and for Hospital 2 (Scenario 2, mainly single use) for 2015. Scenario 3 (completely single use=Scenario 2 plus single-use direct laryngoscope blades) was anecdotally the routine approach in many USA hospitals and to a lesser extent elsewhere. They also interested in the financial and environmental consequences of substitution of only one reusable to single-use device for two further scenarios. Scenarios 4 (reusables except for single-use face masks) and 5 (reusables except for single-use laryngoscope blades) were chosen because they were occurring in Australian hospitals and were high-volume products.		Scenario 1, the current practice at Hospital 1 of using reusable anaesthetic circuits, face masks, 'Proseal'VR (Teleflex, Westneath, Ireland) LMAs, and direct and video laryngoscope blades and handles; Scenario 2, changing the practice at Hospital 1 to that occurring at Hospital 2 of using disposable anaesthetic circuits, and single-use face masks, LMAs, and direct laryngoscope blades, retaining reusable direct laryngoscope handles and	Re-usable anaesthetic equipment	Single use anaesthetic equipment	1 year 2015	**Results** In all five scenarios, the financial cost to process single-use anaesthetic equipment was more than for reusable anaesthetic equipment. Table 3 Summed financial costs (in AUD$) for anaesthetic equipment for Scenario 1 (reusables) and Scenario 2 (mainly single use) in 2015. CSSD, Central Sterile and Supply Department; LMAs, laryngeal mask airways Process/device | All reusable equipment (Scenario 1) | All disposable or single-use equipment except for reusable direct laryngoscope handles and videolaryngoscopes (Scenario 2) Labour in CSSD | $14 560 | $0 Washer loads | $1595 | $290 Steam sterilization | $815 | $0 H_2O_2 sterilization cycles | $4356 | $0 Circuits and bags | $2292 | $3850 Face masks | $2482 | $19 800 LMAs | $8500 | $13 230 Direct laryngoscope blades | $1460 | $19 350 Direct laryngoscope blades' wrappings | $180 | $0 Direct laryngoscope handles | $470 | $470 Videolaryngoscope blades | $0 | $11 500 Videolaryngoscope handles | $0 | $0 Videolaryngoscope blades' packaging | $250 | $250 Waste costs (general waste at $0.25 kg^{-1}) | $25 | $278 Total | $36 985 | $69 018 For all scenarios, using single-use anaesthetic equipment always cost more than using reusable equipment, from approximately AUD$10 000 (£6000) p.a. more for single-use laryngoscope blades alone to almost AUD$90 000 (£54 000) for completely single-use anaesthetic equipment. Labour costs to process all reusable equipment were modest. Most environmental impacts to process anaesthetic equipment were small, with only CO2 emissions and water use being relatively important.	

Bibliographic Citation	Study Type/Methods	LE	Number of Patients & Patient Characteristic	Intervention	Comparison	Length of Follow Up (If Applicable)	Outcome Measures/Effect Size	General Comments
			reusable videolaryngoscopes; Scenario 3, replacing all reusable with single-use/disposable anaesthetic equipment; Scenario 4, from Scenario 1, replacing only reusable with single-use face masks; and Scenario 5, from Scenario 1, replacing only reusable with single-use direct laryngoscope blades.				**Perspective** For perspective, we compare our data with car transport CO2 emissions. The average Australian and UK cars have CO2 emissions of 200 and 136 g CO2 km-1 and yearly distances travelled of 13 800 and 12 640 km respectively. Converting from single-use to reusable anaesthetic equipment for all Australian hospitals would approximate yearly to adding 25 cars to Australian roads, whereas if all UK hospitals had single-use anaesthetic equipment and converted to reusables this would be the equivalent of taking >1000 cars off UK roads. **Conclusion** Reprocessing reusable vs single-use anaesthetic equipment clearly saved money, which if extrapolated elsewhere in Australia could be difficult to ignore. Our methods could be applied to processing anaesthetic equipment elsewhere to enable informed financial and environmental assessments.	

e ISBN 978-967-19299-7-1