REPORT OF THE PASCAR TASK FORCE
ON PACEMAKER AND ICD RE-USE: OCTOBER 2015

Task Force Membership

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<th>Name</th>
<th>Country</th>
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<tr>
<td>1. Prof Bongani M. Mayosi (Chair)</td>
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<td>2. Dr Ashley Chin</td>
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<td>3. Dr. Zaheer Yousef</td>
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<td>4. Dr Thomas Crowford</td>
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<td>5. Dr Kim Eagle</td>
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<td>6. Dr. Thomas Carrigan</td>
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<td>7. Dr. James Rusell</td>
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<td>8. Dr. Constantino Akwanalo</td>
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<td>9. Dr Benedict Anisuiba</td>
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<td>10. Prof Mpiko Nteskhe</td>
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<td>11. Dr. Kevin Weatherwax</td>
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<td>12. Dr. Zimasa Jama</td>
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<td>13. Mr. George Nel</td>
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<td>14. Mr. Balasundaram Lavan</td>
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<td>15. Prof Andrew Thorton</td>
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INTRODUCTION

Pacemakers are an effective treatment for chronic complete heart block, both in relieving symptoms and in prolonging life, and should be available to all who need them. The pacemaker implantation rate in sub-Saharan Africa remains dismally low (<10 pacemakers per million population) compared to that of the United States and other developed countries (>400 per
million population). Similarly, there is a virtual absence of centres that can implant cardioverter defibrillators (ICDs) in the sub-Saharan outside of South Africa.

The high cost of pacemakers is one of the most important barriers to the establishment of an effective cardiac pacing service in sub-Saharan Africa. This may be overcome by re-use of pacemakers, a practice that has been demonstrated to be safe and cost-effective.

The Pan African Society of Cardiology (PASCAR) Task Force on Pacemaker and ICD re-use was established on the 22nd of March 2014 to address among other things the unmet needs of pacemaker/ICDs in sub-Saharan Africa. This followed series of discussions of partnership between the leadership of PASCAR, the Project Myheart Yourheart from the University of Michigan and the Pace4life project in the United Kingdom. Professor Bongani Mayosi chairs the task force and Prof Mahmoud Sani serves as secretary. The frequency of meetings will be 4-monthly. So far the task force has had five meetings in form of teleconferences.

The objectives of the task force are as follows:

1. Prevent and treat CVD in Africa (treat heart block and prevent sudden death): at least one pacing and ICD unit per African country.
2. Educate and train African healthcare professionals about CVD: PASCAR Fellowship in Clinical Cardiology and Cardiac Pacing.
3. Educate laypersons about CVD: Procurement, supply and regulatory issues of used pacemakers and ICDs to participating sites.
4. Invest in CV research: PASCAR Registry on Pacemaker and ICD Re-Use in Africa and RCT on new versus used pacemaker.

**Summary of Activities for 2014**

1. Three successful Teleconferences took place with most members attending and contributing to the meetings
2. Call for expressions of interest for an RCT on pace maker re-use was sent out to the PASCAR mailing list via George Nel. Dr Thomas Crawford of the University of Michigan, USA, coordinates the project and some centers in Africa have expressed interests to participate. Some of the centres have obtained local IRB as well as their countries’ approval as required by the FDA.
3. PASCAR Fellowship and Training Programme at UCT under the Medtronic-funded PASCAR Fellowship in Cardiac Pacing and Clinical Cardiology. Two fellows were selected for this program this year. They are Dr. Constantine Akwanalo (Kenya) and Dr. James Russell (Sierra Leone). Because of issues with South African regulatory body and the impact of Ebola outbreak in the countires of origin on the fellow, the program
was delayed. The training is for 6 months. Dr Akwanalo has started the program in September 2015 while Dr Russell will start in January 2016.

4. Mr. Balasundaram Lavan provided a comprehensive update on the process of procurement, importation and regulatory approvals needed for re-use as well as brand new pacemakers.

5. Dr. James Russell (Sierra Leone) has obtained a letter of approval from the Sierra Leone regulatory body, the Ministry of Health & Sanitation granting permission for the supply of re-used pacemakers/ICD’s

6. Dr Ashley Chin circulated through George Nel, update on pacing activities in Africa in 2014.

7. Dr Ashley CHIN presentation on “Managing Arrhythmias in Africa” during CARDIOSTIM 2014 in NICE, France; by collecting data on statistics of pacemaker implantations in sub-Saharan Africa

Summary of Activities for 2015

1. Two successful teleconferences held. The third physical meeting will be in Mauritius during the PASCAR congress.

2. A satellite symposium on pacemaker and ICD re-use on the 25/01/2015 during the Sudan National Heart Congress (23-27/01/2015) led by Dr. Zaheer Yousef. Prof Bongani Mayosi, Prof Alan Fraser and Mr Lavan Balasundaram also attended. The symposium was a great success. The issues discussed included scale of the problem/setting the scene, ethical/regulatory issues, and summary of current evidence/work in the field, Pace4Life project and the future step including the role of the PASCAR pacemaker/ICD reuse task force. Approximately 50-60 people attended, and whilst there was unanimous agreement that the concept of re-use is sound, economical, and safe….there were some challenges also: participants made analogy between pacemaker re-use and second hand cars, the idea that the FDA is willing to provide an export licence only…i.e. willing to export the devices but not willing for them to be used for their own population, sterility, and risks of technical malfunction. Assessments from the symposium are as follows:
   a. The concept of pacemaker/ICD re-use is good: but to make this academically sound, we need to roll this out as a randomised study (re-use versus brand new)
   b. There is need to bring samples of the end product for people to see. Pictures of used/bloody pacemakers in dustbins ready to be collected and processed are a disincentive. More encouraging would be a sparkling, refurbished device, post gamma-radiation, in a professional looking sealed box with logos etc…. The Michigan team are working on this.
   c. The best to target this programme in the initial stages in African countries that are the most economically challenged, where it is more likely that we would be able to secure a letter of intent from the countries Ministries of Health.
   d. Countries that come to mind at this stage are Ethiopia and/or Eritrea. These are attractive for economic reasons and also because they border Sudan where the cardiologists are willing to provide “local” back-up and mentoring.
   e. There is need to hold a second symposium at the PASCAR meeting in Mauritius where these issues could be discussed further.
   f. Discussions are advanced about writing a grant to support the RCT. The RCT would require a high standard of patient follow-up, documentation, and
3. Training Fellowship:- Dr Constantine Akwanalo has joined the department of Medicine UCT for a 6 months PASCAR/Medtronic pacing fellowship from 1st Sept 2015. Dr James Russell is expected to start as soon as Akwanalo finished. Three months into the fellowship, a supporting Technologist from the same hospital in Kenya will join Akwanalo for the remaining 3 months.

4. A UCT Reuse Experience was published titled “Performance of e-used pacemakers and ICDs compared with new devices at Groote Schuur Hospital Cape Town, South Africa” by members of the task force – Drs Jama, Chin, Mayosi. In this report there were low infection rates and minimal complications. Reference: Cardiovasc J Afr 2015 Jul-Aug 26(4):181-187

5. There has been discussion with the British Heart Foundation for the RCT grant. A collaborative effort between Universities of Michigan and Cardiff in being made to develop the grant proposal.

6. The USA FDA has given approval for device exports to countries that have fully satisfy the requirements.

7. The task force was approached by Medtronic, through Dr Daniel Grossman (Senior Director, Global Health Innovation, Medtronic) for collaboration on pacing in sub Saharan Africa. Discussions are in the very early stage.

Task force Activities planned for 2015/2016

1. PASCAR position statement on pacemaker re-use will be available towards the end of 2015. Dr Zimasa Jama is charged with making the initial draft.

2. Publications are planned from the proceedings of the Pacing symposia (Sudan & Mauritius) Dr Zaheer Yousef will drive these publication, but it would be a collaborative venture with several members of the PASCAR task force submitting sections.
   a. The first would focus on general issues such as – the burden of brady-arrhythmias and the morbidity and mortality from it, in sub-Saharan Africa, brief history of pacing technologies and simplicity of the procedure and the facilities required, concept of pacemaker re-use, ethical and regulatory issue
   b. The second will be similar but with a different emphasis...summary of clinical trials, technicalities; e.g. header, screw issues, infection control etc.

3. Grant application would be submitted for the pacemaker re-use RCT to the British Heart Foundation before the end of 2015. Additional sources of funding – DFID/MRC/Welcome Trust will be explored

4. To start the registry on pacemaker and ICD re-use in earnest. The PASCAR fellow (James Russell) will lead the development of the protocol with the assistance of Thomas Crawford and Kevin Weatherwax

5. To source for standalone suppliers of leads, stylets, screws, screwdrivers etc in India/China who may be willing to sell us these products at discount prices, to be used to run the programme
6. To start the process of procurement, supply, regulatory approvals, importation and use of re-used devices with Sierra Leone as a case study (pilot). The program is planned to be launched in Sierra Leone in early 2016.

7. Establishment of Heart Rhythm Society for Africa or Africa Heart Rhythm Association under the auspices of PASCAR. Prof Andrew Thorton and Dr Aime Bonny will be leading this. This will be the PASCAR body on arrhythmia management and will include such working groups: Sudden cardiac death, cardiac electronic devices, device re-use, electrocardiography, electrophysiology, supraventricular arrhythmias, medical education and training…etc.

Professor Mahmoud U. Sani

Secretary – PASCAR Task Force on Pacemaker/ICD Re-use