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DETERRENCE EFFECTS OF ANTIFRAUD AND ABUSE ENFORCEMENT IN HEALTH CARE

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Dr. Howard has served as a consultant on an unrelated False Claims Act case. The views expressed herein are those of the authors and do not necessarily reflect the views of the National Bureau of Economic Research.

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ABSTRACT

Estimates of the benefits of antifraud enforcement in health care typically focus on direct monetary damages. Deterrence effects are acknowledged but unquantified. We evaluate the impact of a Department of Justice investigation of hospitals accused of billing Medicare for unnecessary implantable cardiac defibrillator (ICD) procedures on their use. Using 100% inpatient and outpatient procedure data from Florida, we estimate that the investigation caused a 22% decline in unnecessary ICD implantations. The present value of savings nationally over a 10 year period is $2.7 billion, nearly 10 times larger than the $280 million in settlements the Department of Justice recovered from hospitals. The investigation had a large and long-lasting effect on physician behavior, indicating the utility of antifraud enforcement as a tool for reducing wasteful medical care.

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Introduction

A large share of health care spending goes towards unnecessary, low-value care (Berwick and Hackbarth, 2012). Reducing unnecessary care is a major goal for policymakers concerned about the financial health of the Medicare program. Providers who bill Medicare for unnecessary care are guilty of fraud (if they know treatment is unnecessary) or abuse (if they do not). Historically, the Department of Justice did not take legal action against hospitals and physicians that submitted claims for unnecessary services. Department prosecutors focused on more blatant forms of fraud, such as filing claims for fictitious patients. More recently, the Department has pursued a number of cases under the False Claims Act against providers accused of providing unnecessary care. Entities that are found guilty under the Act of submitting "false" claims to the federal government are liable for steep fines. Individuals may be imprisoned.

The impact of False Claims Act litigation is typically characterized in terms of penalties and settlements. For example, the Congressional Budget Office scores policies to enforce antifraud statutes in health care assuming they will generate savings of $1.5 for every $1 invested, where the $1.5 represents direct recoveries. Deterrence effects are acknowledged but unquantified. False Claims Act cases that address unnecessary care may have particularly large deterrence effects, especially those that focus on costly, frequently-used treatments.

Application of the False Claims Act to unnecessary care is controversial. Some defendants and their attorneys argue that cases amount to little more than courts "second guessing" physicians' treatment decisions. In light of concerns about the False Claims Act litigation over unnecessary care and Medicare spending on unnecessary care more broadly, quantifying these effects is important for evaluating the role of the False Claims Act in combatting overuse. In this paper, we quantify savings to Medicare from a False Claims Act investigation into the overuse of implantable cardiac defibrillators (ICDs).

ICDs have been available since the 1980s but were rapidly adopted during the 2000s as a treatment to prevent cardiac arrest. In 2009, 141,000 ICDs were implanted (Hammill et al. 2010) at a lifetime cost of $80,000-$100,000 per patient (Sanders et al. 2005). Trials have identified several groups of patients who do not benefit from ICDs and, given the risk of infection and inappropriate shocks, may in fact be harmed (Voigt et al. 2010; van Rees et al. 2011). Medicare declared in 2005 that it would not pay for ICDs in these patients, but hospitals routinely billed for and received reimbursement for ICDs implanted in these patient groups. In 2007, the Department of Justice opened an investigation into the use of ICDs in patients who did not meet Medicare coverage criteria. The Department of Justice ultimately settled suits against 450 hospitals for $280 million.[1]

The ICD case stands out in terms of the number of hospitals involved and the total dollar value of the settlement, but other cases have yielded larger settlements on a per provider basis, such as those against Health Management Associates ($260 million) and Prime Health Care ($65 million) for unnecessary hospital admissions and RehabCare Group ($125 million) for unnecessary rehabilitation services. What makes the ICD case useful for quantifying deterrent effects is that we can clearly identify unnecessary ICD implantations in our data.

Using data on the population of inpatient and outpatient procedures in Florida, we identify medically necessary versus medically inappropriate ICD procedures. We then evaluate the impact of the Department of Justice investigation on the volume of these procedures. All hospitals were exposed to the investigation, and so we cannot take advantage of a control group of hospitals to identify its impact. Instead, we measure trends in the volume of non-covered ICD procedures relative to the volume of covered ICD procedures, thereby accounting for secular trends. According to our preferred specification, the Department of Justice investigation led to a 22% decline in the use of non-covered ICD procedures. The associated reduction in Medicare spending over a ten-year period, $2.7 billion, is much larger than the amount recovered in settlements ($280 million). Not all cases targeting unnecessary care will be so profitable from the government's viewpoint, but results suggest that deterrence effects are large and that antifraud enforcement has a useful role to play in reducing waste in the health care system.

Policy Background

The False Claims Act levies civil and criminal penalties against individuals and companies that submit "false" claims to the federal government. Although the False Claims Act was originally passed in 1865 and later expanded in 1987 to address fraud by defense

[1] The list of hospitals and specific settlement amounts are available at the Department of Justice website, https://www.justice.gov/opa/pr/nearly-500-hospitals-pay-united-states-more-250-million-resolve-false-claims-act-allegations

contractors, health care cases now account for 68% of all new actions and 60% of recoveries (Department of Justice 2017; Howard 2019). The False Claims Act allows individuals to sue on behalf of the government when they have evidence that a company or individual is defrauding the government. Individuals who sue, who are called "relators" in legal proceedings and "whistleblowers" in the media, are entitled to 15% to 30% of penalties and damages recovered by the government. The Department of Justice may elect to join and litigate suits, dismiss suits, or let the relators proceed on their own.

Traditionally, False Claims Act cases in health care have addressed blatant fraud (for example, billing for procedures that were never performed), violations of antikickback and self-referral laws, or off-label promotion of pharmaceuticals. However, Congress amended the Act in 1986, in 2009, and again in 2010 under the Affordable Care Act to make it easier to file and win cases. The 1986 amendments, passed in response to Department of Defense contracting scandals, were especially significant because they made it possible for the government to win cases by showing that defendants acted with "reckless disregard" for the truth rather than having to prove that defendants intentionally defrauded the government.

In 1990, the Department of Justice investigated 35 False Claims Act health care-related cases, of which 16 were brought by relators (the remainder were initiated by the government) (Civil Division, U.S. Department of Justice 2017). In 2017, the Department investigated 544 cases, of which 491 were brought be relators. Amendments to the Act were only partially responsible for the uptick in case volume. As a result of increases in Medicare spending, the rewards from fraud are higher than in the past, and the government has adopted a more aggressive posture towards health care fraud. Federal prosecutors and the private lawyers who handle False Claims Act cases have shown a greater willingness to take on cases that address overuse. For example, California-based Prime Healthcare Services recently agreed to a $65 million settlement with the Department for admitting patients to the hospital who could have been treated on an outpatient basis.

In cases where medical necessity is at issue, the Department of Justice does not have to show that clinicians set out to intentionally defraud the government, only that they exhibited a "reckless disregard" for the truth. The application of the Act to unnecessary care is controversial. Courts have wrestled with how to apply the False Claims Act's "falsity" standard to treatment decisions. Defense attorneys have taken to the editorial pages of the *Wall St. Journal* to argue that their clients were simply acting in the best interests of their patients and do not deserve to be punished (Clark and George 2018; 2019). Despite these concerns, the Department of Justice has recovered a number of multimillion dollar penalties and settlements from hospitals, nursing home chains, hospices, and other providers who billed Medicare for (allegedly) unnecessary care. A few physicians have been sentenced to multi-year prison terms.

Our analysis considers the effects of a False Claims Act investigation of unnecessary ICD implantations. ICDs are designed to prevent cardiac arrest by detecting irregular heartbeats (arrhythmias) and delivering a shock to the heart to restore a normal heartbeat. Following Food and Drug Administration approval in 1985, ICDs were initially used as secondary prevention in patients who previously experienced a cardiac arrest. Following positive trial results, the Center for Medicare & Medicaid Services (CMS) extended Medicare coverage of ICDs in 2003 (Phurrough et al. 2003) and 2005 (Phurrough et al. 2005) for use as primary prevention in patients who had not experienced a cardiac arrest previously. Coverage is subject to a number of restrictions. The two that are relevant for this paper are as follows. First, Medicare will not cover ICDs in patients who had a percutaneous coronary intervention (PCI, known colloquially as "angioplasty") or another type of revascularization procedure in the previous 90 days. The CABG Patch trial (Bigger 1997) found that ICDs did not improve survival in this patient group. Second, Medicare will not cover ICDs in patients who had an acute myocardial infarction (AMI) in the past 40 days. The DINAMIT trial (Hohnloser et al. 2004) found that ICDs did not improve survival in these patients. Despite these restrictions, CMS and its contractors continued to reimburse claims for non-covered ICD implantations in patients with recent PCIs and AMIs.

In the mid 2000s, Leatrice Ford Richards was working as a consultant helping hospitals figure out how to maximize reimbursement for cardiovascular procedures. Part of her job involved reviewing patients' medical records. She noticed that many hospitals were billing Medicare for ICD procedures in patients who had recent heart attacks or revascularization procedures. This practice bothered her not only because it violated Medicare coverage policies but also because, in her judgement as a cardiac nurse, the procedures subjected patients to the risks of an invasive procedure and unnecessary shocks without an offsetting survival benefit. She raised the issue with administrators at client hospitals, but they declined to act. Physicians had recommended these procedures. Medicare paid the bills. Ms. Richardsd teamed up with another consultant who had access to Medicare claims data and found that Medicare was paying for thousands of ICD procedures in patients who fell outside coverage guidelines. Together they filed a False Claims Act lawsuit in 2008.

Following receipt of the ICD False Claims Act case, the Department of Justice launched an investigation. Beginning in March 2010, the Department requested records from hospitals for patients who had ICDs implanted. The initial complaint named about 1,300 hospitals, but in light of the investigative burden, the Department narrowed its focus to a smaller subset of high-volume hospitals.

Two physicians wrote an instructive account of their hospital's experience with the investigation (Steinberg and Mittal 2012). The Department of Justice notified hospital administrators that the hospital was under investigation and scheduled a site visit. The hospital reviewed the medical records of patients who did not meet the Medicare coverage criteria based on submitted Medicare claims. The review found that there was no justification for ICD implantation in 15% of the cases. The remainder fell into two categories: 1) the patient did not meet the coverage criteria but implantation was potentially justifiable or 2) the patient's diagnosis was recorded incorrectly. During the site visit, lawyers and clinical experts from the hospital and Department of Justice discussed the criteria for ICD implantation and the circumstances when it would be acceptable to implant an ICD within 90 days of a PCI or 40 days of an AMI. The physicians wrote that the Department of Justice team, "…were quite sensitive to avoiding situations that could present harm to the patients simply to satisfy the coding guidelines and, in large part, were receptive to the 'exceptions'…" The health system eventually settled with the Department of Justice for $4.9 million. The hospital agreed that physicians would complete a pre-implant checklist to identify patients who should not receive ICDs and prospectively review procedures to determine if they were necessary.

Between 2013 and 2016 the Department settled with nearly 500 hospitals for $280 million. Of that, the two whistleblowers split $41.8 million and the Department retained the rest. The hospitals that settled were mostly members of large, multihospital chains, like Health Care Corporation of American and Catholic Health Initiatives, but also included a few academic medical centers, like the University of Pittsburgh Medical Center and Emory Healthcare.

Desai et al. (2018) described trends in the use of ICDs using data from a national ICD registry. They evaluated trends in the share of ICDs implanted within 40 days of an AMI as a proportion of all ICDs implanted for primary prevention. They found that the share of non-covered ICD implantations declined, both at hospitals that settled as well as among other hospitals and in non-Medicare patients. Desai et al. did not evaluate the impact of the investigation on the use of ICDs in patients following PCI, which accounts for a large share of non-covered procedures.

Relative to Desai et al., our contribution is fourfold. First, we consider the use of ICDs in patients following acute myocardial infarction (AMI) *and* PCI. Second, we evaluate trends in non-covered ICDs relative to trends in the use of alternative procedures, thereby improving our ability to identify the impact of the Department of Justice investigation. Third, we allow for the fact that hospitals may have responded to the investigation by delaying ICD implantations beyond the 90- and 40-day non-coverage windows, potentially offsetting some of the declines observed in ICDs implanted within these windows. Fourth, we estimate the savings to Medicare and other payers from the investigation.

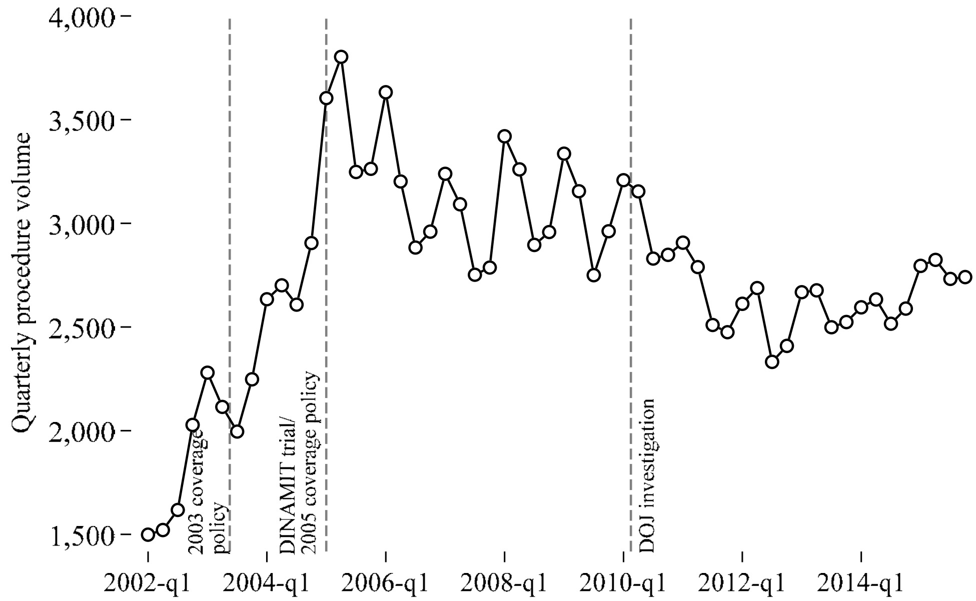
Data and Descriptive Analysis

We evaluated the impact of the Department of Justice investigation on the use of ICDs using all-payer data from Florida, including inpatient and outpatient procedures. The data capture 100% of admissions to community hospitals in the state. We selected Florida because it is a large, diverse state, the data allow us to link multiple admissions for a single patient, and about half the hospitals in the state belong to systems that settled with the Department of Justice. We can identify patients who received ICDs following a recent PCI or AMI at a different hospital as long as it is in Florida.

We identified patients' procedures and diagnoses using Current Procedural Terminology codes and International Classification of Diseases (ICD) version 9 and 10 procedure and diagnosis codes. A complete list of codes is available in Appendix Table 1.

Figure 1 shows total ICD implantations in Florida. Procedure volume increased rapidly after the 2003 coverage memo that expanded coverage for ICDs used as primary prevention. Volume declined after the 2005 memo, possibly because of the new coverage restrictions in the memo. Alternatively, the timing of the decline could be coincidental. By 2005, physicians may have worked their way through the backlog of patients who met the expanded coverage criteria under the 2003 coverage policy. The rest of the paper therefore focuses on trends from 2006 onward.

Figure 1: ICD implantations



We grouped ICD procedures into five, mutually-exclusive categories, A-E, based on clinical and Medicare coverage criteria, as shown in Table 1. The first three categories include ICD procedures in patients who did not have a diagnosis code for a cardiac dysrhythmia (e.g., Ventricular tachycardia, Cardiac arrest), the absence of which indicates that the ICD was implanted for primary prevention. The first category (A) includes patients who had a PCI in the 180 window prior to the ICD procedure. The second (B) includes patients who had an AMI in the 180-day window prior the ICD procedure.[2] These categories are subdivided based on when the AMI or PCI occurred relative to the ICD procedure. The False Claims Act investigation mainly focused on ICDs implanted within the 90- and 40-day non-coverage windows (subcategories A1, A2, B1, and B2), though there were some other patients who, for reasons that we do not observe, received ICDs despite not meeting the detailed criteria in CMS's coverage policy.

[2] Patients who had both an AMI and a PCI recorded on the same encounter as the ICD implantation were assigned to the AMI group. Patients who had both recent PCIs and AMIs (that did not take place during the same encounter) were assigned to one of the PCI groups since non-coverage window is longer for PCI.

The third category (C) includes ICD procedures in patients without a recent PCI or AMI. Most procedures fall into this category. The fourth and fifth categories include ICD procedures for secondary prevention (i.e., the procedure record includes a cardiac dysrhythmia diagnosis code), and are distinguished based on whether the procedure did (D) or did not (E) occur after a PCI or an AMI.

Table 1: ICD procedure counts by time period and category

	Q1 2006-Q1 2010		Q2 2010-Q42016		All years	
	Total	Annual-ized	Total	Annual-ized	Total	Annual-ized
Primary prevention ICDs						
A: ≤180 days post PCI	3,636	856	3,534	524	7,170	652
A.1: Same encounter	1,575	371	839	124	2,414	219
A.2: 1 to 90 days after	1,304	307	1,074	159	2,378	216
A.3: 91 to 180 days after	757	178	1,621	240	2,378	216
B: ≤180 days post AMI	5,163	1,215	5,854	867	11,017	1,002
B.1: Same encounter	3,457	813	2,661	394	6,118	556
B.2: 1 to 40 days after	390	92	435	64	825	75
B.3: 41 to 180 days after	1,316	310	2,758	409	4,074	370
C: No recent PCI/AMI	33,583	7,902	44,420	6,581	78,003	7,091
Seconary prevention ICDs						
D: ≤180 days post PCI/AMI	1,801	424	2,247	333	4,048	368
E: No recent PCI/AMI	9,116	2,145	11,073	1,640	20,189	1,835

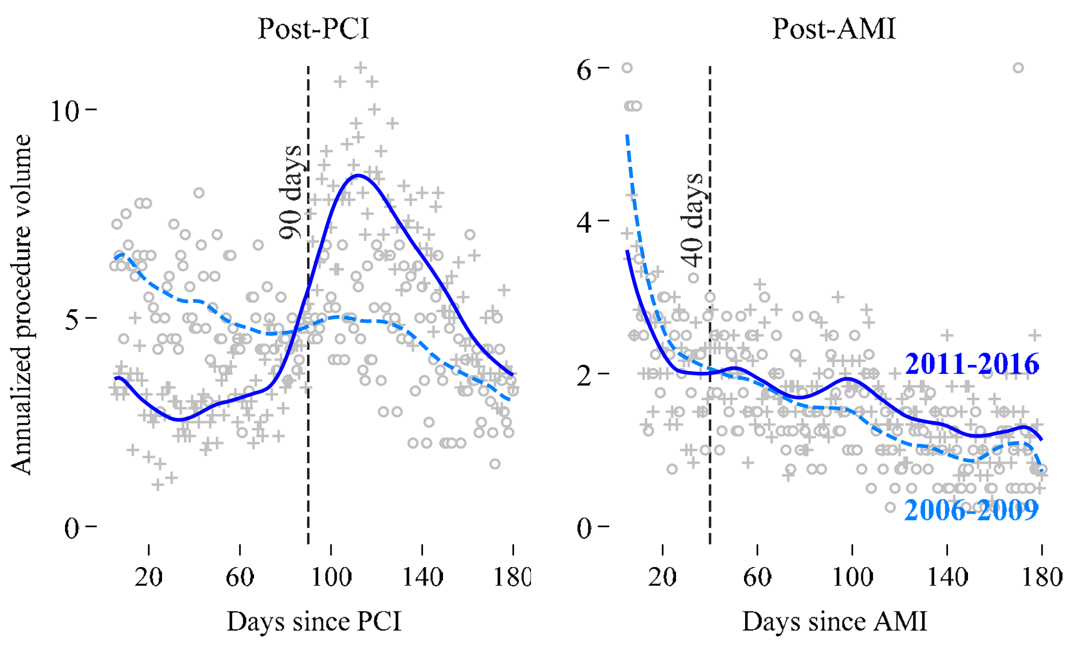
ICD: Implantable cardiac defibrillator, PCI: Percutaneous coronary intervention, AMI: Acute myocardial infarction.

Following the investigation, hospitals could comply with Medicare coverage criteria by delaying procedures in patients with PCIs or AMIs until after 90 and 40 days. To examine whether they did so, we plotted the number of ICD procedures in patients with recent PCIs and AMIs (groups A and B) by the number of days since the PCI or AMI (Figure 2), pre- and post-investigation.

The x-axis depicts the number of days between the ICD implantation and the previous PCI or AMI. The y-axis depicts procedure volume. The raw data are depicted as circles (ICD procedures between 2006 and 2009) and plusses (procedures between 2011 and 2016). We omitted procedures that occurred in 2010 because hospitals first became aware of the investigation in that year, and it may have taken some time for practice patterns to adjust. The lines depict lowess curves. Counts are annualized to adjust for the uneven length of each period. The dashed vertical lines mark the 90-day (for PCI) and 40-day (for AMI) windows.

The left panel of Figure 2 shows that the number of ICDs implanted within 90 days after a PCI declined following the Department of Justice investigation. However, the number implanted shortly after the 90-day threshold increased, suggesting that providers shifted ICD implantations until after the 90-day threshold in response to the investigation. The right panel of Figure 2 presents analogous data for AMI patients. Here, unlike in the case of PCIs, there is not a sudden spike after the non-coverage window (day 40). The implication of these results is that an analysis that restricts attention to ICDs performed within 90 days of a PCI will overstate the impact of the investigation on total ICD procedure volume.

Figure 2: ICD volume by days since PCI or AMI



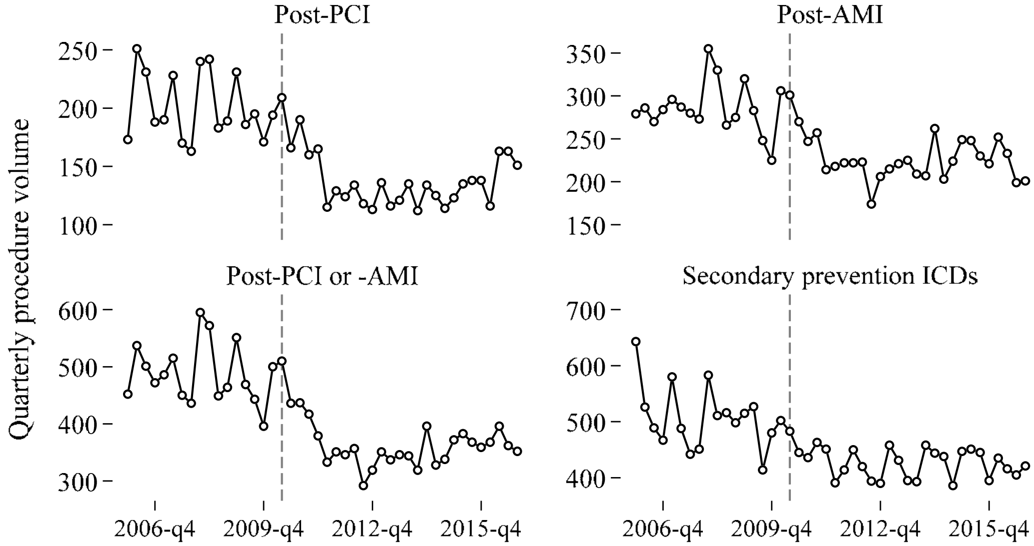
PCI: Percutaneous coronary intervention; AMI: Acute myocardial infarction.
The sample includes patients who had PCIs or AMIs between 5 and 180 days after a PCI or AMI.

Figure 3 shows trends in ICD procedures from 2006 onward by patient group. The dashed line indicates when the Department of Justice investigation became public. The top left panel shows ICD implantations in patients who had a PCI procedure in the prior 180 days (category A in Table 1). The number of implantations in this group dropped sharply after the investigation.

The top right panel shows ICD procedures in patients who had an AMI in the prior 180 days (category B). Similar to the post-PCI patients, the number of implantations declined after the investigation. There was also a sharp decline that began around the 2^{nd} or 3^{rd} quarter of 2009, which corresponds to the presentation of the IRIS trial (Steinbeck et al. 2009) at the American College of Cardiology meetings in March 2009. Like the DINAMIT trial, the IRIS trial found that ICDs do not improve outcomes in patients with a recent AMI.

The lower left panel shows the volume of ICD procedures in patients with either a recent PCI or AMI. ICD use in post-PCI and post-AMI patients declined following the investigation but did not drop to “0”. There are several possible explanations. First, the Department of Justice recognized that there were some circumstances in which it was acceptable to implant an ICD in these patient groups. Second, some hospitals and physicians may have continued to bill for non-covered ICD implantations.

Figure 3: Quarterly ICD implantations



PCI: Percutaneous coronary intervention; AMI: Acute myocardial infarction.
The dashed lines indicate when the Department of Justice investigation become public.
Secondary prevention ICDs are ICDs implanted in patients with a diagnosis code for a cardiac dysrhythmia and who did not have a recent PCI or AMI.

Identification strategy

All hospitals were affected by the Department of Justice investigation, either because they were investigated or thought they could be investigated at a future date. We cannot identify a control group of hospitals. Instead, we evaluate trends in potentially affected ICD implantations relative to a control procedure. The idea is that the control procedure provides a counterfactual about what would have happened to ICD volume in the absence of the Department of Justice investigation. It should reflect factors other than the investigation, such as cardiac health and the release of new evidence, that affect ICD use.

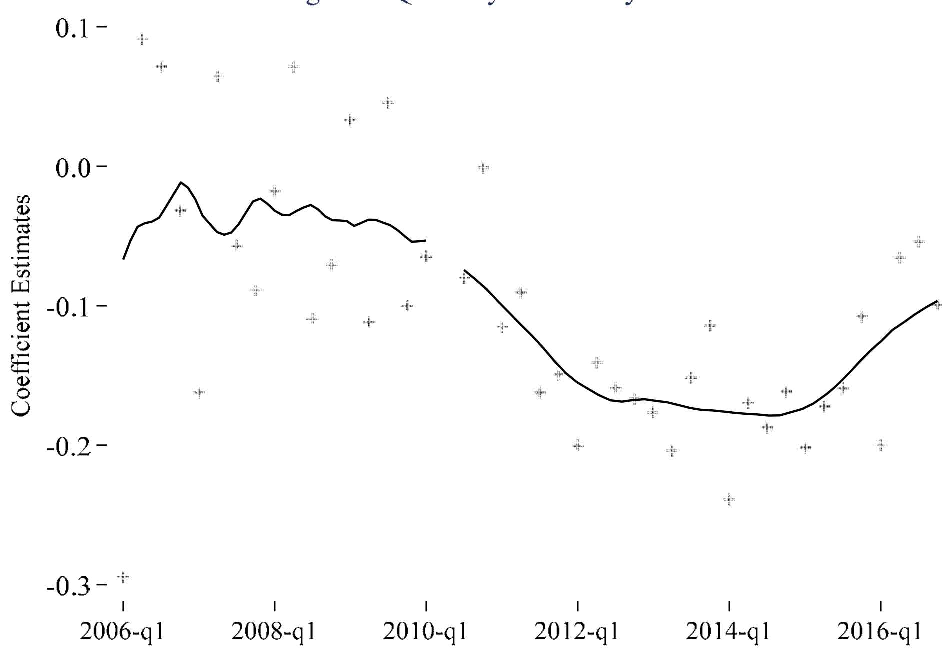
In the baseline analysis, we define our control procedure as secondary prevention ICDs in patients without a recent PCI or AMI (Group E). These procedures were not scrutinized by the Department of Justice. The lower right panel of Figure 3 shows the volume of secondary prevention ICD procedures. These procedures were covered by Medicare and, though they declined over the study period, there is not a sharp decline around the time the investigation became public.

To formally evaluate the presence of differential trends between post-PCI and -AMI ICD procedures and the control procedure, we estimated the following model:

$$y_{hgt} = \beta_0 + \sum_t (\beta_{1t} TREAT_{hg} \times t) + \gamma_t + \eta_{hg} + \varepsilon_{hgt}, \quad [1]$$

where y_{hgt} is the number of ICD procedures in hospital h in category g in period t, which we standardize by subtracting the within-group mean and dividing by the within-group standard deviation. $TREAT_{hg}$ is an indicator set to 1 if the procedure is part of the treated group (ICDs within 180 days following PCI or AMI) and 0 otherwise. γ_t and η_{hg} denote time and hospital/procedure category fixed effects. Using the model, we estimate quarter specific coefficients β_{1t} describing the trajectory of hospital-average procedure volumes. We normalize the coefficients by setting $\beta_{1t} = 0$ for the second quarter of 2010, leaving T-1 coefficients to be estimated. Results are presented in Figure 4, where the dots reflect the point estimates of each of the T-1 coefficients and the line reflects a local polynomial estimation among the point estimates (separately before and after the Department of Justice investigation).

Figure 4: Quarterly event study coefficients



Each data point in Figure 4 reflects the estimated effect of the investigation on ICD implantations relative to secondary prevention ICDs. We see from the figure that, beginning in 2010, there is a large decline in post-PCI and -AMI ICD implantations relative to secondary prevention ICDs. This differential is effectively 0 before the investigation and remains statistically significantly negative through 2016.

Estimates of the decrease in procedure volume

We estimated a model (model 1) of the following form to quantify the magnitude of the decline in ICD procedure volume attributable to the investigation:

$$y_t = \beta_0 + \beta_1 x_t + \beta_2 x_t POST_t + \sum_i q_i + \varepsilon_t, \qquad [2]$$

where y_t is the number of ICDs implanted in period t, $t \in \{1,...,44\}$ indexes quarter of the year, with t =1 corresponding to the first quarter of 2006 and t = 44 corresponding to the fourth quarter of 2016. The variable x_t is the volume of the control procedure in quarter t, the variable $POST_t$ is an indicator for the period after hospitals became aware of the Department of Justice investigation in the second quarter of 2010. The variables q_i are quarter-of-the-year indicators. The coefficients β_1 and β_2 measure the volume of post-PCI or post-AMI ICDs relative to the volume of the control procedure, allowing the relationship to change after the investigation.

The first column of Table 2 displays coefficient estimates from the baseline model. The outcome is the quarterly volume of ICDs implanted in patients with PCIs or AMIs in the previous 180 days. In the first model, the coefficient on the volume of secondary prevention ICDs before the investigation is 0.31, which has a t-statistic of 1.5. The interpretation is that, prior to the Department of Justice investigation, there were 0.31 post-PCI and post-AMI ICD procedures for every secondary prevention ICD procedure, plus the intercept term and the coefficient on the relevant quarter-of-year indicator. The coefficient on the interaction between the post-investigation indicator and the volume of secondary ICD procedures is -0.23 and has a t-statistic of 5.1. An F-test rejects the hypothesis that $\beta_1 = \beta_1 + \beta_2$ (25.7; $p < 0.001$).

Table 2: Coefficients from the regression models estimating the impact of independent variables on the number of ICD implantations in post-PCI and post-AMI patients

	Model 1 β (SE)	Model 2 β (SE)
Volume[a]	0.31 (0.21)	0.31 (0.23)
Volume×Post-DOJ	-0.23 (0.05) **	-0.17 (0.08) *
Volume×Time trend[b]		0.001 (0.004)
Volume×Post-DOJ×Time trend[b]		-0.003 (0.005)
Quarter 2	17.50 (18.54)	17.90 (18.98)
Quarter 2	-14.82 (21.68)	-14.58 (22.94)
Quarter 4	-18.88 (22.35)	-18.34 (23.49)
Constant	331.65 (112.94) **	329.30 (127.98) **

[a]Volume of covered, primary prevention ICDs in patients without recent PCIs or AMIs.
[b]Coefficients are re-scaled (×100) for purposes of display.
ICD: Implantable cardioverter defibrillator; PCI: percutaneous coronary intervention; AMI: Acute myocardial infarction; DOJ: Department of Justice.
*p<0.05, **p<0.01.

We also estimated an alternative specification (model 2):

$$y_t = \beta_0 + \beta_1 x_t + \beta_2 x_t POST_t + \beta_3 x_t t + \beta_4 x_t POST_t t + \sum_i q_i + \varepsilon_t \qquad [4]$$

The second model adds time trend variables that vary by period interacted with the volume of secondary prevention ICDs. The variable t is a time trend. The coefficients β_3 and β_4 capture pre- and post-investigation trends in the relationship between post-PCI and post-AMI ICDs and the control procedure. Predictions from this model assume that pre-Department of Justice investigation trends in the relationship between post-PCI and post-AMI ICD volume and the control procedure would have continued in the absence of the investigation.

The coefficients from the regression models are not, by themselves, particularly informative. We used predicted values to quantify the impact of the investigation. Using the estimated coefficients from model 1, we predicted the volume of ICDs at time t following the Department of Justice investigation.

$$\hat{y}_{t|POST=1} = \hat{\beta}_0 + \hat{\beta}_1 x_t + \hat{\beta}_2 x_t + q_t. \quad [2]$$

We also predicted what volume would have been in the absence of the investigation based on the pre-investigation relationship between post-PCI and post-AMI ICD volume and the control procedure ($\hat{\beta}_1$).

$$\hat{y}_{t|POST=0} = \hat{\beta}_0 + \hat{\beta}_1 x_t + q_t. \quad [3]$$

The difference $\hat{y}_{t|POST=0} - \hat{y}_{t|POST=1}$ for the four quarters of 2016 is our main estimate of the impact of the investigation. We constructed equivalent predictions using the coefficients from model 2.

Figure 5 illustrates this approach. The plus symbols represent the actual data. The bottom line with the hollow circles represents the prediction from model 1 of actual ICD volume ($\hat{y}_{t|POST=1}$). The top line with the gray circles depicts our estimate of what volume would have been in the absence of the investigation ($\hat{y}_{t|POST=0}$). We present the difference in 2016, i.e., the vertical distance between the lines, as our best estimate of the impact of the investigation on the use of ICDs.

The predicted number of ICD procedures in the fourth quarter of 2016 is 1,448 (the actual number was 1,478). We predict that in the absence of the investigation, there would have been 1,840 procedures, a difference of 392 (-22%) procedures. The comparable result from model 2, which allows the relationship between the outcome and the control procedure to vary linearly, is 490 procedures (-26%). These estimates are smaller than what one would calculate based on raw trends in the outcome alone because they take into account the secular decline in the use of ICDs, as captured by the trend in secondary prevention ICDs.

Figure 5: Predicted ICD implantations in post-PCI or post-AMI patients

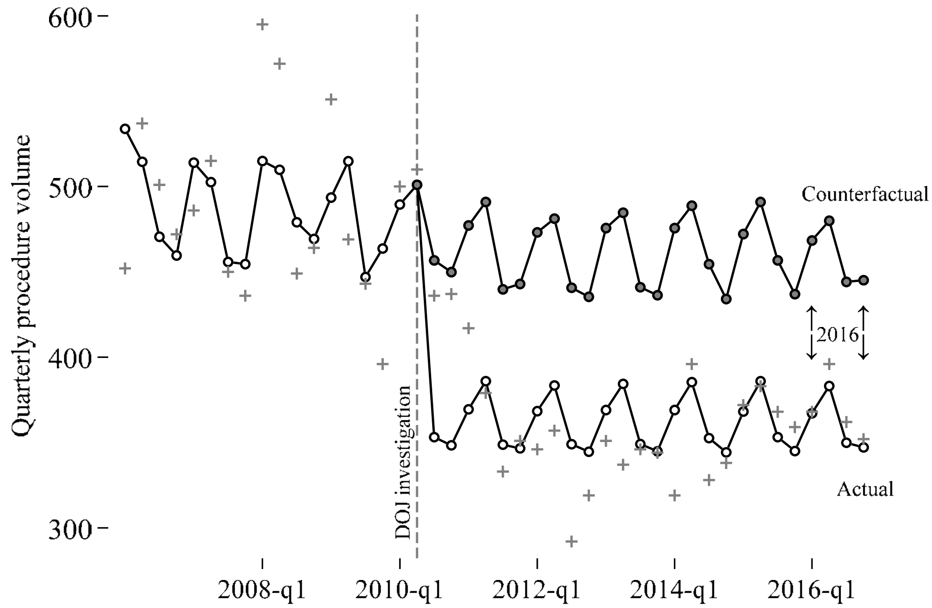


Table 3 presents estimates of the declines in ICD procedure use attributable to the investigation (coefficient estimates are presented in Appendix Table 2). The rows show different outcomes, including estimates for ICD procedures post PCI and post AMI separately. The columns show results for different control procedures: secondary prevention ICDs (the baseline model), all PCIs, and all AMIs.

For each outcome and control procedure we present an estimate of the absolute change in volume and the percent change, to facilitate comparisons across outcomes where baseline volumes differ. We estimated confidence intervals for the percent changes using Monte Carlo simulation (i.e., the Krinsky-Robb method; Dowd et al. 2014).[3] Estimates based on model 2, which allows for the relationship between the outcome and the control procedure to vary linearly over time, are presented in Appendix Tables 3 and 4. They are similar to those from the baseline model.

[3] Note that the point estimates do not fall in the middle of the confidence intervals because the distribution of the ratio of two normally-distributed variables is skewed.

Table 3: Estimates of the impact of the Department of Justice investigation on ICD use in 2016

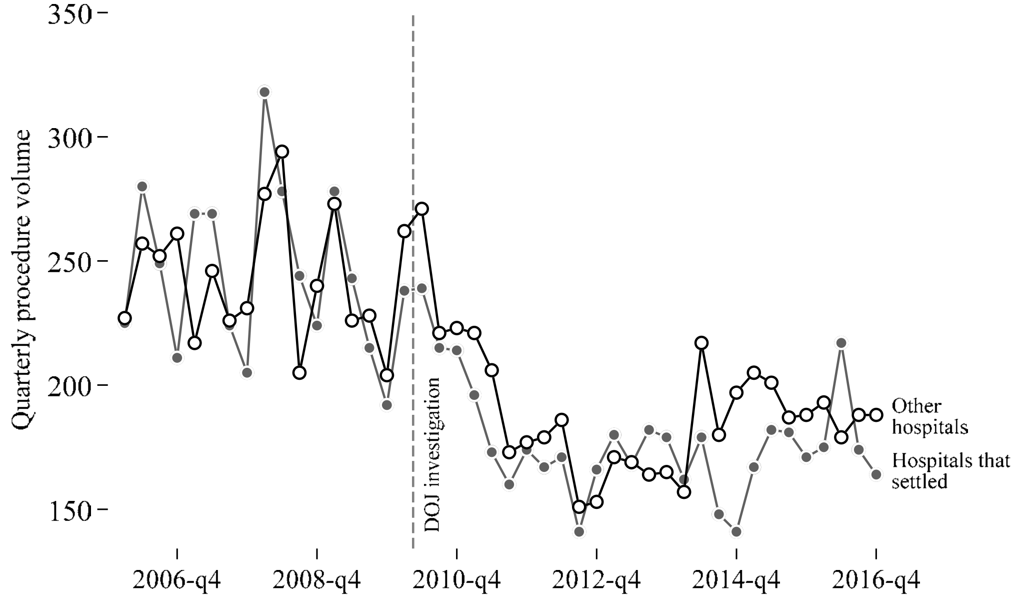
	Control procedure		
Outcome	Secondary prevention ICDs	PCIs	AMIs
ICDs post-PCI or post-AMI			
Absolute change	-392 (-543, -241)	-479 (-574, -383)	-353 (-482, -225)
Percent change	-22% (-29%, -14%)	-26% (-30%, -22%)	-21% (-26%, -14%)
ICDs post-PCI			
Absolute change	-201 (-291, -110)	-258 (-315, -200)	-182 (-259, -106)
Percent change	-27% (-37%, -16%)	-33% (-39%, -26%)	-26% (-34%, -17%)
ICDs post-AMI			
Absolute change	-191 (-278, -104)	-221 (-274, -168)	-171 (-245, -96)
Percent change	-18% (-25%, -11%)	-21% (-25%, -16%)	-17% (-22%, -10%)

95% Confidence intervals shown in parentheses.
Estimates are based on model 1 (equation 2 in the paper).
ICD: Implantable cardioverter defibrillator; PCI: percutaneous coronary intervention; AMI: Acute myocardial infarction.

Penalized versus non-penalized hospitals

Figure 6 shows trends in ICD procedure volume in hospitals that were members of health systems that paid penalties to the Department of Justice and hospitals in systems that did not pay penalties. The Department of Justice investigation took at least 8 years from beginning to end. While the Department quickly narrowed its focus to a subset of implanting hospitals, other hospitals may have feared that the investigation would expand or that they would be named in a future investigation. Still, by 2015 it was clear that the investigation had run its course, and there was little risk that other hospitals would be investigated. Using the baseline model, we estimate that there was a 28% (95% CI: 19% to 36%) decline in ICDs post-PCI or post-AMI in hospitals that settled and a 20% (95% CI: 13% to 26%) decline in hospitals that did not settle (see Appendix Tables 5 and 6).

Figure 6: ICD implantations, by hospital type



Medicare versus privately-insured patients

The False Claims Act applies to government programs only, and so the Department of Justice did not investigate ICD procedures in privately-insured patients. The investigation could have affected the treatment of privately-insured patients if it is financially, administratively, or cognitively costly for physicians to vary treatment decisions based on patients' insurance type (Newhouse and Marquis 1978).[4]

Figure 7 shows trends by insurance type. Using the baseline model, we estimate that there was an 18% (95% CI: 10% to 26%) decline in ICD implantations post-PCI and post-AMI among Medicare beneficiaries and a 28% (95%: 21% to 36%) decline among patients with other types of coverage (although the absolute decline is smaller) (see Appendix Tables 7 and 8).

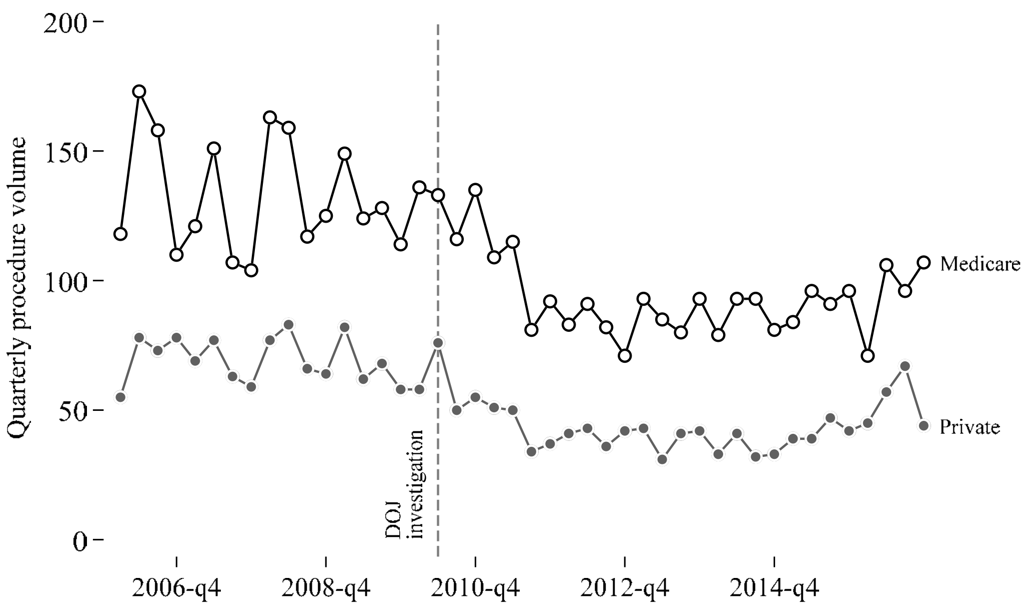
These results are consistent with literature showing that physicians generally adopt a uniform approach to treatment decisions regardless of patients' insurance coverage, and that

[4] An alternative source of spillovers, which will tend to increase variation in treatments across patients, could derive from the presence of supplier induced demand or target incomes (McGuire & Pauly, 1991).

policies adopted by a dominant insurer may affect the treatment of patients with other types of insurance (Frank & Zeckhauser 2007; Hardwick et al. 1975; Eisenberg 1979; Williams et al. 1982; Eisenberg 1985). For example, Glied and Zivin (2002) find that variation in treatment patterns is at least as much a function of the insurance status of a physician's other patients as it is the insurance status of an individual patient. Similarly, Baicker et al. (2013) find that increases in Medicare Advantage penetration rates lead to shorter hospital lengths of stay in traditional Medicare.

Of more direct relevance to our work, Becker et al. (2005) estimated the impact of Medicaid anti-fraud spending, which varies by state and year, on the costs and treatment of Medicare patients with conditions prone to abuse. They argued that state Medicaid investigations would affect the treatment of Medicare patients if there was sufficient overlap in the types of providers and care targeted. They found effects for some subgroups of Medicare patients, but, overall, effects were small and/or non-significant. The results suggest that deterrence effects are small or that state Medicaid investigations tend to focus on Medicaid-specific issues.

Figure 7: ICD implantations, by insurance type



Estimate of savings

We calculated nationwide cost savings over a 10 year period from the reduction in the use of non-covered ICDs by scaling the baseline estimate (-392 procedures) to the US based on Florida's share of the US population (÷0.064), multiplying the number of procedures by an estimate of the impact of ICD implantation on lifetime medical costs (×$50,000), and calculating the net present value of savings over a 10 year period using a discount rate of 3%. Cost-effectiveness studies of ICDs estimate that the incremental lifetime cost of an ICD versus medical therapy is $80,000 or more (Mark et al. 2006; Sanders et al. 2010; Zwanziger et al. 2006). These estimates apply to patient groups where ICDs have been shown to improve survival, and so they may overestimate costs. We used a more conservative cost estimate. We calculate that the Department of Justice investigation reduced total spending on ICD implantations by $2.7 billion over a 10-year period. Of that, $1.4 billion accrued to Medicare. This estimate is probably conservative because it does not consider how the Department of Justice investigation may have reduced other types of ICD procedures that were not covered, such as procedures in patients with newly diagnosed heart failure.

Conclusion

The Department of Justice investigation reduced the number of ICD procedures. Savings to the health care system, $2.7 billion, were an order-of-magnitude larger than the $280 million that hospitals paid in settlements. We have not attempted to quantify the impact on patient survival or other measures of patient welfare, but multiple randomized trials have shown that patients do not benefit from receiving ICDs soon after a PCI or AMI. Based on these results, it is safe to assume that patients were not harmed by the Department of Justice investigation, especially since the Department of Justice allowed hospitals to implant ICDs in patients following PCIs or AMIs if there was a strong medical justification.

Hospitals could have responded to the investigation in a number of ways to diminish its impact on revenues. They could have satisfied the letter of the Medicare coverage policy by having revascularization patients come back after 90 days and AMI patients come back after 40 days to receive an ICD. They could have reduced ICD use in Medicare patients but not privately-insured patients. They could have waited to the conclusion of the Department of Justice investigation and then increased ICD implantations in the targeted patient groups. The investigation seems to have prompted physicians and hospitals to fundamentally re-assess the benefits of ICD implantations and align their decisions with evidence from randomized trials. Our findings indicate that the False Claims Act is a useful policy tool for reducing wasteful care.

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Appendix

Appendix Table 1: Codes used to identify procedures and AMIs

	CPT	ICD-9	ICD-10
PCI	92920, 92921, 92928, 92929, 92933, 92934, 92980, 92981, 92982, 92984, 92925, G0290, G0291, C9600, C1874	00.41, 00.42, 00.43, 00.46, 00.47, 00.48, 36.03, 36.06, 36.07, 36.09, 00.66	02703, 02713, 02723, 02733
CABG		36.1*, 36.2*, 36.3*	021*
ICD	33249	00.51, 37.94	02HK3K, 02H63KZ, 02H43KZ, 02HN0KZ, 02HN4KZ, 02H63KZ, 02HK3KZ, 02HN0KZ, 02HN4KZ, 0JH608Z, 0JH638Z, 0JH808Z, 0JH838Z
AMI		410*	I21* I22*

ICD: Implantable cardioverter defibrillator; PCI: percutaneous coronary intervention; AMI: Acute myocardial infarction; CABG: Coronary artery bypass grafting.

Appendix Table 2: Coefficient estimates from alternative versions of model 1

	Control procedure		
	Secondary prevention ICDs	PCIs	AMIs
		β (SE)	
Outcome: ICDs post-PCI or post-AMI			
Volume[a]	0.314 (0.205)	0.010 (0.010)	0.011 (0.005)
Volume×Post-DOJ	-0.233 (0.046)	-0.007 (0.001)	-0.005 (0.001)
Quarter 2	17.504 (18.540)	24.800 (30.062)	20.837 (18.767)
Quarter 2	-14.822 (21.683)	-7.258 (38.868)	-9.664 (21.711)
Quarter 4	-18.880 (22.353)	-19.105 (27.616)	-15.429 (20.623)
Constant	331.648 (112.944)	310.588 (197.134)	270.244 (117.845)
Outcome: ICDs post-PCI			
Volume[a]	0.177 (0.123)	-0.001 (0.006)	0.006 (0.003)
Volume×Post-DOJ	-0.119 (0.027)	-0.004 (0.000)	-0.003 (0.001)
Quarter 2	20.047 (11.085)	8.370 (18.183)	21.736 (11.222)
Quarter 2	7.669 (12.964)	-10.280 (23.510)	10.203 (12.982)
Quarter 4	3.514 (13.365)	-10.715 (16.704)	5.009 (12.332)
Constant	104.030 (67.529)	217.943 (119.238)	73.354 (70.467)
Outcome: ICDs post-AMI			
Volume[a]	0.138 (0.118)	0.011 (0.006)	0.005 (0.003)
Volume×Post-DOJ	-0.114 (0.026)	-0.003 (0.000)	-0.003 (0.001)
Quarter 2	-2.543 (10.639)	16.430 (16.758)	-0.899 (10.885)
Quarter 2	-22.491 (12.442)	3.022 (21.667)	-19.867 (12.593)
Quarter 4	-22.394 (12.827)	-8.390 (15.395)	-20.438 (11.962)
Constant	227.618 (64.810)	92.644 (109.891)	196.890 (68.354)

[a]Volume of covered, primary prevention ICDs in patients without recent PCIs or AMIs.
ICD: Implantable cardioverter defibrillator; PCI: percutaneous coronary intervention; AMI: Acute myocardial infarction; DOJ: Department of Justice.

Appendix Table 3: Coefficient estimates from alternative versions of the model with time trend interactions (model 2)

	Control procedure		
	Secondary prevention ICDs	PCIs	AMIs
		β (SE)	
Outcome: ICDs post-PCI or post-AMI			
Volume[a]	0.3148 (0.2266)	0.0094 (0.0104)	0.0130 (0.0094)
Volume×Post-DOJ	-0.1710 (0.0831)	-0.0059 (0.0019)	-0.0044 (0.0017)
Volume×Time trend[b]	0.0009 (0.0040)	0.0000 (0.0001)	0.0001 (0.0001)
Volume×Post-DOJ×Time trend[b]	-0.0031 (0.0046)	0.0000 (0.0001)	-0.0001 (0.0001)
Quarter 2	17.8994 (18.9778)	23.2199 (30.6792)	24.4670 (22.2187)
Quarter 2	-14.5810 (22.9434)	-10.4916 (39.8555)	-2.8132 (30.5461)
Quarter 4	-18.3404 (23.4866)	-20.4634 (28.1738)	-9.9344 (26.9625)
Constant	329.3022 (127.9788)	328.9514 (202.6293)	211.6949 (215.1239)
Outcome: ICDs post-PCI			
Volume	0.1606 (0.1357)	-0.0015 (0.0063)	0.0050 (0.0057)
Volume[a]	-0.0907 (0.0498)	-0.0031 (0.0011)	-0.0023 (0.0010)
Volume×Post-DOJ	-0.0002 (0.0024)	0.0000 (0.0001)	0.0000 (0.0001)
Volume×Time trend[b]	-0.0010 (0.0027)	0.0000 (0.0001)	0.0000 (0.0001)
Volume×Post-DOJ×Time trend[b]	19.8194 (11.3695)	6.7467 (18.4432)	20.6060 (13.3745)
Quarter 2	6.6125 (13.7454)	-13.4369 (23.9596)	8.1646 (18.3872)
Quarter 2	2.6902 (14.0707)	-12.1300 (16.9370)	3.3686 (16.2300)
Quarter 4	113.2210 (76.6718)	235.8797 (121.8131)	90.3408 (129.4933)
O Constant			
Volume[a]	0.1542 (0.1302)	0.0109 (0.0059)	0.0080 (0.0054)
Volume×Post-DOJ	-0.0803 (0.0478)	-0.0027 (0.0010)	-0.0021 (0.0010)
Volume×Time trend[b]	0.0011 (0.0023)	0.0000 (0.0001)	0.0001 (0.0001)
Volume×Post-DOJ×Time trend[b]	-0.0021 (0.0026)	0.0000 (0.0001)	-0.0001 (0.0001)
Quarter 2	-1.9200 (10.9079)	16.4733 (17.2158)	3.8610 (12.8047)
Quarter 2	-21.1934 (13.1873)	2.9454 (22.3651)	-10.9778 (17.6038)
Quarter 4	-21.0306 (13.4995)	-8.3333 (15.8098)	-13.3030 (15.5386)
Constant	216.0812 (73.5590)	93.0716 (113.7062)	121.3541 (123.9763)

[a]Volume of covered, primary prevention ICDs in patients without recent PCIs or AMIs.

[b]Coefficients are re-scaled (×100) for purposes of display.

ICD: Implantable cardioverter defibrillator; PCI: percutaneous coronary intervention; AMI: Acute myocardial infarction; DOJ: Department of Justice.

Appendix Table 4: Estimates of the impact of the Department of Justice investigation on ICD use in 2016, based on model 2

	Control procedure		
Outcome	Secondary prevention ICDs	PCIs	AMIs
Volume of ICDs post-PCI or post-AMI			
Absolute change	-490 (-924, -57)	-456 (-940, 29)	-537 (-957, -117)
Percent change	-26% (-42%, -2%)	-24% (-42%, 2%)	-28% (-42%, -7%)
Volume of ICDs post-PCI			
Absolute change	-218 (-478, 42)	-192 (-484, 99)	-232 (-485, 21)
Percent change	-28% (-50%, 8%)	-24% (-51%, 25%)	-29% (-52%, 2%)
Volume of ICDs post-AMI			
Absolute change	-272 (-521, -23)	-263 (-535, 8)	-305 (-547, -63)
Percent change	-24% (-39%, -3%)	-23% (-40%, 0%)	-26% (-40%, -7%)

PCI: Percutaneous coronary intervention; AMI: Acute myocardial infarction.
95% Confidence intervals shown in parentheses.

Appendix Table 5: Estimates of the impact of the Department of Justice investigation on ICD use in 2016, hospitals that settled

	Control procedure		
Outcome	Secondary prevention ICDs	PCIs	AMIs
Volume of ICDs post-PCI or post-AMI			
Absolute change	-249 (-329, -168)	-276 (-332, -220)	-186 (-261, -110)
Percent change	-28% (-36%, -20%)	-30% (-35%, -25%)	-22% (-29%, -15%)
Volume of ICDs post-PCI			
Absolute change	-135 (-183, -87)	-143 (-177, -110)	-101 (-145, -56)
Percent change	-36% (-48%, -24%)	-38% (-45%, -30%)	-30% (-39%, -20%)
Volume of ICDs post-AMI			
Absolute change	-114 (-163, -65)	-132 (-167, -98)	-85 (-132, -39)
Percent change	-22% (-30%, -14%)	-25% (-30%, -19%)	-17% (-24%, -9%)

PCI: Percutaneous coronary intervention; AMI: Acute myocardial infarction.
95% Confidence intervals shown in parentheses.

Appendix Table 6: Estimates of the impact of the Department of Justice investigation on ICD use in 2016, hospitals that did not settle

	Control procedure		
Outcome	Secondary prevention ICDs	PCIs	AMIs
Volume of ICDs post-PCI or post-AMI			
Absolute change	-187 (-262, -112)	-193 (-250, -137)	-171 (-242, -101)
Percent change	-20% (-26%, -13%)	-21% (-26%, -16%)	-19% (-25%, -12%)
Volume of ICDs post-PCI			
Absolute change	-96 (-142, -50)	-114 (-150, -79)	-78 (-120, -36)
Percent change	-25% (-34%, -16%)	-29% (-36%, -21%)	-22% (-30%, -11%)
Volume of ICDs post-AMI			
Absolute change	-91 (-144, -38)	-79 (-117, -41)	-93 (-144, -42)
Percent change	-16% (-24%, -8%)	-15% (-22%, -9%)	-17% (-25%, -8%)

PCI: Percutaneous coronary intervention; AMI: Acute myocardial infarction.
95% Confidence intervals shown in parentheses.

Appendix Table 7: Estimates of the impact of the Department of Justice investigation on ICD use in 2016, patients insured by Medicare

Outcome	Control procedure		
	Secondary prevention ICDs	PCIs	AMIs
Volume of ICDs post-PCI or post-AMI			
Absolute change	-208 (-316, -101)	-300 (-370, -230)	-227 (-321, -133)
Percent change	-18% (-27%, -9%)	-25% (-30%, -20%)	-20% (-26%, -12%)
Volume of ICDs post-PCI			
Absolute change	-101 (-166, -36)	-153 (-195, -111)	-95 (-151, -40)
Percent change	-21% (-33%, -9%)	-30% (-37%, -24%)	-22% (-31%, -11%)
Volume of ICDs post-AMI			
Absolute change	-107 (-173, -42)	-147 (-189, -105)	-131 (-189, -74)
Percent change	-16% (-24%, -7%)	-21% (-26%, -16%)	-19% (-25%, -12%)

PCI: Percutaneous coronary intervention; AMI: Acute myocardial infarction.
95% Confidence intervals shown in parentheses.

Appendix Table 8: Estimates of the impact of the Department of Justice investigation on ICD use in 2016, patients not insured by Medicare

	Control procedure		
Outcome	Secondary prevention ICDs	PCIs	AMIs
Volume of ICDs post-PCI or post-AMI			
Absolute change	-184 (-245, -123)	-179 (-217, -141)	-126 (-178, -75)
Percent change	-28% (-36%, -21%)	-28% (-33%, -22%)	-21% (-27%, -14%)
Volume of ICDs post-PCI			
Absolute change	-100 (-134, -66)	-105 (-126, -84)	-87 (-116, -58)
Percent change	-38% (-48%, -28%)	-39% (-45%, -33%)	-34% (-42%, -26%)
Volume of ICDs post-AMI			
Absolute change	-84 (-130, -38)	-74 (-103, -45)	-39 (-77, -1)
Percent change	-22% (-31%, -11%)	-20% (-27%, -12%)	-11% (-20%, 0%)

PCI: Percutaneous coronary intervention; AMI: Acute myocardial infarction.
95% Confidence intervals shown in parentheses.