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Risk Factors Associated With Food Insecurity in the Medicare Population

Food insecurity is defined as the inability to obtain adequate food for explicitly financial reasons. Associations between food insecurity and worse health outcomes have been attributed to insufficient nutritional intake, trade-offs between food and medical treatment, and functional impairments.[1] Medicare enrollees, who are 65 years or older or who have long-term disabilities, are especially vulnerable to food insecurity. We present detailed national estimates of food insecurity prevalence within the Medicare population.

Methods | Data are from the 2016 Medicare Current Beneficiary Survey, administered by the US Centers for Medicare & Medicaid Services with interviews between July 25, 2016, and August 31, 2017. The Medicare Current Beneficiary Survey uses the 6-item version of the US Department of Agriculture's food security questionnaire,[2] which references respondent experiences from the previous 12 months and asks if their food had ever run out, if they had no money to get more, or if they were unable to eat balanced meals, cut meal size or skipped meals, ate less than they ought, or were hungry because of insufficient money. Using an established algorithm,[2] our outcome designates an individual with any 2 affirmative responses as food insecure. Covariates included previously established predictors of food insecurity or difficulties affording health care.[3-5] All health-related covariates were self-reported. The Centers for Medicare & Medicaid Services administrative data contributed to demographic covariates, supplemental insurance type, and Accountable Care Organization assignment. We restricted analysis to 9674 community-dwellers with continuous 2016 Medicare enrollment who completed the food security interview, using Medicare Current Beneficiary Survey sampling weights to represent a national population of 50 685 869 community-dwelling Medicare enrollees. We separately analyzed respondents as younger than 65 years and 65 years and older. This study was approved by the Harvard Pilgrim Health Care Institutional Review Board with a waiver of informed consent.

Results | We found that 38.3% (95% CI, 34.5%-42.1%) of enrollees younger than 65 reported food insecurity (**Table 1**). Other characteristics of social and clinical vulnerability (eg, income less than $15k per year, 4 or more chronic conditions, and depression) were also particularly common among enrollees younger than 65. Bivariate analyses indicated consistently high rates of food insecurity in this population, ranging 12% to 57% across all covariate strata listed in Table 1.

Among enrollees 65 years or older, 9.1% (95% CI, 8.3%-9.8%) reported food insecurity, with higher rates for especially vulnerable groups, such as income less than $15 000 (25.8%; 95% CI, 22.9%-28.7%) and Medicaid dual enrollment (33.6%; 95% CI, 30.5%-36.7%).

In multivariate logistic regression models (**Table 2**), all 3 lower income categories were associated with food insecurity in both groups (eg, <65 years: odds ratio [OR] for less than $15k vs $50k and over, 7.88; 95% CI, 3.32-18.71; ≥65 years: OR, 12.22; 95% CI, 7.32-20.41). Reporting 4 or more chronic conditions (<65 years: OR, 2.07; 95% CI, 1.30-3.28; ≥65 years: OR, 1.91; 95% CI, 1.33-2.76), depression (<65 years: OR, 2.65; 95% CI, 1.75-4.00; ≥65 years: OR, 1.60; 95% CI, 1.19-2.15); or anxiety (>65 years: OR, 1.72; 95% CI, 1.20-2.47; ≥65 years: OR, 1.44; 95% CI, 1.02-2.04) were also factors associated with food insecurity in both groups. In secondary models examining 10 conditions individually, diabetes showed borderline significance (OR, 1.34; 95% CI, 1.03-1.75) in the group age 65 years or older, but this result was not qualitatively different from results for less food-sensitive conditions. In secondary models adding supplemental insurance, compared with employer-sponsored insurance, Medicaid remained associated with food insecurity among enrollees age 65 years or older (OR, 3.80; 95% CI, 2.20-6.56).

Discussion | Nearly 1 in 10 Medicare enrollees 65 years and older and 4 in 10 enrollees younger than 65 years experience food insecurity, suggesting both poor eating patterns that threaten health and inadequate access to other basic needs. Our estimates for older Americans are consistent with earlier reporting.[4] Long-term disabled enrollees (<65 years) are far less studied. The pervasive food insecurity across segments within the disabled group is striking. We found disabled status, lower incomes, Medicaid dual enrollment, chronic condition burden, depression, and anxiety to be distinct factors. However, our cross-sectional analyses cannot establish causality.

These findings highlight the appropriateness of the Centers for Medicare & Medicaid Services intensifying focus on social determinants of health, exemplified by the Accountable Heath Communities model,[6] which targets dual enrollees, and the recent expansion of allowable supplemental benefits in Medicare Advantage plans. Food insecurity screening and referral programs in clinical settings may benefit from recognition of high-risk patient groups. Autoenrollment and smoother recertification of low-income individuals could help make public efforts like the Supplemental Nutrition Assistance Program and home-delivered meals even more effective.[1] All health system innovations, including direct food provision (eg, through medically tailored meals, outpatient food pharmacies, and care packages at hospital discharge),[1] require rigorous evaluations before broader implementation.

Table 1. Prevalence of Food Insecurity and Characteristics of the Study Population

Characteristic	Enrollees, % (95% CI)[a]	
	Under Age 65 y (n = 1576)	Age 65 y and Over (n = 8098)
Low or very low food security (insecure)	38.3 (34.5-42.1)	9.1 (8.3-9.8)
Age group, y[b]		
18-54	42.3 (39.1-45.5)	NA
55-64	57.7 (54.5-60.9)	NA
65-74	NA	57.7 (56.6-58.8)
75-84	NA	31.1 (30.2-32.0)
≥85	NA	11.2 (10.5-11.9)
Sex		
Male	51.6 (48.5-54.8)	44.0 (42.8-45.2)
Female	48.4 (45.2-51.5)	56.0 (54.8-57.2)
Race		
White	71.7 (68.7-74.8)	83.6 (82.4-84.9)
African American	18.1 (15.6-20.6)	8.7 (7.9-9.5)
Other[c]	8.3 (6.0-10.5)	6.3 (5.3-7.3)
Ethnicity		
Non-Hispanic	87.4 (85.2-89.7)	91.9 (90.7-93.0)
Hispanic	12.0 (9.8-14.2)	7.7 (6.6-8.8)
Educational level		
No high school diploma	21.0 (18.1-23.9)	15.4 (14.2-16.6)
High school diploma	36.2 (33.2-39.1)	25.0 (23.6-26.4)
Some college	33.1 (29.4-36.8)	29.2 (27.6-30.7)
Bachelor degree or higher	8.9 (6.9-11.0)	30.1 (28.1-32.1)
Income, $		
<15k	47.0 (43.6-50.3)	16.0 (15.0-17.1)
15k-25k	22.0 (19.3-24.6)	17.1 (16.0-18.1)
25k-50k	18.6 (15.6-21.5)	27.7 (26.3-29.1)
>50k	12.5 (10.0-14.9)	39.2 (37.7-40.8)
Marital status		
Married	35.1 (31.9-38.3)	56.8 (55.4-58.2)
Widowed	6.3 (4.7-7.8)	23.1 (22.1-24.2)
Single, divorced, or separated	58.6 (55.7-61.6)	19.9 (18.8-21.1)
Region		
Northeast	17.7 (14.8-20.7)	18.5 (17.6-19.4)
Midwest	21.6 (19.0-24.1)	22.3 (21.1-23.4)
West	17.4 (15.1-19.6)	21.6 (20.5-22.7)
South	42.1 (39.2-44.9)	36.8 (35.4-38.2)
Puerto Rico	1.2 (0.5-1.9)	0.9 (0.7-1.0)
Urban/rural area		
Metro (population >50k)	77.7 (75.1-80.3)	79.7 (78.7-80.6)
Micro (population 10k-50k)[d]	14.3 (10.7-17.9)	12.8 (10.1-15.6)
Rural (population <10k)	7.9 (4.5-11.4)	7.5 (4.6-10.4)
General health status		
Excellent, very good, good[e]	45.7 (42.0-49.4)	83.5 (82.5-84.5)
Fair or poor	53.8 (50.1-57.5)	16.2 (15.2-17.2)
Chronic conditions, No.[f]		
0-1	18.3 (16.0-20.7)	27.1 (25.8-28.5)
2-3	39.2 (36.0-42.4)	45.4 (44.1-46.7)
4-10	41.5 (38.1-45.0)	26.5 (25.4-27.7)
BMI[g]		
Underweight (<18.5)	1.4 (0.7-2.0)	1.7 (1.3-2.0)
Healthy weight (18.5-24.9)	20.2 (18.0-22.3)	28.6 (27.3-30.0)
Overweight (25.0-29.9)	27.7 (24.6-30.8)	35.0 (33.6-36.4)
Obese (≥30.0)	46.4 (43.6-49.3)	30.3 (29.0-31.6)
Limitations in ADL[h]		
0	47.2 (43.5-50.8)	75.3 (74.1-76.6)
1-2	29.7 (26.7-32.7)	17.1 (16.1-18.1)
3-6	23.1 (20.3-25.9)	7.5 (6.8-8.2)
Limitations in IADL[h]		
0	37.2 (33.6-40.9)	74.7 (73.4-75.9)
1-2	40.7 (37.1-44.3)	19.8 (18.6-20.9)
3-6	21.7 (18.7-24.8)	5.3 (4.7-5.9)
Depression (PHQ-9)[i]		
None or minimal	34.7 (31.2-38.2)	76.9 (75.8-78.1)
Mild to severe	55.3 (51.8-58.7)	17.1 (16.0-18.2)
Anxiety (GAD-2)[i]		
No	57.6 (54.3-61.0)	86.1 (85.2-87.0)
Yes	32.3 (29.1-35.6)	7.9 (7.2-8.7)
Supplemental insurance[j]		
Medicaid	44.1 (40.6-47.6)	10.9 (9.7-12.0)
Medicare Advantage	17.9 (14.5-21.3)	32.6 (30.8-34.5)
FFS with employer or retiree	7.1 (5.1-9.1)	18.8 (17.5-20.1)
FFS with self-purchased or other	3.2 (1.9-4.5)	16.9 (15.4-18.4)
FFS with no supplement	27.7 (24.6-30.8)	20.8 (19.4-22.1)
Assigned to an ACO		
No	84.3 (81.6-86.9)	82.7 (80.7-84.7)
Yes	15.7 (13.1-18.4)	17.3 (15.3-19.3)

Abbreviations: ACO, Accountable Care Organization; ADL, activities of daily living; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); FFS, traditional fee-for-service Medicare; GAD-7, Generalized Anxiety Disorder 2-item scale; IADL, instrumental activities of daily living; MA, Medicare Advantage; NA, not applicable; PHQ-9, Patient Health Questionnaire.

[a] Denominators include individuals with missing values. Data were missing for less than 0.5% of the study population in all categories, except race (1.9% < 65 y; 1.4% ≥ 65 y), number of chronic conditions (0.9%; 1.0%), BMI (4.3%; 4.4%) and depression and anxiety (10%; 5.9%).

[b] Individuals under age 65 years qualify for Medicare benefits mainly through long-term disabilities. In this sample, 12 qualified based on end-stage renal disease alone.

[c] Other race includes Asian, Native Hawaiian or Pacific Islander, American Indian or Alaska Native, other, and more than one.

[d] Population of the area's urban core.

[e] Excellent, very good, good, fair, and poor health refer to self-reported general health status compared with peers.

[f] Count of self-reported chronic condition diagnoses includes diagnoses of cardiac disease, hypertension, diabetes, cancer, stroke, arthritis, dementia, psychiatric disorder (including depression), neurologic disorder (excluding stroke), and pulmonary illness (including asthma and chronic obstructive pulmonary disease).

[g] Weight categories are defined by the US Centers for Disease Control and Prevention based on BMI.

[h] Limitations in ADL and IADL are measures of functioning.

[i] Depression and anxiety were measured using the PHQ-9 and GAD-2 symptom scales, respectively.

[j] Supplemental insurance types are mutually exclusive and were defined and assigned hierarchically as follows: any Medicaid enrollment during 2016 (either with FFS or with a MA plan); any MA without Medicaid; FFS with employer-sponsored supplement; FFS with other supplement, including self-purchased Medigap plans and US Veteran's Administration benefits; FFS with no supplement reported. Medicare Advantage is included as a supplemental insurance type because MA plans provide benefits beyond those in traditional fee-for-service Medicare.

Table 2. Adjusted Odds Ratio Estimates of Food Insecurity in Medicare Enrollees[a]

Characteristic	Reference Category	Enrollees, Odds Ratio Estimate (95% CI)			
		Under Age 65 y (n = 1503)	*P* Value	Age 65 y and Over (n = 7842)	*P* Value
Age, y					
56-64	18-54	0.90 (0.64-1.27)	.56	NA	NA
75-84	65-74	NA	NA	0.58 (0.45-0.75)	<.001
≥85		NA	NA	0.21 (0.13-0.32)	<.001
Female	Male	1.17 (0.83-1.65)	.37	1.19 (0.95-1.50)	.13
Race					
Black	White	0.99 (0.58-1.68)	.96	2.19 (1.67-2.86)	<.001
Other		0.72 (0.37-1.40)	.33	2.06 (1.38-3.09)	<.001
Hispanic ethnicity	Non-Hispanic	1.44 (0.76-2.72)	.26	1.19 (0.85-1.66)	.32
Educational level					
No high school diploma	Bachelor's or higher	1.76 (0.84-3.70)	.14	1.65 (1.09-2.51)	.02
High school diploma		1.22 (0.61-2.44)	.57	1.30 (0.88-1.91)	.18
Some college		2.12 (1.04-4.31)	.04	1.11 (0.76-1.63)	.59
Income, $					
<15k	>50k	7.88 (3.32-18.71)	<.001	12.22 (7.32-20.41)	<.001
15k-25k		6.65 (2.89-15.30)	<.001	7.67 (4.68-12.57)	<.001
25k-50k		2.93 (1.32-6.49)	.01	4.47 (2.83-7.05)	<.001
Marital status					
Widowed	Married	1.05 (0.51-2.16)	.89	1.10 (0.83-1.46)	.52
Single, divorced, or separated		1.33 (0.86-2.07)	.19	1.49 (1.13-1.97)	.01
Region					
Midwest	Northeast	1.07 (0.61-1.87)	.80	0.65 (0.47-0.90)	.01
West		2.00 (1.09-3.67)	.03	0.83 (0.58-1.19)	.31
South		1.70 (1.01-2.88)	.048	0.99 (0.75-1.32)	.96
Puerto Rico		0.25 (0.02-2.88)	.26	0.41 (0.11-1.56)	.19
Urban/rural area					
Micro (population 10k-50k)[b]	Metro (population >50k)	0.97 (0.63-1.47)	.87	0.82 (0.62-1.08)	.16
Rural (population <10k)		1.52 (0.82-2.81)	.18	0.95 (0.64-1.43)	.81
Fair or poor health	Excellent, very good, or good	1.02 (0.71-1.44)	.94	1.19 (0.92-1.54)	.19
Chronic conditions					
2-3	0-1	1.31 (0.86-2.00)	.20	1.28 (0.92-1.79)	.14
4-10		2.07 (1.30-3.28)	.002	1.91 (1.33-2.76)	<.001
BMI					
Underweight (<18.5)	Healthy weight (18.5-24.9)	0.98 (0.17-5.59)	.98	1.60 (0.61-4.19)	.33
Overweight (25.0-29.9)		1.28 (0.81-2.03)	.29	0.99 (0.73-1.34)	.94
Obese (≥30.0)		1.07 (0.71-1.62)	.74	0.96 (0.69-1.33)	.80
Limitations in ADL					
1-2	None	1.14 (0.75-1.74)	.52	1.43 (1.07-1.92)	.02
3-6		1.20 (0.75-1.93)	.45	1.25 (0.83-1.88)	.28
Limitations in IADL					
1-2	None	0.85 (0.56-1.30)	.45	1.32 (0.92-1.89)	.13
3-6		1.24 (0.76-2.03)	.39	2.04 (1.23-3.39)	.01
Depression (PHQ-9), mild to severe	None or minimal	2.65 (1.75-4.00)	<.001	1.60 (1.19-2.15)	.002
Anxiety (GAD-2), yes	No	1.72 (1.20-2.47)	.004	1.44 (1.02-2.04)	.04

Abbreviations: ADL, activities of daily living; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); GAD-2, Generalized Anxiety Disorder 2-item scale; IADL, instrumental activities of daily living; NA, not applicable; PHQ-9, Patient Health Questionnaire.

[a] Observations with missing values were dropped, except for when missing on BMI or depression or anxiety; in these cases, observations with missing values were modeled as a separate missing category (not shown).

[b] Population of the area's urban core.

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Miscategorization of Deaths in the US Food and Drug Administration Adverse Events Database

As the US Food and Drug Administration (FDA) moves to hasten approval of medical devices, data from postmarketing studies and registries are increasingly relied on to inform decision-making. With less time for premarketing clinical studies, postmarketing data are the principal way adverse events and risks become apparent. Even for high-risk implanted devices, premarketing trials are usually small and have short-term follow-up.[1] The process of reporting adverse events is cumbersome, and reporting rates are low.[2]

Although the FDA's medical device reporting regulations require that device-user facilities report adverse events to the FDA, physician reporting is voluntary.[3] Adverse event data may be recorded in registries such as the Transcatheter Valve Therapy database,[4] which gathers national data on interventional cardiology devices. However, the Transcatheter Valve Therapy registry does not make its data publicly available, which limits its value. Instead, the Transcatheter Valve Therapy registry submits reports to the FDA in summaries that may omit redacted information and obscure important data. Publicly accessible adverse event reports are housed in the FDA's Manufacturer and User Facility Device Experience (MAUDE) database, where they are classified as malfunction, injury, or death events. We examined the misclassification of death reports for the Sapien 3 and MitraClip devices (high-risk interventional cardiac devices that were approved by the FDA in 2013 and 2015, respectively) within the MAUDE database.

Methods | We used the software Device Events,[5] which collates adverse event reports from MAUDE in a more accessible format. We examined adverse event reports on the Sapien 3 and MitraClip devices from their respective approval dates through December 31, 2018. Device Events pulls directly from FDA raw data but in a user-friendly format with faster search times. The critical-events thesaurus within Device Events searches and identifies reports characterized as injuries and malfunctions for terms that indicate that a death may have occurred. We used the critical events thesaurus and search terms (**Box**) comprising synonyms for death, including *expired* and *passed away*, to gather reports in which a patient may have died but the event was misclassified as an injury or malfunction. Two authors (L.M. and E.Y.W.) independently analyzed the reports to determine if a death had in fact occurred. Owing to the use of publicly available deidentified data, the institutional review board at the University of California, San Francisco determined the study did not require approval.

Results | *Sapien 3*. We found 9320 injury and malfunction reports for the Sapien 3 device and 1021 reports of deaths; 217 (2.3%) of the injury and malfunction reports also stated that the patient had died during or after the implantation of the device. In addition to directly using the word *died*, the most commonly used terms in these reports to describe the death of a patient were *expired*, *passed away*, and *autopsy*. Thus, misclassified reports made up 217 of 1238 (17.5%) total patient deaths.

MitraClip. We found 5323 injury and malfunction reports for the MitraClip device and 295 reports of deaths; 97 (1.8%) of the injury and malfunction reports also stated that the patient had died. Terms used in injury and malfunction reports to de-