Unregulated online sales of cardiac implantable electronic devices in the United States: A six-month assessment

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BACKGROUND An estimated 1 million patients require cardiac implantable electronic devices (CIEDs) but go without annually. This disparity exists in low-to-middle-income nations largely owing to the cost of CIED hardware. Humanitarian reuse of CIEDs has been shown to be safe and feasible. However, recent publications have raised concern that promotion of CIED reuse may foster a CIED “black market,” to the dismay of manufacturers, regulators, and clinicians alike.

OBJECTIVE To determine if unregulated CIED sales for potential human use is a real issue by investigating unregulated public online CIED sale listings in the United States of America.

METHODS An observational study was undertaken over 6 months using multiple internet search engines from May 1 to November 1, 2019. We cataloged usable CIEDs (still in packaging, manufactured <7 years) and pricing. Manufacturers were contacted to determine status of sellers and unregulated CIEDs using model/serial numbers.

RESULTS In total, 58 CIEDs—47 implantable cardioverter-defibrillators and 11 permanent pacemakers—from 4 manufacturers were listed for sale on 3 websites. During the study period, 8 of 11 pacemakers and 37 of 47 implantable cardioverter-defibrillators were sold (price range: $100–$1500 [US dollars]). No new listings were seen in the last 3 months of observation, possibly owing to concomitant industry investigation.

CONCLUSION There does exist a public online market for unregulated CIED sales in the United States. This specific market seems to be small and unlikely to significantly expand with active monitoring by manufacturers and regulators.

KEYWORDS Cardiac implantable electronic device (CIED); Defibrillator re-use; Global disparities; Implantable cardioverter-defibrillator; Pacemaker; Pacemaker re-use

Introduction

There are approximately 1.7 million cardiac implantable electronic device (CIED) insertions worldwide each year. However, more than 1 million patients who require such CIED therapies go without treatment annually, highlighting the global disparity that exists in the use of these devices. This disparity exists mainly in low-to-middle-income nations largely owing to the prohibitive costs of the CIED hardware, as noted by implanting physicians in these nations. The approximate negotiated cost for a new pacemaker generator alone is $2500–$8000 (US dollars) and for a new defibrillator generator it is $10,000–$18,000. Consequently, the annual insertion rates of pacemakers and implantable cardioverter-defibrillators (ICDs) are estimated to be >700 per million and >200 per million, respectively, in high-income countries. This is in stark contrast to <7 per million and <2 per million for pacemakers and ICDs, respectively, in low-to-middle-income countries.

Although several device manufacturers donate a limited number of new CIEDs for use in indigent recipients, there remains a large unmet humanitarian need. Hence, the reuse of CIEDs in underserved nations has been investigated as a potential option to reduce the global disparity in CIED therapy. Contemporary observational studies have consistently shown that device reuse utilizing modern reprocessing protocols...
methods
We undertook a prospective observational study employing weekly online searches over 6 months using multiple internet search engines from May 1 to November 1, 2019 (B.A., S.K.S.). These online search engines included Google, Firefox, Bing, and Internet Explorer. Search terms such as “pacemaker,” “defibrillator,” “ICD,” and “implantable cardioverter-defibrillator” for sale were used and the resulting websites were screened to exclude irrelevant items (eg, model trains, yachts, books, automated external defibrillators) that were clearly not CIEDs. We verified and cataloged usable and unregulated CIEDs listed online for sale in the United States as well as the seller’s last recommended selling price and geographic origin.

“Usable CIEDs” were defined as devices manufactured within the last 7 years and still in the original, fully intact manufacturer packaging. “Unregulated CIEDs” were defined as CIEDs that were listed for sale by a seller not employed or approved as a contracted distributor by a manufacturer. Using the model and serial numbers on the original packaging (verified by high-resolution images from the sellers), we contacted manufacturers to determine the last known registered status of the CIEDs identified and to confirm that the seller was not an approved distributor. If an adequate high-resolution image was not provided on the website listing, we endeavored to contact the seller by electronic mail to confirm the veracity and condition of the listed product. Using the information obtained from the manufacturer concerning the last known registered status of the CIEDs identified, we categorized the status of the CIED products as “stolen,” “lost,” “sold,” or “unknown.” Devices sold by sellers outside of the United States or manufactured more than 7 years ago and/or without the original packaging were excluded from study analysis.

Results
During the 6-month study period, there were 58 CIEDs identified—47 ICDs and 11 permanent pacemakers—listed for sale in 6 different states in the United States (Table 1). These devices were manufactured by 4 different companies (Medtronic, Minneapolis, MN; Abbott, Abbott Park, IL; Biotronik, Lake Oswego, OR; and Boston Scientific, Marlborough, MA) and were listed on 3 different websites: MedWOW (Nicosia, Cyprus), DOTmed (New York, NY), and eBay (San Jose, CA). During the study period, 8 of the 11 pacemakers and 37 of the 47 ICDs were sold, with final price listings ranging from $275 to $1500 and $100 to $1000, respectively, during a period of 4–17 weeks. Of significant note, we observed no new listings in the last 3 months of the study (Figure 1).

Discussion
We observed that in the first 3 months of the study, 47 ICDs and 11 pacemakers were listed for sale that appeared to be usable CIEDs. Of serious concern, 81% of the CIEDs (47/58) were verified by communication with the relevant US manufacturer as being either “lost,” “stolen,” or already “sold” to a health system in the past. This indicates that many had been illicitly procured prior to being listed online for sale. Additionally, these devices were listed online for sale to the public
Our study shows that a public online market for unregulated CIED sales in the United States does exist. However, this specific market seems to be small and unlikely to warrant so much concern for fostering a sizable CIED “black market” so as to outweigh the benefits of promoting CIED retrieval antemortem and postmortem in high-income nations for humanitarian reuse in low-income nations.

Limitations
Limitations of our observational study include that it focused on US CIED sale listings and does not account for unregulated sales in many other nations. Also, we investigated public online unregulated CIED sales and thus cannot account for private offline unregulated sales of CIEDs that may have occurred during this time period. Additionally, we lack data on the actual disposition and use of the CIEDs purchased. However, CIED retrieval and disposition data published in a prior study surveying 71 morticians in the United States indicated that 18% of CIEDs were donated for human reuse in lower-income nations and 9% of CIEDs were provided for veterinarian use.

Conclusion
Ongoing active monitoring by CIED manufacturers and regulatory organizations can be instrumental in curbing the sales of unregulated CIEDs and the likelihood of any public “black market” blossoming.
significantly expand publicly in the United States with active monitoring by manufacturers and regulators. Further investigations are necessary, both to quantify online unregulated CIED sales in other nations and to see if the potential “Hawthorne effect” that we noted continues to persist in the United States beyond the observational period in our study.

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**Figure 1**
Number of unregulated online sale listings of verified cardiac implantable electronic devices (CIEDs) in the United States (per month) over the 6-month study period. Telephone icon signifies communication with manufacturers verifying the status of their listed CIEDs; magnifying glass icon signifies that new CIED listings were observed in the first 3 months of study (positive magnifying glass) but not in the last 3 months of study (negative magnifying glass). ICD = implantable cardioverter-defibrillator; PPM = permanent pacemaker.