The Case for a Pacemaker and ICDs re-use Programme in Africa

Mahmoud U. Sani

Bayero University Kano &

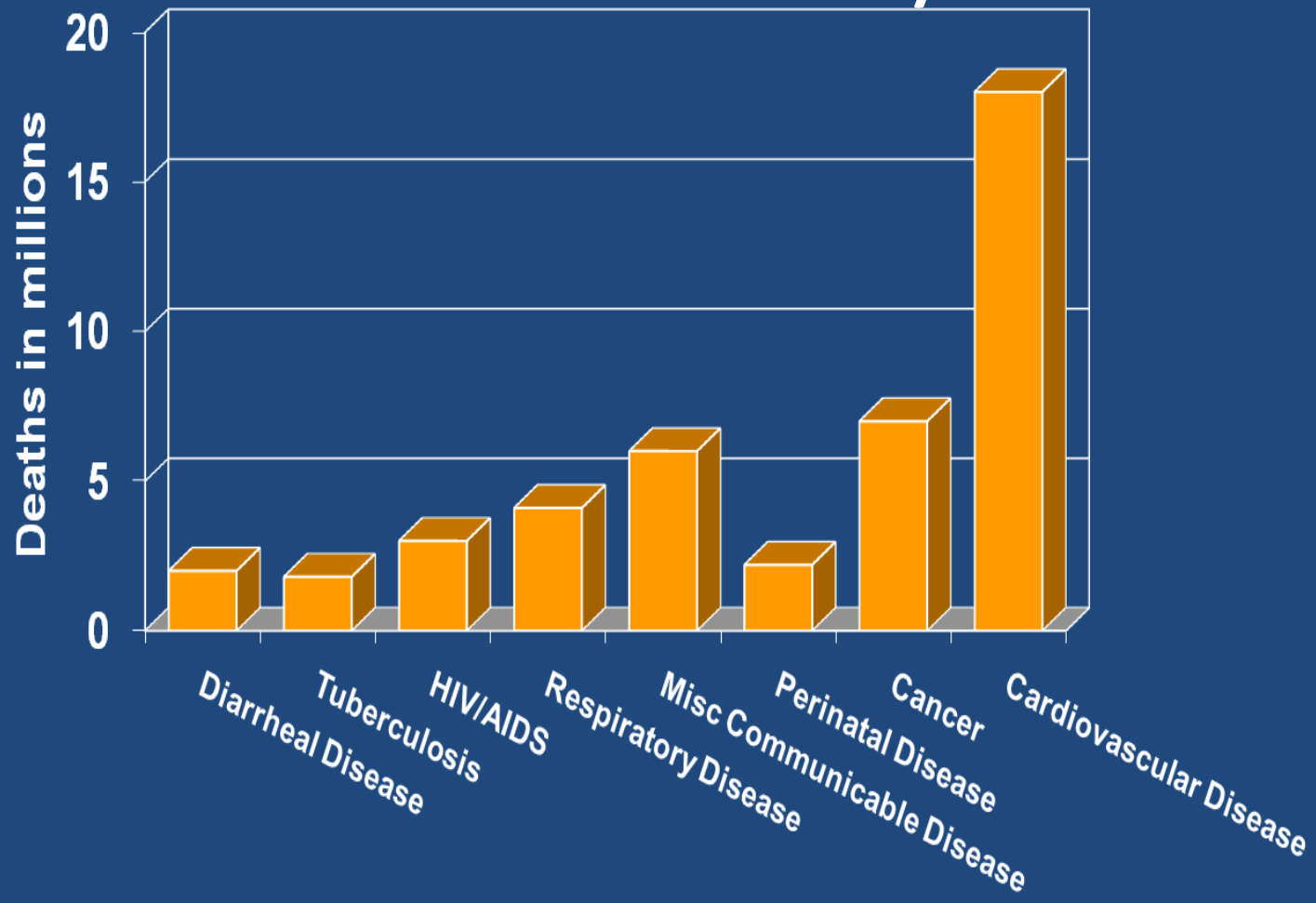
Aminu Kano Teaching Hospital,

Kano, Nigeria.

I.	II.	III.	IV.
I have received (a) research grant(s) / in kind support	I have been a speaker or participant in accredited CME/CPD ...	I have been a consultant / strategic advisor etc. ...	I am a holder of (a) patent / shares / stocks or ownership...
A	**A**	**A**	**A**
... from current sponsor(s)	... from current sponsor(s)	... for current sponsor(s)	... related to presentation
YES: ☐ NO: X	YES: ☐ NO: X	YES: ☐ NO: X	YES: ☐ NO: X
B	**B**	**B**	**B**
... from any institution	... from any institution	... for any institution	... not related to presentation
YES: X NO: ☐	YES: X NO: ☐	YES: X NO: ☐	YES: ☐ NO: X

SCORE: 1234

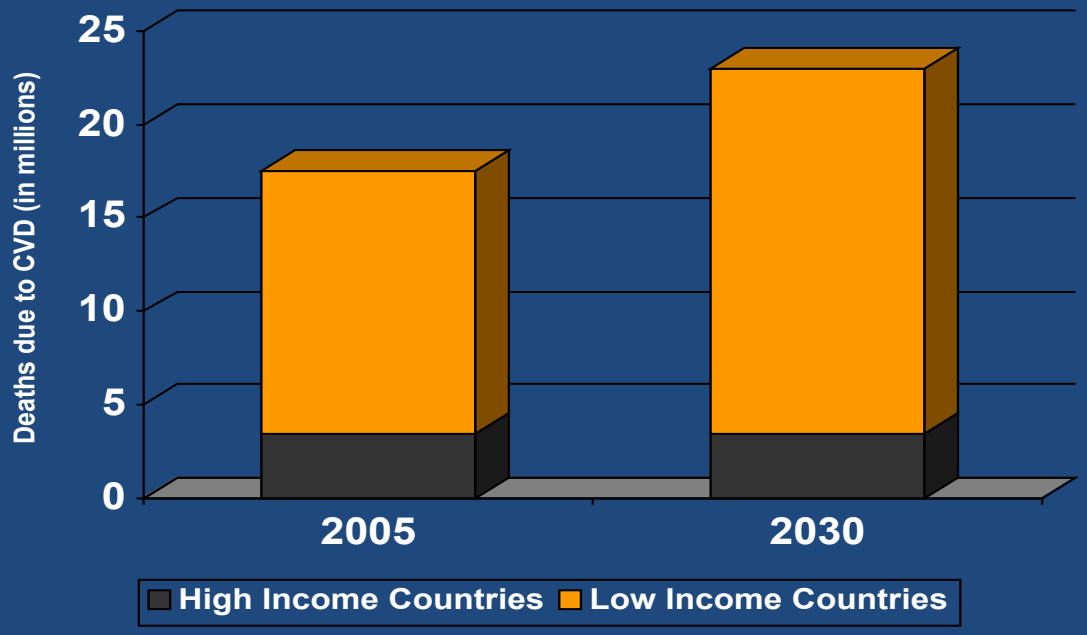
Global Cardiovascular Disease Mortality



Mendis S. *J Hypertension.* 25, 1578-1582

Cardiovascular Disease Burden

- Overwhelming majority of deaths due to CVD occur in low and middle income countries
- About 1-2 m die each year due to lack of access to Pacemaker or ICD globally (WHO)



Joshi R J Am Coll Cardiol. 2008 Dec 2;52(23):1817-25.

Cardiovascular Topics

Mortality from cardiovascular diseases in sub-Saharan Africa, 1990–2013: a systematic analysis of data from the Global Burden of Disease Study 2013

George A Mensah, Gregory A Roth, Uchechukwu KA Sampson, Andrew E Moran, Valery L Feigin, Mohammed H Forouzanfar, Mohsen Naghavi, Christopher JL Murray, for the GBD 2013 Mortality and Causes of Death collaborators

CV Cause	No. deaths 1990	No. deaths 2013	Death rate (per 100 000) 1990	Death rate (per 100 000) 2013	% change in death rate
IHD	138308	258939	91	93	2
Hypertensive HD	37525	86035	27	33	22
Cardiomyopathy	28917	53742	13	15	14
Rheumatic HD	23625	25239	10	7	-37
TOTAL	529880	958713	328	330	1

In 2013, Cardiovascular disease caused 11% of all deaths

Age-adjusted mortality rate unchanged from 1990 to 2013

~250 000 people in SSA may have SCD/year

CVJAFRICA CARDIOVASCULAR JOURNAL OF AFRICA • Volume 25, No 4, July/August 2014 151

Sudden cardiac death in Africa

Ashley Chin

Poor Healthcare systems

Lack of EMS services/defibrillation

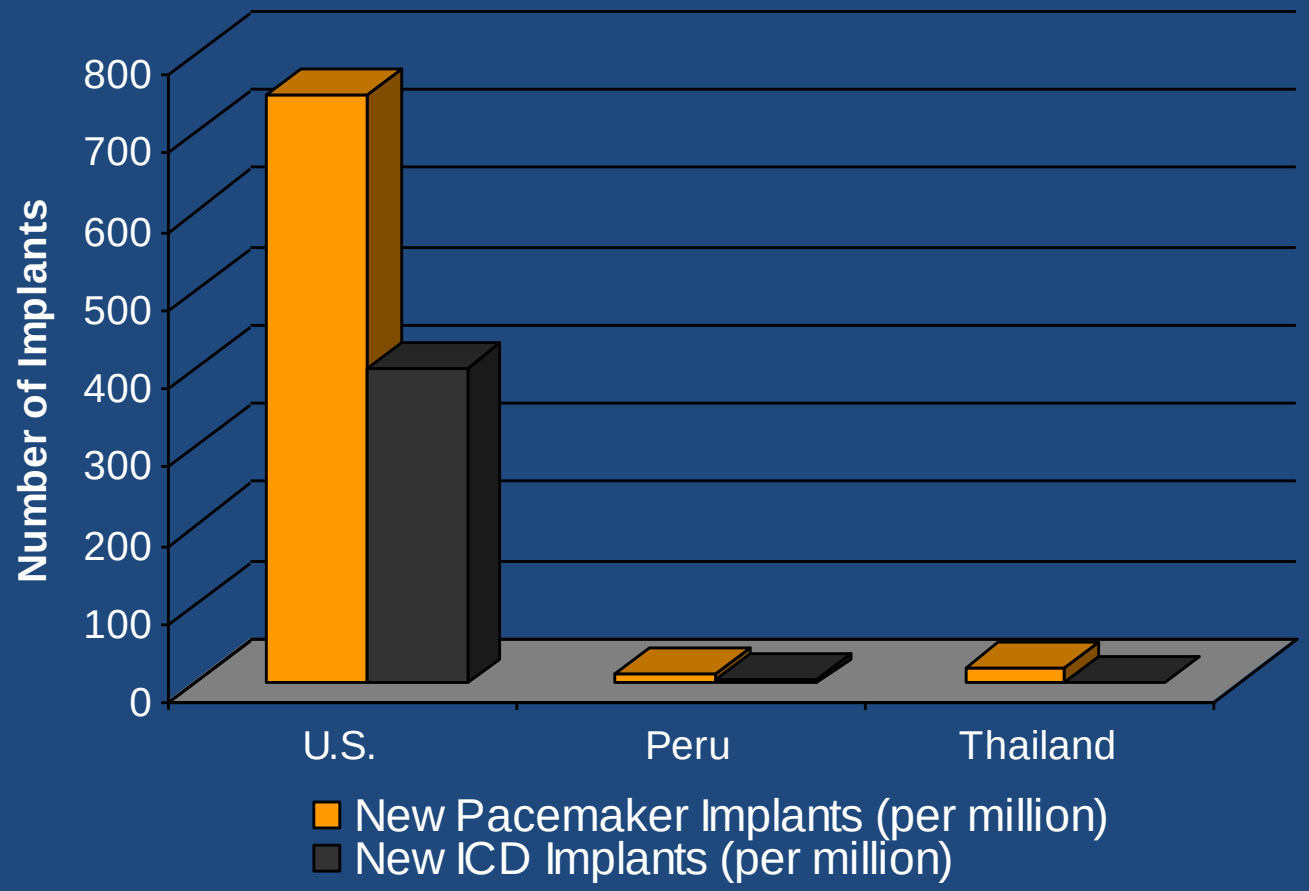
Lack of skilled doctors to make the diagnosis

Lack of autopsy data

Limited specialised investigations to confirm the diagnosis (echocardiography, MRI, EP testing, genetic testing)

Limited treatment options (Pacemakers, ICDs, drugs)

Access to pacemakers/ICDs is highly skewed



Mond HG. *PACE* 2008 Sep;31(9):1202-12.

Pacemaker Implants - Sub Saharan Africa

- No Complete Data
- South Africa 39 implants/million (1998 Survey)
- Pacemaker implantation rate is generally <10/ million
- Limited centers that can implant devices especially ICDs

Barriers for Pacemaker/ICDs Implantation

- Clinical expertise – Not widely available
- Availability of x-ray equipment with fluoroscopy and aseptic conditions
- **Availability/affordability of the pacemakers/ICDs**

Affordability of Pacemakers and ICDs

- Pacemaker generator - US$2 500–3 000 and leads cost US$800–1 000
- ICD generator costs US$20 000–40 000 and leads cost over US$10 000.

Baman TS, Kirkpatrick JN, Eagle KA, et al. Heart Rhythm 2010; 7: 1623–1627.

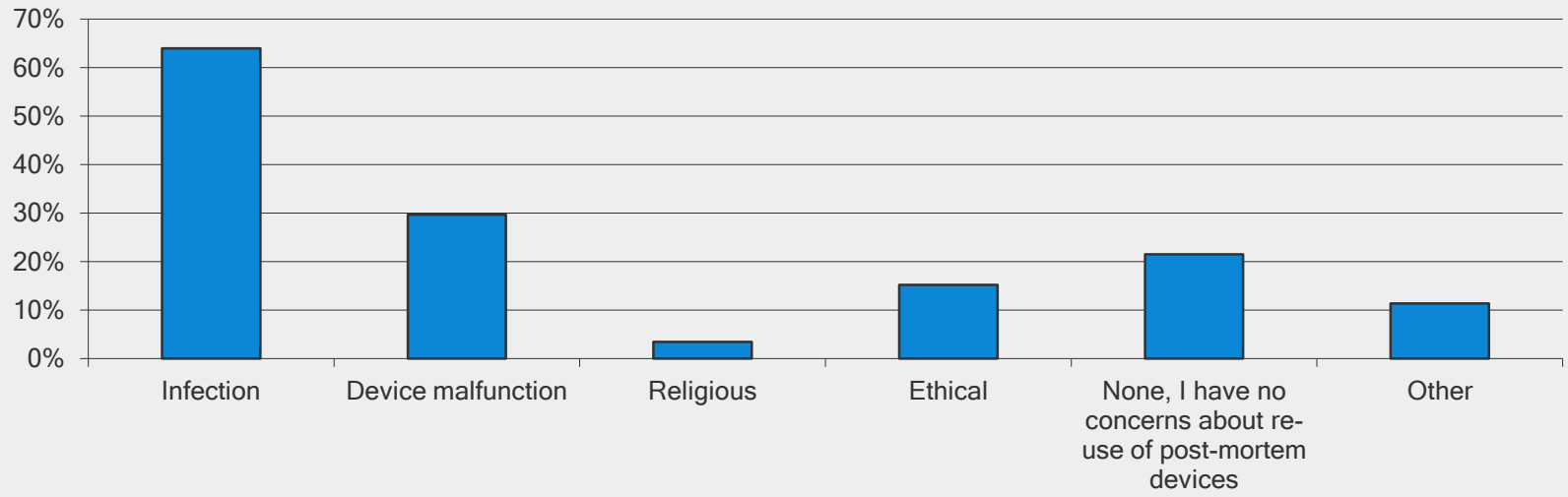
The PASCAR Task Force for Pacemakers and ICDs Re - Use

seeks to address this barrier of cost through collaboration with stakeholders and NGOs by seeking of donations of used pacemakers for re-use in the Sub Saharan African countries

Are Pacemakers/ICDs Safe for Reuse?

Heart Rhythm Society members Concerns on Pacemaker & ICD re-use

What are your greatest concerns regarding the re-utilization of post-mortem pacemakers or ICDs? Please mark all that apply:



Crowford TC et al…..abstract at HRS congress

Safety of Pacemaker Reuse

A Meta-Analysis With Implications for Underserved Nations

Timir S. Baman, MD; Pascal Meier, MD; Joshua Romero, BA; Lindsey Gakenheimer; James N. Kirkpatrick, MD; Patricia Sovitch, NP; Hakan Oral, MD; Kim A. Eagle, MD

- 18 clinical trials
- 2270 patients
- 1^0 endpoint – pacemaker infection or device erosion
- 2^0 endpoint – device malfunction – defect in the structural or electrical integrity of the pulse generator

Safety of Pacemaker Reuse

A Meta-Analysis With Implications for Underserved Nations

Timir S. Baman, MD; Pascal Meier, MD; Joshua Romero, BA; Lindsey Gakenheimer; James N. Kirkpatrick, MD; Patricia Sovitch, NP; Hakan Oral, MD; Kim A. Eagle, MD

- Infection rates – 1.97%; **no difference between re-used & new devices** (OR 1.31 (0.50 – 3.41), P 0.58)
- Device malfunction rates 0.68% (0.27 – 1.28%).
- Risk of malfunction higher in the reuse group (OR 5.8 (1.93 – 17.47), p = 0.002)

Safety of Pacemaker Reuse

A Meta-Analysis With Implications for Underserved Nations

Timir S. Baman, MD; Pascal Meier, MD; Joshua Romero, BA; Lindsey Gakenheimer; James N. Kirkpatrick, MD; Patricia Sovitch, NP; Hakan Oral, MD; Kim A. Eagle, MD

Conclusion……. Pacemaker reuse has an overall low rate of infection and device malfunction and may be a safe and efficacious means of treating patients in underserved nations

Performance of re-used pacemakers and implantable cardioverter defibrillators compared with new devices at Groote Schuur Hospital in Cape Town, South Africa

Zimasa V Jama, Ashley Chin, Motasim Badri, Bongani M Mayosi

Abstract

Objectives: Little is known about the performance of re-used pacemakers and implantable cardioverter defibrillators (ICDs) in Africa. We sought 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.

Methods: This was a retrospective case comparison study of the performance of re-used pacemakers and ICDs in comparison with new devices implanted at Groote Schuur Hospital over a 10-year period. The outcomes were incidence of device infection, device malfunction, early battery depletion, and device removal due to infection, malfunction, or early battery depletion.

Results: Data for 126 devices implanted in 126 patients between 2003 and 2013 were analysed, of which 102 (81%) were pacemakers (51 re-used and 51 new) and 24 (19%) were ICDs (12 re-used and 12 new). 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. 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. 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. In both the pacemaker and ICD groups, there were no procedure-non-related infections documented for the respective follow-up periods.

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 with bradyarrhythmias and tachyarrthythmias.

Submitted 17/2/15, accepted 12/4/15
Cardiovasc J Afr 2015; **26**: 181–187 www.cvja.co.za

DOI: 10.5830/CVJA-2015-048

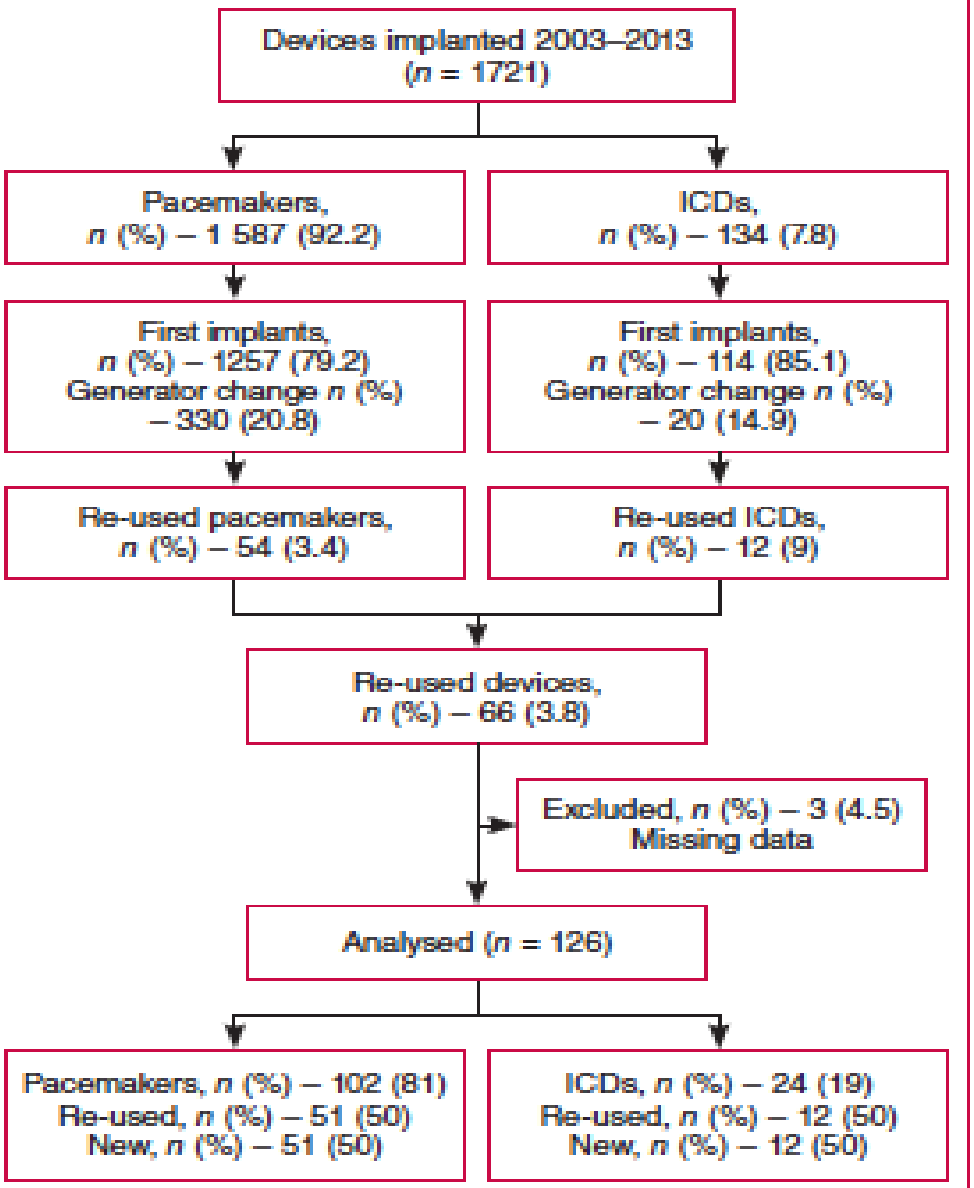
Pacemaker implantation is an effective tool to treat bradyarrhythmias, and implantable cardioverter defibrillators (ICD) reduce mortality in patients at high risk of sudden death.[1] The challenge with pacemakers and ICDs is the high cost of these devices. The pacemaker generator, in its most basic form, costs US$2 500–3 000 and leads cost US$800–1 000.[2] An ICD generator costs US$20 000–40 000 and leads cost over US$10 000.[2] The high cost of pacemakers and ICDs has resulted in limited access of deserving patients in poor countries to these life-saving interventions.[3-5]

Mond *et al.*[6] demonstrated an increase in pacemaker and ICD implantation rates in all countries that participated in the World Survey of Cardiac Pacing in 2009. Despite this increase in implantation rates, there was a huge difference in the number of implants between the developed and underprivileged countries, with more implants in the developed world.[6] This disparity was explained mainly by the high cost of these devices.[6]

Re-use of cardiac pacemakers has been practiced since the early 1970s.[7] The major concern with this practice is the risk of device infection and malfunction.[8-11] Device infection is the most feared complication of cardiac device re-use and is thought to be associated with case fatality rates between 2.6 and 18%.[12-14] However, some studies from America, Europe and Asia that examined the performance of re-used pacemakers and ICDs have shown no significant difference in infection or mortality rates between patients who received re-used and new devices.[14-22]

The aim of this study was to investigate the performance of re-used pacemakers and ICDs at Groote Schuur Hospital, Cape Town, South Africa.

Methods



- Re-used devices (cases) matched by age, gender and date of implantation on a 1:1 basis to patients with new devices (controls).
- Date of implantation (same month for pacemaker, same year for ICDs)
- Median follow up
  - 15.1 months for reuse
  - 55.8 months for new

Outcomes

Pace maker Group

There was no

- device infections
- pacemaker malfunction
- early battery depletion
- explantation due to infection, malfunction and/or early battery depletion

ICD Group

There was no

- device infections
- procedure-non-related infections during follow up

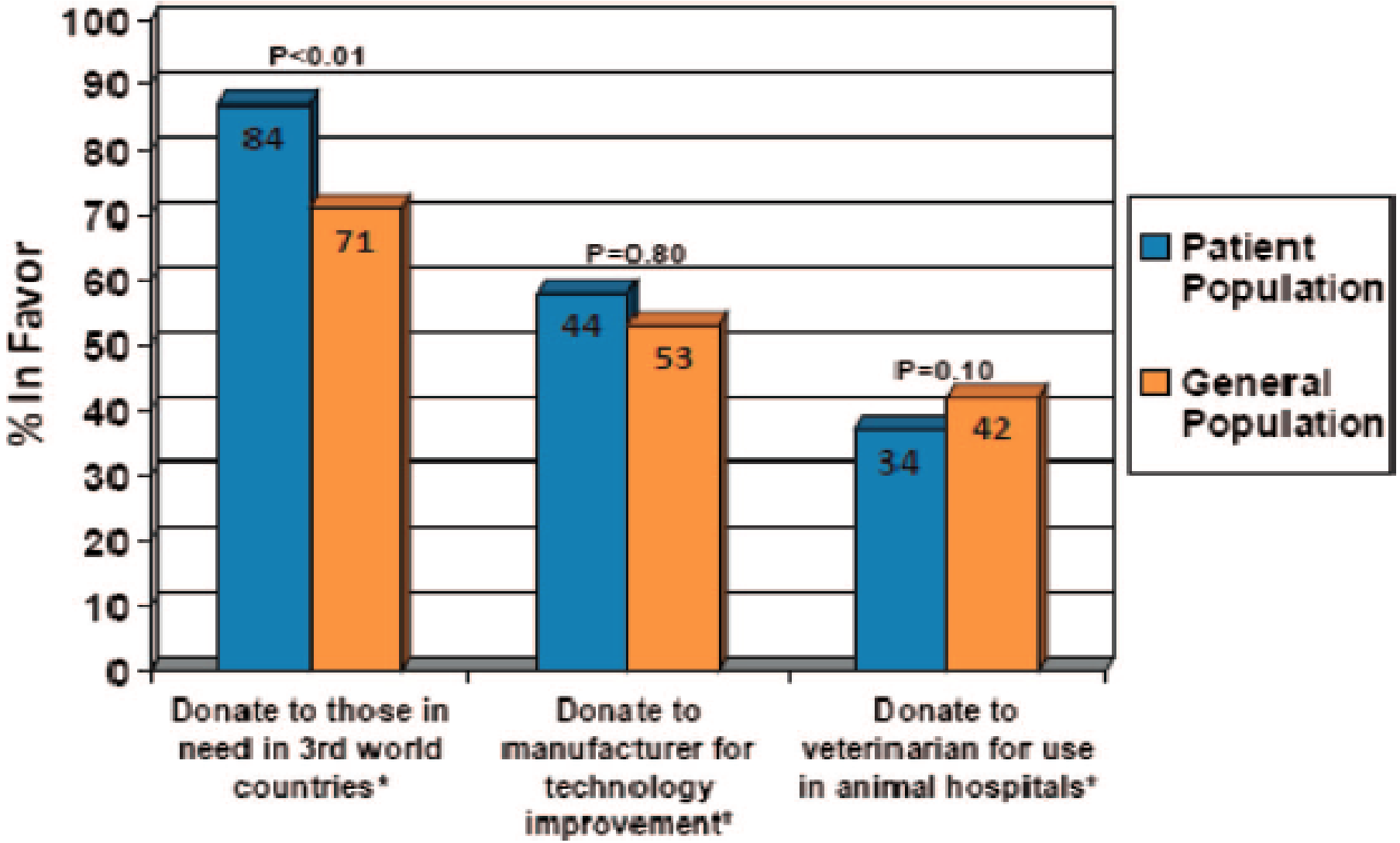


Figure 2. Views of general population and patient population with pacemakers and implantable defibrillators relative to device reuse.

The of Need for an RCT on Pacemaker and ICD Re-use

Clinical Study Protocol

Project My Heart Your Heart: Prospective Evaluation of the Safety and Efficacy of Cardiac Pacemaker Reuse in Low to Middle Income Countries

March 24, 2015, 2015
Version: A

A Joint Collaborative between The University of Michigan Cardiovascular Center, Pace4Life, World Medical Relief, and Pan-African Society of Cardiology, and Physicians to Determine the Safety and Efficacy of Cardiac Device Reutilization in Low and Middle Income Countries

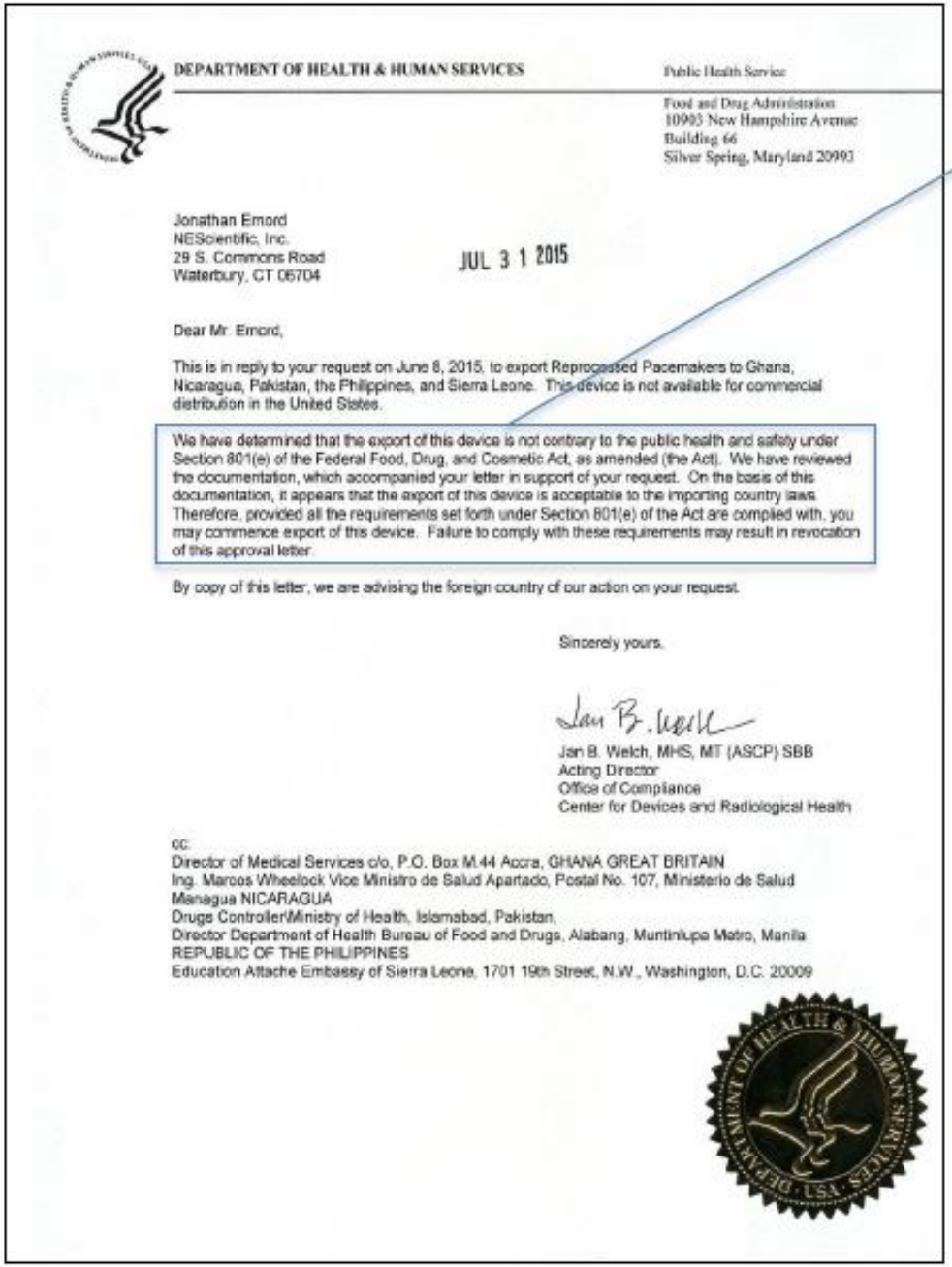
Clinical Study Protocol

Project My Heart Your Heart: Prospective Evaluation of the Safety and Efficacy of Cardiac Pacemaker Reuse in Low to Middle Income Countries

March 24, 2015, 2015

A Joint Collaborative between The University of Michigan Cardiovascular Center, Pace4Life, World Medical Relief, and Pan-African Society of Cardiology, and Physicians to Determine the Safety and Efficacy of Cardiac Device Reutilization in Low and Middle Income Countries

A Joint Collaborative between The University of Michigan Cardiovascular Center, Pace4Life, World Medical Relief, and Pan-African Society of Cardiology, and Physicians to Determine the Safety and Efficacy of Cardiac Device Reutilization in Low and Middle Income Countries



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, Maryland 20993

Jonathan Emord
NEScientific, Inc.
29 S. Commons Road
Waterbury, CT 06704

JUL 3 1 2015

Dear Mr. Emord,

This is in reply to your request on June 8, 2015, to export Reprocessed Pacemakers to Ghana, Nicaragua, Pakistan, the Philippines, and Sierra Leone. This device is not available for commercial distribution in the United States.

We have determined that the export of this device is not contrary to the public health and safety under Section 801(e) of the Federal Food, Drug, and Cosmetic Act, as amended (the Act). We have reviewed the documentation, which accompanied your letter in support of your request. On the basis of this documentation, it appears that the export of this device is acceptable to the importing country laws. Therefore, provided all the requirements set forth under Section 801(e) of the Act are complied with, you may commence export of this device. Failure to comply with these requirements may result in revocation of this approval letter.

By copy of this letter, we are advising the foreign country of our action on your request.

Sincerely yours,

Jan B. Welch

Jan B. Welch, MHS, MT (ASCP) SBB
Acting Director
Office of Compliance
Center for Devices and Radiological Health

cc:
Director of Medical Services c/o, P.O. Box M.44 Accra, GHANA GREAT BRITAIN
Ing. Marcos Wheelock Vice Ministro de Salud Apartado, Postal No. 107, Ministerio de Salud
Managua NICARAGUA
Drugs Controller/Ministry of Health, Islamabad, Pakistan,
Director Department of Health Bureau of Food and Drugs, Alabang, Muntinlupa Metro, Manila
REPUBLIC OF THE PHILIPPINES
Education Attache Embassy of Sierra Leone, 1701 19th Street, N.W., Washington, D.C. 20009

FDA Approval of Export Permit for Pacemaker re-use

- ***Ghana***
- ***Sierra Leone***
- ***Philippines***
- ***Nicaragua***
- ***Pakistan***

Ethics of Pacemaker Re-use

The ethical and legal issues involve

- retrieval of a still usable pacemaker/ICD from a deceased patient
- selection of the patient to receive such a pacemaker or ICD
- consent of the next of kin or the living will of the patient.
- Informed consent of the recipient
- Recipient country's approval for pacemaker reuse

developing world bioethics

Developing World Bioethics ISSN 1471-8731 (print); 1471-8847 (online)
Volume 15 Number 3 2015 pp 125–133

doi:10.1111/dewb.12047

REUSE OF PACEMAKERS IN GHANA AND NIGERIA: MEDICAL, LEGAL, CULTURAL AND ETHICAL PERSPECTIVES

ALOYSIUS OCHASI AND PETER CLARK

Keywords
Bioethics,
developing world,
distributive justice,
health care,
informed consent,
education,
sub-Saharan Africa

ABSTRACT

According to the World Health Organization (WHO) cardiovascular disease (CVD) is the leading cause of death globally. Over 80% of CVD deaths take place in low- and middle-income countries (LMICs). It is estimated that 1 million to 2 million people worldwide die each year due to lack of access to an implantable cardiac defibrillator (ICD) or a pacemaker. Despite the medical, legal, cultural and ethical controversies surrounding the pacemaker reutilization, studies done so far on the reuse of postmortem pacemakers show it to be safe and effective with an infection rate of 1.97% and device malfunction rate of 0.68%. Pacemaker reutilization can be effectively and safely done and does not pose significant additional risk to the recipient. Heart patients with reused pacemakers have an improved quality of life compared to those without pacemakers. The thesis of this paper is that pacemaker reutilization is a life-saving initiative in LMICs of Nigeria and Ghana. It is cost effective; consistent with the principles of beneficence, nonmaleficence, and justice with a commitment to stewardship of resources and the Common Good. Used pacemakers with adequate battery life can be properly sterilized for use by patients in LMICs who cannot afford the cost of a new pacemaker.

- It is cost effective.
- Consistent with the principles of justice and beneficence
- Consistent with a commitment to stewardship of resources and the Common Good
- Used pacemakers with adequate battery life should be properly sterilized for use by the patients in LMICs who cannot afford the cost of a new pacemaker.

Conclusion

- The French philosopher Voltaire wrote that "***the best is the enemy of the good***," a saying often invoked in the context of resource-limited health care.
- In our case, an over-emphasis on offering the best therapy- a new pacemaker- may impede the substantial benefits that can be gained from an otherwise effective treatment, particularly when the current alternative for the target population is no treatment at all.