

Pacemaker Reuse for Patients in Resource Poor Countries: Is Something Always Better Than Nothing?

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Abstract

Cardiovascular disease is the most common cause of death across the globe. Large disparities in access to cardiovascular care exist in the world. An estimated one million people die each year due to lack of access to life saving pacemaker therapy. We discuss the concept of justice in health and health care as it relates to the use of refurbished pacemakers in patients in low- and middle- income countries, where financial circumstances severely limit access to brand new devices. Egalitarianism, utilitarianism, and justice as fairness are examined, as they relate to provision of re-processed pacemakers. This practice, since it holds promise to improve human functioning and capabilities, can be morally justified with some conditions: transparency, further research in its safety and efficacy, and its impact on other needs and priorities in those countries. (Prog Cardiovasc Dis 2012;55:300-306)
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“Technical excellence and political commitment have no value unless they have an ethically sound purpose” Lee Jong-Wook, Director General of the WHO (2003–2006)

Ask most people what health problems are found in low- and middle- income countries (LMIC) and, chances are, you will hear about HIV, malaria, and diarrhea. Some might mention starvation, impure water, or famine, violence and injury, or Ebola virus. The leading causes of death worldwide, however, are not these but non-communicable diseases (NCDs) — cardiovascular and respiratory disease, diabetes and cancer. Together they killed 36 million people in 2008. Almost 80% of those

deaths occurred in LMIC.¹ Of these, cardiovascular disease (CVD) is the most common, contributing to 17 million deaths annually. It is estimated that, even in Africa, where there are still more deaths from infectious diseases than NCDs, the latter diseases will kill more people than communicable diseases by 2030.¹ This epidemic has become so dire that in September 2011, the United Nations General Assembly held a high-level meeting about the global health crisis of NCDs. The only other UN General Assembly meeting focused on a global health crisis, held in 2000, focused on HIV/AIDS.² Not only are NCDs more common in LMIC than in well-off countries, they are also more likely to cause premature death. Twenty-nine percent of NCD deaths in LMIC occur under the age of 60, affecting people in their most productive years, compared to 13% in high-income countries.¹

The United States and other advanced economies have generally managed the challenge of the increasing NCD

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Abbreviations and Acronyms**CVD** = cardiovascular disease**GDP** = gross domestic product**HIV/AIDS** = human immunodeficiency virus/acquired immune deficiency syndrome**ICD** = implantable cardioverter defibrillator**LMIC** = low- and middle-income countries**NCD** = non-communicable diseases**WHO** = World Health Organization

burden with high cost therapies. NCDs garner millions in research and development, which produce a panoply of effective – but expensive – drugs and devices. Nowhere is this more evident than in the field of electrophysiology. Implantable devices prolong life and improve its quality for many patients with brady- and tachyarrhythmias in the developed world. As with many higher-cost therapies, however, access to pacemakers is highly skewed across the globe.

A 2009 survey of pacemaker implantation performed in 61 countries showed widely disparate rates of device implantation; for example 782 implants per million of population in France compared to 4 implants per million in Pakistan.³ It has been estimated that more than one million people die each year due to lack of pacemaker therapy.⁴ Besides premature mortality, lack of access to pacemaker therapy greatly impacts an individual's ability to function due to poor exercise tolerance, persistent fatigue, and recurrent syncope,^{5–9} symptoms that can debilitate those living in demanding environments in the developing world. The global impact due to lost economic opportunity from untreated bradyarrhythmia adds to the rising disability burden in many countries where patients in their productive years do not have access to this costly therapy. In other words, “those most in need of care have least access.”¹⁰

How should profound disparities between countries be addressed? Unlike the need to address communicable diseases, the prevention and treatment of non-communicable diseases, which “cannot spread” across national borders, have not been prioritized by donors. Only 3% of global development assistance for health went towards combating NCDs in 2007.¹¹ Some would argue that the most cost-effective approach to this growing epidemic involves public health measures to *prevent* cardiovascular disease. However, humanitarian considerations justify treatment of those already affected. Margaret Chan, Director-General of the World Health Organization (WHO), eloquently stated the need for both prevention and care: “We need population-wide preventive measures for NCDs, developed with other sectors, but we also need to help individual people. We need to detect early, treat, manage complications and often provide prolonged or even life-long care.”¹⁰

Appreciation of the unmet need for pacemakers in LMIC has led to the establishment of reuse programs for

such devices. Although pacemaker reuse was once standard of care in some countries such as Sweden and Canada, their reuse is not approved in the United States or the European Union.^{12,13} Pacemakers have been explanted post-mortem, interrogated for adequate battery life, and sterilized with the intent to send them to implanting centers in resource poor countries.^{14,15} A recent meta-analysis has found the reuse of pacemaker associated with infection rates similar to unused devices, but with a slightly increased risk of mechanical malfunction. Reused devices malfunctioned at a rate of 0.68% (compared to new, OR 5.80 [1.93 to 17.47], $P=0.002$); none of these malfunctions led to death or severe harm.¹⁵

In the United States, attention to medical devices tends to focus on quality and safety, not cost, with predictable consequences for the price, and therefore access to these products, as well as consequences for medical waste. Policies to enable safe reuse include requiring that medical device reprocessors comply with the same requirements that apply to original equipment manufacturers, including a pre-market 510(k) clearance.¹⁶ When done properly, the reuse of medical devices is legal and generally accepted by healthcare professionals in the United States.¹³ It is estimated that at least 20–30% of U.S. hospitals reprocess single use devices.^{13,17,18} While preliminary data suggest safety and efficacy of pacemaker reuse for devices that have adequate remaining battery life, to date implantable pacemakers are not approved for reuse in the U.S. or European Union. Many other devices, such as electrophysiology catheters, endoscopes and hemodialyzers, are approved for reuse.

Does donating a device not approved for use in the donor country create a double standard too great to be morally acceptable?^{19,20} Or, when the likely alternative is no device at all, is something always better than nothing? Besides the moral requirement of transparency – that both patients and professionals using such devices know that they are used, and are aware of the risks and uncertainties – the refurbishment and reuse of medical devices in LMICs require attention to distributive justice. In this paper we examine how device reuse might be judged using egalitarianism, utilitarianism and justice as fairness.

Justice in health and healthcare

Why do we need to consider justice when making decisions about health services and resources? A lack of healthcare, like a lack of food, will cause pain and suffering; food stamp programs attest to a social concern that no one should lack that primary good. Healthcare, like education, can be considered a public and private good — a public good because of society's interest in healthy, educated citizens who can participate fully as citizens, and

a private good because of the effect of health and learning on well-being and the ability to pursue life plans. Healthcare, like education and food, affects equality of opportunities.²¹ Given the special moral importance of health, meeting health needs at some level, including “preventive, curative, rehabilitative, compensatory personal medical services (and devices)” is required for a just society.²¹

Walzer notes “there cannot be a just society, until there is a society”.²² Given the current connectedness of people and communities worldwide, as evidenced in communication technology and transportation systems, there is, at least at some level, “a” global society, necessitating greater attention to the just distribution of social goods, including health and healthcare between, not only within, national borders.

Egalitarianism

Egalitarianism rests on the claim that all human persons are equal in fundamental worth and moral status.²³ Different conceptions of egalitarianism support equality of a variety of sorts, for instance equal resources, equal opportunity, equal capability, or equal freedom, to name a few. WHO Medical Device Regulations emphasize that the quality of devices should be equal: “There should be no double standard in quality. If an item is unacceptable in the donor country it is also unacceptable as a donation.”²⁰ The WHO regulations responded to reports of bad experiences with used equipment. Sometimes, used or refurbished medical devices were traded to developing countries through opportunistic third parties with no technical expertise. Sometimes no technical support or spare parts were available after purchase.²⁰ Since refurbished pacemakers are not approved for use in the United States due to fear of infection and malfunction,²⁴ they would be considered “unacceptable” as a donation by the WHO. The WHO guidelines appeal to egalitarian principles based on equal quality, while the donation and use of refurbished devices aim to improve equality of access to those devices and equality of health outcomes for people in LMICs. Anderson argues for two fundamental aims of egalitarianism, eliminating oppression and creating a community in which people stand in relations of equality to others. The latter entitles people to the capabilities needed to function as equal citizens, not just exercising political rights, but participating in the economy. “To function as a human being, one needs adequate nutrition...one does not need the quantity or quality of food intake of a gourmet. Democratic equality therefore requires that everyone has effective access to adequate nutrition...”²⁵ Like adequate nutrition, equality of access to some basic level of health care that can affect health outcomes would be justified by most conceptions of egalitarianism. Egalitarianism based on functioning as an equal citizen, or other conceptions that

emphasize equality of opportunity, would not necessarily require that health services always be of equal quality. Equal quality would only be demanded when needed to enable equal functioning as a citizen or equality of opportunity.

Egalitarian principles that emphasize equality of resource quality – like the WHO guidelines for donations of medical devices – would argue against this practice. Anderson’s democratic egalitarianism would permit it.²⁵

Utilitarianism

Utilitarian theories of distributive justice aim to increase overall utility (well-being), the greatest good for the greatest number. For instance, the UN General Assembly stresses the priority of public health measures, as these will have “the greatest reduction in NCD” with the most “cost-effective investment”.²⁶

Assuming the need for electrophysiology devices is greater than the supply, utilitarian principles would certainly support the reuse of pacemakers, since that would increase the supply and therefore decrease unmet need. Food banks collect and distribute food, some of which may no longer be ‘readily marketable,’ to those who could otherwise not afford adequate nutrition. Food banks appear favorable as seen through a utilitarian lens, in part because the well-being foregone by the donors is much less than the increased well-being of the recipients. Policies work to minimize the risk of negative effects due to food poisoning so the ratio of those benefiting from the donation is much greater than any harm potentially resulting. For instance, in the United States, the Bill Emerson Good Samaritan Food Donation Act (1996) was enacted to protect vendors from liability as long as donated food meets liability and labeling standards.²⁷ Similar conditions must be met to claim that reuse of pacemakers improves overall well-being. First, there needs to be evidence that pacemaker refurbishment and reuse provide benefit (and avoid harm) to individuals and communities receiving them. This can and should include an assessment of benefits other than health measures; for instance preventing an adult’s death from dysrhythmia could affect the economic well-being of a family, village or country. Second, aggregate net benefit to recipients should exceed harm to donors. When Americans are made aware of device donation programs, most people are willing to donate devices after death of their loved ones;²⁸ no harm to the deceased occurs. Finally, the resources needed to enable safe and effective reuse (refurbishment, supplies, workforce, facilities) need to be described, and, if they could be used to affect well-being in other ways (e.g., sanitation, vaccination, food) the impact on well-being from use of these resources for pacemaker reuse needs to be compared to the impact on well-being of alternative uses.

Given its emphasis on aggregate well-being, utilitarianism has been criticized for inattention to equity and disparities in health. While utilitarian theories generally do not consider the distribution of benefit, based on the understanding that everyone's "good" counts for the same amount,²⁹ some methods for incorporating equity and distribution (e.g., the Gini index) can be and have been used in utility-based approaches to resource allocation, like health cost-effectiveness analysis.³⁰ With or without equity adjustments, assuming the number of new pacemakers globally is relatively fixed due to expense, utilitarianism would allocate new devices to those who will incur the maximum amount of good from the longer battery life of new devices compared to refurbished ones; reprocessed pacemakers would be preferentially allocated to patients with the shortest life expectancy. Currently, pacemaker distribution is determined more by a person's birthplace than by life expectancy or age; many new devices are implanted in elderly patients in well-off countries.

Since public health measures to combat NCDs are almost always the most efficient in improving aggregate health, how would utilitarianism prioritize those already afflicted with disease, or those who take all of the proper preventative precautions (risk reduction) but still become ill? How does one balance using resources to provide a very small benefit to large numbers of people against providing a very large benefit to few people?³¹ Again, the distribution of benefit (to those who are worse off, health-wise) and humanitarian considerations (caring for the sick) need to be considered, and would not typically be supported by a utilitarian analysis.¹⁰

In sum, utilitarian conceptions of justice could support refurbishment and reuse, so long as resources needed for such efforts were not better used elsewhere. Utilitarian conceptions would allocate new (vs. refurbished) devices on the basis of maximum benefit rather than geography. However, in allocating resources, utilitarian conceptions would maximize well-being achieved even if the well-being was inequitably distributed, for example providing small benefits to large number of people, or disproportionately benefitting those who are relatively healthy or better off.

Justice as fairness

In *A Theory of Justice* and *Political Liberalism* John Rawls described three core elements of justice and their order of priority. First, each person has an equal claim to a fully adequate scheme of equal basic rights and liberties. Second, "Social and economic inequalities are to be arranged so that they are both (a) to the greatest benefit of the least advantaged [the Difference principle] and (b) attached to offices and positions open to all under conditions of fair equality of opportunity".³² Fair equality of opportunity has lexical priority over the

Difference principle. Rawls stipulated in his theory, however, that people are fully functional over a normal lifespan, that is, that they suffer no disability, disease or premature death. Norman Daniels, among others, has nonetheless fruitfully drawn insights for justice in health and healthcare from Rawls' theory.³³ As Daniels notes, "The central moral importance, for purposes of justice, of preventing and treating disease and disability with effective healthcare services ... derives from the way in which protecting normal functioning contributes to protecting opportunity.... By maintaining normal functioning, healthcare protects an individual's fair share of the normal range of opportunities (or plans of life) reasonable people would choose in a given society."³³ Hence, like Anderson's democratic egalitarianism, fair equality of opportunity would support providing people with adequate nutrition to pursue their life plans, and with pacemakers if they prevent premature death and preserve normal functioning.

Whether the Difference Principle would support refurbishment and reuse of pacemakers depends on whether this particular inequality (distributing new vs. used pacemakers on the basis of economic conditions rather than need) benefits people who are least well off. In India, where the Gross Domestic Product (GDP) per capita in 2011 was less than 3700 USD, the cost of a new device without leads or physician fees was between 2200 and 6600 USD.¹⁴ The WHO *World Health Report 2010* states that each year 100 million people are pushed into poverty because they had to pay directly for health services.²⁶ If providing used pacemakers effectively improves physical functioning and well-being at the individual patient level, and prevents impoverishment among the poor from the purchase of new devices, it seems the Difference principle would tolerate the inequality as benefitting the least well off. Yet, as with utilitarian analysis, a critical examination of the benefits and harms of this practice for LMIC is needed, with particular attention to whether other limited resources – e.g., workforce – are diverted to enable acceptance of such donations, and whether those resources would be prioritized for other uses by recipient communities.³⁴

A different difference principle

We have established that inequalities in the quality of resources received by patients and populations with equivalent needs could be just according to many conceptions of justice. The different difference principle we propose considers the degree of inequality that is acceptable. Burdens, harms, and risks need to be balanced against benefit, and the uncertainty of potential harms must be considered. Donating contaminated or expired food that can make someone ill, even if "informed consent" is obtained from recipients desperate with

hunger, could cause diminished well-being and opportunity. Applying this principle to reuse of electrophysiological devices, the use of refurbished pacemakers appears to provide substantially more benefit than harm. The same might not hold true for high voltage devices, i.e. implantable cardioverter defibrillators (ICDs). Without assuring appropriate follow-up care with immediate access to skilled personnel to handle emergencies, the risk of frequent recurrent shocks could cause serious harm to a patient, leaving him or her worse off than before the implant. Similarly, for pacemakers, an excess of donated devices should be available at the institution where the implant occurs, so that if a device is found defective during the implantation procedure, the patient is still able to receive a device and will not have gone through a surgical procedure without a tangible benefit.

Among the groups studying pacemaker reuse, different battery life thresholds have been proposed to minimize possible harm to recipients due to increased replacement surgeries. Kantharia et al. chose a cut off of 3 years of battery life remaining as acceptable for re-implantation¹⁴ which allows about 50% of collected devices from funeral homes to be utilized. Project My Heart Your Heart has suggested $\geq 75\%$ of the initial battery life or at least 4 years of battery life remaining for an acceptable threshold, which allows about 20% of devices donated from funeral homes and crematories to be eligible for refurbishment.³⁵ There are obvious tradeoffs — the longer one requires for battery life from donated devices, the fewer devices are eligible for reallocation.

With many groups working towards bridging global disparities in healthcare by reusing medical devices, who decides what the acceptable criterion for a reused medical device is? Although it is important to have discussions of this nature within the scientific and donor communities, Daniels discusses the importance of community involvement to “broaden the deliberative process and to ensure that value questions are addressed, not submerged as merely technical issues about capacity in the existing system.”²¹ Donors may not share similar values or understand the local culture. Once evidence exists about a medical device’s safety and efficacy, judgments currently made by “outsiders,” decisions about the threshold of acceptable battery life should be made by physicians, community leaders, and other members of the community receiving the pacemakers. For pacemaker reuse, what quality is too poor to be acceptable? What if this means fewer pacemakers? How does the cost of a device – and who bears the cost – affect the decision? Although improving access to medical devices globally is important, a donation is never completely free, as the resources needed to use these devices are not available for other healthcare interventions. Recipient communities – not just individuals with the disease, given the impact on other health priorities – should deliberate about such decisions.

Studies have shown, and common sense would agree, that there is a strong correlation between stakeholder involvement and accountability.^{21,36} An unfair distribution of donated devices within resource poor settings (for example, selling of devices on the black market) would weigh strongly against an assessment that device donation benefits the least well off or contributes to equality of opportunity or equal functioning as citizens. It is possible that involving the community could mitigate inequitable distribution of donated devices.

The responsibility of the donating organization

What are the roles and responsibilities of the donor organizations refurbishing and distributing pacemakers? To legally export a used pacemaker not approved for use in the United States, special FDA permission must be obtained under a process akin to investigational device exemption. Responsible, just donation of used devices requires the evidence needed to assess risk and create procedures and guidelines establishing safe practices. A research initiative is under way to examine the safety and efficacy of refurbished devices. Such an effort by organizations wanting to donate used medical equipment internationally must be guided by a set of principles and protocols (See Table 1). For example, all devices must be checked against a recall list before donation, and if replacement of the device is recommended by the original manufacturer or appropriate regulatory body in the donor country *after* donation, arrangements and resources should be available to replace any such device. If this trial demonstrates the safety and efficacy of refurbished devices, further export permits will be required for a larger number of devices refurbished under a standardized

Table 1
Steps and key considerations regarding device reuse in LMIC.

1. Working relationship with recipient community
2. Site selection
 - a. Demonstrate need and technical competence
 - b. Properly trained physicians to handle implantation, complications, and follow-up
3. Organizational oversight to assess risk and set standards
4. Expanded clinical research to prove safety and efficacy
5. Sterilization protocols
6. Technical protocols
 - a. Set Screw Evaluation
 - b. Battery Life
7. Export certificate
 - a. Pre Investigational Device Exemption (pre-IDE)
 - b. United States “Export Certificate” Section 801(e)(2) grants permission for the export of unapproved medical devices which are not equivalent to devices cleared for marketing in the USA
8. Device Labeling
9. Recall procedures and device tracking
10. Continued technical support from donating organization

and validated protocol. Given the importance, for justice, of knowing the risks, benefits and burdens of reusing devices, there is a great need for both research and policy development regarding pacemaker reuse.

Besides evidence about safety, efficacy and the distribution of benefit favoring the least well off, donor organizations should meaningfully and respectfully partner with LMICs, recognizing that their organization's activities might not conform to local values. They should also encourage and foster informed, deliberative health and healthcare priority setting in recipient LMICs.

Conclusion

“Global justice is a hotly disputed area of philosophical work in part because it is so new.... The content of a theory of global justice and the justification for it can only emerge from the work of a generation of thinkers and doers grappling with the problem.”²¹ This paper has attempted to wrestle with the concept of healthcare justice and the donation of reused devices to LMIC. This practice, since it holds promise to improve human functioning and capabilities, can be morally justified with some conditions. First, transparency requires that both patients and professionals using such devices know that they are used, and are aware of the risks and uncertainties. Second, the inequalities in device quality need continued research to ensure that benefits and risks are better understood and uncertainty is reduced. Third, the degree of inequality, and the impact on other needs and priorities of receiving the devices, should engage the communities involved. Research, policy, and humanitarian aid should constantly be working toward decreasing the inequities in access and quality of medical devices as well as the underlying causes.

Statement of Conflict of Interest

All authors declare that there are no conflicts of interest.

References

- Alwan A, Armstrong T, Bettcher D, et al. Global status report on noncommunicable diseases 2010. Geneva: WHO Press; 2012.
- Marrero SL, Bloom DE, Adashi EY. Noncommunicable diseases: a global health crisis in a new world order. *JAMA*. 2012;307:2037-2038.
- Mond HG, Proclemer A. The 11th world survey of cardiac pacing and implantable cardioverter-defibrillators: calendar year 2009—a World Society of Arrhythmia's project. *Pacing Clin Electrophysiol*. 2011;34:1013-1027.
- Mond HG, Mick W, Maniscalco BS. Heartbeat International: making “poor” hearts beat better. *Heart Rhythm*. 2009;6:1538-1540.
- Ekpe EE, Aghaji MA, Edaigbini SA, Onwuta CN. Cardiac pacemaker treatment of heart block in Enugu a 5-year review. *Niger J Med*. 2008;17:7-12.
- Friedberg CK, Donoso E, Stein WG. Nonsurgical acquired heart block. *Ann N Y Acad Sci*. 1964;111:835-847.
- Johansson BW. Complete heart block. A clinical, hemodynamic and pharmacological study in patients with and without an artificial pacemaker. *Acta Med Scand Suppl*. 1966;451:1-127.
- Gadboys HL, Wisoff G, Litwak RS. Surgical treatment of complete heart block. An analysis of 36 cases. *JAMA*. 1964;189:97-102.
- Donmoyer TL, DeSanctis RW, Austen WG. Experience with implantable pacemakers using myocardial electrodes in the management of heart block. *Ann Thorac Surg*. 1967;3:218-227.
- Maher D, Ford N. Action on noncommunicable diseases: balancing priorities for prevention and care. *Bull World Health Organ*. 2011;89:547-A.
- Nugent R, Feigl A. Center for Global Development. Where have all the donors gone?: Scarce donor funding for non-communicable diseases. Center for Global Development; 2010.
- CPG Sec 310.100 pacemaker reuse (CPG 7124.12). Available from: <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073891.htm>. Accessed October 8, 2012.
- Tessarolo FCI, Nollo G. Critical issues in reprocessing single-use medical devices for interventional cardiology. In: Komorowska MA, Olszynska-Janus S, editors. *Biomedical Engineering, Trends, Research and Technologies*; 2011.
- Kantharia BK, Patel SS, Kulkarni G, et al. Reuse of explanted permanent pacemakers donated by funeral homes. *Am J Cardiol*. 2012;109:238-240.
- Baman TS, Meier P, Romero J, et al. Safety of pacemaker reuse: a meta-analysis with implications for underserved nations. *Circ Arrhythm Electrophysiol*. 2011;4:318-323.
- Reprocessing of single-use devices. Available from: <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/default.htm>. Accessed July 31, 2012.
- Groeneveld PW, Laufer SB, Garber AM. Technology diffusion, hospital variation, and racial disparities among elderly Medicare beneficiaries: 1989–2000. *Med Care*. 2005;43:320-329.
- GAO report: single-use medical devices: little available evidence of harm from reuse, but oversight warranted. Available from: <http://www.gao.gov/new.items/he00123.pdf>. 2000. Accessed October 8, 2012.
- Stanyon R. Donation of explanted pacemakers for reuse in underserved nations. *J Healthc Risk Manag* 2010;29:4, 6–8, 14.
- WHO medical device regulations. Available from: http://www.who.int/medical_devices/publications/en/MD_Regulations.pdf.
- Daniels N. *Just health: meeting health needs fairly*. New York: Cambridge University Press; 2008.
- Walzer M. *Spheres of justice: a defense of pluralism and equality*. Basic Books; 1983.
- “Egalitarianism”, the Stanford encyclopedia of philosophy. Available from: <http://plato.stanford.edu/archives/spr2009/entries/egalitarianism>.
- CPG Sec. 310.100 pacemaker reuse. Available from: <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm073891.htm>. Accessed July 30, 2012.
- Anderson ES. What is the point of Equality. *Ethics*. 1999;109:287-337.
- Prevention and control of non-communicable diseases United Nations General Assembly. Available from: http://www.un.org/ga/search/view_doc.asp?symbol=A/66/83&Lang=E. Accessed July 11, 2012.
- Bill Emerson Good Samaritan Food Donation Act. Available from: <http://www.law.cornell.edu/uscode/text/42/1791>. Accessed October 1, 2012.
- Gakenheimer L, Lange DC, Romero J, et al. Societal views of pacemaker reutilization for those with untreated symptomatic bradycardia in underserved nations. *J Interv Card Electrophysiol*. 2011;30:261-266.
- The history of utilitarianism. Available from: <http://plato.stanford.edu/archives/sum2009/entries/utilitarianism-history/>. 2009. Accessed July 31, 2012.

30. Norheim O. Gini impact analysis: measuring pure health inequity before and after Interventions. *Public Health Ethics*. 2010;3: 282-292.
31. Goold S, Blacksher E. Resources, rarity and rationing. *Bioeth-Forum*. 2011;4:106-108.
32. Rawls J. A theory of justice. Cambridge (Ma): Harvard University Press; 1971.
33. Daniels N. Justice, Health, and Healthcare. *Am J Bioeth*. 2001;1:2-16.
34. Kapiriri L. Priority setting in low income countries: the roles and legitimacy of development assistance partners. *Public Health Ethics*. 2012;5:67-80.
35. Baman TS, Crawford T, Sovitch P, et al. Feasibility of postmortem device acquisition for potential reuse in underserved nations. *Heart Rhythm*. 2012;9:211-214.
36. Loewenson R. Participation and accountability in health systems: the missing factor in equity. *Equinet Policy Series*; 2000. p. 9.