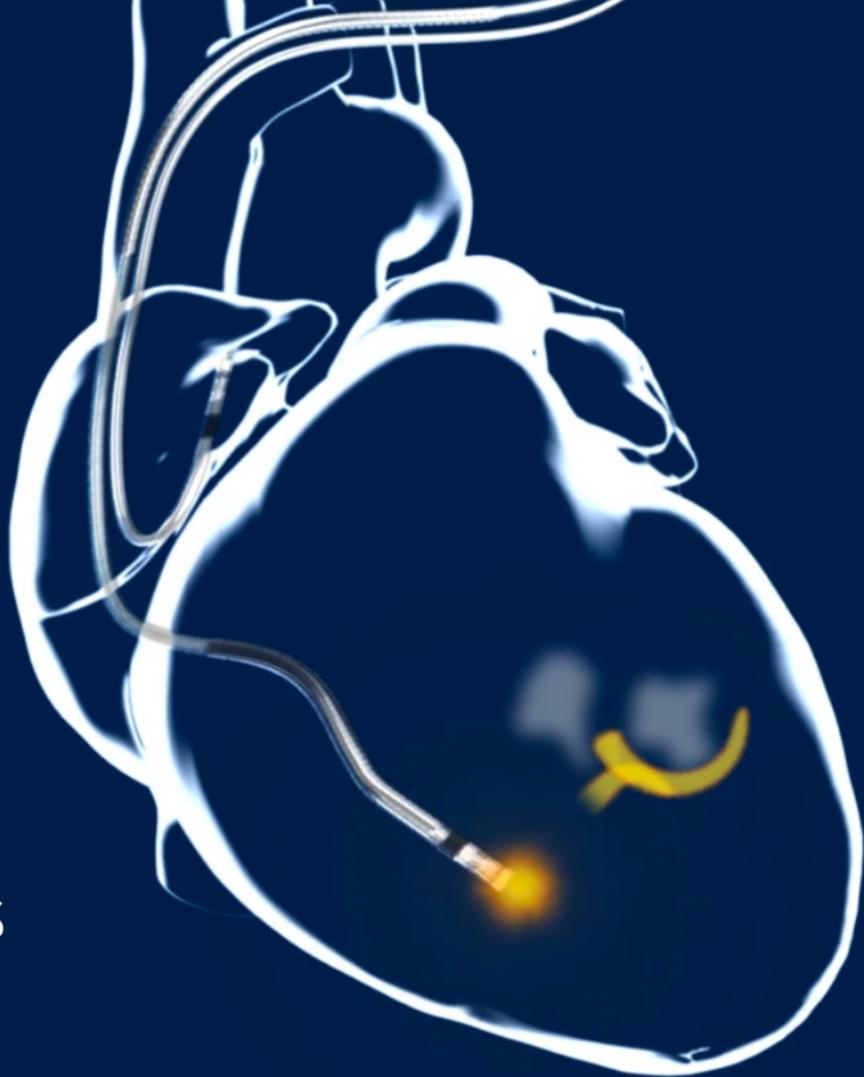


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Patients' and family members' views on pacemaker reuse: An international survey

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Abstract

Introduction: The reuse of cardiac implantable electronic devices may help increase access to these therapies in low- and middle-income countries (LMICs). No published data exist regarding the views of patients and family members in LMICs regarding this practice.

Methods and Results: An article questionnaire eliciting attitudes regarding pacemaker reuse was administered to ambulatory adult patients and patients' family members at outpatient clinics at Centro Nacional Cardiologia in Managua, Nicaragua, Indus Hospital in Karachi, Pakistan, Hospital Carlos Andrade Marín, and Hospital Eugenio Espejo in Quito, Ecuador, and American University of Beirut Medical Center in Beirut, Lebanon. There were 945 responses (Nicaragua – 100; Pakistan – 493; Ecuador – 252; and Lebanon – 100). A majority of respondents agreed or strongly agreed that they would be willing to accept a reused pacemaker if risks were similar to a new device (707, 75%), if there were a higher risk of device failure compared

with a new device (584, 70%), or if there were a higher risk of infection compared to a new device (458, 56%). A large majority would be willing to donate their own pacemaker at the time of their death (884, 96%) or the device of a family member (805, 93%). Respondents who were unable to afford a new device were more likely to be willing to accept a reused device (79% vs. 63%, $p < .001$).

Conclusions: Patients and their family members support the concept of pacemaker reuse for patients who cannot afford new devices.

KEYWORDS

global health, pacemaker, reutilization, reuse, views

1 | INTRODUCTION

Pacemakers remain unaffordable for many individuals in low- and middle-income countries (LMICs), resulting in disparities in pacemaker utilization.¹ The reuse of pacemakers – which involves extraction of devices from deceased donors, resterilization, and reimplantation in recipient patients – has been proposed as a potential solution to this unmet need.² Pacemaker reuse has been previously conducted in LMICs on a small scale and these experiences suggest that it is safe, efficacious, and feasible.^{3–5}

Previously published survey data have shown that the vast majority of funeral directors, patients with pacemakers, and their families in the United States support donations of explanted pacemakers.⁶ An international survey of the members of the Heart Rhythm Society indicated that the concept of pacemaker reuse was well supported by the respondents in potential donor and recipient countries.⁷ Yet to our knowledge no study to date has assessed the attitudes toward postmortem pacemaker reuse among potential device recipients LMICs. Understanding these viewpoints is critical to the successful adoption of a wide-scale reuse program, specifically regarding religious, cultural, and psychological factors, which may impact the acceptance of reconditioned pacemakers from deceased persons. In this study, we aimed to quantitatively evaluate the opinions of pacemaker reuse among patients and family members in LMICs and to identify demographic factors which may predict these views.

2 | METHODS

2.1 | Study design

This study utilized an anonymous, fourteen-question paper survey originally written in English and translated into Urdu, Spanish, and Arabic. The survey instrument is shown in [Appendix](#). Demographic questions included age, gender, country of residence, health status, level of education, marital and employment status, the presence of a personal or family history of heart disease, and the ability to afford the full cost of a new pacemaker whose market value was estimated to be \$700 USD (or equivalent amount of local currency). Of note,

pacemaker cost is the responsibility of the patient in the absence of private insurance in the countries surveyed. Respondents were asked to rate their level of agreement with five positive statements regarding pacemaker reuse using a 5-point Likert-type scale (1 = strongly agree, 2 = agree, 3 = neutral, 4 = disagree, and 5 = strongly disagree).

The University of Michigan Institutional Review Board (IRB) declared the study exempt from the review due to a lack of identifying information collected and no capacity for patient harm. In Nicaragua, the survey was approved by the Ministry of Health; in Pakistan, it was approved by the local IRB; in Ecuador and Lebanon, it was approved by the local hospital administrations.

The survey was administered to patients and family members in the waiting room of the outpatient clinics at Centro Nacional Cardiología in Managua, Nicaragua (over a 2-day period in April 2012), Indus Hospital in Karachi, Pakistan (over a 2-week period in May 2012), Hospital Carlos Andrade Marín and Hospital Eugenio Espejo in Quito, Ecuador (over a 2-week period in July 2014), and American University of Beirut Medical Center in Beirut, Lebanon (over a 2-month period from June to July 2015). The World Bank classifies Nicaragua and Pakistan's economies as "lower-middle-income" with per capita gross national incomes (GNI) of \$1910 USD and \$1530 USD, respectively; it classifies Ecuador and Lebanon's economies as "upper-middle-income" with per capita GNI of \$ 6080 USD and \$7600, respectively.⁸

No compensation was provided for participation. Respondents were advised that survey participation was voluntary, responses would remain anonymous, and that their participation and responses would not affect their clinical care or eligibility for charity care. Participants completed surveys on a paper form out of direct view of the person administering the survey, though study personnel assisted respondents who wished to participate in the survey but were unable to do so (generally due to illiteracy or infirmity). Participants returned surveys to the study personnel distributing surveys. The responses from the paper forms were later tabulated electronically by study personnel.

2.2 | Data analysis

Views regarding pacemaker reuse were represented as the number of respondents who indicated "agree" or "strongly agree" for each

question as a proportion of non-neutral responses. Demographic variables were analyzed as categorical variables and agreement with each statement regarding pacemaker reuse was tabulated by country of origin and by demographic variables. Differences in opinion across countries or demographic variables were tested using the χ^2 test. Multivariate logistic regression using the χ^2 test was performed to assess whether the country of residence and/or ability to afford a new device were independent predictors of various opinions of device reuse.

Analyses were performed using SAS version 9.3 (SAS Institute). $p < .05$ was deemed statistically significant.

3 | RESULTS

3.1 | Respondent characteristics

A total of 945 respondents participated in the survey (Nicaragua – 100; Pakistan – 493; Ecuador – 252; and Lebanon – 100). The overall response rate was estimated at greater than 80%. The demographic characteristics of survey respondents are shown in Table 1. The mean age of respondents was 48. The majority (582, 62%) were women. Less than half of respondents (354, 38%) were married or living with a partner. Most of the respondents had no more than 10 years of formal education (536, 57%) and most were not employed outside the home (576, 61%). A majority of respondents classified their own health as fair or poor (565, 60%) and 725 respondents (77%) reported a history of heart disease either in themselves or a family member. A significant majority of respondents reported being unable to afford the full cost of a new pacemaker (537, 78%).

3.2 | Opinions regarding pacemaker reuse

Patient and family members' level of agreement with various statements about pacemaker reuse stratified by country of residence and demographic characteristics are shown in Table 2. Attitudes regarding device donation and reuse were overall positive. A majority of respondents agreed or strongly agreed that they would be willing to accept a reused pacemaker if risks were similar to a new device (707, 75%), if there were a higher risk of device failure compared with a new device (584, 70%), or if there were a higher risk of infection compared with a new device (458, 56%). A large majority would be willing to donate their own pacemaker at the time of their death (884, 96%) or the device of a family member (805, 93%).

3.3 | Predictors of attitude toward pacemaker reuse

Respondents who reported being unable to afford a new pacemaker were more likely to accept a reused device if the risks were similar to a new device (79% vs. 63%, $p < .001$), or if the risk of device

TABLE 1 Demographic characteristics of survey respondents by country of residence

Demographic variable	Nicaragua N (%)	Pakistan N (%)	Ecuador N (%)	Lebanon N (%)	All countries N (%)	p
Mean age (years \pm standard deviation)	52.6 \pm 12.4	41.5 \pm 13.8	55.8 \pm 14.9	53.4 \pm 16.8	47.8 \pm 15.7	<.001*
Gender (female)	65/100 (65.0%)	299/493 (60.6%)	173/252 (68.7%)	45/99 (45.5%)	582/944 (61.7%)	<.001*
Marital status (married or living with partner)	52/100 (52.0%)	67/493 (13.6%)	155/252 (61.5%)	80/100 (80.0%)	354/945 (37.5%)	<.001*
Education (10 years or less of formal education)	67/99 (67.7%)	243/493 (49.3%)	174/249 (69.9%)	52/100 (52.0%)	536/941 (57.0%)	<.001*
Employment status (employed outside the home)	36/100 (36.0%)	294/493 (59.6%)	107/251 (42.6%)	53/99 (53.5%)	369/943 (39.1%)	.003*
Self-classified health status (fair or poor)	62/100 (62.0%)	309/493 (62.7%)	164/251 (65.3%)	30/100 (30.0%)	565/944 (59.9%)	<.001*
Personal or family history of heart condition	75/100 (75.0%)	432/493 (87.6%)	133/252 (52.8%)	85/100 (85.0%)	725/945 (76.7%)	<.001*
Unable to afford the cost of a new pacemaker	91/98 (92.9%)	236/256 (92.2%)	181/246 (73.6%)	29/86 (33.7%)	537/686 (78.3%)	<.001*

Abbreviation: ANOVA, analysis of variance.
* $p < .05$ by ANOVA for age; otherwise, by χ^2 .

TABLE 2 Patient and family members' agreement with statements regarding pacemaker reuse by country of residence and demographic characteristics

	Willing to accept a used pacemaker if risks similar to a new device		Willing to accept a used pacemaker if higher risk of failure		Willing to accept a used pacemaker if higher risk of infection		Willing to donate own pacemaker		Willing to donate family member's pacemaker	
	N (%)	p	N (%)	p	N (%)	p	N (%)	p	N (%)	p
All respondents	75.1% (707/942) ^a		69.9% (584/835)		56.0% (458/818)		95.7% (884/924)		92.7% (805/868)	
Country of residence										
Nicaragua	80/100 (80.0%)	<.001*	67/87 (77.0%)	<.001*	45/81 (55.6%)	<.001*	92/97 (94.8%)	.900	82/87 (94.3%)	.047*
Pakistan	373/493 (70.4%)		294/446 (65.9%)		252/447 (56.4%)		471/490 (96.1%)		411/454 (90.5%)	
Ecuador	205/252 (81.4%)		172/210 (81.9%)		134/201 (66.7%)		231/243 (95.1%)		230/239 (96.2%)	
Lebanon	49/97 (50.5%)		51/91 (56.0%)		27/89 (30.3%)		90/94 (95.7%)		82/88 (93.2%)	
Age group (years)										
18-44	308/393 (78.4%)	.096	248/350 (70.9%)	.816	204/343 (59.5%)	.163	374/387 (96.6%)	0.439	338/368 (91.9%)	.487
45-64	286/391 (73.2%)		241/347 (69.5%)		182/337 (54.0%)		366/385 (95.1%)		335/359 (93.3%)	
≥65	92/131 (70.2%)		76/112 (67.9%)		57/113 (50.4%)		120/127 (94.5%)		112/118 (94.9%)	
Gender										
Male	260/360 (72.2%)	.118	238/330 (72.1%)	.259	118/329 (57.1%)	.568	339/357 (95.0%)	0.401	309/333 (92.8%)	.958
Female	446/581 (76.8%)		345/504 (68.5%)		269/488 (55.1%)		544/566 (96.1%)		495/534 (92.7%)	
Marital status										
Married/living with partner	254/351 (72.4%)	.142	229/314 (72.9%)	.144	172/308 (55.8%)	.948	324/345 (93.1%)	.043*	302/325 (92.9%)	.874
Not married or living with partner	453/591 (76.7%)		355/521 (68.1%)		286/510 (56.1%)		560/579 (96.7%)		503/543 (92.6%)	
Education										
10 years or less of formal education	408/534 (76.4%)	.311	338/474 (71.3%)	.286	262/463 (56.6%)	.617	504/525 (96.0%)	.556	458/495 (92.5%)	.802
More than 10 years of formal education	297/404 (73.5%)		243/358 (67.9%)		193/352 (54.8%)		377/396 (95.2%)		344/370 (93.0%)	
Employment status										
Employed outside the home	271/369 (73.4%)	.312	232/326 (71.2%)	.552	185/322 (57.5%)	.481	345/362 (95.3%)	.572	313/340 (92.1%)	.473
Not employed outside the home	436/571 (76.4%)		351/507 (69.2%)		272/495 (55.0%)		538/560 (96.1%)		491/526 (93.4%)	

TABLE 2 (Continued)

	Willing to accept a used pacemaker if risks similar to a new device		Willing to accept a used pacemaker if higher risk of failure		Willing to accept a used pacemaker if higher risk of infection		Willing to donate own pacemaker		Willing to donate family member's pacemaker	
	N (%)	p	N (%)	p	N (%)	p	N (%)	p	N (%)	p
Self-classified health status										
Excellent or good	275/377 (72.9%)	.204	245/343 (71.4%)	.422	196/345 (56.8%)	.686	356/371 (96.0%)	.722	336/357 (94.1%)	.192
Fair or poor	432/564 (76.6%)		338/491 (68.8%)		262/473 (55.4%)		527/552 (95.5%)		469/511 (91.8%)	
Presence of personal or family history of heart condition										
Personal or family history of heart condition	543/722 (75.2%)	.843	449/652 (68.9%)	.201	363/636 (57.1%)	.243	681/711 (95.8%)	.765	616/671 (91.8%)	.049*
No personal or family history of heart condition	164/220 (74.6%)		135/183 (73.8%)		95/182 (52.2%)		203/213 (95.3%)		189/197 (95.9%)	
Ability to afford the cost of a new pacemaker										
Able to afford the cost of a new pacemaker	93/148 (62.8%)	<.001*	83/131 (63.4%)	.016*	69/131 (52.7%)	.273	133/141 (94.3%)	.274	127/138 (92.0%)	.562
Unable to afford the cost of a new pacemaker	422/536 (78.7%)		348/470 (74.0%)		263/453 (58.1%)		505/524 (96.4%)		456/488 (93.4%)	

*Percentages represent responses of either "Strongly Agree" or "Agree" as a proportion of non-neutral responses. N = 942.

*p < .05 by χ^2 .

malfunction were greater (74% vs. 63%, $p < .001$). Those with a personal or family history of a heart condition were slightly less likely to be willing to donate a family member's pacemaker (92% vs. 96%, $p = .049$). The vast majority of respondents who were married or living with a partner would be willing to donate their own pacemaker at the time of their death but at a slightly lower rate than other respondents (97% vs. 93%, $p = .043$). Other analyzed demographic variables including age group, gender, health, level of education, or employment status were not associated with variation in attitude toward pacemaker reuse.

Compared to respondents from other countries, those from Lebanon were more likely to be able to afford a new device (66% vs. 15%, $p < .001$) and less likely to be willing to undergo reimplantation with a reused device (51% vs. 78%, $p < .001$). Lebanese respondents were also less willing than other respondents to undergo reimplantation if there were a greater risk of device malfunction (56% vs. 63%, $p < .001$) or if there were a greater risk of infection (30% vs. 51%, $p < .001$).

Multivariable logistic regression was performed to determine whether the country of residence or ability to afford a device were independent predictors of positive viewpoints of device reuse. This analysis showed that Lebanese residence and ability to afford a new pacemaker were each independent negative predictors of willingness to accept a used pacemaker for two statements regarding reuse ("if risks similar" and "if a higher risk of failure"; $p < .05$) but the ability to afford a new pacemaker did not independently predict the other statements.

4 | DISCUSSION

4.1 | Major findings

A large majority of respondents in the four surveyed low- to middle-income countries have positive attitudes towards postmortem donation of pacemakers and embrace the concept of a reconditioned device for their medical care. These positive attitudes persist even in hypothetical scenarios in which these devices carry a higher risk of device malfunction or infection.

A successful wide-scale pacemaker reutilization program requires participation of patients, their family members, the funeral industry in donor countries, as well as health authorities, physicians, patients, and the families in recipient countries. With regard to patients in potential donor countries, Gakenheimer et al reported that 87% of patients with cardiac implantable electronic devices (CEIDs) and 71% of the general population in the United States would be willing to donate them to indigent patients in LMICs.⁶ This study also found that 89% of Michigan funeral directors would support a cardiac device reuse initiative. From the physician perspective, in a web-based survey of 429 Heart Rhythm Society (HRS) members (primarily cardiac electrophysiologists), 81% of physician respondents reported being comfortable asking their patients to consider donating their CIED and 84% reported willingness to reimplant a resterilized device if the

practice were legally sanctioned. Importantly, HRS members from high-income countries supported CIED reuse at rates similar to those from lower- and upper-middle-income countries.⁷ The present study complements the existing survey data by demonstrating broad support for pacemaker reuse among patients and their family members in LMICs, where an unmet need for pacemakers persists despite economic progress.

Respondents were less likely to accept a reused pacemaker in a hypothetical scenario in which a reused device is more likely to malfunction and even less likely in a hypothetical scenario in which a reused device is more likely to cause infection, although a majority of respondents were still agreeable to accepting a pacemaker under either of these scenarios. In the aforementioned survey of HRS members, when asked about their potential concerns about CIED reuse, 64% of physicians cited infection and 29% cited device malfunction.⁷ In a meta-analysis comprising 18 studies and 2270 patients who underwent pacemaker reuse, device malfunction was more frequent with reused devices than new ones (odds ratio 5.80 [1.93–17.47], $p = .002$), but only occurred in 0.7% of reimplanted devices. Most malfunctions were related to set screw abnormalities, which may be identified during a thorough validation process before donation, or even during the implantation procedure when the pacemaker with the faulty screw may be replaced by a back-up device. The risk of infection among reconditioned devices was 2.0%, statistically similar to the risk for new devices.⁹ Standardized sterilization protocols are needed to minimize the risk of infection. Our group proposed a standardized sterilization protocol to clean, test, and sterilize CIEDs to meet industry standards for sterility of reconditioned implantable medical devices.¹⁰ This sterilization and reuse process is to be distinguished from a practice in some LMICs in which patients with CIED pocket infection undergo reinsertion of their original resterilized CIED after completion of a course of antibiotics. Yet even if the risks associated with reused devices are higher, our survey suggests that patients in LMICs perceive an increased risk of infection or malfunction to be an acceptable tradeoff when the alternative is not receiving appropriate care due to lack of access to a new device. Reconditioned pacemakers should only be offered to patients who would not otherwise be able to obtain a new device, and such implantation should only be performed following thorough informed consent.⁷ Ethically, we may be obligated to offer such a resterilized device to those whom no other treatment is available.¹¹

The finding that respondents who are unable to afford a new device were more likely to be willing to accept a reused device is not surprising given that the primary justification for device reuse is cost reduction. It is remarkable that the rates of acceptance of a reused pacemaker were greater than 50% even among patients who stated that they *could* afford a new device, suggesting that the cost savings of a reused device are a tangible benefit even when a new device is not prohibitively expensive.

The finding that respondents from Lebanon were less likely than respondents from other countries to be willing to undergo reimplantation is partly due to the fact that these respondents were more likely to be able to afford a new device, which we found in

logistic regression to be negatively associated with willingness to accept a new device even when accounting for country of residence. Lebanon is the highest-income country among our survey sample and these trends of opinion may be similar in other upper-middle-income countries.

4.2 | Study limitations

Since this survey was voluntary, there is a risk of participation bias in that individuals who agreed to complete the survey may have been predisposed to have positive viewpoints of device reuse compared with those who declined, or that the researchers were wanting them to approve of the practice. The response rate was not quantitatively tracked; however, it was estimated to be at least 80% across the four study sites. Our sample was limited to patients and family members in the waiting rooms of a small subset of outpatient clinics in four countries. Detailed questions regarding respondents' personal medical history were not asked even though this information may have been useful in characterizing the sample. This choice was made to keep the survey short and help maximize the response rate. Many factors – such as the local economy, the healthcare system, level of trust in the healthcare system, and variations in ethical standards and cultural beliefs – may have influenced these opinions and these findings are therefore not necessarily generalizable to all LMICs or the global community. The mean age of 48 years in our sample reflects the fact that the survey was administered at a variety of outpatient clinics (some of which were primary care clinics), which represents a younger, on average, sample than patients likely to be offered a pacemaker. Despite these potential biases, the overwhelmingly positive attitudes toward the donation and acceptance of reused pacemakers among this large and geographically diverse sample suggest that these opinions are likely to at least directionally reflect the views of people living in other LMICs as well.

5 | CONCLUSIONS

Reuse of properly reconditioned pacemakers may allow patients in LMICs to receive essential bradycardia therapy despite their financial inability to obtain a new device. A significant majority of patients and family members residing in countries that could benefit from reuse have positive attitudes toward the postmortem donation of pacemakers. This finding underscores the importance of further study to better demonstrate the safety of pacemaker reuse and to advocate for changes in the regulatory environment to enable pacemaker reuse for the benefit of disadvantaged patients in LMICs.

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CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

AUTHOR CONTRIBUTIONS

Andrew B. Hughey: Data collection, data analysis/interpretation, manuscript development. **Palaniappan Muthappan:** Concept/design, data collection, manuscript development; critical revision of article. **Timir Baman:** critical revision of article. **Naila Baig-Ansari:** Data collection, critical revision of article. **Fayez Jawed:** Data collection, critical revision of article. **Abdul B. Khan:** Data collection, critical revision of article. **Qingmei Jiang:** Statistics. **Katherine L. Hughey:** Data collection, critical revision of article. **Rolando Jirón Toruño:** Data collection, critical revision of article. **Christian Machado:** Data collection, critical revision of article. **Auroa Badin:** Data collection, critical revision of article. **Marwan M. Refaat:** Data collection, critical revision of article. **Patrick Zakka:** Data collection, critical revision of article. **Mostafa Hotait:** Data collection, critical revision of article. **Kim A. Eagle:** Concept/design, critical revision of article. **Thomas C. Crawford:** Concept/design; critical revision of article.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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