

Table 2. Campaign Contributions to Members of the Senate Health, Education, Labor, and Pensions Committee During the 2016 Election Cycle^a

Member	Contribution Amount, \$										
	Amerisource	Cardinal	McKesson ^b	Allergan ^b	Endo	Johnson & Johnson	Mallinckrodt	Mylan	Purdue	Teva	Total
Richard Burr (R, NC) ^c	6500	7500	5000	2500	1000	9000	3500	2500	10 000	1000	48 500
Patty Murray (D, WA) ^c	6000	10 000	10 000	3500		5500		1000		5000	41 000
Tim Scott (R, SC) ^c	10 000	5000	7000			7000	2500	1000	1000	2500	36 000
Orrin G. Hatch (R, UT)	8000	5000	7500	5000	2000	1000					28 500
Bob Casey (D, PA)	8750	2500				3500				10 000	24 750
Johnny Isakson (R, GA) ^c	2000		6000	1000		8000	2000	2000			21 000
Michael F. Bennet (D, CO) ^c		5000	7500			5000		1000		1000	19 500
Bill Cassidy (R, LA)	3500		5000	10 000							18 500
Todd Young (R, IN) ^c	6000		5000			1000					12 000
Lamar Alexander (R, TN) ^d	1000	10 000									11 000
Tim Kaine (D, VA)	3500	2500				2500					8500
Pat Roberts (R, KS)	5000			2500							7500
Lisa Murkowski (R, AK) ^c	1000		2000			2000					5000
Mike Enzi (R, WY)				3000							3000
Tammy Baldwin (D, WI)							1500				1500
Total ^e	61 250	47 500	55 000	27 500	3000	44 500	9500	7500	11 000	19 500	286 250

^a Members who did not receive payments: Susan Collins (R, ME), Maggie Hassan (D, NH; up for election in the 2016 cycle), Doug Jones (D, AL), Christopher Murphy (D, CT), Rand Paul (R, KY; up for election in the 2016 cycle), Bernie Sanders (D, VT), Tina Smith (D, MN), Elizabeth Warren (D, MA). See Table 1 footnote for data source and political action committee details.

^b Associated with 2 political action committees.

^c Members up for election in the 2016 cycle.

^d Committee chair.

^e Mean contribution, \$19 083; median, \$18 500 (range, \$1500–\$48 500).

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Use of Death Counts From Vital Statistics to Calculate Excess Deaths in Puerto Rico Following Hurricane Maria

The official death toll for Hurricane Maria, which devastated Puerto Rico on September 20, 2017, has remained at 64 since December 29, 2017. Accurate estimates of deaths from environmental disasters are important for informing rescue, recovery, and policy decisions.

Using preliminary death counts through October 2017, excess deaths related to the hurricane were estimated at 1085.¹ However, other estimates suggest that the number of excess deaths may be as high as 4645.² The variance in estimates is due to differences in methodology. The official government death toll includes only deaths in which documentation of “hurricane-related” as the cause of death appears on the individual’s death certificate and does not account for indirect deaths, including from infectious disease outbreaks or lack of services (such as electricity, water, and medical care). Estimates of excess deaths address both direct and indirect deaths and typically use either death counts from government agencies¹ or surveys,² which are susceptible to larger margins of error. We calculated the number of excess deaths following Hurricane Maria through December 2017, using death counts from vital statistics records, updating a previous estimate.¹

Methods | Monthly death counts, from January 2010 through December 2017, including previously unavailable death counts for January through December 2017, were obtained from the Puerto Rico vital statistics system to calculate excess deaths in Puerto Rico following Hurricane Maria; this system has a 99% coverage rate based on previous analyses.³ Because these data are deidentified aggregate counts of deceased individuals, this study is considered to be research not involving human subjects as defined by US regulation (45 CFR 46.102[d]).

Consistent with prior studies,^{4,5} death counts from vital records from 2010 through 2016 were used to establish expected monthly deaths (mean), and historical ranges of natural variability (95% CIs). For September through December 2017, we used the difference between number of deaths from

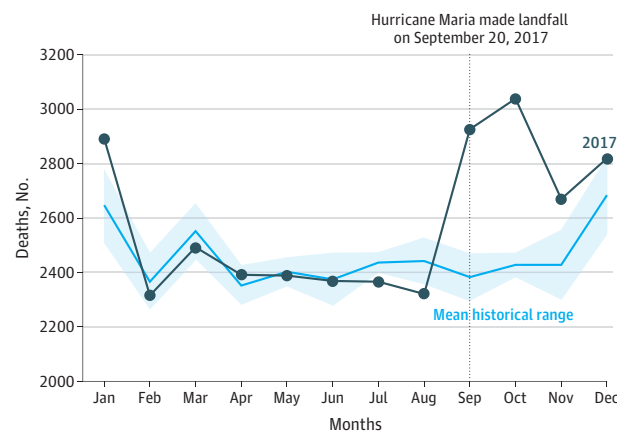
Table. Historical Patterns of Deaths, 2017 Death Counts, and Estimated Excess Deaths in Puerto Rico^a

Month	2010-2016 Historical Patterns of Deaths, Mean (95% CI)	2017 Death Counts	Excess Deaths (95% CI) ^b
January	2612 (2485-2739)	2894	
February	2375 (2255-2495)	2315	
March	2560 (2439-2681)	2494	
April	2348 (2261-2434)	2392	
May	2405 (2343-2466)	2390	
June	2378 (2261-2494)	2369	
July	2448 (2413-2482)	2367	
August	2460 (2370-2550)	2321	
September	2383 (2297-2469)	2928	459 (425-493)
October	2429 (2380-2476)	3040	564 (531-597)
November	2428 (2299-2555)	2671	116 (50-182)
December	2685 (2543-2827)	2820	

^a Source: Puerto Rico vital statistics system, 2010-2016 and actual counts from 2017.

^b Excess deaths are the difference between the upper limit of the CI and the count for each month following Hurricane Maria.

Figure. 2017 Deaths and Mean Historical Range (2010-2016) Deaths in Puerto Rico



Shaded area indicates the mean historical range 95% CI (2010-2016).

vital statistics records and the upper 95% CI bound as a measure of excess mortality. The upper 95% CI limits were calculated as:

$$\bar{x} + t_{[1-\alpha/2n-1]} \frac{s}{\sqrt{n}}$$

where \bar{x} is the mean value, t is the 2-sided value of the student t -distribution, α is the alpha level (.05), n is the number of observations ($n = 7$), and s is the standard error of the mean. The 1-sample t test was used to calculate 95% CIs around the excess death estimates. Analyses were conducted using SAS (SAS Institute), version 9.4.

Results | The expected numbers of deaths were 2383 in September, 2429 in October, 2428 in November, and 2685 in December (Table). The upper bounds (95% CIs) for the same months were 2469, 2476, 2555, and 2827, respectively, whereas the actual numbers of deaths were 2928, 3040, 2671, and 2820. There were 1139 (95% CI, 1006-1272) excess deaths: 459 (95% CI, 425-493) in September, 564 (95% CI, 531-597) in October, and 116 (95% CI, 50-182) in November. Although August and July experienced lower numbers of deaths than expected, September and

October had higher numbers of deaths than expected, the number of deaths decreased in November, and by December had returned to a level within historical variation (Figure).

Discussion | Based on death records following Hurricane Maria, the estimated hurricane-related mortality burden of 1139 excess deaths through December 2017 was higher than the official death toll of 64. The estimate is conservative, because the expected number of deaths used the upper 95% CI and did not consider the population denominators, which were decreasing. The strength of the present approach is that it is based on death counts from vital statistics records and is consistent with previous estimates¹ and methods.^{4,5} The primary limitation of the study is that the specific cause of each individual death is not known; thus only an aggregate number of deaths in excess of historical variation can be estimated. Another recent study² suggested that there were 4645 excess deaths (95% CI, 783-8498), but it was based on a survey that underestimated prehurricane mortality, overestimated posthurricane mortality, and had a large CI, indicating a high level of uncertainty. Future studies would benefit from careful analysis of deaths from vital records rather than surveys.

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Correction: This article was corrected online August 28, 2018, to fix an error in the upper 95% CI limit of excess deaths in September 2017 and again on May 21, 2019, to update data in the column of mean historical deaths in the Table and corresponding numbers in the Results paragraph.

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Author Contributions: Drs Santos-Lozada and Howard had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: All authors.

Acquisition, analysis, or interpretation of data: All authors.

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Statistical analysis: All authors.

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COMMENT & RESPONSE

Meta-analysis of LDL-C Lowering and Mortality

To The Editor In a meta-analysis by Dr Navarese and colleagues concerning low-density lipoprotein cholesterol (LDL-C) levels and mortality after LDL-C lowering,¹ we identified several potential errors related to trials conducted by our research group.

First, in reporting data from the Justification for the Use of Statins in Prevention: an Intervention Trial Evaluating Rosuvastatin (JUPITER), Navarese and colleagues presented a cardiovascular mortality rate ratio (RR) of 0.53 (95% CI, 0.41-0.69). These values, however, are for the trial end point of myocardial infarction, stroke, or death from cardiovascular disease.² The correct published values for confirmed deaths from cardiovascular causes in the rosuvastatin and placebo groups of JUPITER were 35 and 43, respectively, with a corresponding hazard ratio (HR) of 0.82 (95% CI, 0.52-1.27).³

Second, regarding the Studies of PCSK9 Inhibition and the Reduction of Vascular Events 1 (SPIRE-1) trial, Navarese and colleagues reported a cardiovascular mortality RR of 1.14 (95% CI, 0.80-1.62). The correct published HR was 1.20 (95% CI, 0.74-1.95).⁴

Third, Navarese and colleagues reported a cardiovascular mortality RR of 0.91 (95% CI, 0.63-1.32) in the SPIRE-2 trial. The correct published HR was 0.82 (95% CI, 0.50-1.36).⁴

The above errors do not reflect differences between RRs and HRs.

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entities including the National Heart, Lung, and Blood Institute, the National Cancer Institute, the American Heart Association, the Doris Duke Charitable Foundation, the Leducq Foundation, the Donald W. Reynolds Foundation, and the James and Polly Annenberg La Vea Charitable Trusts; receiving investigator-initiated research support from Astra-Zeneca, Novartis, Pfizer, and Kowa, as well as nonfinancial research support from Amgen; being listed as a co-inventor on patents held by the Brigham and Women's Hospital that relate to the use of inflammatory biomarkers in cardiovascular disease that have been licensed to Siemens and AstraZeneca; and serving during the past year as a research consultant to Quintiles, Novartis, Corvidia, Inflazome, Eisai, Sanofi, and Janssen. No other authors reported disclosures.

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In Reply Dr Duran and colleagues suggest there were errors in data extracted from 3 trials for our meta-analyses¹ and that the “errors do not reflect differences between RRs and HRs.” Hazard ratios were inconsistently reported for the cardiovascular and all-cause mortality end points in trials included in our meta-analyses. Although often similar, RRs are not the same as HRs. In the absence of a reported HR, there are several possible analytic approaches: (1) omit the study from the analysis, producing selection bias; (2) calculate the risk ratio, ignoring follow-up duration and creating heterogeneity and imprecision, particularly when there is a large variation in trial duration across studies, as is the case with lipid-lowering trials; or (3) calculate the RR, thereby considering different follow-up durations and ensuring a uniform approach to estimation of effect size across all trials.²

To ensure consistency and reduce heterogeneity, we therefore calculated RRs, adjusting for person-years of follow-up, which took into account the different trial durations. Rate ratios have been used in previous meta-analyses such as the one from the Cholesterol Treatment Trialists' Collaboration.³ Indeed, calculating RRs using person-years of follow-up for the trial-level data from the trials included in the collaboration meta-analysis yielded the same RR values that were derived from individual-level data.⁴

Duran and colleagues provided data on confirmed deaths from cardiovascular causes for JUPITER that were not reported in the original publication but were provided in a letter to the editor, which we overlooked in our search. The RR, adjusted for trial duration as described above, calculated for the new event rate counts is 0.81 (95% CI, 0.52-1.27), which is only slightly different from the HR of 0.82 (95% CI, 0.52-1.27) reported by the JUPITER investigators. We have updated our meta-analysis with this new information and find it does not alter the conclusion regarding the