Table. Sample Characteristics in Florida, 2009-2013

Characteristic	Mean Values[a] All	Practice Peers of Physicians With 1 Injury Report	Physicians in Practices With No Injury Reports	*P* Value for Difference[b]
Physicians, No.	20 200	361	19 839	NA
Physician quarters, No.	193 530	2918	190 612	NA
Rate of imaging	0.029	0.023	0.029	<.001
Age, y	77.2	77.2	77.2	.60
Female sex	0.578	0.592	0.578	.005
Minority race/ethnicity[c]	0.195	0.149	0.196	<.001
Elixhauser score[d]	4.99	4.88	4.99	.001

Abbreviation: NA, not applicable.

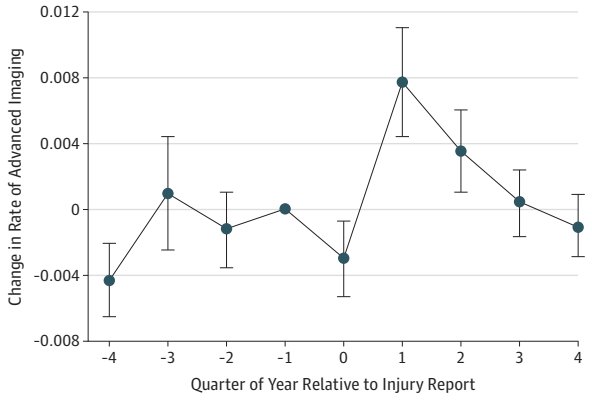
[a] Across all physician quarters.

[b] Calculated using *t* tests.

[c] Race/ethnicity was self-reported. *Minority* refers to any race/ethnicity that is not non-Hispanic white.

[d] Elixhauser Comorbidity software identifies up to 31 patient comorbidities, such as hypertension and diabetes, based on diagnosis codes found in administrative data, and the Elixhauser comorbidity score is the sum of these comorbidities.

Figure. Change in Rate of Advanced Imaging After an Injury Report Against a Physician Peer in Florida, 2009-2013



The bands are SEs clustered at the practice level. Estimates are from a regression that includes physician fixed effects, quarter-by-year fixed effects, and controls for mean age, sex, non-Hispanic white race/ethnicity, and Elixhauser score of a physician's patients in a given quarter. The quarter prior to the malpractice report is the reference category. Elixhauser Comorbidity software identifies up to 31 patient comorbidities, such as hypertension and diabetes, based on diagnosis codes found in administrative data, and the Elixhauser score is the sum of these comorbidities.

Discussion | Rates of advanced imaging increased 0.78 per 100 E&M visits compared with a mean of 2.3 in the first quarter after an injury report against a physician's peer, but this increase did not persist. These results are consistent with prior research that suggests that perceived malpractice risk, rather than objective malpractice risk, may influence defensive medicine.[2] Limitations to this study include an inability to distinguish responses based solely on malpractice concerns from responses based on wanting to avoid similar injuries. Results are limited to the Medicare population in Florida and may not be generalizable to other populations.

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Findings From the Behavioral Risk Factor Surveillance System on Health-Related Quality of Life Among US Transgender Adults, 2014-2017

The National Institutes of Health has prioritized research into disparities affecting the transgender population. An important domain in disparities research is health-related quality of life (HRQOL), which reflects the burden of chronic and acute physical and mental health conditions as well as unmet health care needs.[1] Historically, a lack of routine, standardized data collection has hindered explorations of transgender population health and HRQOL. In 2014, however, the Centers for Disease Control and Prevention (CDC) introduced an optional Sexual Orientation and Gender Identity module for the Behavioral Risk Factor Surveillance System (BRFSS). In 2014 through 2017, 36 states and territories representing almost 75% of the US population used the module at least once. This study compared HRQOL between transgender and cisgender adults in this rare probability sample of the transgender population.

Methods | The BRFSS is the largest continuously operating health survey in the world and is fielded annually by every state. The Sexual Orientation and Gender Identity module includes a question that asks, "Do you consider yourself to be transgender?" with the following primary answer options: (1) yes, transgender, male to female; (2) yes, transgender, female to male; (3) yes, transgender, gender nonconforming; and (4) no. Gender identity in the pooled 2014 through 2017 BRFSS data set was classified as transgender (response options 1-3;

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3075 responses) and cisgender (response option 4; 719 484 responses). Respondents who answered "don't know/not sure" (response option 7; n = 3799) or refused to answer (n = 5800) were excluded. The need for study approval was waived by the Johns Hopkins School of Public Health Institutional Review Board. Informed consent was not applicable to this study because it is based on publicly available data from the CDC.

A core component of the BRFSS is a standard 4-item set of Healthy Days questions, which constitute the CDC HRQOL-4 measure. These items are (1) self-reported health and, of the past 30 days, the number of days that the respondent (2) felt physically unhealthy, (3) felt mentally unhealthy, and (4) limited usual activities. Following CDC recommendations,[2] results of the HRQOL-4 are reported in this analysis as (1) fair or poor health; (2) severe mental distress, defined as 14 or more mentally unhealthy days in the previous 30 days; (3) mean combined physically and mentally unhealthy days; and (4) mean activity-limited days.

Descriptive bivariate comparisons of transgender and cisgender adults were performed using design-corrected *F* tests. Logistic and zero-inflated negative binomial regression models were estimated for dichotomous and count outcomes, respectively. All models were adjusted for state and, following earlier literature,[3] sociodemographic factors and chronic health conditions. All analyses were performed in Stata, version 14 (StataCorp LP) and weighted to account for the BRFSS complex survey design. Variances were scaled to account for strata with single sampling units. Statistical significance was set at 2-sided $P = .05$.

Results | Transgender individuals comprised an estimated 0.55% (95% CI, 0.51%-0.59%) of the sample, which is equivalent to 1.27 million transgender adults in the general US population. Compared with cisgender adults, more transgender adults reported current cigarette use (19.2% vs 16.3%; $P = .04$) and physical inactivity (35.0% vs 25.6%; $P < .001$), and fewer reported having health insurance coverage (79.9% vs 85.4%; $P = .001$) (**Table 1**).

Transgender adults were more likely to report diminished HRQOL in the previous 30 days as measured by greater odds of fair or poor health (adjusted odds ratio [AOR], 1.30; 95% CI, 1.03-1.62; $P = .02$) or severe mental distress (AOR, 1.66; 95% CI, 1.36-2.01; $P < .001$) (**Table 2**). They also reported more days of combined poor physical and mental health (adjusted

Table 1. Characteristics of US Transgender and Cisgender Adults

Characteristic	No. (%)[a] Transgender (n = 3075)	Cisgender (n = 719 567)	*P* Value[b]
Sociodemographic Characteristics			
Age, y			
18-24	314 (21.7)	36 636 (11.8)	<.001
25-34	349 (15.4)	65 595 (15.9)	
35-44	335 (14.2)	81 132 (16.1)	
45-54	508 (15.0)	118 056 (17.6)	
55-64	676 (16.5)	164 436 (17.5)	
≥65	893 (17.3)	253 712 (21.2)	
Race/ethnicity			
White, non-Hispanic	2066 (55.4)	557 261 (63.3)	<.001
Black, non-Hispanic	317 (16.1)	53 098 (11.5)	
Asian, Native Hawaiian, or Pacific Islander	144 (5.0)	24 258 (5.6)	
Other, non-Hispanic	188 (4.6)	27 745 (2.6)	
Hispanic	298 (18.9)	46 435 (16.9)	
Educational level			
Did not graduate high school	438 (20.6)	51 219 (14.0)	<.001
Graduated high school	1116 (32.9)	199 671 (28.0)	
Some college or technical school	833 (32.3)	195 514 (31.3)	
Graduated college or technical school	674 (14.2)	271 289 (26.7)	
Employment			
Employed[c]	1376 (50.3)	358 026 (56.6)	<.001
Unemployed	210 (8.4)	29 902 (5.6)	
Homemaker, student, or retired	1064 (29.2)	276 553 (30.9)	
Unable to work	397 (12.1)	50 995 (6.9)	
Annual income, $			
<15 000	471 (17.0)	59 455 (10.9)	<.001
15 000-24 999	606 (21.8)	99 481 (16.5)	
25 000-34 999	330 (13.3)	66 724 (10.5)	
35 000-49 999	355 (10.6)	88 833 (13.6)	
50 000-74 999	337 (12.6)	100 047 (14.9)	
≥75 000	535 (24.7)	202 610 (33.5)	

(continued)

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Table 1. Characteristics of US Transgender and Cisgender Adults (continued)

Characteristic	No. (%)[a] Transgender (n = 3075)	Cisgender (n = 719 567)	*P* Value[b]
Home ownership			
Own	1797 (55.0)	521 886 (68.3)	<.001
Rent	1054 (35.1)	162 721 (26.2)	
Other arrangement	211 (9.9)	31 173 (5.5)	
Marital status			
Married or coupled	1425 (46.5)	398 808 (56.1)	<.001
Divorced, separated, or widowed	885 (20.6)	205 943 (20.7)	
Never married	747 (32.9)	111 145 (23.2)	
Child aged <18 y in household	740 (32.0)	185 860 (36.8)	.02
Veteran	446 (11.8)	93 017 (10.4)	.25
Sexual orientation			
Heterosexual	2241 (68.7)	681 569 (95.9)	<.001
Lesbian or gay	203 (9.6)	10 137 (1.7)	
Bisexual	365 (15.2)	10 808 (2.0)	
Other	130 (6.5)	2598 (0.4)	
Health Risk Factors			
Alcohol use			
None	1666 (58.4)	336 302 (47.6)	<.001
Light to moderate[d]	825 (24.8)	262 535 (34.6)	
≥1 Episode of binge drinking (≥4 drinks at 1 time) in past 30 d	475 (16.8)	101 469 (17.8)	
Cigarette use			
Never or past	2441 (80.9)	608 230 (83.7)	.04
Current	608 (19.2)	105 923 (16.3)	
No physical exercise in past 30 d	984 (35.0)	185 236 (25.6)	<.001
Health care access			
Insurance[e]	1818 (79.9)	411 946 (85.4)	.001
Regular provider	2502 (75.9)	616 442 (79.0)	.08
Checkup in past year	2270 (73.0)	540 135 (71.1)	.29
Financial barrier to care	448 (19.1)	69 396 (13.1)	<.001
Health conditions			
No chronic conditions[f]	1316 (54.6)	307 002 (52.4)	.11
1 Chronic condition	806 (23.1)	210 160 (26.5)	
≥2 Chronic conditions	953 (22.3)	202 303 (21.0)	
Ever diagnosed with depression	865 (29.4)	135 637 (18.1)	<.001

[a] Numbers are raw frequencies; percentages are calculated using design weights.

[b] *P* values reflect design-corrected *F* tests for differences between the weighted proportions of transgender and cisgender respondents.

[c] Employed indicates for wages or self-employed.

[d] Light to moderate alcohol use was defined as 1 to 3 drinks maximum at any time in the past 30 days.

[e] Insurance data are given only for individuals younger than 65 years.

[f] Chronic conditions were defined as having ever received a diagnosis of angina, arthritis, asthma, cancer, chronic obstructive pulmonary disease, coronary heart disease, diabetes, or chronic kidney disease or having a history of myocardial infarction or stroke.

Table 2. Health-Related Quality of Life by Gender Identity[a]

Health-Related Quality of Life	Transgender (n = 3075)	Cisgender (n = 719 567)	Unadjusted OR (95% CI) or Unadjusted Mean Difference (SE)	*P* Value[b]	AOR (95% CI) or Adjusted Mean Difference (SE)	*P* Value[b]
Fair or poor health, No. (%)[c]	819 (24.5)	132 486 (18.2)	1.46 (1.21-1.75)	<.001	1.30 (1.03-1.62)	.02
Severe mental distress in last 30 d, No. (%)[c]	566 (20.3)	73 396 (11.6)	1.94 (1.61-2.34)	<.001	1.66 (1.36-2.01)	<.001
Total mentally and physically unhealthy days in past 30 d	9.40 (0.46)[d]	6.57 (0.03)[d]	2.83 (0.46)[e]	<.001	1.20 (0.04)[f]	<.001
Activity-limited days in past 30 d	4.53 (0.37)[d]	2.57 (0.02)[d]	1.96 (0.37)[e]	<.001	1.34 (0.09)[f]	<.001

Abbreviations: AOR, adjusted odds ratio; OR, odds ratio.

[a] Data are based on answers to the standard 4-item set of Healthy Days questions in the Behavioral Risk Factor Surveillance System. The questions are listed in the Methods section. All analyses were adjusted for number of multiple chronic conditions, race/ethnicity, age, marital status, educational level, and state.

[b] *P* values reflect weighted data analyses.

[c] Numbers are raw frequencies; percentages were calculated using design weights.

[d] Unadjusted mean (SE).

[e] Unadjusted mean difference (SE).

[f] Adjusted mean difference (SE) (weighted zero-inflated negative binomial regression coefficient).

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mean [SE] difference: 1.20 [0.04] days; $P < .001$) and of activity limitation (1.34 [0.09] days; $P < .001$).

Discussion | This analysis confirms the findings of previous studies that have identified severe health and HRQOL disparities affecting the transgender population.[4,5] These disparities require informed attention from clinicians and policy makers and further investigation by researchers. Until all states and territories field the BRFSS Sexual Orientation and Gender Module, however, the generalizability of the findings in this study remains limited. Given ongoing nationwide debates about public accommodations access, nondiscrimination protections, and other issues that influence transgender health,[6] all states and territories should field the module to facilitate research that draws on fully representative samples of the US transgender population. Furthermore, future analyses should investigate differences within the transgender population by factors such as gender, race/ethnicity, and sexual orientation.

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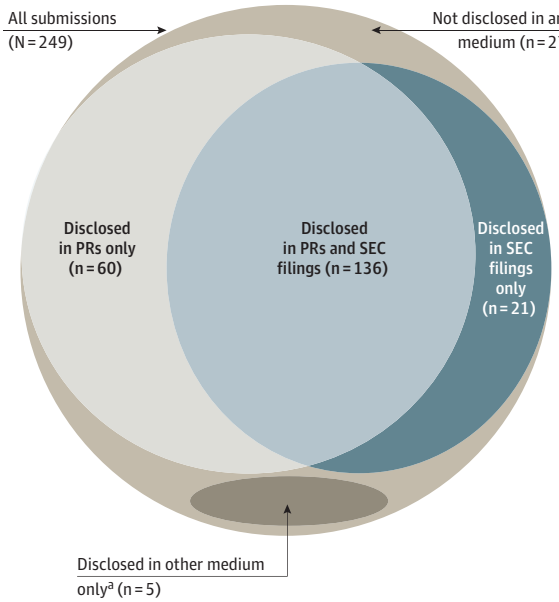
Public Disclosure of the Filing of New Drug and Therapeutic Biologics Applications With the US Food and Drug Administration

Current regulations prohibit the US Food and Drug Administration (FDA) from publicly disclosing the existence of pending New Drug Applications (NDAs) or Biologics License Applications (BLAs) unless previously publicly disclosed or acknowledged.[1] Applicants may disclose applications in press releases, Securities and Exchange Commission (SEC) filings, or in other media; how frequently they do so is not known.

Editor's Note page 1145

Figure. Public Disclosure of Application Submissions in Press Releases (PRs), Regulatory Filings From the US Securities and Exchange Commission (SEC), and Any Other Documents



Data from a subscription-based database (secondary outcome) are not included.

[a] The "other" documents were only searched when a PR or SEC filing was not found (n = 32). The following documents were found: a financial highlights document (n = 1), a notice of patent extension (n = 1), a stockholder update document (n = 1), and miscellaneous press articles (n = 2).

Methods | We conducted a cross-sectional study of all NDAs for new molecular entities and BLAs for new and biosimilar biological products submitted to the FDA between January 1, 2010, and December 31, 2016. Data were collected in July 2017. Because this was a cross-sectional study based on nonclinical data, we did not submit this study for human subjects ethics review.

Primary outcomes included disclosures of applications in press releases, SEC filings, and other media. For press releases, we searched applicants' websites and websites where press releases are disseminated. For SEC disclosures, we searched a public SEC database for filings from firms publicly traded in the United States.[2] If disclosures were not found, we conducted Google searches to identify any disclosures in other media (eg, investor materials or annual reports). We calculated the percentage of submissions disclosed and the median time to disclosure (days with interquartile range [IQR]).

We also searched Pharmaprojects, a subscription-based drug development database, and determined the percentage of submissions disclosed; such a listing was not considered to be public disclosure.[3]

Results | Of the 249 applications (188 NDAs and 61 BLAs), 222 (89.2%) were disclosed in at least 1 public medium (**Figure**), including in a press release for 196 applications (78.7%) (**Table**). Of the press releases, 196 (86.2%) were found on applicants' websites. Of the applications, 157 (63.1%) were disclosed in SEC filings, including 136 (54.6%) in press releases and SEC filings. The overall rates of public disclosures increased from

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