

Dynamic Automated External Defibrillator (AED) Registry

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Disclosures

- National Heart Lung Blood Institute, Bethesda, MD, Resuscitation Outcomes Consortium Data Coordinating Center, U01 HL077863-07; Co-PI, Significant.
- Food and Drug Administration, Silver Spring, MD; Cardiac Science Corp, Waukesha, WI; Heartsine Technologies Inc., Newtown, PA; Philips Healthcare Inc., Bothell, WA; Physio-Control Inc., Redmond, WA; ZOLL Medical Inc., Chelmsford, MA, Dynamic AED Registry, U01FD004933-02; PI, Modest.
- American Heart Association, Dallas, TX, Simple EMS Registry; PI, no compensation.
- Neuroprotexon Inc., San Francisco, CA, Xena Trial; PI, Significant.



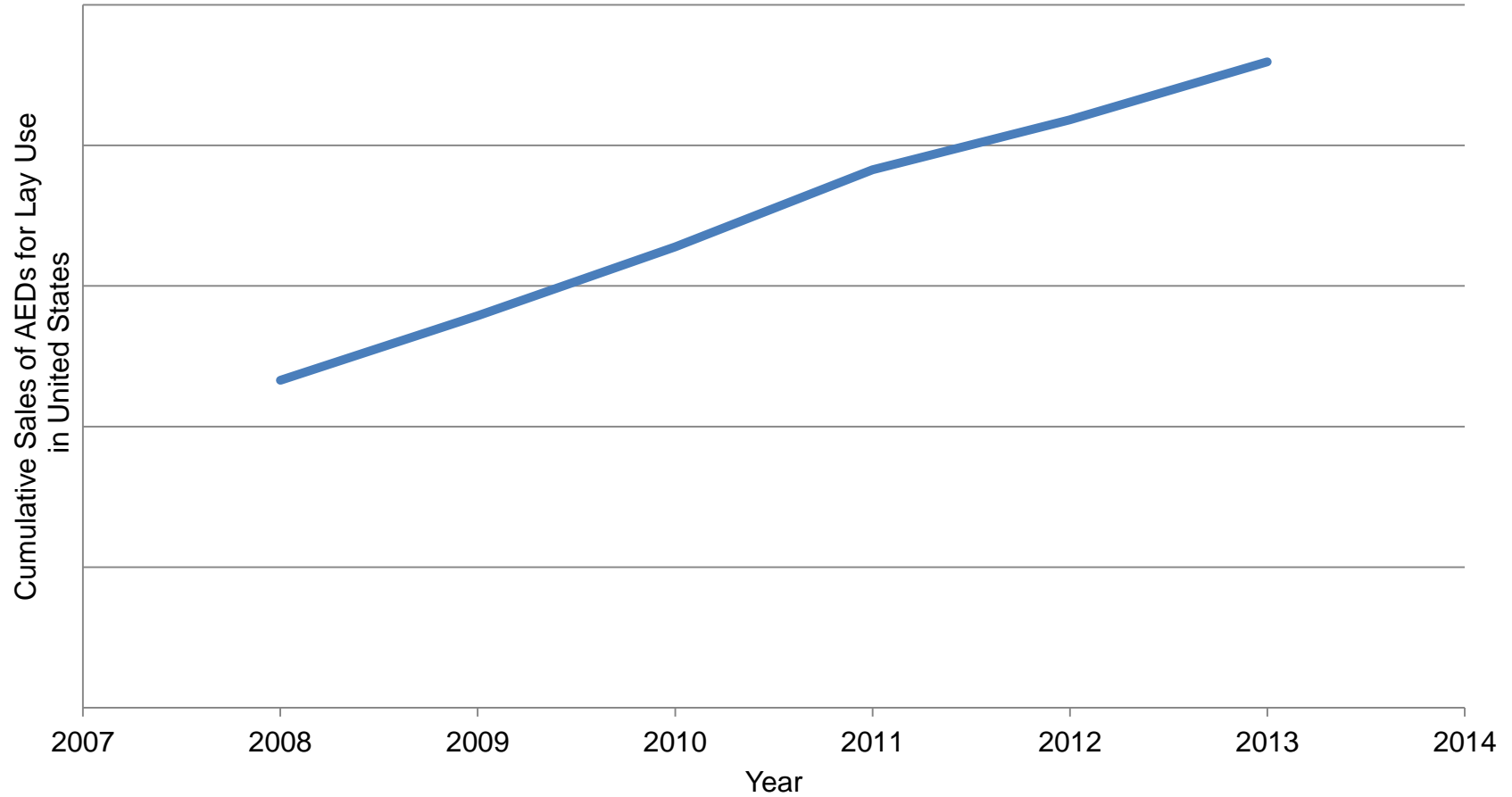
Lay Use of Automated External Defibrillators Before Arrival of EMS Providers on Scene Increases Survival After OHCA

PAD Trial Investigators N Engl J Med 2004

	CPR Only	CPR + AED	P Value	
			Unadjusted	Adjusted
Definite CA	107	128	0.09	
Residential	37	33		
Public	70	95		
Survivors of definite arrest	15	30	0.03	0.03
Residential	1	1		
Public	14	29		
CPC of survivors			0.9	
Normal	10 (71)	22 (73)		
Mildly imp.	3 (21)	5 (17)		
Mod. Imp.	1 (7)	3 (10)		

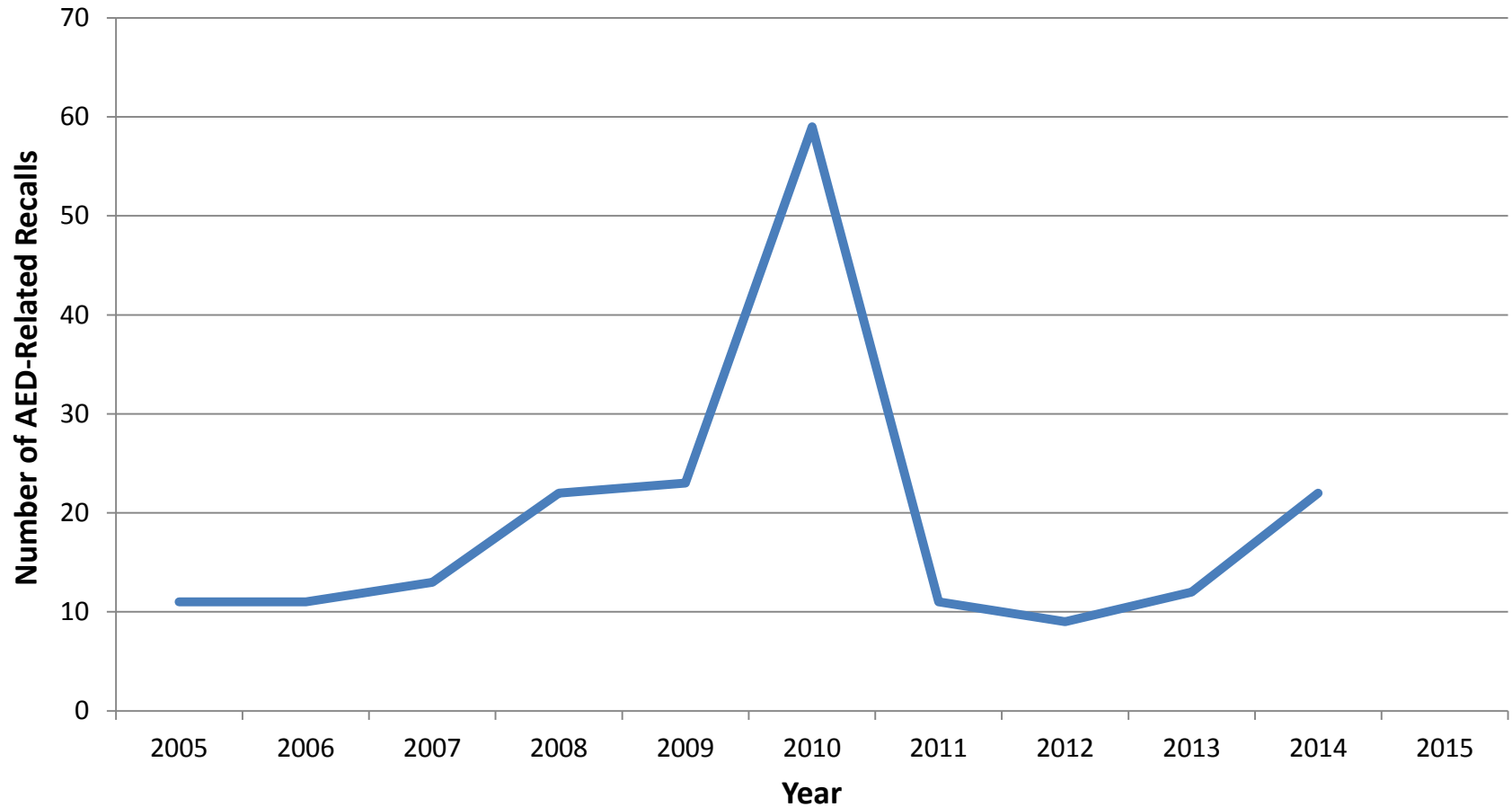
Dissemination of AEDs into Public Locations

Cumulative US Sales Data, AED Manufacturers



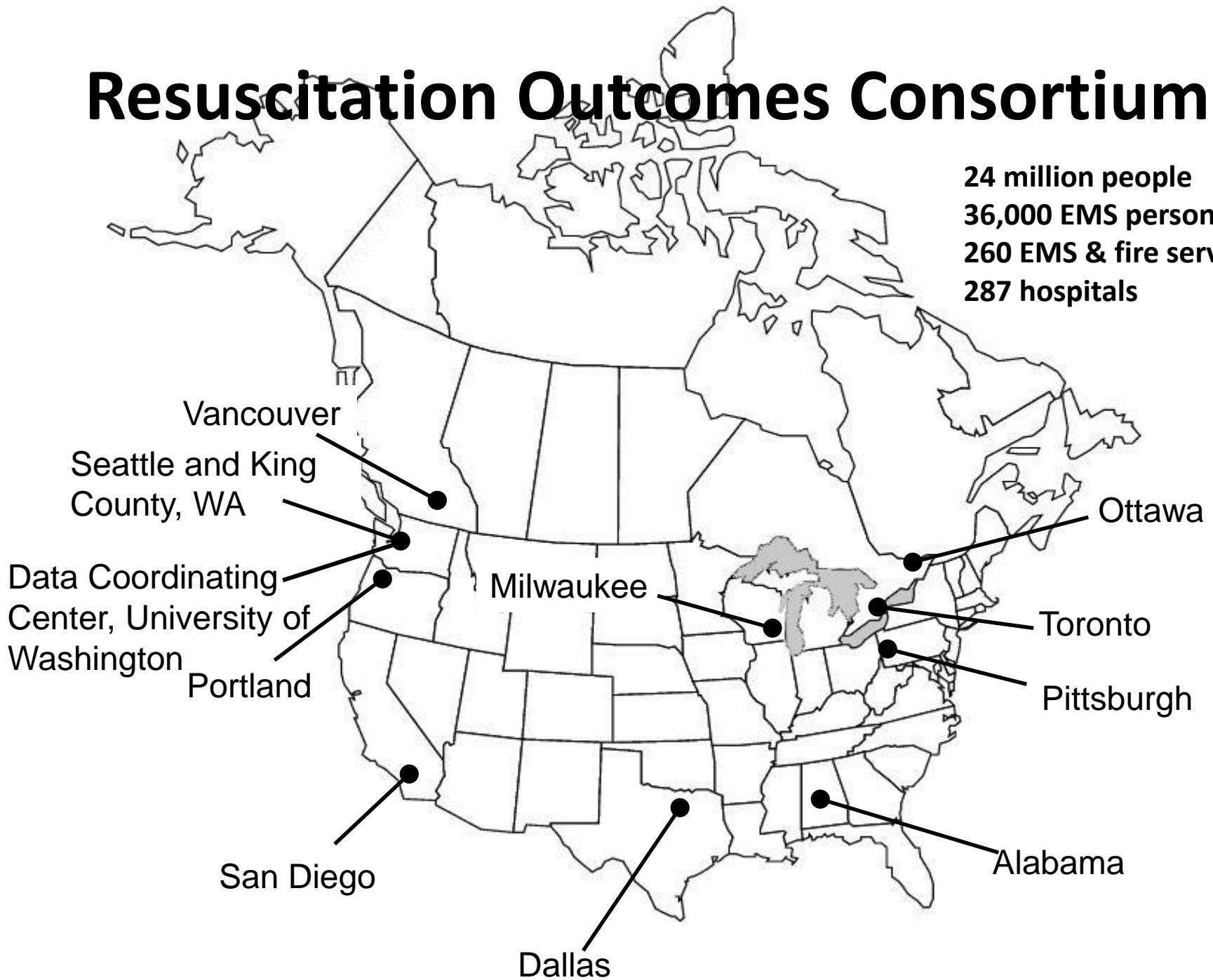
AED-Related Recalls Increasing Over Time

www.accessdata.fda.gov accessed on Sep 7, 2015



Resuscitation Outcomes Consortium

24 million people
36,000 EMS personnel
260 EMS & fire services
287 hospitals



Public Health Surveillance of FDA-Approved AEDs

- Clinical use of AED not elective.
- Difficult to know in advance:
 - Which patient exposed to which device;
 - Which operator will use device;
 - What operational status of the device is.
- Lack of standardization of form and function adds to difficulty in use and maintenance of these devices.
- Moved periodically from one location to another.
- Requirements for registration vary widely from state to state.
- Unclear who is responsible or accountable.

Crowdsourcing

Merriam-Webster Dictionary

- Practice of obtaining needed services by soliciting contributions from large group of people, especially from an online community, rather than from traditional employees or suppliers.
- Often used to subdivide tedious work (e.g. Amazon Mechanical Turk) or to fund-raise startup companies (e.g. Kickstarter) and charities.
- Combines efforts of crowds of self-identified volunteers or part-time workers, where each one on their own adds a small portion that combines into greater result.

Use of 2D Matrix Code As Dynamic Device Identifier for AED Surveillance





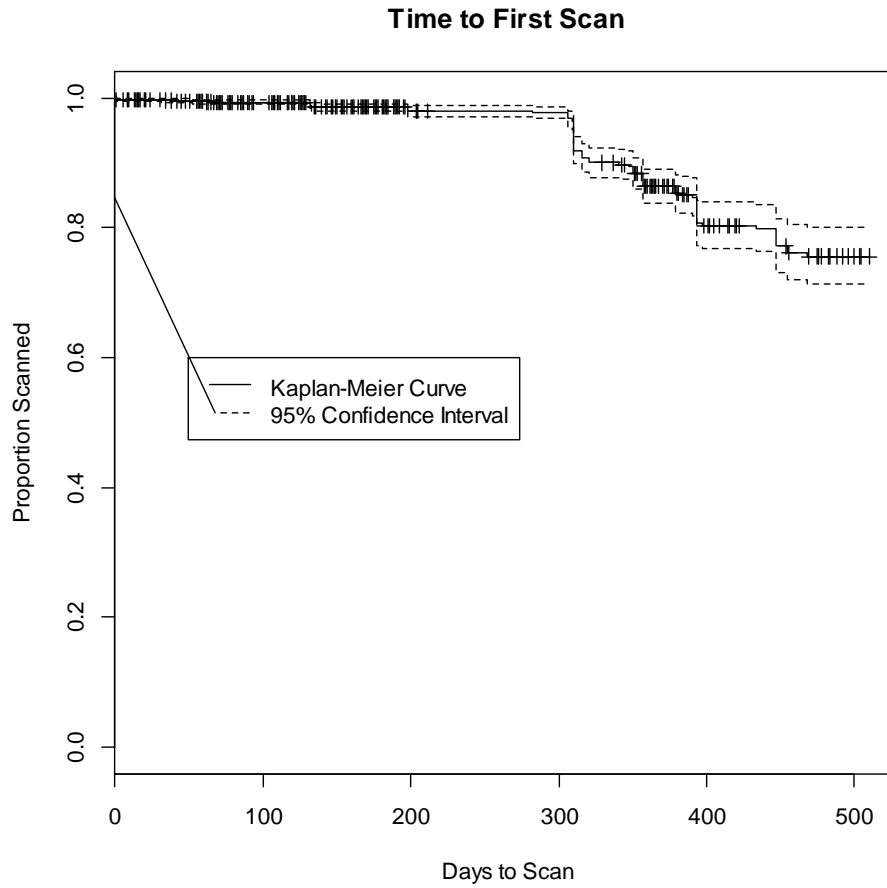
Help Save
Lives!
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aed.uwctc.org/m/9x62z1z

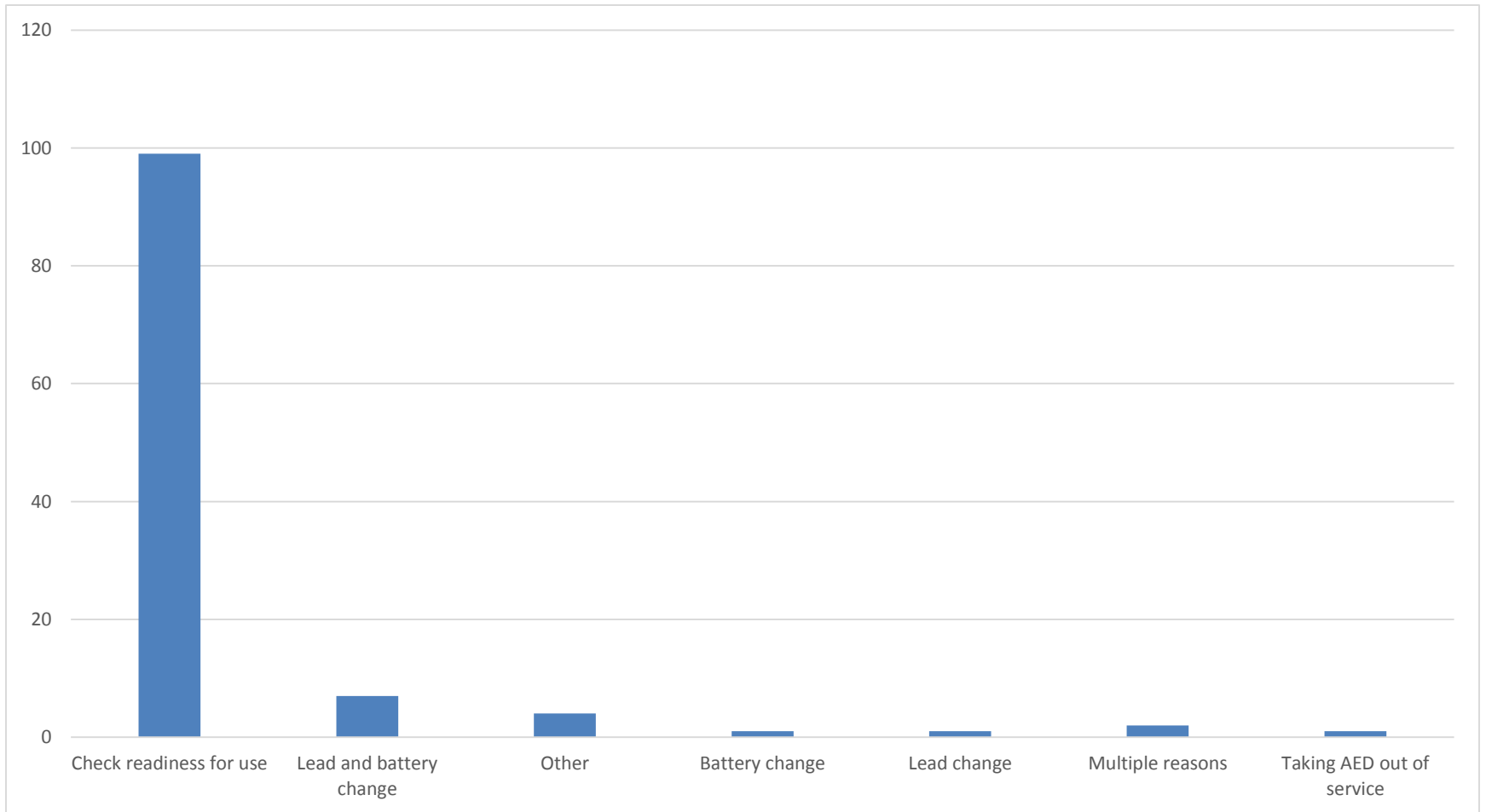
Dynamic Device Identifier for Automated External Defibrillators

- AEDs included in municipal registry supplemented by crowdsourcing.
- Each AED tagged with unique two-dimensional (2D) matrix code (e.g. QR code, Denso Wave Inc., Chita-gun, Japan).
- 2D matrix code is recorded as well as location and status of AED by using open-source software native to any contemporary smartphone (e.g. Google Goggles, Google Inc., Mountain View, CA).
- Elements automatically passed via internet to secure database in real time.
- Information verified by user by answering finite set of questions when smartphone is connected to database.
- To date, > 25,000 AEDs identified; >2,500 tagged.

Time to Rescan



Non-Clinical Use



Clinical Uses

- All patients treated for OHCA in participating communities, regardless of initial rhythm:
 - Lay use of AED;
 - CPR or defibrillation by EMS provider.
- Followed up to hospital discharge to verify vital status.

Outcomes with and without Lay Use of AED

Dynamic AED Registry 2014, as of Jul 1, 2015

		A	B	C	D	E	F
VF or shockable rhythm	Lay AED Use	5/21 (24%)	7/11 (64%)	1/4 (25%)	0/0 (0%)	2/4 (50%)	1/2 (50%)
	Lay AED Not Used	31/179 (17%)	23/51 (45%)	7/34 (21%)	9/30 (30%)	20/30 (67%)	7/67 (10%)
not VF or non shockable rhythm	Lay AED Use	6/98 (6%)	2/41 (5%)	4/83 (5%)	5/14 (36%)	4/15 (27%)	0/11 (0%)
	Lay AED Not Used	41/941 (4%)	18/396 (5%)	11/169 (7%)	9/78 (12%)	20/240 (8%)	8/280 (3%)

Multiple Approaches to Identify Potential Adverse Events

- In event of clinical use, providers asked whether AED not available in its recorded location, missing parts that limited its use (e.g. ECG lead, battery), or did not function as intended. Not an adverse event, but does impact on ability to use device to treat patient in cardiac arrest.
- Cardiac arrests associated with use of an AED are reviewed at site level, and classified as shock advised vs. not and shock delivered versus not. Participating sites are instructed to retain index event recording if an EMS provider reports that device appeared to not function correctly.
- At event review, query whether first rhythm recorded after their arrival on scene was shockable/VF vs. not shockable/PEA/asystole. Then compare classification of shockable by AED vs. shockable by EMS providers as one measure of potential adverse events.





Organic Growth of AED Registry via 3d Party

- MD Solutions International provides medical oversight for corporate public access defibrillation programs throughout US.
- Customers have ~20,000 AEDs installed.
- MDSI encouraging customers to tag AEDs and include them in Dynamic AED Registry.

Organic Growth through Prospective Tagging

- ZOLL Medical Corp.
 - Largest monitor/defibrillator manufacturer by sales volume in 2015.
 - Implementing prospective tagging of new AEDs sold for use by laypersons.
- Expect others would agree to do so if required to conduct post-market surveillance as part of PMA process.

Google Maps

HeartMap AED Education News Seattle AED Tagging    Graham 

325 Ninth Ave, Seattle, WA, United States

AED within 1 kilometer

Location	Distance (km)
First Hill Apartments	Distance (km): 0.00
	Distance (km): 0.00
	Distance (km): 0.00
	Distance (km): 0.16
	Distance (km): 0.19
	Distance (km): 0.26
	Distance (km): 0.27
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	Distance (km): 0.27
	Distance (km): 0.38
	Distance (km): 0.40
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Grant of Authority for Public Health Surveillance

- AED functions under grant of authority for public health surveillance from FDA to UW.
- Health Insurance Portability and Accountability Act (HIPAA) permits covered entities to disclose Protected Health Information without individual authorization and without the need to obtain approval by or waiver of HIPAA authorization from an IRB.



Pharos

- Ongoing public health surveillance and quality improvement program to guide providers to provide safe, effective and efficient care by using wireless vital sign monitors in field, emergency department and hospital.
- Public-private partnership between Sotera Wireless Inc. (San Diego, CA) and the University of Washington-Harborview Center for Prehospital Emergency Care (Seattle, WA).
- Sotera manufactures and markets ViSi Mobile System which is capable of continuous non-invasive monitoring of heart rate, blood pressure, respiratory rate, and pulse oximetry, with wireless transmission of data and alerts.