



Unmet Need In Celiac Disease -Patients' Views

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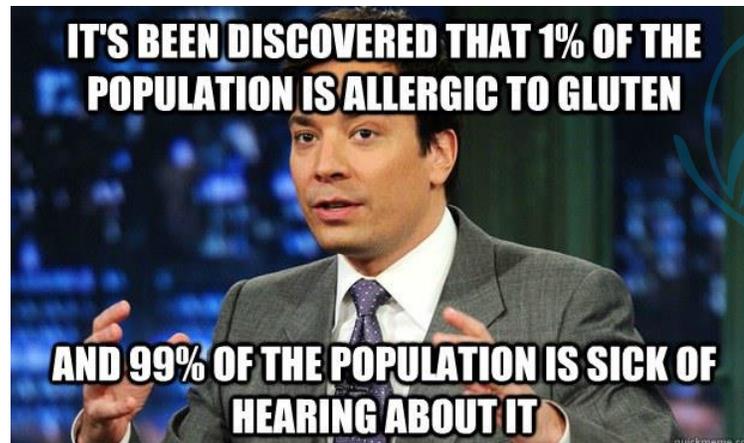
How the USA Views Celiac Disease



sewprickly
@kelsi_metoxen

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@PartyCity your new ad mocking people who eat gluten free is inconsiderate and wrong at best. My celiac disease is not your punchline.
youtu.be/4x92O_ez2gs 🙄 😡



Celiac Disease
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Celiac Disease Patients Want To Be Taken Seriously



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CeD Patients Want Physician Education, Research Funding for Treatments and Cure, and Gluten Disclosure in Foods and Medicines

- ▶ **Testify before Congressional Committee for celiac disease research funding**
 - ▶ 800+ stories of delayed diagnosis, gluten-free diet struggle, ongoing symptoms, and need for therapeutic treatments and a cure
 - ▶ Committee Chair: *“I have a colleague here who has celiac disease and I watch how carefully she eats. I don’t think it is taken as seriously, and that it is not on a radar screen. Your spotlighting of this gives me an understanding of how serious this disease is, and how seriously we need to respond to it.”*
- ▶ **Lobby for Gluten Disclosure in Medicine**
 - ▶ 22,000 emails sent to Congress
 - ▶ 34 cosponsors
 - ▶ Liaise with Food and Drug Administration (FDA)

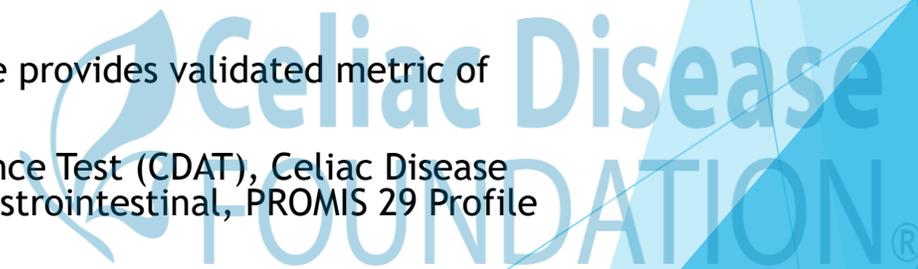


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iCureCeliac[®] Online Patient Registry - USCIRB

Launched in 2016 with government funding, iCureCeliac[®] is the Celiac Disease Foundation's online registry for patients to provide self-reported critical insights into life with celiac disease, including information on:

- ▶ **Diagnostic journey and current monitoring of celiac disease**
 - ▶ Tests to confirm diagnosis, reason/how diagnosed
 - ▶ Number and type of healthcare providers seen and diagnostic delay
 - ▶ Current disease management and frequency of visits
- ▶ **Adherence to the gluten-free diet and treatment preferences**
 - ▶ Self rated “strict gluten-free diet” and validated measure of adherence
 - ▶ Frequency of inadvertent and intentional gluten exposure
 - ▶ Interest in hypothetical treatments based on route of admission, frequency, and cost
- ▶ **Quality of life and burden of disease**
 - ▶ Patient-reported outcome (PRO) measure of quality of life provides validated metric of celiac disease burden
 - ▶ Celiac Symptoms Index (CSI), Celiac Dietary Adherence Test (CDAT), Celiac Disease Quality of Life Measure (CD-QOL), SF-36, PROMIS Gastrointestinal, PROMIS 29 Profile and PROMIS Pediatric 25 Profile
 - ▶ Impact on activities of daily living and social interactions
 - ▶ Includes number of work/school days missed due to celiac disease



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What is iCureCeliac®?

iCureCeliac® is a free online registry for patients, or their caregivers, to provide critical insights into life with celiac disease and gluten/wheat sensitivity to help researchers improve treatments and find a cure.

The First 2 Years

44%

of participants claim their health has not significantly improved since their diagnosis.

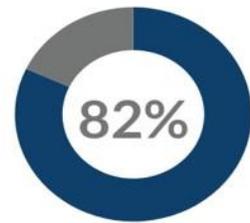
93%

of participants are interested in a celiac disease treatment other than the gluten-free diet.

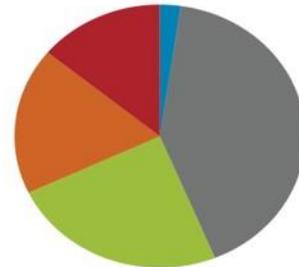
46%

of participants saw three or more healthcare providers for their gluten-related disorder prior to diagnosis.

5,000+ participants have entered data so far... **2018 Results**

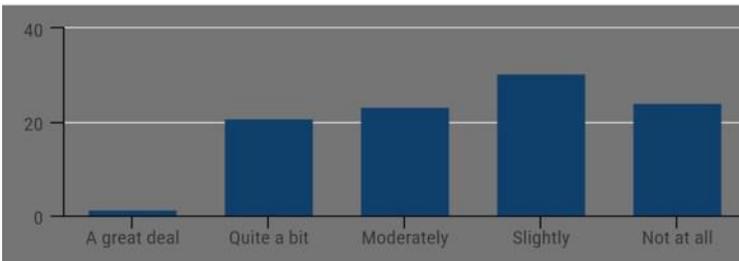


82% of participants feel limited by their gluten-related disorder.



Percentage of participants who feel socially stigmatized for having a gluten-related disorder.

● A great deal (2.3%) ● Quite a bit (41.4%) ● Moderately (24%)
● Slightly (18%) ● Not at all (14%)



Percentage of participants who feel they cannot live a normal life because of their gluten-related disorder.

January 2018



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Adherence to the gluten-free diet and celiac disease patient outcomes: real-world evidences from an international patient registry, iCureCeliac®¹

- ▶ Biopsy Reported Celiac Disease (N=2327)
- ▶ Celiac Symptoms Index and Celiac Dietary Adherence Test (N=522)
 - ▶ Demographics
 - ▶ 81% Female
 - ▶ 31.3 Mean age of Diagnosis
 - ▶ 5 years mean time since CeD Diagnosis
 - ▶ 94.6% White
 - ▶ Geographically diverse US population
 - ▶ 75% diagnosed due to presence of symptoms
 - ▶ 55% saw 3+ healthcare practitioners prior to diagnosis, 21.5% saw 5+
 - ▶ 22% self managing care
 - ▶ 24% report low disease symptom burden, 33% report high disease burden



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¹Jennifer Drahos, Kaili Ren, Marilyn G. Geller, Song Wang, Daniel A. Leffler.

Symptom Burden and Gluten-Free Diet (GFD) Adherence

Celiac Symptom Index (CSI)	Overall (N=522)	Excellent GFD Adherence (CDAT≤12) (N=262)	Fair GFD Adherence (CDAT≤16) (N=181)	Poor GFD Adherence (CDAT≥16) (N=79)
Low Disease Symptom Burden (CSI≤30)	126 (24.1%)	108 (41.2%)	18 (9.9%)	N/A
Moderate Disease Symptom Burden (31≤CSI≤44)	239 (45.8%)	130 (49.6%)	80 (44.2%)	29 (36.7%)
High Disease Symptom Burden (CSI≥45)	157 (30.1%)	24 (9.2%)	83 (45.9%)	50 (63.3%)

Quality of Life and Annual Work/School Days Missed By Disease Symptom Burden

Celiac Symptom Index (CSI)	Celiac Disease Quality of Life (CD-QOL), mean (SD)	Annual work/school days missed owing to gluten exposures, mean (SD)
Low Disease Symptom Burden (CSI ≤ 30) (N=126)	72.0 (11.9) (N=121)	5.7 (7.1) (N=39)
Moderate Disease Symptom Burden (31 ≤ CSI ≤ 44) (N=239)	61.0 (13.2) (N=230)	12.0 (24.2) (N=129)
High Disease Symptom Burden (CSI ≥ 45) (N=157)	54.0 (12.5) (N=148)	37.1 (68.4) (N=112)



Annual Work/School Days Missed By Symptom Burden and GFD Adherence

Celiac Symptom Index (CSI)	Excellent GFD Adherence (CDAT ≤ 12) (N=262)	Fair GFD Adherence (13 ≤ CDAT ≤ 16) (N=181)	Poor GFD Adherence (CDAT > 16) (N=79)
Low disease symptom burden (CSI ≤ 30) (N=126)	5.6 (7.3) (N=35)	7.0 (5.5) (N=4)	N/A
Moderate disease symptom burden (31 ≤ CSI ≤ 44) (N=239)	7.2 (11.2) (N=64)	15.3 (28.7) (N=52)	22.5 (42.1) (N=13)
High disease symptom burden (CSI ≥ 45) (N=157)	21.3 (36.2) (N=18)	39.0 (75.9) (N=58)	42.1 (68.4) (N=36)

Accidental Gluten Exposure

- ▶ Most patients understood that accidental exposure to gluten had a negative impact on their health, however, 74% had accidental gluten exposure in the last 30 days.
- ▶ Despite excellent adherence to a GFD (CDAT \leq 12); 62.1% of patients with CeD still had accidental exposure in the past 30 days.

Significant Unmet Patient Needs in CeD

- ▶ **Education of Primary Care Physicians to Assure Prompt Diagnosis and Follow-Up Care**
 - ▶ Standardization of diagnostic and treatment guidelines
- ▶ **Better Monitoring Tools**
 - ▶ 96% reported “always or often” maintaining a strict GFD BUT only 41% reported low symptom burden
- ▶ **Better Treatment Options**
 - ▶ Half of the patients with CeD in the study were unable to effectively adhere to a GFD
 - ▶ Symptom burden is strongly and inversely correlated with quality of life
 - ▶ Despite adherence to a GFD, many patients still had persistent high symptom burden and reduced quality of life
 - ▶ Inadvertent gluten exposure results in significant loss of productivity
 - ▶ 93% of iCureCeliac® patients want a treatment other than a GFD





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Celiac Disease Symposium

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SEPTEMBER
5th - 7th, 2019

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