**Supporting Information**

Supplemental Table. Demographic, risk factor, clinical, and outcome characteristics of the cases and controls – Kentucky, Michigan, and West Virginia, 2016–20191

|  |  |  |  |
| --- | --- | --- | --- |
|  | Overall | Cases | Controls |
| Characteristic | Cases,n (%) | Controls, n (%) | KY,n (%) | MI,n (%) | WV,n (%) | KY,n (%) | MI,n (%) | WV,n (%) |
| Sample size | 110 | 414 | 59 | 30 | 21 | 223 | 109 | 82 |
| Age, year |  |  |  |  |  |  |  |  |
| Mean (SE) | 53.6 (1.4) | 51.9 (0.7) | 49.7 (1.7) | 61.2 (3.0) | 53.7 (2.8) | 48.0 (0.7) | 58.7 (1.5) | 53.3 (1.4) |
| Median (range) | 55.0 (24.0-87.0) | 53.0 (21.0-90.0) | 47.0 (26.0-85.0) | 58.5 (24.0-87.0) | 56.0 (24.0-71.0) | 47.0 (25.0-75.0) | 57.0 (21.0-90.0) | 56.0 (23.0-72.0) |
| Age categories |  |  |  |  |  |  |  |  |
| 20-29 | 6 (5.5) | 21 (5.1) | 3 (5.1) | 2 (6.7) | 1 (4.8) | 9 (4.0) | 8 (7.3) | 4 (4.9) |
| 30-39 | 11 (10.0) | 51 (12.3) | 7 (11.9) | 2 (6.7) | 2 (9.5) | 35 (15.7) | 8 (7.3) | 8 (9.8) |
| 40-49 | 28 (25.5) | 104 (25.1) | 23 (39.0) | 1 (3.3) | 4 (19.0) | 85 (38.1) | 3 (2.8) | 16 (19.5) |
| 50-69 | 47 (42.7) | 189 (45.7) | 20 (33.9) | 14 (46.7) | 13 (61.9) | 85 (38.1) | 56 (51.4) | 48 (58.5) |
| ≥70 | 18 (16.4) | 49 (11.8) | 6 (10.2) | 11 (36.7) | 1 (4.8) | 9 (4.0) | 34 (31.2) | 6 (7.3) |
| Sex |  |  |  |  |  |  |  |  |
| Male | 75 (68.2) | 264 (63.8) | 42 (71.2) | 17 (56.7) | 16 (76.2) | 144 (64.6) | 67 (61.5) | 53 (64.6) |
| Female | 35 (31.8) | 150 (36.2) | 17 (28.8) | 13 (43.3) | 5 (23.8) | 79 (35.4) | 42 (38.5) | 29 (35.4) |
| Race/Ethnicity |  |  |  |  |  |  |  |  |
| Caucasian/NH | 85 (96.6) | 195 (84.8) | 45 (100.0) | 25 (89.3) | 15 (100.0) | 87 (97.8) | 71 (69.6) | 37 (94.9) |
| African American/NH | 3 (3.4) | 33 (14.3) | 0 (0.0) | 3 (10.7) | 0 (0.0) | 2 (2.2) | 29 (28.4) | 2 (5.1) |
| Other2 | 0 (0.0) | 2 (0.9) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 2 (2.0) | 0 (0.0) |
| **Risk Factor3** |  |  |  |  |  |  |  |  |
| Drug use |  |  |  |  |  |  |  |  |
| Yes | 47 (52.2) | 188 (55.1) | 30 (66.7) | 8 (29.6) | 9 (50.0) | 123 (73.7) | 33 (32.4) | 32 (44.4) |
| No | 43 (47.8) | 153 (44.9) | 15 (33.3) | 19 (70.4) | 9 (50.0) | 44 (26.3) | 69 (67.6) | 40 (55.6) |
| Injection drug use4 |  |  |  |  |  |  |  |  |
| Yes | 31 (39.2) | 122 (39.4) | 18 (51.4) | 6 (23.1) | 7 (38.9) | 90 (61.6) | 10 (10.4) | 22 (32.4) |
| No | 48 (60.8) | 188 (60.6) | 17 (48.6) | 20 (76.9) | 11 (61.1) | 56 (38.4) | 86 (89.6) | 46 (67.6) |
| Noninjection drug use4 |  |  |  |  |  |  |  |  |
| Yes | 23 (33.8) | 109 (41.1) | 12 (44.4) | 6 (24.0) | 5 (31.3) | 53 (54.1) | 28 (28.3) | 28 (41.2) |
| No | 45 (66.2) | 156 (58.9) | 15 (55.6) | 19 (76.0) | 11 (68.8) | 45 (45.9) | 71 (71.7) | 40 (58.8) |
| Homelessness, unstable housing, or transient living |  |  |  |  |  |  |  |  |
| Yes | 11 (11.2) | 38 (10.8) | 5 (8.6) | 4 (16.0) | 2 (13.3) | 16 (7.7) | 11 (12.2) | 11 (20.4) |
| No | 87 (88.8) | 315 (89.2) | 53 (91.4) | 21 (84.0) | 13 (86.7) | 193 (92.3) | 79 (87.8) | 43 (79.6) |
| MSM5 |  |  |  |  |  |  |  |  |
| Yes | 3 (15.8) | 14 (12.2) | 1 (9.1) | 1 (14.3) | 1 (100.0) | 4 (6.5) | 10 (19.2) | 0 (0.0) |
| No | 16 (84.2) | 101 (87.8) | 10 (90.9) | 6 (85.7) | 0 (0.0) | 58 (93.5) | 42 (80.8) | 1 (100.0) |
| Incarcerated |  |  |  |  |  |  |  |  |
| Yes | 3 (7.5) | 34 (16.7) | 2 (20.0) | 1 (4.0) | 0 (0.0) | 26 (37.1) | 3 (3.0) | 5 (14.7) |
| No | 37 (92.5) | 170 (83.3) | 8 (80.0) | 24 (96.0) | 5 (100.0) | 44 (62.9) | 97 (97.0) | 29 (85.3) |
| International travel |  |  |  |  |  |  |  |  |
| Yes | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| No | 69 (100.0) | 283 (100.0) | 30 (100.0) | 26 (100.0) | 13 (100.0) | 128 (100.0) | 103 (100.0) | 52 (100.0) |
| Epidemiologically linked |  |  |  |  |  |  |  |  |
| Yes | 14 (51.9) | 66 (50.4) | 8 (72.7) | 3 (30.0) | 3 (50.0) | 40 (62.5) | 18 (35.3) | 8 (50.0) |
| No | 13 (48.1) | 65 (49.6) | 3 (27.3) | 7 (70.0) | 3 (50.0) | 24 (37.5) | 33 (64.7) | 8 (50.0) |
| **Clinical** |  |  |  |  |  |  |  |  |
| History of hepatitis B |  |  |  |  |  |  |  |  |
| Yes | 22 (21.8) | 36 (10.8) | 14 (25.9) | 2 (7.4) | 6 (30.0) | 27 (14.7) | 4 (4.8) | 5 (7.7) |
| No | 79 (78.2) | 297 (89.2) | 40 (74.1) | 25 (92.6) | 14 (70.0) | 157 (85.3) | 80 (95.2) | 60 (92.3) |
| History of hepatitis C |  |  |  |  |  |  |  |  |
| Yes | 49 (46.2) | 142 (39.1) | 34 (58.6) | 4 (14.3) | 11 (55.0) | 105 (51.5) | 10 (10.9) | 27 (40.3) |
| No | 57 (53.8) | 221 (60.9) | 24 (41.4) | 24 (85.7) | 9 (45.0) | 99 (48.5) | 82 (89.1) | 40 (59.7) |
| Other pre-existing liver disease |  |  |  |  |  |  |  |  |
| Yes | 60 (81.1) | 55 (49.1) | 32 (82.1) | 15 (68.2) | 13 (100.0) | 29 (52.7) | 7 (19.4) | 19 (90.5) |
| No | 14 (18.9) | 57 (50.9) | 7 (17.9) | 7 (31.8) | 0 (0.0) | 26 (47.3) | 29 (80.6) | 2 (9.5) |
| Diabetes |  |  |  |  |  |  |  |  |
| Yes | 41 (42.7) | 60 (22.9) | 21 (42.9) | 13 (44.8) | 7 (38.9) | 23 (21.3) | 23 (22.3) | 14 (27.5) |
| No | 55 (57.3) | 202 (77.1) | 28 (57.1) | 16 (55.2) | 11 (61.1) | 85 (78.7) | 80 (77.7) | 37 (72.5) |
| Pregnancy6 |  |  |  |  |  |  |  |  |
| Yes | 0 (0.0) | 3 (3.3) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 2 (4.7) | 0 (0.0) | 1 (9.1) |
| No | 27 (100.0) | 89 (96.7) | 11 (100.0) | 13 (100.0) | 3 (100.0) | 41 (95.3) | 38 (100.0) | 10 (90.9) |
| Immunosuppression |  |  |  |  |  |  |  |  |
| Yes | 7 (8.1) | 12 (5.9) | 4 (8.5) | 3 (13.0) | 0 (0.0) | 5 (5.6) | 7 (11.1) | 0 (0.0) |
| No | 79 (91.9) | 191 (94.1) | 43 (91.5) | 20 (87.0) | 16 (100.0) | 85 (94.4) | 56 (88.9) | 50 (100.0) |
| Cardiovascular disease |  |  |  |  |  |  |  |  |
| Yes | 66 (69.5) | 125 (52.7) | 34 (68.0) | 19 (73.1) | 13 (68.4) | 49 (45.4) | 44 (56.4) | 32 (62.7) |
| No | 29 (30.5) | 112 (47.3) | 16 (32.0) | 7 (26.9) | 6 (31.6) | 59 (54.6) | 34 (43.6) | 19 (37.3) |
| Signs or symptoms |  |  |  |  |  |  |  |  |
| Fever |  |  |  |  |  |  |  |  |
| Yes | 50 (48.5) | 141 (36.4) | 28 (48.3) | 15 (60.0) | 7 (35.0) | 61 (27.5) | 43 (45.3) | 37 (52.9) |
| No | 53 (51.5) | 246 (63.6) | 30 (51.7) | 10 (40.0) | 13 (65.0) | 161 (72.5) | 52 (54.7) | 33 (47.1) |
| Headache |  |  |  |  |  |  |  |  |
| Yes | 16 (19.5) | 48 (15.1) | 8 (13.8) | 4 (44.4) | 4 (26.7) | 19 (8.6) | 10 (23.3) | 19 (34.5) |
| No | 66 (80.5) | 270 (84.9) | 50 (86.2) | 5 (55.6) | 11 (73.3) | 201 (91.4) | 33 (76.7) | 36 (65.5) |
| Malaise |  |  |  |  |  |  |  |  |
| Yes | 61 (64.2) | 208 (55.8) | 30 (51.7) | 19 (86.4) | 12 (80.0) | 74 (33.6) | 81 (92.0) | 53 (81.5) |
| No | 34 (35.8) | 165 (44.2) | 28 (48.3) | 3 (13.6) | 3 (20.0) | 146 (66.4) | 7 (8.0) | 12 (18.5) |
| Anorexia |  |  |  |  |  |  |  |  |
| Yes | 42 (44.7) | 145 (39.2) | 17 (29.3) | 16 (80.0) | 9 (56.3) | 37 (16.7) | 60 (70.6) | 48 (75.0) |
| No | 52 (55.3) | 225 (60.8) | 41 (70.7) | 4 (20.0) | 7 (43.8) | 184 (83.3) | 25 (29.4) | 16 (25.0) |
| Nausea |  |  |  |  |  |  |  |  |
| Yes | 79 (79.0) | 317 (78.7) | 45 (77.6) | 18 (81.8) | 16 (80.0) | 179 (80.6) | 74 (71.8) | 64 (82.1) |
| No | 21 (21.0) | 86 (21.3) | 13 (22.4) | 4 (18.2) | 4 (20.0) | 43 (19.4) | 29 (28.2) | 14 (17.9) |
| Vomiting |  |  |  |  |  |  |  |  |
| Yes | 53 (53.0) | 176 (46.1) | 26 (44.8) | 14 (63.6) | 13 (65.0) | 81 (36.7) | 47 (55.3) | 48 (63.2) |
| No | 47 (47.0) | 206 (53.9) | 32 (55.2) | 8 (36.4) | 7 (35.0) | 140 (63.3) | 38 (44.7) | 28 (36.8) |
| Diarrhea |  |  |  |  |  |  |  |  |
| Yes | 32 (34.8) | 112 (32.2) | 15 (26.3) | 12 (54.5) | 5 (38.5) | 63 (28.4) | 27 (33.8) | 22 (47.8) |
| No | 60 (65.2) | 236 (67.8) | 42 (73.7) | 10 (45.5) | 8 (61.5) | 159 (71.6) | 53 (66.3) | 24 (52.2) |
| Abdominal pain |  |  |  |  |  |  |  |  |
| Yes | 73 (70.9) | 285 (70.9) | 44 (75.9) | 15 (62.5) | 14 (66.7) | 154 (69.4) | 73 (71.6) | 58 (74.4) |
| No | 30 (29.1) | 117 (29.1) | 14 (24.1) | 9 (37.5) | 7 (33.3) | 68 (30.6) | 29 (28.4) | 20 (25.6) |
| Dark urine |  |  |  |  |  |  |  |  |
| Yes | 42 (49.4) | 196 (54.6) | 16 (28.6) | 14 (93.3) | 12 (85.7) | 81 (37.0) | 57 (82.6) | 58 (81.7) |
| No | 43 (50.6) | 163 (45.4) | 40 (71.4) | 1 (6.7) | 2 (14.3) | 138 (63.0) | 12 (17.4) | 13 (18.3) |
| Acholic stool |  |  |  |  |  |  |  |  |
| Yes | 13 (41.9) | 67 (50.8) | 2 (40.0) | 6 (50.0) | 5 (35.7) | 18 (72.0) | 21 (44.7) | 28 (46.7) |
| No | 18 (58.1) | 65 (49.2) | 3 (60.0) | 6 (50.0) | 9 (64.3) | 7 (28.0) | 26 (55.3) | 32 (53.3) |
| Jaundice/icterus |  |  |  |  |  |  |  |  |
| Yes | 92 (85.2) | 296 (76.7) | 48 (84.2) | 25 (83.3) | 19 (90.5) | 155 (76.7) | 76 (71.0) | 65 (84.4) |
| No | 16 (14.8) | 90 (23.3) | 9 (15.8) | 5 (16.7) | 2 (9.5) | 47 (23.3) | 31 (29.0) | 12 (15.6) |
| Date of symptom onset (range) | 9/1/2016–5/23/2019 | 8/17/2016–6/1/2019 | 2/5/2018–5/23/2019 | 9/1/2016–5/17/2019 | 3/27/2018–1/21/2019 | 10/7/2017–6/1/2019 | 8/17/2016–2/15/2019 | 4/16/2018–3/9/2019 |
| Laboratory results |  |  |  |  |  |  |  |  |
| ALT (IU/L) |  |  |  |  |  |  |  |  |
| N | 108 | 404 | 58 | 30 | 20 | 220 | 105 | 79 |
| Mean (SE) | 1935.7 (179.2) | 1805.7 (77.1) | 1734.8 (220.4) | 2414.5 (384.6) | 1800.2 (435.6) | 1582.8 (95.6) | 2230.4 (168.2) | 1861.9 (174.7) |
| AST (IU/L) |  |  |  |  |  |  |  |  |
| N | 108 | 402 | 58 | 30 | 20 | 218 | 105 | 79 |
| Mean (SE) | 2333.7 (249.0) | 1471.6 (74.2) | 2079.6 (274.5) | 2728.0 (513.9) | 2479.1 (776.0) | 1237.6 (77.4) | 1896.3 (190.5) | 1552.8 (168.7) |
| AST/ALT ratio |  |  |  |  |  |  |  |  |
| N | 108 | 402 | 58 | 30 | 20 | 218 | 105 | 79 |
| Mean (SE) | 1.6 (0.2) | 0.9 (0.0) | 1.6 (0.2) | 1.8 (0.6) | 1.3 (0.2) | 0.8 (0.0) | 1.0 (0.1) | 0.8 (0.0) |
| Total bilirubin (mg/dL) |  |  |  |  |  |  |  |  |
| N | 103 | 279 | 54 | 30 | 19 | 139 | 89 | 51 |
| Mean (SE) | 11.4 (0.9) | 7.0 (0.3) | 11.2 (1.1) | 11.1 (1.8) | 12.5 (2.0) | 7.2 (0.4) | 5.9 (0.5) | 8.5 (0.9) |
| Platelet count (K/uL) |  |  |  |  |  |  |  |  |
| N | 101 | 256 | 54 | 28 | 19 | 121 | 84 | 51 |
| Mean (SE) | 178.8 (10.2) | 209.7 (4.9) | 173.8 (14.8) | 192.0 (18.6) | 173.5 (20.6) | 206.2 (7.8) | 218.4 (8.0) | 203.7 (9.8) |
| MELD score |  |  |  |  |  |  |  |  |
| N | 99 | 225 | 53 | 28 | 18 | 99 | 82 | 44 |
| Mean (SE) | 29.0 (0.8) | 19.5 (0.4) | 29.5 (1.3) | 28.3 (1.4) | 28.8 (1.9) | 19.1 (0.6) | 19.2 (0.7) | 20.8 (1.0) |
| HBsAg |  |  |  |  |  |  |  |  |
| Positive/Reactive | 16 (15.8) | 19 (5.7) | 11 (19.3) | 1 (3.7) | 4 (23.5) | 16 (8.1) | 0 (0.0) | 3 (5.8) |
| Negative/Nonreactive | 85 (84.2) | 317 (94.3) | 46 (80.7) | 26 (96.3) | 13 (76.5) | 181 (91.9) | 87 (100.0) | 49 (94.2) |
| IgM anti-HBc |  |  |  |  |  |  |  |  |
| Positive/Reactive | 8 (7.9) | 21 (6.4) | 6 (10.5) | 1 (3.8) | 1 (5.6) | 17 (8.9) | 3 (3.5) | 1 (2.0) |
| Negative/Nonreactive | 90 (89.1) | 304 (93.0) | 48 (84.2) | 25 (96.2) | 17 (94.4) | 174 (90.6) | 81 (95.3) | 49 (98.0) |
| Indeterminate/Borderline | 3 (3.0) | 2 (0.6) | 3 (5.3) | 0 (0.0) | 0 (0.0) | 1 (0.5) | 1 (1.2) | 0 (0.0) |
| anti-HCV |  |  |  |  |  |  |  |  |
| Positive/Reactive | 47 (45.6) | 129 (37.6) | 34 (58.6) | 3 (11.1) | 10 (55.6) | 101 (50.2) | 10 (11.0) | 18 (35.3) |
| Negative/Nonreactive | 56 (54.4) | 214 (62.4) | 24 (41.4) | 24 (88.9) | 8 (44.4) | 100 (49.8) | 81 (89.0) | 33 (64.7) |
| HCV RNA viral load |  |  |  |  |  |  |  |  |
| Undetectable | 18 (46.2) | 28 (49.1) | 7 (30.4) | 5 (55.6) | 6 (85.7) | 13 (38.2) | 8 (72.7) | 7 (58.3) |
| Detected but not quantifiable | 5 (12.8) | 9 (15.8) | 4 (17.4) | 1 (11.1) | 0 (0.0) | 7 (20.6) | 0 (0.0) | 2 (16.7) |
| Detected and quantifiable | 16 (41.0) | 20 (35.1) | 12 (52.2) | 3 (33.3) | 1 (14.3) | 14 (41.2) | 3 (27.3) | 3 (25.0) |
| HIV serology |  |  |  |  |  |  |  |  |
| Positive/Reactive | 0 (0.0) | 6 (8.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 3 (9.1) | 3 (11.1) | 0 (0.0) |
| Negative/Nonreactive | 36 (100.0) | 68 (90.7) | 23 (100.0) | 9 (100.0) | 4 (100.0) | 30 (90.9) | 24 (88.9) | 14 (93.3) |
| Indeterminate | 0 (0.0) | 1 (1.3) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 1 (6.7) |
|  |  |  |  |  |  |  |  |  |
| Hospitalized |  |  |  |  |  |  |  |  |
| Yes | 103 (95.4) | 248 (61.2) | 54 (93.1) | 30 (100.0) | 19 (95.0) | 115 (52.8) | 87 (79.8) | 46 (59.0) |
| No | 5 (4.6) | 157 (38.8) | 4 (6.9) | 0 (0.0) | 1 (5.0) | 103 (47.2) | 22 (20.2) | 32 (41.0) |
| Length of hospitalization, days7  |  |  |  |  |  |  |  |  |
| N | 101 | 245 | 52 | 30 | 19 | 112 | 87 | 46 |
| Mean (SE) | 13.1 (1.1) | 5.8 (0.3) | 11.9 (1.4) | 15.0 (2.2) | 13.4 (3.1) | 5.0 (0.3) | 6.2 (0.4) | 6.8 (1.2) |
| Intensive care unit7 |  |  |  |  |  |  |  |  |
| Yes | 81 (83.5) | 26 (11.1) | 41 (82.0) | 27 (93.1) | 13 (72.2) | 4 (3.7) | 19 (22.4) | 3 (7.1) |
| No | 16 (16.5) | 209 (88.9) | 9 (18.0) | 2 (6.9) | 5 (27.8) | 104 (96.3) | 66 (77.6) | 39 (92.9) |
| Number of hepatitis A-related hospitalizations7 |  |  |  |  |  |  |  |  |
| 1 | 62 (60.2) | 229 (92.3) | 33 (61.1) | 17 (56.7) | 12 (63.2) | 109 (94.8) | 77 (88.5) | 43 (93.5) |
| 2 | 32 (31.1) | 18 (7.3) | 17 (31.5) | 10 (33.3) | 5 (26.3) | 5 (4.3) | 10 (11.5) | 3 (6.5) |
| 3 | 6 (5.8) | 1 (0.4) | 2 (3.7) | 2 (6.7) | 2 (10.5) | 1 (0.9) | 0 (0.0) | 0 (0.0) |
| >3 | 3 (2.9) | 0 (0.0) | 2 (3.7) | 1 (3.3) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| **Outcome** |  |  |  |  |  |  |  |  |
| Acute liver failure  |  |  |  |  |  |  |  |  |
| Yes | 74 (80.4) | 14 (5.3) | 37 (80.4) | 23 (79.3) | 14 (82.4) | 4 (3.3) | 8 (8.8) | 2 (3.9) |
| No | 18 (19.6) | 248 (94.7) | 9 (19.6) | 6 (20.7) | 3 (17.6) | 116 (96.7) | 83 (91.2) | 49 (96.1) |
| Liver transplant |  |  |  |  |  |  |  |  |
| Yes | 1 (1.1) | 0 (0.0) | 0 (0.0) | 1 (3.3) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| No | 90 (98.9) | 264 (100.0) | 45 (100.0) | 29 (96.7) | 16 (100.0) | 121 (100.0) | 92 (100.0) | 51 (100.0) |
| Death |  |  |  |  |  |  |  |  |
| Yes | 110 (100.0) | 6 (1.6) | 59 (100.0) | 30 (100.0) | 21 (100.0) | 1 (0.5) | 2 (1.8) | 3 (5.5) |
| No | 0 (0.0) | 376 (98.4) | 0 (0.0) | 0 (0.0) | 0 (0.0) | 217 (99.5) | 107 (98.2) | 52 (94.5) |

Abbreviations: KY, Kentucky; MI, Michigan; WV, West Virginia; SE, standard error; NH, non-Hispanic; MSM, men who have sex with men; ALT, alanine aminotransferase; AST, aspartate aminotransferase; MELD, Model for End-Stage Liver Disease; HBsAg, hepatitis B surface antigen; IgM anti-HBc, immunoglobulin M hepatitis B core antibody; anti-HCV, hepatitis C antibody

1 Percentages are calculated based on participants with available information and may not sum to 100.0% due to rounding.

2 Other: Hispanic ethnicity

3 Risk factors were assessed based on their presence or absence during a participant’s exposure period (i.e., the 15–50 days prior to symptom onset).

4 Restricted to those with available information on reported drug use (n=431).

5 Restricted to male study participants (n=339).

6 Restricted to female study participants (n=185).

7 Restricted to hospitalized study participants (n=351).