Post-Mortem Cardiac Device Retrieval for Re-Use in Third World Nations: Views of Funeral Directors

University of Michigan Hospitals
Baman TS, Kirkpatrick JN, Lange DC, Oral H, Goldman EB, Eagle KA
# Heart Rhythm 2009 Disclosure Slide

<table>
<thead>
<tr>
<th>Relationship</th>
<th>Name of Commercial Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consulting Fees/Honoraria</td>
<td>None</td>
</tr>
<tr>
<td>Speakers’ Bureau</td>
<td>None</td>
</tr>
<tr>
<td>Equity Interests/Stock Options</td>
<td>None</td>
</tr>
<tr>
<td>Equity Interests</td>
<td>None</td>
</tr>
<tr>
<td>Royalty Income</td>
<td>None</td>
</tr>
<tr>
<td>Non-Royalty Payments</td>
<td>None</td>
</tr>
<tr>
<td>Officer, Director, or In Any Other Fiduciary Role</td>
<td>None</td>
</tr>
<tr>
<td>Ownership/Partnership/Principal</td>
<td>None</td>
</tr>
<tr>
<td>Research Grants</td>
<td>None</td>
</tr>
<tr>
<td>Fellowship Support</td>
<td>None</td>
</tr>
<tr>
<td>Salary</td>
<td>None</td>
</tr>
<tr>
<td>Ownership/Partnership/Principal</td>
<td>None</td>
</tr>
</tbody>
</table>
Outline

- Introduction / Background Information
- Hypothesis
- Methods
- Results
- Conclusions
Introduction

- Approximately 1 million people are dying annually from untreated bradyarrhythmia worldwide.
- Previous survey research has found that patients with pacemakers and ICDs as well as members of the general population strongly support donation of used devices to underserved countries.
- Participation of funeral directors is a vital component of any proposed pacemaker reuse initiative.
Hypothesis

- We believe that funeral directors would support a pacemaker reutilization program if given the opportunity
The purpose of this study is to determine the views of funeral directors regarding post-mortem retrieval and donation of pacemakers (PMs) and implantable defibrillators (ICDs) using an anonymous mail survey.
Methods

- All Funeral Homes within a 50 mile radius of Ann Arbor, MI were identified using yellowpages.com search engine.
- Funeral Homes were then contacted during normal business hours and the names of all funeral directors were obtained for a direct mailing of surveys.
- If funeral directors were not available, a call back number was left with the receptionist.
Methods

- A 32 question anonymous survey was created to assess yearly volume, current practices regarding device extraction, and views on philanthropic device donation to underserved nations.
- Survey questions were adapted from a previous study examining device donation\(^1\).
- Approval was obtained to distribute and collect surveys for analysis from University of Michigan Institutional Review Board.

Methods:
Survey Distribution

- Surveys with enclosed postage-paid return envelopes were mailed to all funeral directors within a 50 mile radius of Ann Arbor, MI
- Each survey contained a $20 activated gift card
- Use of gift card was only dependent upon opening of survey and not upon survey completion
- Funeral directors were asked to complete an anonymous survey as a part of a research study
Methods:
Data Analysis

- Survey data was entered into a Microsoft Excel spreadsheet
- Data was analyzed using SPSS
  - Simple descriptive statistics
  - T-tests for continuous variables
  - Chi-Square tests for categorical variables
  - $p \leq 0.05$
Results

- 152 funeral directors were identified and sent surveys by mail
- 90 (59%) funeral directors completed and returned surveys to the University of Michigan
- 5 funeral directors returned surveys incomplete with unused gift cards
Results

Of the deceased with pacemakers and ICDs, 45% have their device extracted prior to burial/cremation. 

1 All deceased receiving cremation must have their device explanted due to risk of explosion.
### Results: Funeral Director Survey

#### Survey Questions

<table>
<thead>
<tr>
<th>Survey Questions</th>
<th>Percentage of Funeral Directors (n=90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discard pacemakers in waste or store with no intended purpose</td>
<td>84%</td>
</tr>
<tr>
<td>Return pacemakers to device manufacturer</td>
<td>4%</td>
</tr>
</tbody>
</table>

The vast majority of explanted devices are discarded in waste or stored with no intended purpose.
# Results: Funeral Director Survey

<table>
<thead>
<tr>
<th>Survey Questions</th>
<th>Percentage of Funeral Directors (n=90)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Support a central independent organization to regulate device distribution back to manufacturers</td>
<td>81%</td>
</tr>
<tr>
<td>Willing to donate the devices to charitable organizations if given the opportunity</td>
<td>89%</td>
</tr>
<tr>
<td>Have previously donated a device for reuse in 3rd world countries</td>
<td>10%</td>
</tr>
</tbody>
</table>

The overwhelming majority of funeral directors are willing to donate devices to charitable organizations for reuse in the 3rd world.
Results

- A total of 166 PMs and ICDs are currently stored in southeastern Michigan funeral homes with no intended purpose.
Conclusions

- Funeral Directors estimate that 45% of the deceased with pacemakers and ICDs currently will have their device explanted due to request or per protocol.
- The vast majority of devices explanted are discarded in waste or stored with no purpose.
- An overwhelming majority of funeral directors have the desire and ability to perform post-mortem cardiac device removal for philanthropic reuse in underserved nations if given the opportunity.
Limitations

- Funeral Directors were limited to one specific area in Michigan
- Opinions of funeral directors may not be applicable to other regions of the country
- Limited funeral director sample size
Conclusion

• Patients, citizens and funeral directors have expressed an overwhelming interest to participate in a nationwide initiative for pacemaker and ICD reutilization in order to alleviate the healthcare disparity seen in many underserved nations.

What are the necessary next steps in creating a successful program for device reutilization for those in low and middle income countries?
Project My Heart to Your Heart: A Collaborative between Citizens, Physicians, and Funeral Directors of the State of Michigan, the University of Michigan Cardiovascular Center, and World Medical Relief, Inc.
Legal Counsel:
- Provide legal consent and guidelines for distribution to funeral homes
- Consent family and explant devices

Funeral Homes:
- Consent family and explant devices

Center of Excellence:
- Establish communication with funeral homes to facilitate safe device distribution and collection
- Sterilize and package devices per protocol
- Maintain database of all devices received and distributed

Non Profit Charitable Organization:
- Assess qualifications and safety record of implanting centers
- Maintain database of all devices received and distributed

National Funeral Directors Association:
- Facilitate awareness and interaction between funeral homes and academic center
- Provide guidance to funeral directors regarding device explantation

LMIC Device Implantation Center:
- Safely and effectively implant devices and provide follow-up monitoring
- Assess financial status of possible recipients
- Provide detailed patient documentation and follow-up information for all devices implanted

Food and Drug Administration:
- Authorize IDE for safe and legal device distribution
Acknowledgements

- University of Michigan Hospitals
  - Kim Eagle
  - Pat Sovitch
  - Kara Morgenstern
  - Edward B Goldman
  - Kay Fuller
  - Hakan Oral
  - Josh Romero

- University of Pennsylvania
  - James N Kirkpatrick

- World Medical Relief
  - Al Romero
  - George Samson
  - Rita Grezlik
  - Christian Machado

- Philippines General Hospital
  - Eric O Sison
  - Rogelio V Tangco
  - Nelson S Abelardo

- Komfo Medical Center, Ghana
  - Isaac Owusu
  - Ohene Opare-Sem