

Supplementary Online Content

Desai NR, Bourdillon PM, Parzynski CS, et al. Association of the US Department of Justice investigation of implantable cardioverter-defibrillators and devices not meeting the Medicare National Coverage Determination, 2007-2015. *JAMA*. doi:10.1001/jama.2018.8151

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This supplementary material has been provided by the authors to give readers additional information about their work.

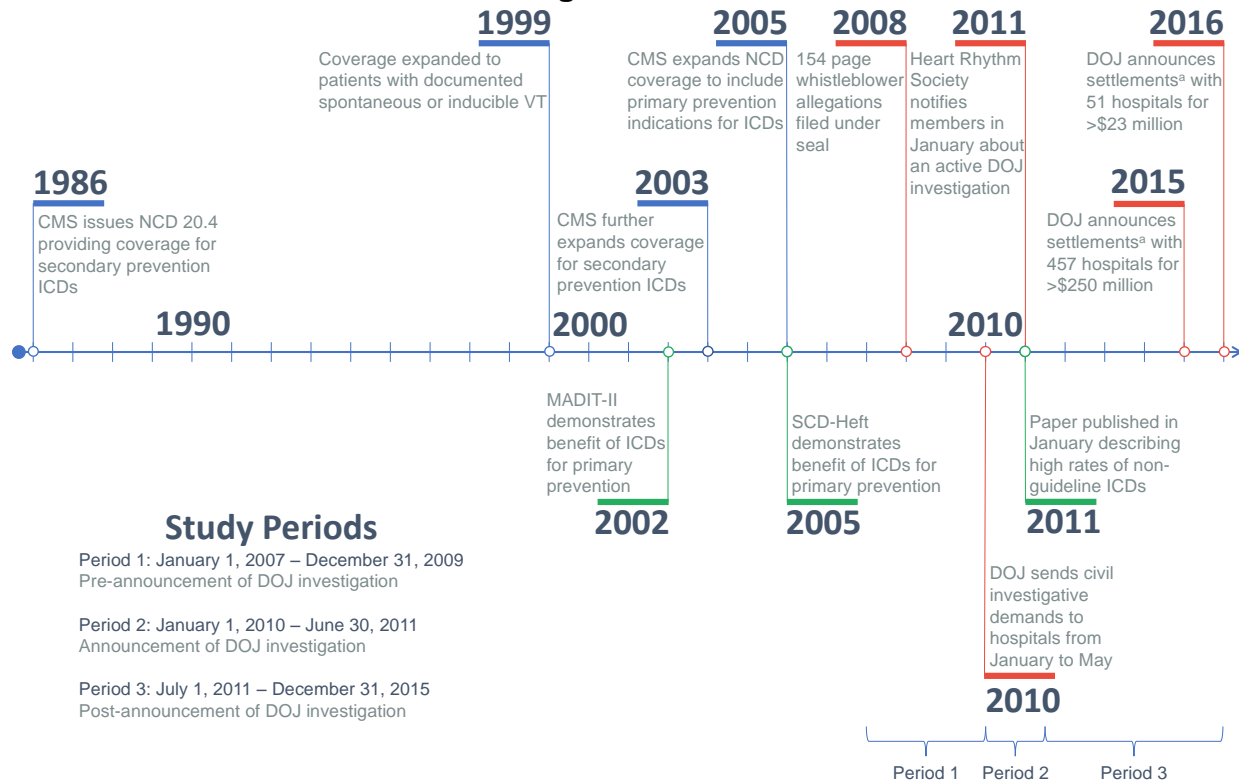
eTable. Hospital Characteristics Stratified by DOJ Settlement Status

Characteristics	Total ^a	Settled with DOJ	Did Not Settle with DOJ	Standardized Difference
N (%)	1,809 (100.0)	452 (25.0)	1,357 (75.0)	
Patient Beds, Median (IQR)	280 (171-413)	307 (199-431)	268 (162-409)	0.19
Annual ICD Volume, Median (IQR)	63 (23-144)	92 (47-182)	50 (20-128)	0.43
Annual Pacemaker Volume, Median (IQR)	111 (53-200)	157 (78-256)	100 (50-186)	0.43
Annual PCI Volume, Median (IQR)	360 (145-691)	489 (250-875)	320 (120-605)	0.44
Teaching Hospital	625 (34.6)	151 (33.4)	474 (34.9)	0.03
Public Hospital	651 (36.0)	180 (39.8)	471 (34.8)	0.10
Setting				
Rural	396 (21.9)	64 (14.2)	332 (24.5)	0.26
Suburban	580 (32.1)	157 (34.7)	423 (31.2)	0.08
Urban	833 (46.1)	231 (51.1)	602 (44.4)	0.14
Facility Type				
Government	41 (2.3)	1 (0.2)	40 (3.0)	0.22
Private or Community	1,635 (90.4)	427 (94.5)	1,208 (89.0)	0.20
University	133 (7.4)	24 (5.3)	109 (8.0)	0.11
Participant Classification				
Free Standing Catheterization Lab or Clinic	1 (0.1)	0 (0.0)	1 (0.1)	0.04
Free Standing Catheterization Lab	8 (0.4)	1 (0.2)	7 (0.5)	0.05
Health System or Network	69 (3.8)	16 (3.5)	53 (3.9)	0.02
Hospital	1,591 (88.0)	411 (90.9)	1,180 (87.0)	0.13
Hospital or Health Network	132 (7.3)	23 (5.1)	109 (8.0)	0.12
Other	6 (0.3)	1 (0.2)	5 (0.4)	0.03
Private Cardiovascular Practice	2 (0.1)	0 (0.0)	2 (0.2)	0.05
Census Region				
Midwest	460 (25.6)	109 (24.2)	351 (26.1)	0.04
Northeast	242 (13.5)	37 (8.2)	205 (15.2)	0.22
South	750 (41.8)	205 (45.5)	545 (40.5)	0.10
West	344 (19.2)	100 (22.2)	244 (18.1)	0.10

Abbreviations: DOJ, Department of Justice; ICD, implantable cardioverter-defibrillator; IQR, interquartile range; PCI, percutaneous coronary intervention

^aThe total sample of 1809 hospitals includes all institutions with complete data in the NCDR ICD registry between January 1, 2007 and December 31, 2015.

eFigure 1. Timeline of Major Events in Development of CMS NCD for Primary Prevention ICDs and the DOJ Investigation

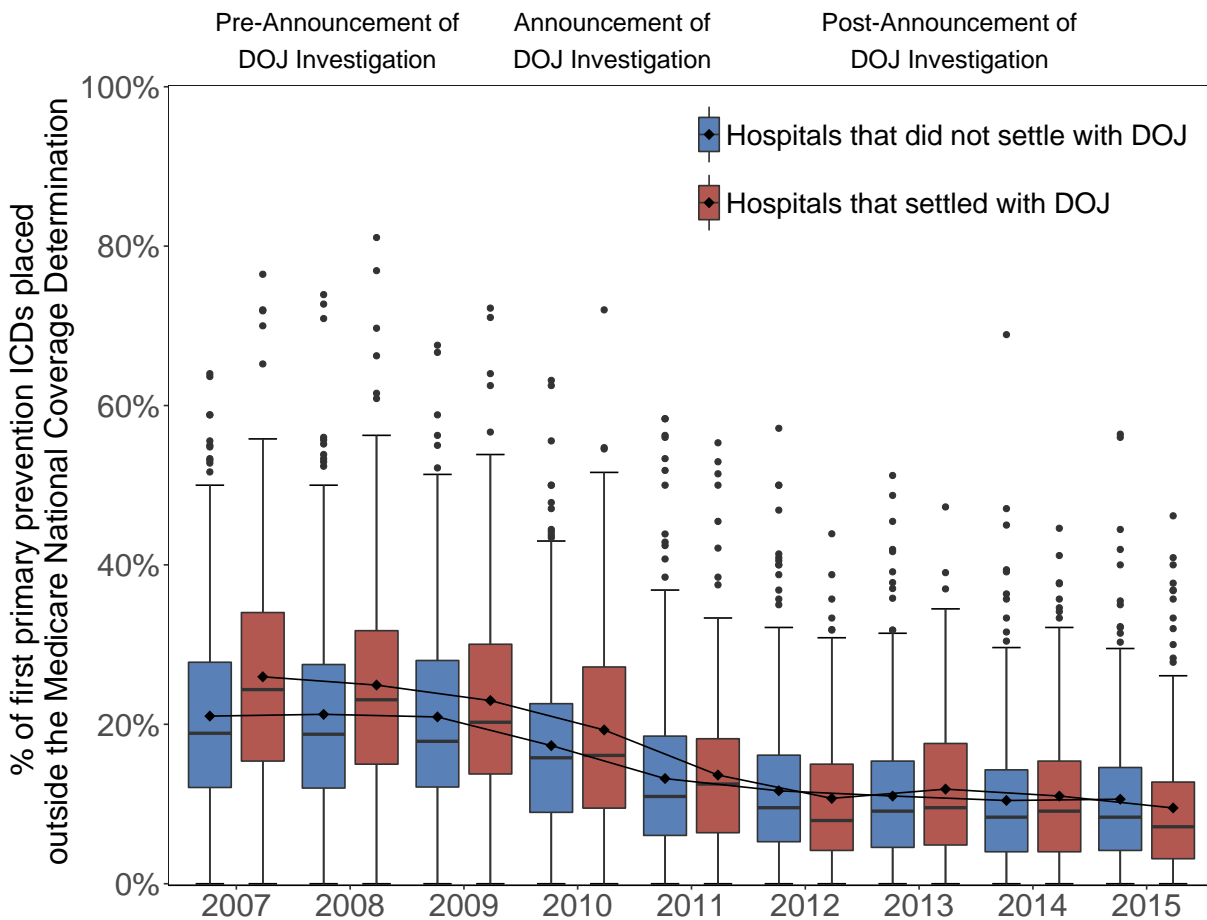


Abbreviations: CMS, Centers for Medicare and Medicaid Services; DOJ, Department of Justice; ICDs, implantable cardioverter-defibrillators; MADIT-II, Second Multicenter Automatic Defibrillator Implantation Trial; NCD, National Coverage Determination; SCD-HeFT, Sudden Cardiac Death in Heart Failure Trial; VT, ventricular tachycardia

Timeline illustrating major clinical trials of primary prevention ICDs, the establishment of the CMS NCD, and the DOJ investigation into devices not meeting the NCD criteria.

^aThe DOJ announced settlements with 457 institutions in 2015 and 51 in 2016, of which 502 were unique hospitals. We were able to match 482 (96.0%) hospitals in the ICD registry with 470 direct matches. We then excluded 18 facilities that had either closed or submitted incomplete data to the registry leading to a final sample of 452 hospitals that settled with the DOJ for analysis.

eFigure 2. Proportions of Initial Primary Prevention ICDs Outside the CMS NCD Guidelines in Medicare Beneficiaries at 6-Month Intervals, Stratified by DOJ Settlement Status at the Hospital Level



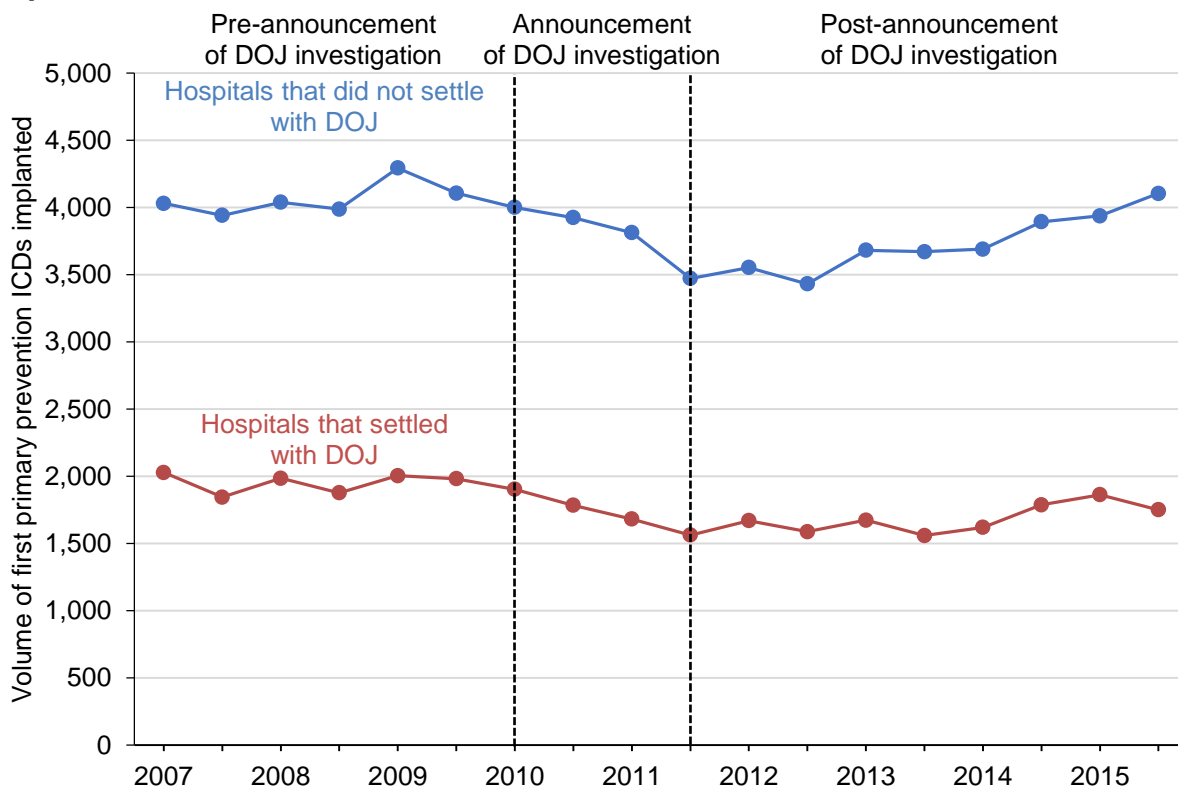
Median and interquartile range of annual hospital volume of first primary prevention ICDs

Median (IQR)	2007	2008	2009	2010	2011	2012	2013	2014	2015
Settled With DOJ	43 (26-71)	42 (28-67)	39 (27-60)	37 (26-52)	32 (23-47)	31 (23-47)	32 (22-50)	32 (22-48)	33 (20-54)
Did Not Settle	44 (27-71)	40 (25-63)	40 (25-64)	38 (24-57)	34 (22-56)	33 (22-50)	35 (23-53)	36 (24-54)	38 (26-57)

Abbreviations: CMS, Centers for Medicare and Medicaid Services; DOJ, Department of Justice; ICDs, implantable cardioverter-defibrillators; IQR, interquartile range; NCD, National Coverage Determination

Rates of first primary prevention ICDs implanted outside the CMS NCD in Medicare beneficiaries from January 1, 2007 to December 31, 2015 in six-month intervals at the hospital level including 180 hospitals that settled with the DOJ and 325 hospitals that did not settle. The horizontal line in the center of each box indicates the median; the dot indicates the mean; the bottom and top box boundaries indicate the 25th and 75th percentiles, respectively; error bars indicate 1.5 times the interquartile range; points above the error bars indicate individual hospitals with rates outside 1.5 times the interquartile range.

eFigure 3. Volume of Initial Primary Prevention ICDs in Non-Medicare Beneficiaries at 6-Month Intervals, Stratified by DOJ Settlement Status at the Hospital Level



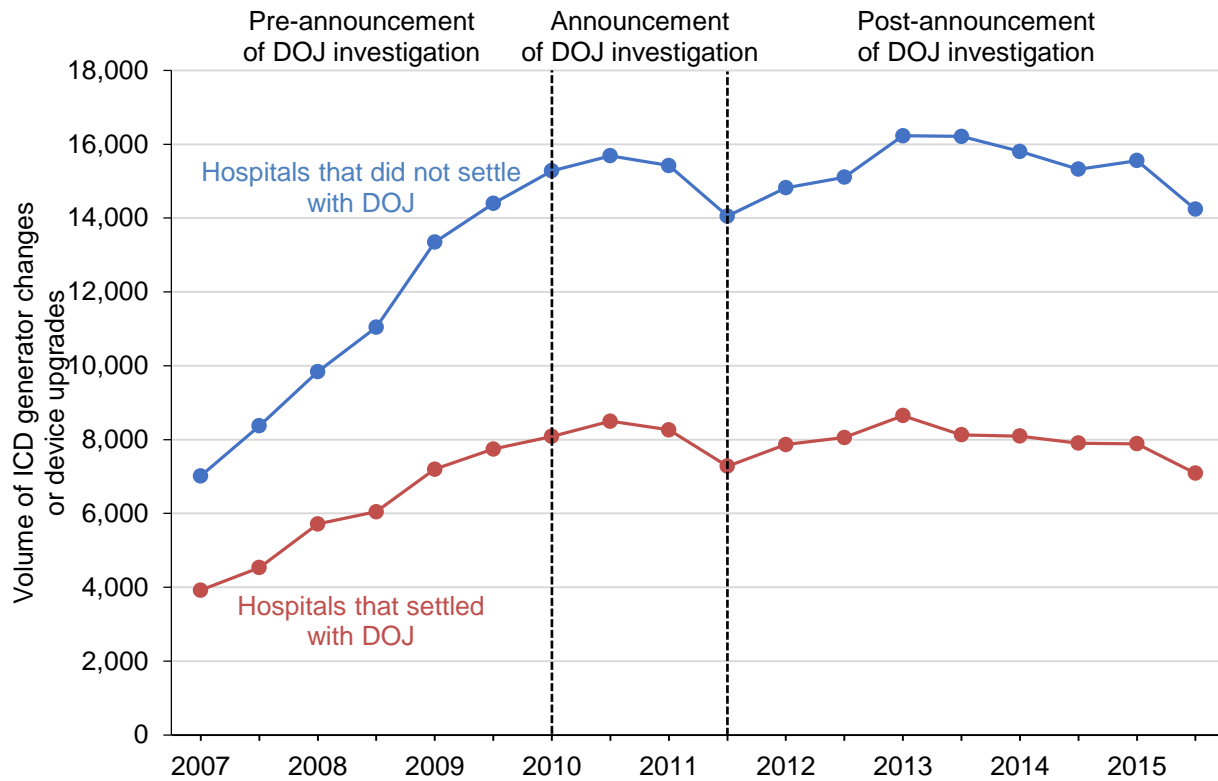
Median and interquartile range of annual hospital volume of first primary prevention ICDs

Median (IQR)	2007	2008	2009	2010	2011	2012	2013	2014	2015
Settled With DOJ	38 (20-59)	34 (23-54)	36 (23-54)	34 (22-53)	31 (22-42)	30 (18-41)	27 (18-46)	30 (21-48)	34 (23-47)
Did Not Settle	33 (22-49)	33 (22-48)	34 (24-50)	33 (21-49)	31 (21-44)	30 (21-42)	30 (22-43)	32 (24-43)	33 (24-49)

Abbreviations: CI, confidence interval; DOJ, Department of Justice; ICDs, implantable cardioverter-defibrillators; IQR, interquartile range

Volume of first primary prevention ICDs implanted in non-Medicare beneficiaries from January 1, 2007 to December 31, 2015 in six-month intervals at the hospital level including 92 hospitals that settled with the DOJ and 212 hospitals that did not settle. The period of time delineating the announcement of the DOJ investigation from January 2010 through June 2011 is demarcated by vertical dotted lines. There was a -13.7% (95% CI, -19.2% to -8.2%) relative change and -278 (95% CI, -157 to -399) absolute change in the volume of first secondary prevention ICDs at hospitals that settled with the DOJ as compared with a 1.8% (95% CI, -2.6% to 6.3%) relative change and 74 (95% CI, -103 to 251) absolute change at hospitals that did not settle.

eFigure 4. Volume of ICD Generator Changes or Device Upgrades in Medicare Beneficiaries at 6-Month Intervals, Stratified by DOJ Settlement Status at the Hospital Level



Median and interquartile range of annual hospital volume of ICD generator changes or device upgrades

Median (IQR)	2007	2008	2009	2010	2011	2012	2013	2014	2015
Settled With DOJ	22 (9-46)	30 (15-68)	39 (17-83)	45 (22-94)	44 (26-77)	46 (26-86)	48 (26-85)	46 (27-80)	46 (25-79)
Did Not Settle	18 (6-37)	23 (10-49)	31 (14-65)	36 (18-71)	37 (19-71)	37 (20-69)	41 (21-74)	41 (21-70)	39 (20-67)

Abbreviations: CI, confidence interval; DOJ, Department of Justice; ICD, implantable cardioverter-defibrillator; IQR, interquartile range

Volume of ICD generator changes or device upgrades in Medicare beneficiaries from January 1, 2007 to December 31, 2015 in six-month intervals at the hospital level including 251 hospitals that settled with the DOJ and 582 hospitals that did not settle. The period of time delineating the announcement of the DOJ investigation from January 2010 through June 2011 is demarcated by vertical dotted lines.