

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

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Introduction

There are approximately 1.7 million cardiac implantable electronic device (CIED) insertions worldwide each year.¹ 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.¹ 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.^{1,2} The approximate negotiated cost for a new pace-

maker generator alone is \$2500–\$8000 (US dollars) and for a new defibrillator generator it is \$10,000–\$18,000.³ 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.⁴

Although several device manufacturers donate a limited number of new CIEDs for use in indigent recipients, there remains a large unmet humanitarian need.^{1,3} 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

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KEY FINDINGS

- There exists a public online market for sales of *usable* and *unregulated* cardiac implantable electronic devices (CIEDs) by unapproved distributors in the United States.
- During a recent 6-month period, 58 usable CIEDs—47 implantable cardioverter-defibrillators and 11 permanent pacemakers—made by 4 US manufacturers were publicly listed for sale on 3 private websites (MedWOW, DOTmed, eBay).
- Most unregulated CIEDs (81%) were likely illicitly procured (verified as lost, stolen, or sold to a health system by their respective manufacturer registries).
- No new unregulated CIED sale listings were observed in the final 3 months of study, most likely owing to active investigation by the US manufacturers that we had contacted.
- The public online market for unregulated CIEDs in the United States seems to be small and unlikely to expand publicly with active monitoring by manufacturers and regulators.

does not significantly increase the risk of infection, malfunction, premature battery depletion, or device-related death.^{3,5} Accordingly, the humanitarian reuse of CIEDs has been determined to be a safe and feasible option for indigent patients. In fact, the potential impact of this humanitarian effort prompted a recent “call to action” by several academic experts in January 2019 advocating that professional societies, the electrophysiology physician community, and governmental regulatory agencies should support Project My Heart Your Heart (Detroit, MI) and other registered international charities seeking approaches to close the pacemaker care delivery gap.⁶

Nevertheless, recent concerns have been raised in the academic community that the widespread public promotion of unregulated CIED reuse may also create a “black market” for usable CIEDs following their antemortem or postmortem retrieval.⁷⁻⁹ Accordingly, some manufacturers, civil service regulators, and health care providers may be hesitant to support humanitarian CIED reuse efforts if they fear unwittingly helping to foster the illicit resale of such CIEDs. Therefore, the objective of this prospective study was to determine if unregulated CIED sales for potential human use is a real and quantifiable public health issue by investigating unregulated online CIED sale listings in the United States of America, where >400,000 CIED generators are inserted annually, making it by far the world’s largest CIED market.⁴

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 online 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

Table 1 Specific characteristics of each online sale listing of cardiac implantable electronic devices in the United States during the 6-month observational study period

Website	US seller location (state)	CIED type	Model	Product year	N	Serial #	Online price (USD)	Time on listing (weeks)	Manufacturer and status
MedWOW	NC	ICD	Evera MRI XT DR SureScan	2017	35	No*	\$100	8 weeks	Medtronic STOLEN
MedWOW	MN	PPM	Adapta ADSR01	2016	1	Yes	\$500	26+	Medtronic LOST
eBay	KY	PPM	Accent SR RF PM1210	2012	1	Yes	\$275	8 weeks	Abbott SOLD TO HEALTH SYSTEM
DOTmed	FL	PPM	Adapta ADDR01	2013	2	Yes	\$700	26+	Medtronic SOLD TO HEALTH SYSTEM
DOTmed	FL	PPM	Adapta ADSR01	2014	1	Yes	\$700	26+	Medtronic SOLD TO HEALTH SYSTEM
DOTmed	FL	ICD	Ellipse VR CD1411-36Q	2016	2	Yes	\$700	10 weeks 17 weeks	Abbott STOLEN
MedWOW	CA	ICD	Iperia 7 DR-T	2018	10	No*	\$1000	20+	Biotronik UNKNOWN
MedWOW	CA	PPM	Entovis SR-T	2018	1	No*	\$1500	19+	Biotronik UNKNOWN
DOTmed	WA	PPM	Accolade MRI DR EL L331	2017	3	Yes	\$1197	5 weeks	Boston Scientific STOLEN
DOTmed	WA	PPM	Accolade MRI DR L311	2017	2	Yes	\$1151	5 weeks 4 weeks	Boston Scientific STOLEN

CIED = cardiac implantable electronic device; ICD = implantable cardioverter-defibrillator; PPM = permanent pacemaker.

*Inadequate images but credible e-mail correspondence regarding authenticity.

at a fraction of their original price without evident restrictions on human use. In fact, only 5% (3/58 CIEDs) were specified in the sellers' listings as being for "educational use" only.

Remarkably, our observational study also identified no new online listings for unregulated CIED sales in the last 3 months of investigation. This significant reduction in online CIED listings in the US may be due to a "Hawthorne effect" (the alteration of behavior by the subjects of a study owing to their awareness of being observed) resulting from concomitant industry investigation triggered by our communicated observations during the course of the study period.¹⁰ In fact, the manufacturers that we contacted (Abbott, Boston Scientific, and Medtronic) during our study (to verify the official status of CIEDs with identifiable model/serial numbers listed for sale) each indicated their intention to further investigate how these unregulated CIED listings occurred. We believe it is likely that their efforts in notifying the specific websites involved of the potentially illicit source of the CIED listings led to greater subsequent scrutiny of potential sellers and their CIED products. This in turn may have resulted in the unexpected salutary dissipation of unregulated online CIED sale listings. Alternatively, given the modest size of the online market under study and the limited period of observation, we cannot rule out the possibility of a cyclical market fluctuation or else subsequent migration of sellers of unregulated CIED products to other (offline or private) markets not prone to online public scrutiny.

Overall, our 6-month observational study highlights the existence of a public online market for unregulated sales of

CIEDs in the United States. 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.

Thus, the unregulated sales of CIEDs do not seem 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.¹¹

Conclusion

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

Unregulated On-Line Sale Listings of Verified CIEDs in the United States (N = 58)

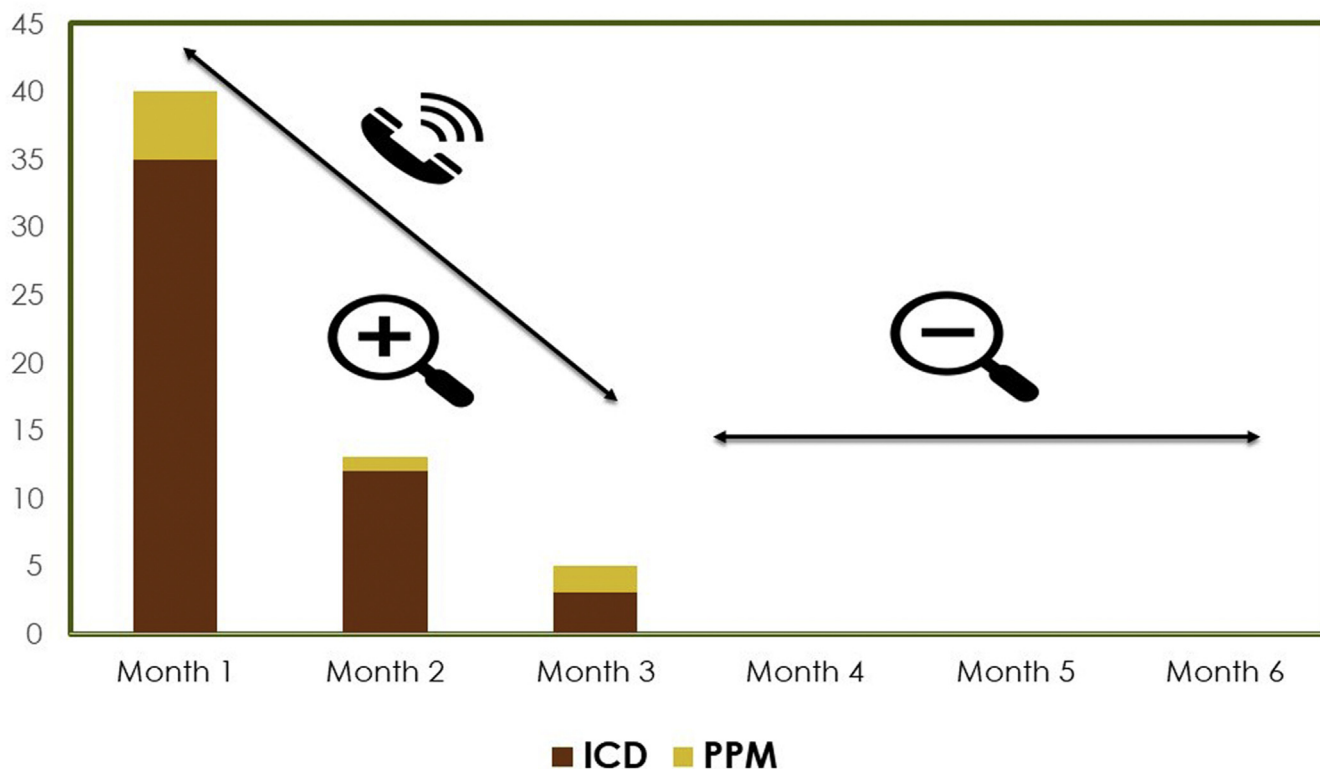


Figure 1 Number of unregulated online sale listings of verified cardiac implantable electronic devices (CIEDs) in the United States (per month) over the 6-month study period. Telephone icon signifies communication with manufacturers verifying the status of their listed CIEDs; magnifying glass icon signifies 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.

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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