

Detection of Gluten in Gluten-Free Labeled Restaurant Food: Analysis of Crowd-Sourced Data

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INTRODUCTION: Adherence to a gluten-free (GF) diet is the mainstay of therapy for celiac disease. Until now, those wishing to avoid gluten in restaurants had to rely on menu labels, word of mouth, intuition, and restaurant workers' advice, with a relative dearth of supporting data. We used crowd-sourced data from users of a portable gluten detection device to estimate rates of, and identify risk factors for, gluten contamination of supposed GF restaurant foods.

METHODS: We analyzed data from a portable gluten detection device (Nima), collected across the United States during an 18-month period by users who opted to share the results of their point-of-care tests. Data were sorted by region, time of day, median household income in the restaurant's vicinity, restaurant genre, and food items. We used the χ^2 test for bivariate analysis and multiple logistic regression for multivariate analysis to identify predictors of gluten detection in restaurant food.

RESULTS: There were 5,624 tests, performed by 804 users, in the examined period. Gluten was detected in 32% of GF labeled foods. Rates of gluten detection differed by meal, with 27.2% at breakfast and 34.0% at dinner ($P = 0.0008$). GF labeled pizza and pasta were most likely to test positive for gluten, with gluten detected in 53.2% of pizza and 50.8% of pasta samples. On multivariate analysis, GF labeled food was less likely to test positive for gluten in the West than in the Northeast United States (odds ratio 0.80; 95% confidence interval 0.67–0.95).

CONCLUSIONS: This study of crowd-sourced data suggests that a substantial fraction of GF labeled restaurant foods contain detectable gluten. Although the highly sensitive Nima device may detect gluten at levels <20 parts per million (ppm), leading to gluten exposure of unknown clinical significance, our findings raise a potential concern. In addition, our findings of higher rates of gluten detection in pizza and pasta provide practical data when providing dining strategies for patients with celiac disease.

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INTRODUCTION

Celiac disease (CD) is an autoimmune disorder triggered by the consumption of gluten, a protein found in cereal grains, wheat, rye, and barley. CD currently affects approximately 1% of the population (1,2), and its prevalence is increasing (3). The disease primarily affects the small intestine, and common symptoms include iron deficiency, bloating, constipation, chronic fatigue, and abdominal pain (4).

Adherence to a gluten-free (GF) diet is the mainstay of therapy for CD. Despite its effectiveness, as many as 80% of patients with CD report difficulty maintaining this lifestyle (5). Indeed, inadvertent gluten ingestion has been cited as the leading cause of nonresponsive CD (6,7), and a recent study measuring traces of gluten in urine and stool suggested that many patients with CD

accidentally consume enough gluten to trigger symptoms and cause intestinal damage (8).

To protect patients with CD from unintentionally ingesting gluten, the Food and Drug Administration issued a rule in August 2013 that packaged GF labeled foods must contain less than 20 ppm of gluten. No similar rule applies to restaurant foods claiming to be GF and, consequently, potential gluten exposure when dining out is a source of anxiety for many patients with CD. In one study, 83% of patients with CD or non-celiac gluten sensitivity found the GF diet to be a problem in restaurants and 63% avoided restaurants altogether (9). Multiple surveys of patients with CD found dining out to be the most common lifestyle situation presenting difficulty when following a GF diet, more so than traveling, socializing, and personal relationships (5,10).

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In the present study, we aimed to quantify rates of gluten contamination of restaurant foods and identify risk factors associated with the presence of gluten. The recent advent of a portable gluten detection device allowed us to use crowd-sourced data to estimate the prevalence of gluten contamination in restaurants throughout the United States.

METHODS

Gluten sensor

We obtained uploaded data from users of Nima, a commercially available gluten detection device. Nima consists of a 3-inch-tall sensor and single-use capsules that contain test strips loaded with proprietary antigluten antibodies. To test food for the presence of gluten, users place a pea-sized sample into the capsule. Screwing on the lid grinds the sample, which is then mixed with an extraction buffer. The resulting solution passes onto the test strip, which is then read by an optical sensor. The output of the sensor is a binary result, either gluten detected (displayed as a wheat symbol) or gluten not detected (displayed as a smiley face). The Nima sensor currently sells for \$229 on Amazon; each test capsule costs \$6. Recently published validation data suggest that Nima has high sensitivity for detecting gluten at levels of 20 ppm or more. The device’s specificity is high for purely GF ingredients, but when testing foods that are intentionally “spiked” with gluten at levels < 20 ppm, the specificity is considerably lower; for a food “spiked” to a level in the 10 ppm range (still considered GF by regulatory standards), the device’s specificity is closer to 50% (11,12). Users of Nima have the option of pairing the device with their smartphones, enabling them to share test results with Nima and other users.

Study design

We examined all shared tests performed in the United States between August 2016 and January 2018. Each test included a date, time, restaurant name, address, food item tested, the presence or absence of a GF label, and test result. Using these parameters, we calculated rates of gluten detection by region, meal, median household income in the restaurant’s vicinity, restaurant genre, and specific foods.

For geographic analysis, we used the 4 regions used by the Census Bureau: Northeast (Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, Vermont), Midwest (Illinois, Indiana, Iowa, Kansas, Michigan, Minnesota, Missouri, Nebraska, North Dakota, Ohio, South Dakota, Wisconsin), South (Alabama, Arkansas, Delaware, District of Columbia, Florida, Georgia, Kentucky, Louisiana, Maryland, Mississippi, North Carolina, Oklahoma, South Carolina, Tennessee, Texas, West Virginia, Virginia), and West (Alaska, Arizona, California, Colorado, Idaho, Hawaii, Montana, Nevada, New Mexico, Oregon, Utah, Washington). For analysis by meal, we defined breakfast time as 5 AM–10:59 AM, lunchtime as 11 AM–2:59 PM, and dinner time as 3 PM–11:59 PM. Median household income in a restaurant’s vicinity was extrapolated from zip codes and the 2016 American Community Survey. Zip codes were ranked by median household income and then divided into quartiles.

Building on previous methods used in the neighborhood food environment literature, we categorized restaurants into quick service, fast casual, and casual dining (13). We did this by cross-referencing the restaurants in our dataset with a list of nearly 400 restaurant chains sorted by restaurant type. We made this list by combining several annual lists of top chains from Technomics (a consulting firm for the restaurant industry; Chicago, IL) and Dun

& Bradstreet (a company that tracks commercial data; Short Hills, NJ), with results from Google searches of “CITY NAME and Top Fast Food Restaurants.” Although we were able to sort several restaurants into additional categories using this methodology (fine dining, sweets, and coffee establishments), these categories were not included in the analysis because of a low number of tests performed in these settings.

The names of specific foods were free-texted by users. Given this heterogeneity, we classified foods manually, first reviewing the data to identify common dishes and then assigning each test to a food category. We excluded tests that included more than one food item, and we restricted our analysis to food types with >100 tests.

Statistical analyses

All statistical analyses were performed in SAS University Edition (SAS Institute, Cary, NC). For bivariate analyses, categorical variables were compared using the χ^2 test. For multivariate analyses, we used multiple logistic regression, adjusting for region, median household income, and meal time, for calculating odds ratios (ORs) and 95% confidence intervals (CIs). A 2-tailed *P* value of <0.05 was considered statistically significant. This study was deemed “not human subjects research” by the Institutional Review Board of Columbia University Medical Center because data were deidentified before being provided to the investigators.

RESULTS

General characteristics of gluten tests

During the study period, there were 5,624 tests performed by 804 users. Eighty-four percent of tested foods carried a GF label (Table 1). Fifty-nine percent of tests were performed during dinner hours; 27% were during lunch hours; about 11% were during breakfast hours; and 3% of tests were done outside of

Table 1. General characteristics of Nima tests

| | |
|--|---------------|
| GF label | |
| Yes | 4,732 (84.1%) |
| No | 892 (15.9%) |
| Time of day/meal | |
| Breakfast (5 AM–10:59 AM) | 635 (11.3%) |
| Lunch (11 AM–2:59 PM) | 1,494 (26.6%) |
| Dinner (3 PM–11:59 PM) | 3,327 (59.2%) |
| Other (12 AM–4:59 AM) | 168 (3.0%) |
| Region | |
| Northeast | 980 (17.4%) |
| South | 1,378 (24.5%) |
| Midwest | 690 (12.3%) |
| West | 2,576 (45.8%) |
| Median household income, zip code quartile | |
| First (lowest) | 423 (7.7%) |
| Second | 622 (11.3%) |
| Third | 1,027 (18.6%) |
| Fourth (highest) | 3,449 (62.5%) |
| GF, gluten-free. | |

these hours. Tests were reported from 50 states. The greatest number of tests was performed in the West, accounting for about 46% of the data, followed by the South, accounting for another 25%. Regarding the distribution of data by median household income, most tests were performed at restaurants in the wealthiest quartile of zip codes, and 81% were performed in the wealthier half of zip codes.

Overall rate of gluten detection

In total, 32.2% of all foods in our study tested positive for gluten. The rate of gluten detection was essentially the same when we restricted this calculation to those 4,732 foods that were specifically labeled GF (32.0%).

Bivariate analysis of factors associated with gluten detection in GF labeled foods

After determining the overall rate of gluten detection, we searched for factors associated with detection of gluten in GF labeled foods. Through bivariate analysis, we found that rates of gluten detection did not differ significantly by region or median household income in the area around the restaurant. However, rates of gluten detection differed significantly by meal time, with 27% of GF labeled foods at breakfast testing positive for gluten, 30% at lunch, and 34% at dinner ($P = 0.0008$) (Table 2). Moreover, among restaurant types, fast casual had significantly lower rates of gluten detection (22%) when comparing this setting with all other foods tested ($P = 0.0063$). GF labeled pizza and pasta had the highest rates of gluten detection compared with all other tested foods, 53% ($P < 0.0001$) and 51% ($P < 0.0001$), respectively.

Multivariate analysis of factors associated with gluten detection in GF labeled foods

Multivariate analysis adjusting for region, median household income, and time of day revealed a decreased likelihood of gluten detection in the West as compared with the Northeast (OR 0.80, 95% CI 0.67–0.95, $P = 0.01$). There was also an increased likelihood of gluten detection at dinner as compared with breakfast (OR 1.46, 95% CI 1.18–1.81, $P = 0.0008$) (Figure 1).

Regarding restaurant types, GF labeled foods at casual (OR 0.79, 95% CI 0.65–0.97, $P = 0.02$) and fast-casual (OR 0.57, 95% CI 0.39–0.84, $P = 0.004$) restaurants were less likely to test positive for gluten when comparing these settings with all other foods tested. Consistent with the bivariate analysis, pizza (OR 2.54, 95% CI 2.04–3.16, $P < 0.0001$) and pasta (OR 2.14, 95% CI 1.48–3.10, $P < 0.0001$) were more likely than other GF labeled foods to have gluten detected (Figure 1).

DISCUSSION

In this study of crowd-sourced data, approximately one-third of restaurant foods labeled GF tested positive for gluten. Rates of gluten detection were highest during dinner hours and lowest during breakfast hours. The West was the region within the United States with the lowest rate of gluten detection. Likewise, casual and fast-casual restaurants stood out for lower rates of gluten detection. Pizza and pasta were the most likely to contain gluten, with more than 50% of samples testing positive.

Adherence to a GF diet is currently the only effective treatment for CD. Ingestion of as little as 50 mg of gluten per day can cause measurable damage to the small intestinal mucosa of patients with CD (14). As a result of the vigilance required to maintain

Table 2. Factors associated with detection of gluten in GF labeled foods^a

| | Gluten present in GF labeled food | P value |
|---|-----------------------------------|---------|
| Region | | |
| Northeast | 294/853 (34.5%) | |
| South | 382/1,188 (32.2%) | 0.0668 |
| Midwest | 205/595 (34.5%) | |
| West | 633/2096 (30.2%) | |
| Median household income quartile | | |
| First (lowest) | 95/343 (27.2%) | |
| Second | 157/503 (31.2%) | 0.2801 |
| Third | 297/914 (32.5%) | |
| Fourth (highest) | 942/2,877 (32.7%) | |
| Time of day/meal | | |
| Breakfast | 138/508 (27.2%) | 0.0008 |
| Lunch | 358/1,213 (29.5%) | |
| Dinner | 977/2,873 (34.0%) | |
| Restaurant type | | |
| Casual | 158/552 (28.6%) | 0.0708 |
| Fast casual | 37/166 (22.3%) | 0.0063 |
| Quick service | 67/201 (33.3%) | 0.6767 |
| Food item | | |
| French fries | 53/175 (30.3%) | 0.6213 |
| Pizza | 199/374 (53.2%) | <0.0001 |
| Salad | 78/261 (29.9%) | 0.4522 |
| Dessert | 59/195 (30.3%) | 0.5951 |
| Burger | 50/165 (30.3%) | 0.6353 |
| Soup | 35/125 (28.0%) | 0.3318 |
| Taco | 32/110 (29.1%) | 0.5088 |
| Pasta | 62/122 (50.8%) | <0.0001 |
| Vegetables | 22/94 (23.4%) | 0.0713 |
| Fish | 29/98 (29.6%) | 0.6063 |
| GF, gluten-free. | | |
| ^a P values derived from χ^2 tests. In the case of restaurant type and food items, 2×2 χ^2 tests were performed, comparing each restaurant/food item with all other tested foods not in that classification. | | |

a truly GF diet, the burden of treatment of CD is high. Patients with CD rated their burden of treatment higher than patients with hypertension did, similar to patients with diabetes and end-stage renal disease (15). Multiple studies cite exposure to gluten while dining out as a leading source of anxiety for patients with CD (5,9,10). Our study results lend some credence to widespread anecdotal reports offered by patients with symptoms suggestive of gluten exposure after eating in restaurants, although recent work has shown that symptoms are poorly predictive of mucosal injury (16).

Beyond suggesting an overall high rate of gluten contamination at restaurants, we identified several specific associations with

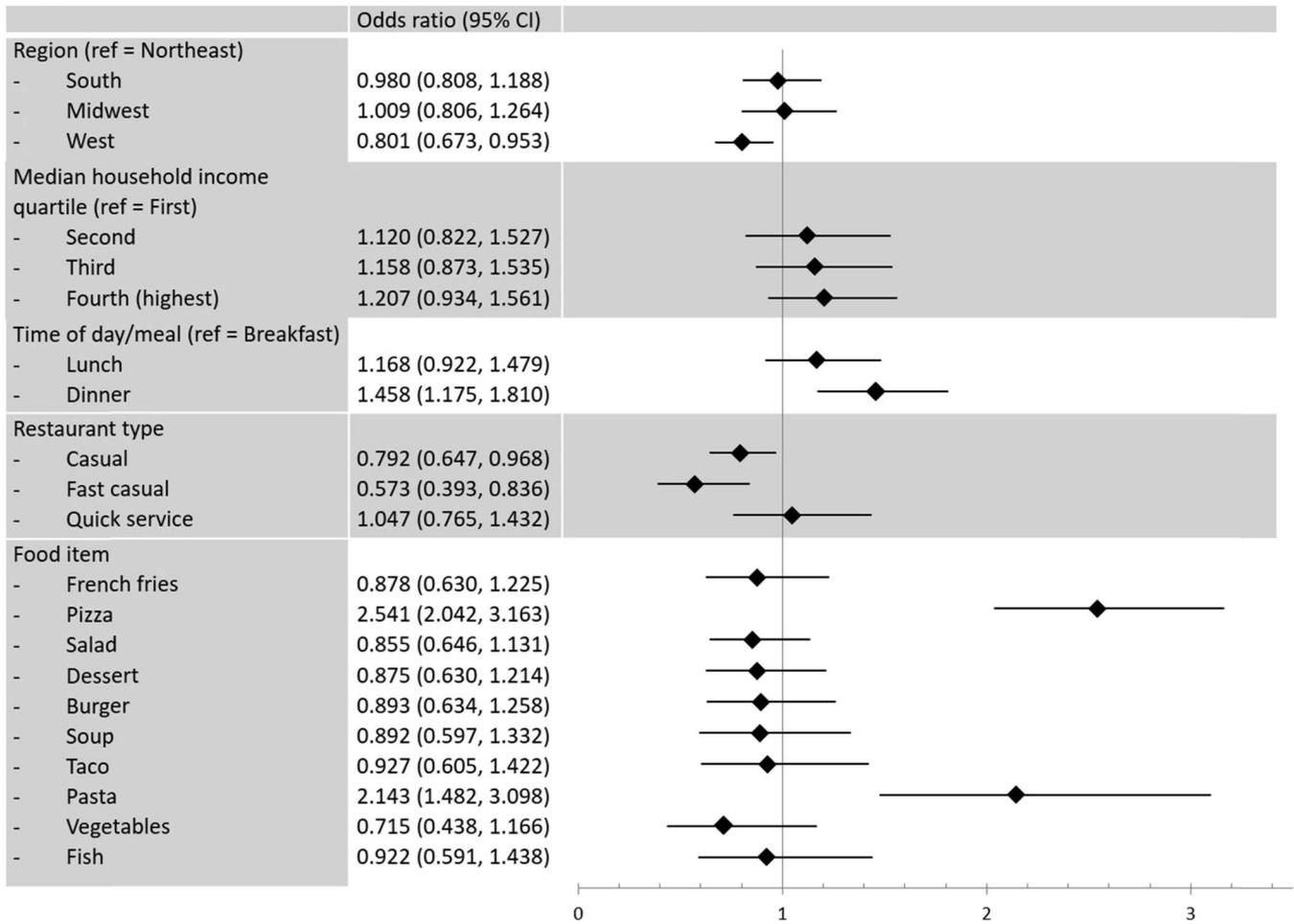


Figure 1. Multivariate analysis of factors associated with detection of gluten in GF labeled foods. ORs for region, median household income, and time of d/meal were mutually adjusted. Analyses for the restaurant type and food items were run for each type/item vs all the other types/items combined and adjusted for region, median household income, and time of d/meal. Analysis of food items was limited to food items with >100 tests. GF, gluten-free; OR, odds ratio.

higher or lower rates of gluten detection. For example, lower rates of gluten contamination were found in the West. Although data are sparse regarding regional differences in interest and knowledge about GF diets, higher rates of produce consumption and overall healthy lifestyle have been reported in the West (17), suggesting that people living in the Western United States may be more health-conscious and thus more knowledgeable about diets perceived to be healthy. We previously found that the ratio of non-celiac gluten sensitivity to CD appears to be highest in the Western United States (18). Given the rapid rise in gluten avoidance in recent years, outpacing the rise in CD diagnosis (19), regional differences in the rise of non-celiac gluten sensitivity might yield greater awareness among both diners and restaurant staff. Food workers may take better precautions to guard against cross-contamination, and diners may make safer selections, such as avoiding salad dressings that are at risk of contamination.

Our finding of higher rates of gluten detection during dinner hours may reflect cumulative contamination of GF ingredients and/or equipment over the course of the day. It is not entirely clear why pizza and pasta were more likely to test positive for gluten than other GF labeled foods. GF pizza may become contaminated by aerosolized wheat flour during various stages of

production. Sharing of ovens with gluten-containing pizza is a common concern, although a recent study suggests that it is not an inevitable setting for contamination (20). Although gluten is generally poorly soluble in water, it is possible that GF pasta may become contaminated by being cooked in the same water as conventional pasta. Alternatively, it is possible that the sauce on GF pizza or pasta is responsible for the detected gluten content. Although these are both basic precautions, knowledge deficits among food preparers are likely considerable; indeed, a 2010 survey found that 23% of chefs had not heard of CD, and a significant minority incorrectly believed that peanut butter and wine contain gluten (9).

Lower rates of gluten detection at casual and fast-casual restaurants were an unexpected finding. The survey of chefs referenced above found a direct relationship between average check price and chefs' awareness of CD (9). One might therefore have expected more expensive restaurants to have lower rates of gluten contamination. Conversely, less expensive/chain restaurants may have more standardized training of their personnel regarding gluten contamination. Admittedly, our analysis of restaurant genre was limited by the fact that only one-fifth of all tests came from chain restaurants that were categorizable. Despite this

limitation, it is fair to conclude that less expensive restaurants and chain restaurants do not fair worse than their more expensive and independent counterparts regarding gluten contamination.

As alluded to above, the vigilance required to maintain a strictly GF diet can be the source of significant anxiety. In fact, anxiety is more common in patients with CD who have achieved mucosal healing on follow-up biopsy, which is a reflection of strict adherence (21). Similarly, patients with CD classified as “hyper-vigilant” in their efforts to avoid gluten have been found to report lower quality of life than their less vigilant counterparts (22). So as to not cause undue alarm, it is therefore important to note the limitations of these results.

First, our study did not involve systematic testing of all GF restaurant foods; it was a crowd-sourced study, and the foods tested could have been conceivably chosen specifically because of doubts regarding their GF status. Furthermore, Nima users may be more inclined to share “gluten-found” than “gluten-free” results. Perhaps more importantly, our study relied on data from a portable gluten detection device that variably reports “gluten-found” at levels less than 20 ppm. Although a recent study from the makers of Nima reported a 7.8% false-positive rate, they defined false-positive as gluten being detected when the food actually contained less than 2 ppm gluten, although 20 ppm is the widely recognized threshold for packaged GF foods (11). Similarly, a third-party evaluation of Nima found the device frequently detects gluten at levels of 5 and 10 ppm (12). This high level of sensitivity may protect patients with CD from potentially harmful gluten that may be present in greater quantity given the nonhomogenized sampling inherent in point-of-care restaurant testing, but this same feature may also overestimate the prevalence of contamination of foods with >20 ppm of gluten. The accuracy of our reported rates of gluten contamination is critically dependent on the underlying distribution of gluten concentrations (i.e. the percentage of positive tests containing 10, 30, or 300 ppm), data that are unknown in restaurant foods. However, even if we were to assume that only half of the reported positive tests contained >20 ppm, cutting our estimated rate of contamination from 32% to 16%, that would still be triple the rate quantified for packaged GF labeled foods (23). In addition, the differences we found between regions, time of day, and specific foods are unlikely to be differentially affected by overestimation resulting from a hypersensitive sensor.

It is also important to consider the clinical significance of our findings. In CD, intestinal damage is related to the quantity of ingested gluten, not its concentration within food. Therefore, eating a single food portion with >20 ppm gluten will not necessarily cause symptoms or villus atrophy. Rather, the 20-ppm threshold is valuable because it keeps the intake of gluten below potentially toxic quantities (which vary between individuals but are commonly injurious at levels of 50 mg per day) (14).

Despite the above caveats, this study provides much needed data for patients with CD and the healthcare providers who treat and advise them. The crowd-sourced nature of these data provides an unprecedented view of restaurant testing of food throughout the United States. As such, this is the largest study to date on gluten contamination of restaurant foods. It capitalizes on a newly available technology and reveals that a significant percentage of GF labeled restaurant foods contain detectable levels of gluten. Our findings of increased gluten detection in pizza, pasta, and evening hours lend themselves to practical advice for patients with CD and also hint at possible

mechanisms of contamination. Future studies should focus on quantifying the degree of gluten contamination in specific foods and the development of interventions for reducing gluten contamination in restaurants.

CONFLICTS OF INTEREST

Guarantor of the article: Benjamin Lebwohl, MD, MS.

Specific author contributions: B.A.L., P.H.R.G., and B.L.: planning and conducting the study. B.A.L., L.P.V., S.Y., A.G.R., P.H.R.G., and B.L.: collecting and/or interpreting the data. B.A.L.: drafting the manuscript. B.A.L., L.P.V., S.Y., A.G.R., P.H.R.G., and B.L.: critically reviewing and revising the manuscript.

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Potential competing interests: B.L. serves as a consultant for Takeda and serves on the Advisory Board of Innovate Biopharmaceuticals. S.Y. is the Chief Executive Officer of Nima. B.L. and P.G. are both unpaid members of Nima’s Scientific Advisory Board.

Study Highlights

WHAT IS KNOWN

- ✓ Adherence to a GF diet is the mainstay of therapy for CD.
- ✓ Exposure to gluten while dining out is a major barrier to quality of life for patients with CD.

WHAT IS NEW HERE

- ✓ We used crowd-sourced data from users of a portable gluten detection device to estimate rates of and identify risk factors for gluten contamination of supposed GF restaurant foods.
- ✓ Approximately one-third of restaurant foods labeled GF contained detectable levels of gluten.
- ✓ Rates of gluten detection were highest during dinner hours.
- ✓ Pizza and pasta were the foods most likely to contain gluten, with more than 50% of samples testing positive.

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