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2 Title: Patients' opinions on cardiac implantable electronic device reuse in Bolivia.

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Patients' opinions on cardiac implantable electronic device reuse in Bolivia.

Introduction:

Due to the high cost of cardiac implantable electronic devices (CIEDs), for many Bolivians suffering from bradyarrhythmia is impossible to afford the vital treatment they need [1]. Resterilising used devices has been endorsed as a feasible and safe option to provide a low-cost life-saving treatment [2]. However, resterilized devices fall out of the manufacturers specifications, so informing patients about these practices and implications becomes an important duty [3,4]. Despite the fact that CIED reuse could potentially provide a treatment option for many Bolivians (who may be unable to afford new devices), to date no study has described the opinions of local patients on this topic, nor the different factors that may influence these opinions [5]. Therefore, the aim of our study was to assess the opinions of Bolivian patients on pacemaker reuse and to compare them depending on the ability to pay for a new device and other sociocultural factors.

Methods:

This study was conducted in the George Duez Popular Hospital, a 2nd level medical care centre of a private non-profit nature, targeting poor families of urban and peri-urban neighbourhoods in the city of Sucre, Bolivia. A total of 180 anonymous, voluntary surveys containing 17 questions, were administered by a physician to patients who presented to the hospital for outpatient medical consultations. The physician ensured that participants understood and appreciated the risks associated of reusing CIEDs. Data collection was carried out between June and July of 2021. Participants were not selected on the basis of whether they had an indication for a device or not in order to collect a closer opinion to that of the general population. The survey instrument was based on the one used in the study carried out by Hughey et al [6]. It consisted of demographic questions including ones about age, sex, level of education, employment status, marital status, number of children, health status, personal and family history of cardiovascular disease, presence of family members or friends in need of a CIED and ability to afford a new pacemaker. The cost of a new pacemaker was estimated to be equivalent to 700 US dollars in the local currency (bolivianos), based on tenders for pacemaker procurement by the Bolivian government [7]. Participants indicated their level of agreement with five questions regarding CIED reuse, using a five-point Likert-type scale (1= Strongly Agree, 2= Agree, 3= Neutral, 4= Disagree, 5= Strongly Disagree) and there was a final section in which they could freely indicate their concerns about the practice.

Results:

1 A total of 150 responses were obtained (a response rate of 83%). We found that 46% of the
2 participants agreed or completely agreed that they would accept a resterilised CIED if the risks
3 were similar to those for a brand-new device, 34% would agree to this if the risk of infection
4 were higher than for a new device, and 35% would agree to it if the risk of malfunction were
5 greater compared to a new device. The data show that 40.8% of participants would be willing to
6 donate their own CIED, while 33% would be willing to donate a family members device after
7 death. Among the main reasons for concern regarding reprocessing used CIEDs, infection was
8 mentioned by 32%, malfunction by 30%, early battery life depletion by 11%, and other concerns
9 such as cultural, legal or religious considerations by 16% of participants. The remaining 11%
10 indicated that they had no concerns regarding CIED reuse. Participants who indicated they could
11 not afford a pacemaker, compared to those who could afford it, were more amenable to
12 receiving a resterilised device under the following conditions: if the general risks were similar
13 (61% vs 26.5%, $p<0.001$); if the risk of infection was higher (48% vs 14.7%, $p<0.001$); or if the risk
14 of malfunction was higher (45.5% vs 18.2%, $p<0.001$) compared to new devices (Table 1).
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25 Discussion:

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27 The overall acceptance rate in our sample was lower than expected. The study carried out by
28 Hughey et al., and pooled data from the different low-and middle-income countries, the general
29 acceptance percentages were lower in our study for accepting a resterilized device according to
30 the 3 different possible risks (46%, 34% and 35% vs. 78.7%, 74% and 58.1%) [5,6]. However, we
31 found that the ability to pay for a new device had a statistically significant association with
32 expressed opinions, as the opinions of the neediest were significantly more positive. Having a
33 family or friend in need of a CIED also showed a relation to these variables, which could imply
34 that these participants were more concerned and sensitive to the diminished quality of life of
35 these pathologies.
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44 Limitations: This study was conducted in one specific location and in patients without specific
45 indications for CIED implantation, and our results may not reflect the opinions of all Bolivians
46 nor of patients in need of CIEDs. However, our results suggest that patients without the ability
47 to pay for a new device who suffer from recurrent symptoms may be more willing to receive a
48 resterilized device. Therefore, CIED reuse could be considered as a treatment alternative for
49 patients in need in Bolivia.
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55 Conclusions:

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57 In conclusion, our findings suggest that a significant percentage of patients in Bolivia have
58 positive opinions on CIED reuse, but the percentage of patients accepting resterilized ICDs is
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1 lower compared to other low- and middle-income societies. The reasons for this lower rate of
2 acceptance are unclear, and were not elucidated by this study. If true in other societies, then
3 the current push to CIED reutilization should be tempered by societal considerations in
4 individual recipient nations. However, the inability to pay for a new device was strongly
5 associated with greater acceptance of a resterilized CIED.
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Keywords: Cardiac implantable electronic devices, pacemaker, defibrillator, reuse, opinions, perspectives.

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Informed consent: Not applicable.

References:

1. Clark, E. H., Sherbuk, J., Okamoto, E., Jois, M., Galdos-Cardenas, G., Vela-Guerra, J., ... Peru, for the W. G. on C. D. in B. and. (2014). Hyperendemic Chagas Disease and the Unmet Need for Pacemakers in the Bolivian Chaco. *PLOS Neglected Tropical Diseases*, 8(6), e2801. Retrieved from <https://doi.org/10.1371/journal.pntd.0002801>

2. Psaltikidis, E. M., Costa, E. A. M., & Graziano, K. U. (2021). Reuse of pacemakers and implantable cardioverter-defibrillators: systematic review, meta-analysis and quality assessment of the body of evidence. *Expert review of medical devices*, 18(6), 553–567. <https://doi.org/10.1080/17434440.2021.1927706>

3. Tessarolo, F., Caola, I., & Nollo, G. (2011). Critical Issues in Reprocessing Single-Use Medical Devices for Interventional Cardiology. *Biomedical Engineering, Trends, Research and Technologies*. <https://doi.org/10.5772/13582>

4. Tandon, K., Tate, T., & Kirkpatrick, J. N. (2017). Pacemaker reuse in low-income/middleincome countries: moral duty or dangerous precedent? *Heart*, 103(23), 1846 LP – 1847. <https://doi.org/10.1136/heartjnl-2017-311572>

5. Iñigo, L. R. (2021). Reuse of cardiac implantable electronic devices in developing countries perspectives: A literature review. *Pacing and Clinical Electrophysiology*, n/a(n/a). <https://doi.org/https://doi.org/10.1111/pace.14422>

1
2 . Hughey AB, Muthappan P, Badin A, Baman T, Baig-Ansari N, Jawed F, Khan AB, Jiang Q, Hughey
3
4 KL, Toruño RJ, Machado C, Refaat MM, Zakka P, Hotait M, Eagle KA, Crawford TC. Patients' and
5
6 family members' views on pacemaker reuse: An international survey. J Cardiovasc
7
8 Electrophysiol. 2022 Mar;33(3):473-480. doi: 10.1111/jce.15367. Epub 2022 Jan 29. PMID:
9
10 35040526.

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12 6. INFOSISCON. (n.d.). Retrieved May 11, 2022, from <https://infosiscon.com/>
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Tables:

Table 1. Relationships between the different demographic variables and opinions regarding reuse.

		Would you accept a resterilized CIED if the overall risks were similar to a new device?		Would you accept a resterilized CIED if the risks of infection were greater compared to a new device?		Would you accept a resterilized CIED, if the risks of malfunction were greater compared to a new device?		Would you donate your CIED for reuse in other patients after your death?		Would donate the CIED of a family member for reuse in other patients after their death?	
		n (%)	p value	n (%)	p value	n (%)	p value	n (%)	p value	n (%)	p value
Sex	Male	33/71 (46.47)	0.868	47/71 (66.19)	0.859	20/70 (28.57)	0.288	26/70 (37.14)	0.496	21/70 (30)	0.479
	Female	33/74 (44.59)		51/74 (68.91)		28/73 (38.35)		32/73 (43.83)		26/72 (36.11)	
Education level	Unschooling	7/12 (58.33)	0.478	2/12 (16.66)	0.242	3/11 (27.27)	0.663	3/11 (27.27)	0.02	0/11 (0)	0.008
	Primary education	3/10 (30)		4/10 (40)		3/10 (30)		3/10 (30)		4/10 (40)	
	High school graduate	6/18 (33.33)		5/18 (27.77)		6/18 (33.33)		5/18 (27.77)		4/18 (22.22)	
	Vocational education	19/47 (40.42)		14/47 (29.78)		16/45 (35.55)		15/45 (33.33)		13/45 (28.88)	
	University education	31/58 (53.44)		22/58 (37.93)		20/59 (33.89)		32/59 (54.23)		26/58 (44.82)	
Employment status	Unemployed	10/21 (47.61)	0.228	10/21 (47.61)	0.2	8/21 (38.09)	0.071	8/21 (38.09)	0.223	8/21 (38.09)	0.508
	Student	23/39 (58.97)		16/39 (41.02)		19/38 (50)		21/38 (55.26)		14/38 (36.84)	
	Employed	26/68 (38.23)		18/68 (26.47)		18/68 (26.47)		26/68 (38.23)		23/67 (34.32)	
	Retired	8/18 (44.44)		5/18 (27.77)		4/17 (23.52)		5/17 (29.41)		3/17 (17.64)	
Marital status	Single	30/58 (51.72)	0.671	23/58 (39.65)	0.199	27/57 (47.36)	0.005	30/57 (52.63)	0.021	22/57 (38.59)	0.231
	Married or living with significant other	21/49 (42.85)		15/49 (30.61)		10/49 (20.40)		17/49 (34.69)		16/48 (33.33)	
	Divorced	11/28 (39.28)		10/28 (35.71)		11/27 (40.74)		12/27 (44.44)		9/27 (33.33)	
	Widow(er)	5/12 (41.66)		1/12 (8.333)		1/11 (9.09)		1/11 (9.090)		1/11 (9.090)	
Referred health status	Very good	8/13 (61.53)	0.459	5/13 (38.46)	0.42	7/13 (53.84)	0.301	6/13 (46.15)	0.045	6/13 (46.15)	0.094

	Good	29/62 (46.77)		23/62 (37.09)		22/63 (34.92)		33/63 (52.38)		23/62 (37.09)	
	Neutral	22/53 (41.50)		18/53 (33.96)		17/51 (33.33)		15/51 (29.41)		15/51 (29.41)	
	Bad	7/18 (38.88)		3/18 (16.66)		3/17 (17.64)		6/17 (35.29)		4/17 (23.52)	
	Very bad	1/1 (100)		0/1 (0)		0/1 (0)		0/1 (0)		0/1 (0)	
Cardiovascular pathologies	Yes	27/57 (47.36)	0.801	19/57 (33.33)	0.858	18/55 (32.72)	0.154	21/55 (38.18)	0.527	19/55 (34.54)	0.765
	No	19/38 (50)		12/38 (31.57)		18/38 (47.36)		17/38 (44.73)		12/38 (31.57)	
Family member or friend in need of CIED	Yes	17/54 (31.48)	0.013	9/54 (16.66)	0.002	10/53 (18.86)	0.006	20/53 (37.73)	0.432	20/52 (38.46)	0.372
	No	48/91 (52.74)		38/91 (41.75)		37/90 (41.11)		40/90 (44.44)		28/90 (31.11)	
Could afford a CIED	Yes	18/68 (26.47)	<0.001	10/68 (14.70)	<0.001	12/66 (18.18)	0.001	25/66 (37.87)	0.36	26/66 (39.39)	0.189
	No	47/77 (61.03)		37/77 (48.05)		35/77 (45.45)		35/77 (45.45)		22/76 (28.94)	

CIED=Cardiac implantable electronic device The frequencies and percentages represent the responses "Strongly agree" and "Agree" in proportion to the non-neutral responses with respect to opinion variables. Statistical analysis = Chi square test.