Title Cost-Effectiveness Analysis of the Federal Menu Calorie Labeling and Obesity-Associated Cancer Burdens in the United States

Du M, *et al. BMJ Open* 2023; 13:e063614. doi: 10.1136/bmjopen-2022-063614

Appendix 1. Estimate the association between menu calorie labeling policy and calorie intake from restaurant meals

To understand the effects of the federal menu calorie labeling policy, we performed a comprehensive literature search and reviewed the evidence on how the policy affected consumer behaviors and industry.

To estimate the policy effect on consumer behavior alone, we reviewed individual studies in both real-world and experimental settings as well as meta-analyses (**Appendix Table 1**). A meta-analysis of natural experimental studies showed that menu calorie labeling was associated with a 7.3% (95% CI: 4.4% to 10.1%) reduction in calories per meal consumed/purchased.[1] This effect estimate is corresponding to an average reduction of 23.5 kcal per meal consumed by NHANES participants from 56.5% of full-service restaurants[2] and all fast-food restaurants. This estimate was consistent with evidence from a previous meta-analysis and a recent real-world study.[3, 4] A previous meta-analysis estimated that the menu calorie labeling would lead to about an 18 kcal reduction ordered per meal.[3] A recent longitudinal study used data from a large restaurant franchise in the southern U.S. and estimated that, after labeling implementation, a decrease of 60 kcal per transaction was observed in the first year, followed by an increasing trend of 0.71 kcal per transaction per week over two years.[4] These together attenuated the calorie reduction to 23 kcal per transaction by the end of the third year of the policy implementation.[5] Compared to other studies, the 7.3% calorie reduction per meal represents a more conservative estimate. It was reported in a cross-sectional study that customers at the labeled full-service restaurants purchased food with 151 fewer calories.[6] One meta-analysis of studies that evaluated energy ordered in a real-world setting showed that the calorie labeling policy would lead to a mean reduction of 77.8 in calories purchased per meal.[7] In a laboratory setting, there was a significant reduction of 115.3 kcal per meal ordered.[8] Integrating both the real-world and experimental studies, the policy was estimated to generate a significant reduction of 100.3 in calories purchased.[7] Therefore, we decided to use a reduction of calorie intake per meal by 7.3% (95% CI: 4.4% to 10.1%) as the model input given it is the most updated and conservative estimate supported by existing evidence. This policy effect on consumer behavior alone was assumed to take effect during the first year of implementation and no further reduction thereafter.

Based on the published literature, we estimated that there was a 5% reduction in calories consumed per meal from chain restaurants due to industry reformulation, the introduction of new low-calorie menu items, or the replacement of menu items high in calories with low-calorie menu options. [9-13] Bleich et al. estimated the calorie changes in chain restaurants' menu items using data from the largest chain restaurants in the U.S. [9-13] Using the estimated mean calorie per menu item from the two published studies shown in **Appendix Table 2**,[11, 12] we calculated the mean change in calories per menu item before and after the policy implementation. Given the national law was announced in 2010, using data from the trend analysis, we treated the mean calorie per menu item measured in 2008 as the baseline and found there was an 11% reduction in calories per menu item two years after the affordable care act was enacted. The change decreased to 7% in 2015, one year after the FDA announced the final rule for the industry to comply with. In the study evaluated the calorie content in current menu items, eliminated menu items, and newly introduced menu items, we estimated that there was a 1% reduction in mean per-item calories in 2013-2014 compared to that in 2012, and the reduction increased to 5% in 2015. Based on this de novo analysis, we chose a reduction in calories per meal consumed by 5% to represent a modest industry reformulation in response to the federal menu calorie labeling by chain restaurants. We assumed no industry response in the first year, then the reformulation activities would occur in the rest of the years over the model lifetime, resulting in a net reduction of 5% in calories consumed per meal.

Appendix Table 1. Policy impact of menu calorie labeling on consumer behaviors

Study	**Design**	**Year, country**	**Estimate size** mean (95% CI)	**Comment**
Shangguan et. al., 2019[1] A Meta-Analysis of Food Labeling Effects on Consumer Diet Behaviors and Industry Practices	Meta-analysis 13 studies (5 RCTs) with 19 interventions on changes in calorie intake per meal, among children and adults	2000 to 2015, US, Canada, UK, Sweden	-7.3% (-10.1%, -4.4%) in calorie intake per meal	Corresponds to a 23.5 kcal per meal consumed by NHANES participants from 56.5% of full-service restaurants[2] and all fast-food restaurants
Petimar et. al., 2019[4] Estimating the effect of calorie menu labeling on calories purchased in a large restaurant franchise in the southern United States: quasi-experimental study	Quasi-experimental longitudinal study Transaction data from 104 restaurants of a national fast food company with three different restaurant chains located in the Louisiana, Texas, and Mississippi in the US	2015 to 2018 (pre-labeling: April 2015 to April 2017; post-labeling: April 2017 to April 2018), US	-60 (-48, -72) kcal in calorie purchased per transaction, followed by a post-implementation increasing trend of 0.71 kcal per transaction per week	Because of the post-implementation increase, the estimated reduction in calorie per transaction was 23 kcal lower than the counterfactual.
Cantu-Jungles et. al., 2017[8] A Meta-Analysis to Determine the Impact of Restaurant Menu Labeling on Calories and Nutrients (Ordered or Consumed) in U.S. Adults	Meta-analysis 14 studies that evaluated menu calorie labeling on changes in calorie chosen in laboratory and away-from-home settings, among children and adults	1996 to 2014	-115.2 (-130.87, -99.5) kcal in calorie ordered or consumed per meal in laboratory setting	N/A
Littlewood et. al., 2016[7] Menu labelling is effective in reducing energy ordered and consumed: a systematic review and meta-analysis of recent studies	Systematic review and meta-analysis 12 studies (6 RCTs) on changes in calorie consumed, ordered, or selected in both real-world and experimental settings, among children and adults	2011 to 2014, US, Canada, Australia,	-100.3 (-146.6, -54.0) kcal in calorie consumed in both settings per meal or transaction (3 studies) -77.8 (-121.6, -34.1) kcal in calorie purchased per meal or transaction in real-world setting (5 studies)	N/A
Long et. al., 2015[3] Systematic Review and Meta-analysis of the Impact of Restaurant Menu Calorie Labeling	Systematic review and meta-analysis 19 studies (11 RCTs, 8 natural experiments) on changes in calorie purchased per meal or per transaction, among children and adults	2008 to 2013, US	-18.1 (-33.6, -2.70) kcal in calorie purchased per meal or per transaction When stratifying by restaurant and non-restaurant settings (RCTs), the changes were -6.7 (-20.21, 6.81) kcal and -58.2 (-102.4, -13.9) kcal in calorie	N/A

			purchased per meal or per transaction	
Auchincloss et. al., 2013[6] Customer responses to mandatory menu labeling at full-service restaurants	Cross-sectional study 648 customer surveys and transaction receipts at 7 restaurant outlets of 1 large full-service restaurant chain (2 outlets with menu calorie labels and 5 without), among adults	2011, US	-151 kcal (-270, -33) for foods purchased from full-service restaurants (per meal)	Was included in the meta-analysis conducted by Cantu-Jungles et. al., 2017[8]

Appendix Table 2. Policy impact of menu calorie labeling on restaurant industry response

Study		Year				
		2008	**2012**	**2013**	**2014**	**2015**
Bleich et. al., 2017[11] Calorie changes in large chain restaurants from 2008 to 2015 44 of the 100 largest chain restaurants	# of menu items (n)	6,601	9,526	10,278	10,654	11,034
	mean per-item calories (kcal)	368.0	329.1	330.1	337.2	340.6
	diff. (%)		2012 vs. 2008 -38.9 (-11%)			2015 vs. 2008 -27 (-7%)
Bleich et. al., 2018[12] Higher-Calorie Menu Items Eliminated in Large Chain Restaurants 66 of the 100 largest chain restaurants	# of menu items (n)		14,705	17,219 (2013-2014)		13,920
	mean per-item calories (kcal)		374.4	370.9		357.4
	diff. (%)			2013-2014 vs. 2012 -3.52 (-1%)		2015 vs. 2012 -17.05 (-5%)

Appendix 2. Baseline cancer incidence and methods of cancer incidence projections for 13 types of cancers

We estimated the cancer incidence rate projections for the defined 32 demographic subgroups as inputs for the DiCOM model. We first obtained age-adjusted incidence rates from 2006 to 2015 from the United States Cancer Statistics combining data from the Surveillance, Epidemiology, and End Results (SEER) database and the Centers for Disease Control and Prevention's National Program of Cancer Registries (NPCR) database.[14]

Based on the trends from 2006 to 2015, we projected age-adjusted cancer incidence rates in the next 15 years from 2016 to2030 using the average annual percent change (AAPC) method.[15, 16] Because longer-term projections may not be valid, we chose to hold age-adjusted cancer incidence rates constant from 2030 to 2095. Specifically, the annual percent change was calculated for each cancer site in each of the 32 subgroups by fitting a regression line to the natural logarithm of the age-adjusted rates (I) in the years 2006 through 2015 (y). The equation for AAPC: $\ln(I)= \alpha + \beta y$, where α and β were coefficients to be estimated and y is the calendar year.[15, 16] We then combined the AAPC projected cancer incidence rates with the projected US population to account for the change in population age distribution over time. The projected US population in each of the 32 subgroups from 2016 to 2060 were extracted from the National Interim Projections of the US population.[17] Because projections were only available through 2060, further projections after 2060 were not considered. We further applied the cohort-period method to estimate cancer incidence in each of the 32 subgroups in the closed cohort of US adults from 2015 to 2095 as they age. Details were illustrated in **Appendix Table 3** using colon and rectum cancer incidence among non-Hispanic white females (NHWF) as an example.

Du M, *et al. BMJ Open* 2023; 13:e063614. doi: 10.1136/bmjopen-2022-063614

Appendix Table 3. Estimating "crude" incidence after applying cohort-period method

EXAMPLE: Colon and Rectum Cancer, Non-Hispanic White Females																
Age	2015		2016				2017				2018					
	Baseline Incidence Rate	Population Size	AAPC Predicted Incidence	US Census Predicted Population Size	Cancer Cases Predicted	Age Shifted "crude" Incidence	AAPC Predicted Incidence	US Census Predicted Population Size	Cancer Cases Predicted	Age Shifted "crude" Incidence	AAPC Predicted Incidence	US Census Predicted Population Size	Cancer Cases Predicted	Age Shifted "crude" Incidence		
20	8.531	30523184	8.694	1134235		10.154	8.859	1126079		11.694	9.028	1117775		13.182		
21	8.531		8.694	1156761	100565		8.859	1137549			9.028	1129379				
22	8.531		8.694	1177144	102337		8.859	1159788	102748		9.028	1140620				
23	8.531		8.694	1196469	104017		8.859	1180122	104550		9.028	1162784	104976			
24	8.531		8.694	1238910	107707		8.859	1199459	106263		9.028	1183136	106813			
25	8.531		8.694	1283513	111585		8.859	1241739	110009		9.028	1202329	108546			
26	8.531		8.694	1294013	112497		8.859	1286229	113950		9.028	1244499	112353			
27	8.531		8.694	1250740	108735		8.859	1296475	114858		9.028	1288797	116352			
28	8.531		8.694	1232421	107143		8.859	1253062	111012		9.028	1298770	117252			
29	8.531		8.694	1216039	105719		8.859	1234519	109369		9.028	1255161	113315			
30	8.531		8.694	1228929	106839		8.859	1217844	107892		9.028	1236330	111615			
31	8.531		8.694	1244281	108174		8.859	1230337	108999		9.028	1219312	110079			
32	8.531		8.694	1205955	104842		8.859	1245249	110320		9.028	1231390	111169			
33	8.531		8.694	1226950	106667		8.859	1206736	106908		9.028	1246013	112489			
34	8.531		8.694	1226234	106605		8.859	1227540	108751		9.028	1207377	109001			
35	8.531		8.694	1217701	105863		8.859	1226721	108678		9.028	1228051	110868			
36	8.531		8.694	1228467	106799		8.859	1218141	107918		9.028	1227199	110791			
37	8.531		8.694	1160971	100931		8.859	1228796	108862		9.028	1218528	110008			
38	8.531		8.694	1139547	99069		8.859	1161267	102879		9.028	1229044	110958			
39	8.531		8.694	1127605	98030		8.859	1139679	100967		9.028	1161414	104852			
40	8.531		8.694	1088875	94663		8.859	1127530	99891		9.028	1139635	102886			
41	8.531		8.694	1130467	98279		8.859	1088644	96446		9.028	1127272	101770			
42	8.531		8.694	1101345	95747		8.859	1129951	100105		9.028	1088229	98245			
43	8.531		8.694	1130264	98262		8.859	1100615	97506		9.028	1129228	101946			
44	8.531		8.694	1210411	105229		8.859	1129268	100045		9.028	1099713	99282			
45	41.269	14238423	41.919	1319769	553230	43.775	42.579	1208976	514771	45.825	43.250	1128045	487878	47.459		
46	41.269		41.919	1346596	564476		42.579	1317806	561110		43.250	1207332	522169			
47	41.269		41.919	1292274	541705		42.579	1344191	572344		43.250	1315541	568969			
48	41.269		41.919	1264917	530237		42.579	1289694	549140		43.250	1341533	580211			
49	41.269		41.919	1295410	543019		42.579	1262140	537408		43.250	1286923	556592			
50	41.269		41.919	1325816	555765		42.579	1292230	550220		43.250	1259139	544576			
51	41.269		41.919	1432079	600309		42.579	1322198	562980		43.250	1288813	557410			
52	41.269		41.919	1489756	624487		42.579	1427705	607904		43.250	1318321	570172			
53	41.269		41.919	1510286	633093		42.579	1484805	632216		43.250	1423107	615492			
54	41.269		41.919	1532940	642589		42.579	1504858	640755		43.250	1479608	639928			
55	59.736	15111568	58.496	1575080	921363	65.864	57.283	1526976	874691	71.195	56.094	1499151	840934	75.804		
56	59.736		58.496	1579128	923731		57.283	1568482	898466		56.094	1520747	853048			
57	59.736		58.496	1554236	909170		57.283	1572018	900492		56.094	1561581	875954			
58	59.736		58.496	1566074	916095		57.283	1546788	886040		56.094	1564631	877664			
59	59.736		58.496	1559941	912507		57.283	1558015	892471		56.094	1539019	863298			
60	59.736		58.496	1509257	882859		57.283	1551289	888618		56.094	1549572	869217			
61	59.736		58.496	1507776	881993		57.283	1500225	859367		56.094	1542165	865062			
62	59.736		58.496	1469467	859583		57.283	1497943	858060		56.094	1490621	836149			
63	59.736		58.496	1428612	835685		57.283	1458963	835731		56.094	1487453	834372			
64	59.736		58.496	1384020	809600		57.283	1417465	811960		56.094	1447782	812119			
65	147.246	20639658	140.189	1344027	1884181	140.189	133.471	1372210	1831501	133.471	127.075	1405568	1786119	127.075		
66	147.246		140.189	1307657	1833194		133.471	1331467	1777121		127.075	1359584	1727685			
67	147.246		140.189	1291598	1810681		133.471	1294222	1727410		127.075	1318007	1674851			
68	147.246		140.189	1292613	1812104		133.471	1277026	1704458		127.075	1279794	1626292			
69	147.246		140.189	1382868	1938632		133.471	1276471	1703717		127.075	1261379	1602891			
70	147.246		140.189	987587	1384490		133.471	1363827	1820312		127.075	1259177	1600093			
71	147.246		140.189	982267	1377032		133.471	972764	1298357		127.075	1343441	1707171			
72	147.246		140.189	972611	1363496		133.471	966021	1289357		127.075	956905	1215982			
73	147.246		140.189	1012982	1420091		133.471	954967	1274603		127.075	948632	1205469			
74	147.246		140.189	874564	1226044		133.471	992594	1324824		127.075	936077	1189515			
75	147.246		140.189	796574	1116711		133.471	855200	1141443		127.075	970797	1233635			
76	147.246		140.189	747848	1048402		133.471	777087	1037185		127.075	834495	1060430			
77	147.246		140.189	706707	990727		133.471	727604	971140		127.075	756255	961007			
78	147.246		140.189	679404	952451		133.471	685495	914936		127.075	705976	897115			
79	147.246		140.189	625026	876219		133.471	656756	876578		127.075	662851	842315			
80	147.246		140.189	595777	835215		133.471	601790	803215		127.075	632555	803816			
81	147.246		140.189	572977	803252		133.471	571026	762154		127.075	577004	733225			
82	147.246		140.189	512332	718234		133.471	546330	729192		127.075	544674	692142			
83	147.246		140.189	496976	696707		133.471	485519	648027		127.075	517986	658228			
84	147.246		140.189	475655	666817		133.471	467692	624233		127.075	457134	580901			
85	147.246		140.189	452173	633898		133.471	444106	592752		127.075	436898	555186			
86	147.246		140.189	428834	601179		133.471	418526	558610		127.075	411316	522678			
87	147.246		140.189	383933	538233		133.471	393130	524714		127.075	383961	487917			
88	147.246		140.189	356801	500196		133.471	348261	464827		127.075	356875	453497			
89	147.246		140.189	320644	449508		133.471	319862	426923		127.075	312475	397076			
90	147.246		140.189	278562	390514		133.471	283710	378670		127.075	283306	360010			
91	147.246		140.189	246568	345662		133.471	242960	324281		127.075	247721	314790			
92	147.246		140.189	209022	293026		133.471	211695	282551		127.075	208839	265381			
93	147.246		140.189	169864	238131		133.471	176399	235441		127.075	178878	227308			
94	147.246		140.189	138657	194382		133.471	140691	187782		127.075	146313	185927			
95	147.246		140.189	109277	153195		133.471	112531	150196		127.075	114362	145325			
96	147.246		140.189	80177	112399		133.471	86769	115811		127.075	89499	113730			
97	147.246		140.189	56739	79542		133.471	62172	82982		127.075	67414	85666			
98	147.246		140.189	42046	58944		133.471	42907	57268		127.075	47105	59858			
99	147.246		140.189	27405	38419		133.471	30959	41321		127.075	31659	40231			
100	147.246		140.189	49314	69133		133.471	50716	67691		127.075	52719	66992			

Appendix 3. Cancer survival for 13 types of cancers

We estimated the 5-year relative survival for the defined 32 demographic subgroups. We obtained five-year relative survival rates using the period analysis method from the United States Cancer Statistics which incorporates data from the Surveillance, Epidemiology, and End Results (SEER) database.[14] The five-year survival for 2014, which was the most recently available data at the time of analysis, was used. These rates were extracted for each cancer type and by the defined 32 demographic subgroups for each cancer type. The rates are on a scale of 0-1.

Relative survival is a net survival measure representing cancer survival in the absence of other causes of death. Relative survival is defined as the ratio of the proportion of observed survivors in a cohort of cancer patients to the proportion of expected survivors in a comparable set of cancer-free individuals.[18] Relative survival is the preferred method to estimate survival from cancer registry data.

The period analysis is a method that enhances up-to-date monitoring of survival.[19, 20] In contrast to traditional cohort analysis of survival, period analysis derives long-term survival estimates exclusively from the survival experience of patients within some recent calendar period.[19, 20] Three-year intervals were chosen which results in the years 2008-2014 is used to calculate 5-year survival. Using seven years of data to calculate 5-year survival is the standard method used by SEER and used in SEER publications.[21]

The first interval contributed to the one-year survival and used cases diagnosed in 2012-2014, the second interval contributed to the two-year survival and used cases diagnosed in 2011-2013, the third interval contributed to the three-year survival and used cases diagnosed in 2010-2012, the fourth interval contributed to the four-year survival and used cases diagnosed in 2009-2011 and the fifth interval contributed to the five-year survival and used cases diagnosed in 2008-2010.

This analysis, therefore, used 2008-2014 diagnoses to calculate for 5-year relative survival for 2014. The highlighted orange boxes represent survival contributions for each year of diagnosis and year of follow-up (**Appendix Table 4**). The annual probability of death was calculated as 1-exp[ln(5-year relative survival)/5].

Appendix Table 4. Period method for 5-year relative survival for 2014

YEARS OF DIAGNOSIS															
	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
1															
2															
3															
4															
5															

Du M, *et al. BMJ Open* 2023; 13:e063614. doi: 10.1136/bmjopen-2022-063614

Appendix 4. Methods of estimating the health-related quality of life among 13 types of cancers

Health utility values range from 0 (dead) to 1 (perfect health and were assigned for each cancer type and by phase of care (initial, continuous, end of life), if available. We first searched databases for systematic reviews pertaining to utility weights or HRQOL measures for each cancer type of interest separately. We started with PubMed and searched Google Scholar if needed. The following search string was used for each cancer type : ("health related quality of life" OR "HRQOL" OR "quality of life" OR "QOL" OR "preference weight*" OR “utility weight*” OR “health state utilit*” OR “health utility*”) AND (“cancer of interest”) AND ("cancer" OR “neoplasm*”) AND ("review" OR “systematic review”).

When an appropriate systematic review was identified, we read the articles included in the review and determined if the paper met the following data needs. Data Extraction Hierarchy: 1) cancer type specific to the type of interest; 2) consistent in the instrument used, prefer EQ-5D whenever available; 3) US samples preferred; 4) phase of care (assume same utility weights by phase if the phase of care data were not available). If no systematic reviews were available, we searched for individual studies about the utility weights of the cancer of interest. Additionally, check how often the paper is cited to see if it is a frequently used utility weight.

Du M, *et al. BMJ Open* 2023; 13:e063614. doi: 10.1136/bmjopen-2022-063614

Appendix 5. Methods of estimating policy implementation costs

We estimated the costs of implementing the federal menu calorie labeling for both government and industry, including government administration costs, monitoring and evaluation costs, industry compliance costs and reformulation costs, based on the FDA's budget report,[22] the Nutrition Review Project report,[23] and FDA's RIA[24] (**Appendix Table 5**).

It was estimated by FDA that approximately 298,600 establishments, organized under 2,130 chains were covered by the menu calorie labeling policy. Among the covered establishments, 115,000 (38.5%) were full-service restaurants and drinking places organized under 530 (24.9%) chains, and 116,200 (38.9%) were limited-service restaurants organized under 540 (25.4%) chains. In total, about 231,200 (77.4%) restaurants organized under 1,070 (50.2%) chains were covered by this policy.[24]

For industry compliance (#3) and reformulation costs (#4), the FDA estimated the costs by the type of establishments. Therefore, we only included the relevant costs incurred by restaurants as this approach generated more conservative estimates. In addition, the industry compliance costs consist of initial costs and recurring costs associated with new chains. In FDA's RIA, the initial costs were presented as a one-time cost, while the recurring costs associated with new chains were presented as annual costs and assumed to be incurred for 20 years starting from the 2nd year of policy implementation. According to FDA, 20 years is more appropriate for interventions that play out over long periods and whose effects deal with chronic conditions. Similarly, the reformulation costs (#4) estimated by FDA were presented as annual costs in FDA's RIA using the same assumption. We followed the same assumption and presented the annual compliance costs (#3) and annual reformulation costs (#4) incurred by restaurants in **Appendix Table 5**.

Du M, *et al. BMJ Open* 2023; 13:e063614. doi: 10.1136/bmjopen-2022-063614

The cost of implementing the menu calorie labeling is fixed by the government. Uncertainty for the costs associated with government administration (#1) and government monitoring and evaluation (# 2) was not provided in the source materials.[22, 23] We assumed that uncertainty is 20% around these costs.

For annual costs, namely the government monitoring and evaluation costs (#2) and the recurring costs in industry compliance (part of #3), and the reformulation costs (#4), we applied a 3% discounting rate recommended by the Second Panel on cost-effectiveness in health and medicine[4] to reflect the present value of future costs of government monitoring and evaluation, industry compliance and industry reformulation. The model is a closed cohort model, so we computed the discounted present value of per-person costs and total national costs for persons alive at implementation who remained alive in each subsequent year (not for the larger total US population in each year, which also has growth from immigration and new persons reaching the threshold age). The year-specific discounting factor is estimated by 1/(1+3%)^(t-1) (t is the number of years of policy intervention, t=1, 2, 3, …, lifetime). As our model estimated the costs and health outcomes based on a closed cohort and the population size decline over time, we need to express the annual costs in proportion to the population at risk. The population at risk was estimated based on the proportion of death ($P_{dt,}$ t=1, 2, 3, …) in each year. We first obtained the proportion of people who are alive each year by calculating 1-P_{dt} (t=1, 2, 3, …). Then we multiplied the baseline population size of 235 million by the proportion of people who are alive each year (**Appendix Table 6**).

We then estimated the per-person annual cost for cost categories #2, #3 (annual part), and #4, by dividing the annual cost estimated in the second year of implementing the policy among all US populations by the population size in the second year. Specifically, for government monitoring and evaluation, the per person annual cost is estimated $503,648/233,719,989=$0.00215, the per person annual cost for industry compliance recurring component is $/233,719,989=$, and that for reformulation

Du M, *et al. BMJ Open* 2023; 13:e063614. doi: 10.1136/bmjopen-2022-063614

is $662,800,000 /233,719,989=$2.83587. Taken together, to estimate the discounted annual cost of #2, #3 (annual part), and #4, we multiplied the population at risk, the per person annual cost estimated at year-2, and the year-specific discounting factor, using: discounted annual cost = population at risk x per-person annual cost x 1/(1+3%)^(t-1).

Appendix Table 5. Implementation cost estimates for the federal menu calorie labeling policy (in 2015 US dollars)

Policy Effect	Cost Category	One-time Cost*	Annual Cost*	Source	Major Elements
Consumer behavior	1. Government administration#	$9,073,620 ($7,258,896 to $10,888,344)	N/A	FDA FY 2012 Budget Report[22]	1) Costs for outreach, education, review of regulatory issues, developing training for inspectors, etc.
	2. Government monitoring and evaluation#	N/A	$503,648 ($402,918 to $604,378) (starting from 2nd year and last for a lifetime)	Nutrition Review Project report[23]	1) Monitor industry compliance 2) Evaluate the accuracy, usefulness, and health impact of the policy intervention
	3. Industry compliance	$276,632,470 ($225,552,530 to $327,205,740)	$27,648,591 ($16,756,003 to $38,649,212) (starting from 2nd year and last for a lifetime)	FDA's RIA[24] Table 4-8	1) Collecting and managing records of nutritional analysis for each standard menu item (initial cost + recurring cost associated with new chains) 2) Revising or replacing existing menus, menu boards, and providing full written nutrition information (initial cost + recurring cost associated with new chains) 3) Training employees to understand the nutrition information to help ensure compliance with the final requirements (initial cost + recurring cost associated with new chains) 4) Legal review (initial cost + recurring cost associated with new chains)
Industry response^	4. Industry reformulation	N/A	$15,059,100 ($5,791,900 to $24,124,700) (starting from 2nd year and last for a lifetime)	FDA's RIA[24] Table 4-8	1) Annually recurring costs of nutrition analysis refer to the nutrition cost that will be incurred by the covered establishments due to the introduction of a new standard or reformulated standard menu items in their menus and the cost that will be incurred by new chains entering the industry 2) Annually recurring changes to menus or menu boards will be tied to new or reformulated standard menu items. In general, these future changes to menus will be incorporated into the natural menu

					replacement cycle, so there will be no additional recurring menu update costs. However, all chain retail food establishments will need to provide additional written nutrition information for the reformulated or newly introduced menu items Average formula count, 6 new menu items, and 6 reformulated items per year FDA reformulation cost model

*Policy intervention costs were inflated to 2015 US (December) dollars using the Consumer Price Index.
Given no range of uncertainty was provided in source materials, we assumed 20% uncertainty around these costs.
^Some chains or establishments may respond to increased consumer interest in caloric content standard menu items by reformulating existing menu items or by introducing new, lower-calorie items. The change in manufacturing costs associated with reformulating these items has not been included in the cost estimation, the FDA includes the cost associated with analyzing the nutrition information of new or reformulated items.

Appendix Table 6. The population size of people who are alive each year over a lifetime (in millions)

Year	Population Size (Million)
1	235.2
2	233.7
3	232.1
4	230.4
5	228.2
⋮	⋮
67	5.832
68	4.348
69	3.157
70	2.233

Appendix 6. Annual health-related costs among cancer patients and the general population without cancer

The annual health-related costs data include: 1) medical expenditure, 2) productivity loss from missed workdays or disability, and 3) patient time cost associated with receiving care for cancer survivors by age (under 65 vs. above 65 years old) and phase of care (initial, continuing, end-year of life); 4) medical expenditure, 5) productivity loss, and 6) patient time cost for individuals without cancer by age and status of end year of life. The description of the data source and data structure were provided in **Appendix Table 7**.

We extracted the raw data for each of the costing components from the published literature.[15, 25-29] The overall assumptions for data extraction include: 1) health-related costs for breast cancer among postmenopausal females, advanced prostate cancer, esophageal adenocarcinoma, and stomach cardia cancer, by age, sex, and phase of cancer care, were the same as those for breast cancer, prostate cancer, esophagus cancer, and stomach cancer; 2) if no data available for a specific cancer type, we assumed the costs for that cancer type were the same as the estimates of costs for all-cancer sites, e.g., medical expenditure for all-cancer sites were used to replace the medical expenditures for multiple myeloma, gallbladder, liver, and thyroid cancers; 3) we extracted the costs for end-year of life due to cancer death and assumed that death due to other causes is not a competing outcome; 4) we assumed that the end-year life medical expenditure for individuals without cancer does not vary by the 32 subgroups.

If a specific costing component was not reported directly in the raw data, we calculated the cost for that component based on available data. For example, the annual productivity loss for colorectal cancer was reported as a percentage of total health-related costs.[29] We multiplied the percentage and the total health-related costs to obtain the productivity loss for colorectal cancer. We also performed data imputation for unavailable data. For instance, the annual productivity loss for all-cancer sites was reported by time interval since cancer diagnosis (diagnosed within one year vs. diagnosed greater than one year).[25] To obtain this costing component by the defined phases of care, we calculated the weighted means which was used as the annual productivity loss for the continuous phase. We then assumed that the productivity loss in the initial phase and end-of-life phase of cancer care are 1.3 times and 4 times the mean estimates based on available data for other cancers.[15, 25] For individuals without cancer, we assumed that the end-of-life productivity loss is 4 times to the mean estimate of the productivity loss. The same rules applied to data imputation for patient time costs.

We then applied the age shifting to keep the expenditures consistent within each age group. Starting from 2021, individuals in the cohort of 55-64 years old have turned into the cohort of 65 years and older. Therefore, we assumed that starting from 2021, the health-related expenditures for individuals who were in the cohort of 55-64 years old would be the same as those for individuals who were in the cohort of 65 years and older at the beginning of the DiCOM model. Based on the same assumption, starting from 2031 and 2047, the health-related expenditures for the cohort of 45-54 years old and those for the cohort of 20-44 years old were projected to be the same as those for the cohort of 65 years and older, respectively. We followed the same rule and applied the age shifting for the health-related expenditures for individuals without cancer. All estimations and projections were performed in SAS 9.4. All health-related expenditures were inflated to 2015 US dollars using the Personal Health Care (PHC) index.

Appendix Table 7. Description of the data source of health-related expenditures

	A. Cancer Survivors		**B. Individuals without Cancer**	
	Data source (Excess or Total)	Category	Data source	Category
Medical expenditure	Mariotto et al. 2011, SEER-Medicare, in 2010 US dollars (Excess)	-by phase of care[1] -by age (under 65 vs. above 65 years old) -by sex	Kim et al. 2018, MEPS 2013-2014, *in vivo* analysis, in 2014 US dollars (Total)	-Medical expenditure among all US adults -by 32 subgroups stratified by age, sex, and race/ethnicity
			Hogen et al. 2001, SEER-Medicare (65+), in 2001 US dollars (Total)	-Medical expenditure in the end year of life among all US adults
Productivity loss	Zheng et al. 2016, MEPS 2008-2012, data available for colorectal, female breast, and prostate cancers, in 2012 US dollars (Total)	-by age		
	Guy et al. 2013, MEPS 2008-2010, all types of cancer, in 2010 US dollars (Total)	-by age -by time interval since cancer diagnosis (less than 1 year vs. greater than 1 year)[2]	Guy et al. 2013, MEPS 2008-2010, in 2010 US dollars (Total)	-by age
Patient time cost	Yabroff et al. 2014, MEPS 2008-2011, all types of cancer, in 2011 US dollars (Total)	-by age	Yabroff et al. 2014, MEPS 2008-2011, in 2011 US dollars (Total)	-by age

1. The definition of phases of care: 1) initial phase, defined as the first 12 months following diagnosis, 2) end-year of life phase, defined as the final 12 months of life, and 3) the continuing phase, defined as all the months between the initial phase and the end-year of life. The costs of end-year of life varied by cause of death, either cancer-specific death or death due to other causes.
2. Weighted means were calculated based on sample sizes and strata means.

Reference

1. Shangguan S, Afshin A, Shulkin M, et al. A Meta-Analysis of Food Labeling Effects on Consumer Diet Behaviors and Industry Practices. *American journal of preventive medicine*. Feb 2019;56(2):300-314. doi:10.1016/j.amepre.2018.09.024
2. Food and Drug Administration. Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments; Calorie Labeling of Articles of Food in Vending Machines; Final Rule In: Department of Health and Human Services, editor. 2014.
3. Long MW, Tobias DK, Cradock AL, Batchelder H, Gortmaker SL. Systematic review and meta-analysis of the impact of restaurant menu calorie labeling. *Am J Public Health*. 2015;105(5):e11-e24. doi:10.2105/AJPH.2015.302570
4. Petimar J, Zhang F, Cleveland LP, et al. Estimating the effect of calorie menu labeling on calories purchased in a large restaurant franchise in the southern United States: quasi-experimental study. *BMJ (Clinical research ed)*. 2019;367:l5837-l5837. doi:10.1136/bmj.l5837
5. Kaur A, researcher, Briggs ADM, academic v. Calorie labelling to reduce obesity. *BMJ (Clinical research ed)*. 2019;367:l6119-l6119. doi:10.1136/bmj.l6119
6. Auchincloss AH, Mallya GG, Leonberg BL, Ricchezza A, Glanz K, Schwarz DF. Customer responses to mandatory menu labeling at full-service restaurants. *American journal of preventive medicine*. 2013;45(6):710-719. doi:10.1016/j.amepre.2013.07.014
7. Littlewood JA, Lourenço S, Iversen CL, Hansen GL. Menu labelling is effective in reducing energy ordered and consumed: a systematic review and meta-analysis of recent studies. *Public Health Nutr*. 2016;19(12):2106-2121. doi:10.1017/S1368980015003468
8. Cantu-Jungles TM, McCormack LA, Slaven JE, Slebodnik M, Eicher-Miller HA. A Meta-Analysis to Determine the Impact of Restaurant Menu Labeling on Calories and Nutrients (Ordered or Consumed) in U.S. Adults. *Nutrients*. 2017;9(10):1088. doi:10.3390/nu9101088
9. Bleich SN, Wolfson JA, Jarlenski MP. Calorie changes in chain restaurant menu items: implications for obesity and evaluations of menu labeling. *American journal of preventive medicine*. Jan 2015;48(1):70-5. doi:10.1016/j.amepre.2014.08.026
10. Bleich SN, Wolfson JA, Jarlenski MP. Calorie Changes in Large Chain Restaurants: Declines in New Menu Items but Room for Improvement. *American journal of preventive medicine*. 2016;50(1):e1-e8. doi:10.1016/j.amepre.2015.05.007
11. Bleich SN, Wolfson JA, Jarlenski MP. Calorie changes in large chain restaurants from 2008 to 2015. *Preventive medicine*. Jul 2017;100:112-116. doi:10.1016/j.ypmed.2017.04.004
12. Bleich SN, Moran AJ, Jarlenski MP, Wolfson JA. Higher-Calorie Menu Items Eliminated in Large Chain Restaurants. *American journal of preventive medicine*. Feb 2018;54(2):214-220. doi:10.1016/j.amepre.2017.11.004
13. Bleich SN, Wolfson JA, Jarlenski MP, Block JP. Restaurants With Calories Displayed On Menus Had Lower Calorie Counts Compared To Restaurants Without Such Labels. *Health affairs (Project Hope)*. 2015;34(11):1877-1884. doi:10.1377/hlthaff.2015.0512
14. Centers for Disease Control and Prevention. NPCR and SEER Incidence – U.S. Cancer Statistics Public Use Databases. United States Department of Health and Human Services, Centers for Disease Control and Prevention and National Cancer Institute. Accessed September 4, 2019. www.cdc.gov/cancer/uscs/public-use
15. Mariotto AB, Yabroff KR, Shao Y, Feuer EJ, Brown ML. Projections of the cost of cancer care in the United States: 2010-2020. *Journal of the National Cancer Institute*. Jan 19 2011;103(2):117-28. doi:10.1093/jnci/djq495
16. Clegg LX, Hankey BF, Tiwari R, Feuer EJ, Edwards BK. Estimating average annual per cent change in trend analysis. *Statistics in medicine*. Dec 20 2009;28(29):3670-82. doi:10.1002/sim.3733
17. United States Census Bureau. 2014 National Population Projections Tables. Accessed July 3, 2019. https://www.census.gov/data/tables/2014/demo/popproj/2014-summary-tables.html

18. National Cancer Institute. Surveillance research Program. Measures of Cancer Survival. https://surveillance.cancer.gov/survival/measures.html
19. Brenner H, Hakulinen T. Up-to-date and precise estimates of cancer patient survival: model-based period analysis. *American journal of epidemiology*. Oct 1 2006;164(7):689-96. doi:10.1093/aje/kwj243
20. Brenner H, Hakulinen T. Up-to-date cancer survival: period analysis and beyond. *International journal of cancer*. Mar 15 2009;124(6):1384-90. doi:10.1002/ijc.24021
21. National Cancer Institute. Surveillance Research Program. Cancer Survival Statistics: Cohort Definition Using Diagnosis Year. https://surveillance.cancer.gov/survival/cohort.html
22. Food and Drug Administration. *Justification of Estimates for Appropriations Committees Fiscal Year 2012*. 2012. https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM243370.pdf
23. Food and Drug Administration. *The Nutrition Review Project. Report to the Director, Center for Food Safety and Applied Nutrition*. 2014. http://www.fdalawblog.net/wp-content/uploads/archives/docs/Nutrition%20Review%20Project.pdf
24. S. FaDAaHH. Food labeling; nutrition labeling of standard menu items in restaurants and similar retail food establishments. Final rule. *Fed Regist*. 2014;79(230):71155-71259.
25. Guy GP, Jr., Ekwueme DU, Yabroff KR, et al. Economic burden of cancer survivorship among adults in the United States. *Journal of clinical oncology : official journal of the American Society of Clinical Oncology*. Oct 20 2013;31(30):3749-57. doi:10.1200/jco.2013.49.1241
26. Hogan C, Lunney J, Gabel J, Lynn J. Medicare beneficiaries' costs of care in the last year of life. *Health affairs (Project Hope)*. Jul-Aug 2001;20(4):188-95. doi:10.1377/hlthaff.20.4.188
27. Yabroff KR, Davis WW, Lamont EB, et al. Patient time costs associated with cancer care. *Journal of the National Cancer Institute*. Jan 3 2007;99(1):14-23. doi:10.1093/jnci/djk001
28. Yabroff KR, Guy GP, Jr., Ekwueme DU, et al. Annual patient time costs associated with medical care among cancer survivors in the United States. *Medical care*. Jul 2014;52(7):594-601. doi:10.1097/mlr.0000000000000151
29. Zheng Z, Yabroff KR, Guy GP, Jr., et al. Annual Medical Expenditure and Productivity Loss Among Colorectal, Female Breast, and Prostate Cancer Survivors in the United States. *Journal of the National Cancer Institute*. May 2016;108(5)doi:10.1093/jnci/djv382