Patient burden and treatment experience in celiac disease

Benjamin Lebwohl [1], David S Sanders[2], Heidi Urwin[3], Marilyn G. Geller[4], Song Wang[5], Sarah Clifford[6], Hannah Lewis[7], Margaret Cho[6], Diandra Latibeaudiere[7], Vivien Ong[6], Daniel A. Leffler[5]

[1] Celiac Disease Center, Columbia University Medical Center, NY, USA; [2] Royal Hallamshire Hospital and University of Sheffield, UK; [3] Coeliac UK, Bucks, UK; [4] Celiac Disease Foundation, Woodland Hills, CA, USA; [5] Takeda Pharmaceuticals International Co., Cambridge MA USA; [6] ICON plc., South San Francisco, CA, USA; [7] ICON plc., London, UK

00087

Background

- Currently, strict adherence to a Gluten-Free Diet (GFD) is the sole treatment option for patients with celiac disease (CeD). Despite GFD adherence, many patients' CeD symptoms and complications persist, compelling the use of medical services, which is in addition to the costs of maintaining a GFD.[1–5]
- Few studies have explored patients' perceptions of the extent of the symptom and treatment-related burden of CeD, which is important for further development of treatments for CeD.

Study objective

- To assess the burden of CeD and treatment experience through a patient survey.

Methods

- A cross-sectional burden of illness survey was conducted in collaboration with patient advocates, clinicians, outcomes researchers and patients with CeD.
- Survey content was informed by CeD literature and patient interviews (n=10), recruited via advocacy groups. Sixty-minute interviews were conducted to obtain insight into CeD symptoms and impacts, obstacles to GFD adherence, and key concepts for inclusion in the survey.
- The online survey was pilot tested with 5 patients to evaluate comprehensiveness and usability prior to launch.
- Survey content:
  - De novo questions were developed to evaluate issues such as: pathway to diagnosis, barriers to health care resources, symptoms, complications, comorbidities and diet.
  - Several patient-reported outcome (PRO) measures were included to assess core concepts related to CeD experience:
    - » CeD symptoms: Celiac Symptom Index (CSI)[6]
    - » Impact of CeD symptoms: Impact of Celiac Disease Symptom Questionnaire (ICDSQ)[7]
    - » Adherence to a GFD: Celiac Dietary Adherence Test (CDAT)[8]
    - » Impact of a GFD: Impact of a Gluten-Free Diet Questionnaire (IGFDQ)[7]
    - » Work productivity/impairment: Work Productivity and Activity Impairment Questionnaire: Specific Health Problem (WPAI-SHP)[9]
    - » Overall health-related quality of life (HRQoL): PROMIS Global Health (Physical, Mental)[10]
- Participants from the USA were recruited through online panels and recruiters to complete the survey. Adult patients were eligible to participate if they had self-reported biopsy-confirmed CeD (or serology with family history of CeD) and were on a GFD for at least 6 months.
- Data were analyzed using SAS v9.4 to produce descriptive summary statistics.

Table 1. Sociodemographic and clinical characteristics

Characteristic	USA (N=100)
Age – mean (SD)	37.2 (10.6)
Gender – female, n (%)	60 (60.0)
Race, n (%)	
White – Caucasian or White other	78 (78.0)
Black – Caribbean/African/African-American or Black other	5 (5.0)
Asian – Chinese or Asian other	3 (3.0)
American Indian or Alaska Native	8 (8.0)
Other	6 (6.0)
Ethnicity, n (%)	
Hispanic or Latino	22 (22.0)
Employment status, n (%)	
Employed full-time	68 (68.0)
Employed part-time	10 (10.0)
Studentw	8 (8.0)
Seeking employment	1 (1.0)
Unemployed	1 (1.0)
Retired	2 (2.0)
Self-employed	4 (4.0)
Stay at home	6 (6.0)
Education, n (%)	
No formal qualifications	1 (1.0)
Left school between age 16-18 with qualifications (GCSEs, high school diploma, GED or equivalent)	6 (6.0)
Technical/vocational qualification from a college or job	10 (10.0)
2-year college diploma	20 (20.0)
Bachelor's degree	41 (41.0)
Graduate degree (master's, doctoral, professional)	18 (18.0)
Other	4 (4.0)
Marital status, n (%)	
Single	25 (25.0)
Partnership	5 (5.0)
Married	66 (66.0)
Divorced/separated	4 (4.0)
Self-reported symptom severity, n (%)	
Mild	27 (27.0)
Moderate	30 (30.0)
Severe	31 (31.0)
Very severe	12 (12.0)

GCSE, General Certificate of Secondary Education; GED, General Educational Development.

Figure 1. Most commonly reported obstacles to maintaining a GFD

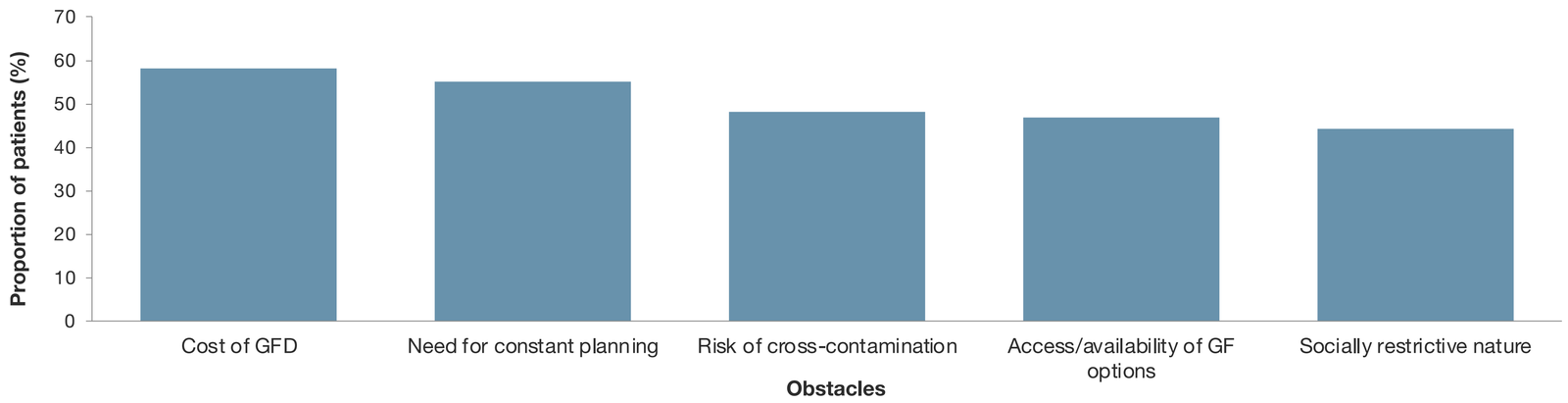
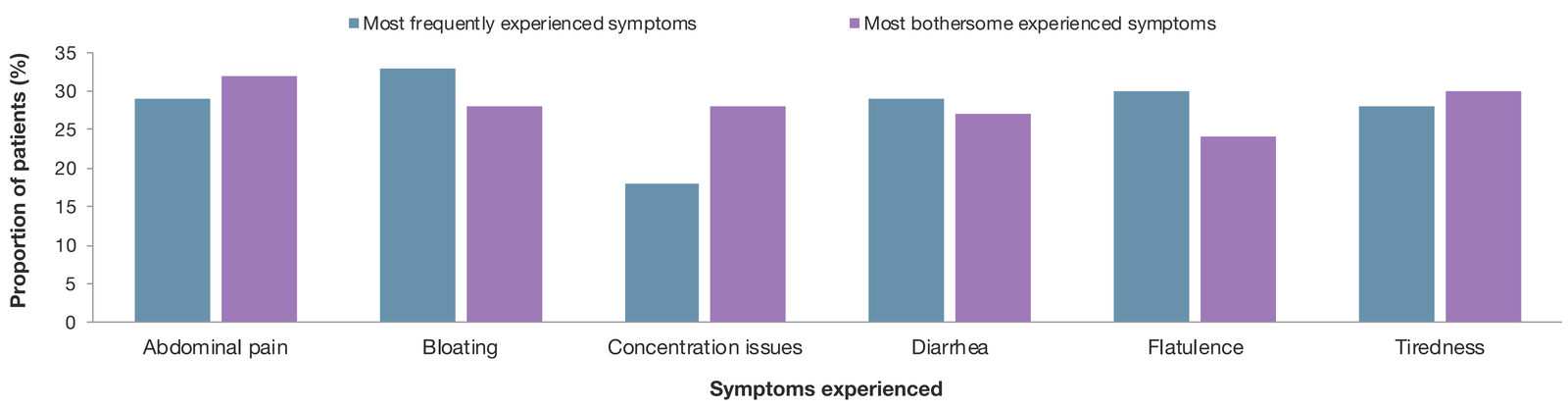


Figure 2. Most frequent and bothersome symptoms experienced (reported as "quite a bit" or "very much" in the past month)



Results

Demographic and clinical characteristics

- One-hundred US participants (60% via online panels, 40% via recruiters) completed the survey, with 27% self-reporting their CeD as mild, 30% as moderate, 31% as severe and 12% as very severe. Participants' demographics are presented in **Table 1**. 80% were diagnosed by biopsy (20% serology alone) and mean (standard deviation [SD]) time since diagnosis was 8.6 (9.2) years.

Diagnosis experience

- Patients reported experiencing symptoms or complications, on average, for 4.6 years before obtaining diagnosis. Most common symptoms leading to diagnosis were abdominal pain (69%), diarrhea (64%), bloating (46%), acid reflux (36%) and nausea (34%), with abdominal pain (55%) noted as the most bothersome.
- On average, it took 2.2 years for patients to receive a confirmed diagnosis. Obstacles to prompt diagnosis included: physician's lack of awareness of CeD (35%), lack of time or delay in seeking care (33%), misdiagnosis of another condition (27%) and barriers to healthcare such as cost/access (27%).

Follow-up care and adherence to a GFD

- 76% of patients were referred to a gastroenterologist after diagnosis, and approximately one-quarter received a referral to a dietician (26%) or nutritionist (22%).
- Most patients (76%) reported adhering "often" or "always" to a GFD, with roughly half (52%) finding adherence to be "somewhat" to "very much" difficult. Most common obstacles to maintaining a GFD are presented in **Figure 1**.

Symptoms and disease burden

- 75% of patients reported experiencing CeD symptoms more than once per month, and 57% reported at least one episode of symptomatic gluten exposure within the last month.
- As seen in **Figure 2**, the most commonly reported symptoms experienced either "quite a bit" or "very much" over the past month included bloating (33%), flatulence (30%), diarrhea (29%), abdominal pain (29%) and tiredness (28%); the most bothersome of these symptoms was abdominal pain (32%) followed by bloating (28%).

PRO instrument results

- As seen in **Table 2**, mean (SD) CSI and ICDSQ scores suggest symptom burden and impact on daily functioning.
- Mean CDAT scores suggest fair to poor adherence, while mean IGFDQ scores indicate the impact of a GFD on dietary choices, social activities and emotional wellbeing. Thirty-one patients had excellent/very good adherence (CDAT<13).
- Mean WPAI-SHP percentage scores for absenteeism, impairment while working, work productivity loss and overall activity impairment were as follows: 18.4, 39.9, 47.4, and 44, respectively. As comparisons, the US general population estimates are 3.5, 13.0, 15 and 22.1, and estimates for patients with Crohn's disease (CD) are 19.5, 42, 47.5, and 53.5.[11,12]
- Mean (SD) PROMIS physical and mental health T-scores were 44.2 (7.5) and 47.0 (8.8), respectively, which are similar to the US average of 50 for each.

Study limitations

- Selection bias may exist as participants were recruited through patient advocacy organizations and specialist patient recruitment agencies.
- Potential recall bias from self-reported information.

Table 2. PRO instrument scores

PRO measure (N=100)*	Mean (SD)	Median (IQR)
CSI[a] total score	41.7 (11.8)	42.0 (14.0)
ICDSQ[b] total score	7.3 (4.5)	7.1(6.1)
Daily activities score	1.8 (1.2)	1.6 (1.5)
Social activities score	1.8 (1.2)	2.0 (1.7)
Emotional wellbeing score	1.9 (1.2)	1.8 (1.8)
Physical functioning score	1.8 (1.3)	2.0 (2.0)
CDAT[c] total score	15.6 (4.7)	16.0 (6.5)
IGFDQ[d] total score	5.9 (3.3)	5.6 (4.4)
Dietary choices score	2.1 (1.2)	2.0 (1.2)
Social activities score	1.9 (1.2)	2.0 (2.0)
Emotional wellbeing score	1.8 (1.1)	1.8 (1.7)
WPAI-SHP[e] absenteeism score (n=81)	18.4 (24.0)	9.1 (26.3)
Presenteeism (impairment while working) score (n=80)	39.9 (27.8)	45.0 (50.0)
Work productivity loss score (n=80)	47.1 (31.0)	52.9 (53.3)
Activity impairment score	44.0 (26.4)	50.0 (30.0)
PROMIS[f] physical health t-score	44.2 (7.5)	42.3 (9.1)
Mental health t-score	47.0 (8.8)	45.8 (12.2)

*Sample size n=100 for each instrument, unless otherwise specified (e.g. WPAI-SHP). [a]CSI scores range from 16 to 80, with higher scores indicating higher severity in symptoms and reduced HRQoL. [b]ICDSQ includes 4 domain scores, each ranging from 0 to 4. The total score, calculated by averaging the domain scores, ranges from 0 to 16, with high scores suggesting high level of symptom impacts. [c]CDAT scores range from 7 to 35, with lower scores suggesting better adherence. A total score of 13 suggests excellent or very good GFD adherence, while a total score of >17 suggest fair to poor adherence to GFD. [d]IGFDQ includes 3 domain scores, each ranging from 0 to 4. The total score, by averaging the domain scores, ranges from 0 to 12 with high scores suggesting high impact. [e]WPAI-SHP elicits 4 scores expressed as percentages (0 to 100%), with higher values indicating greater impairment and less work productivity. [f]PROMIS Global Health scores range from 16.2–67.7 for physical health and 21.2–67.6 for mental health, with higher scores indicating better health. IQR, interquartile range.

Conclusions

- The US sample reported experiencing significant obstacles to prompt diagnosis, inconsistencies in follow-up care, and some level of difficulty adhering to a strict GFD.
- Despite adhering to a GFD, many patients reported experiencing a range of symptoms, with bloating, flatulence, abdominal pain, diarrhea and tiredness being the most frequently reported.
- Overall, results suggest that CeD impacts daily functioning, creates impairment while working and reduces work productivity. WPAI-SHP scores are much higher than the general population estimates, suggesting relatively high impairment comparable to the experience of CD patients, while PROMIS scores were similar to the US average.

References

1. Rubio-Tapia A et al. *Am J Gastroenterol* 2013;108:656–76.
2. Guandalini S et al. *Dig Dis Sci* 2016;61:2823–30.
3. Ukkola A et al. *BMC Gastroenterol* 2012;12:136.
4. Missbach B et al. *PeerJ* 2015;3:e1337.
5. Burden M et al. *Postgrad Med J* 2015;91:622–6.
6. Leffler DA et al. *Clin Gastroenterol Hepatol* 2009; 7(12):1328–34.
7. Acaster S et al. Celiac specific instrument development stage 3: psychometric validation, 2011 [Report].
8. Leffler DA et al. *Clin Gastroenterol Hepatol* 2009;7(5): 530–36.
9. Reilly MC et al. *PharmacoEconomics* 1993;4(5):353–65.
10. Hays RD et al. *Quality of Life Research* 2009; 18(7):873–80.
11. Witt EA et al. *Value in Health* 2015;18(3):A176.
12. Reilly MC et al. Poster presented at ISPOR 9th Annual European Congress, 28–30 October 2006, Copenhagen, Denmark.

Disclosures

This study was funded by Takeda Pharmaceuticals International, 40 Landsdowne Street, Cambridge, MA 02139 US. Poster was developed with assistance from Oxford Pharmagenesis.

Acknowledgments

We are very grateful to all the patients who participated in this study.

Presented at the 18th International Celiac Disease Symposium • September 5-7, 2019 • Paris, France

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

Jennifer Drahos,[1] Kaili Ren,[1] Marilyn G. Geller,[2] Song Wang,[1] Daniel A. Leffler[1,3]

[1]Takeda Pharmaceuticals USA, Inc., IL, USA; [2]Celiac Disease Foundation, CA, USA;
[3]Beth Israel Deaconess Medical Center, MA, USA

P2-14

Background

- Celiac disease (CeD) is a chronic, multisystem autoimmune disease of the small intestine, in which ingestion of dietary gluten triggers an inflammatory response in genetically susceptible individuals.
- The incidence of CeD in Europe and the USA has been estimated at between 11.8 and 17.4 per every 100,000 persons per year,[1,2] consistent across adults and children (<16 years of age).
- Globally, the prevalence of CeD was shown to be 0.5–1%.[3,4]
- At present, the only option for patients with CeD is a strict, lifelong adherence to a gluten-free diet (GFD), which involves complete avoidance of proteins from wheat, barley, and rye.
- Few studies have evaluated GFD adherence and its association with patient outcomes.

Study objectives

- To assess the real-world adherence to GFD in patients with CeD and the associated patient outcomes.

Methods

- A retrospective cohort analysis (**Figure 1**).

Data source

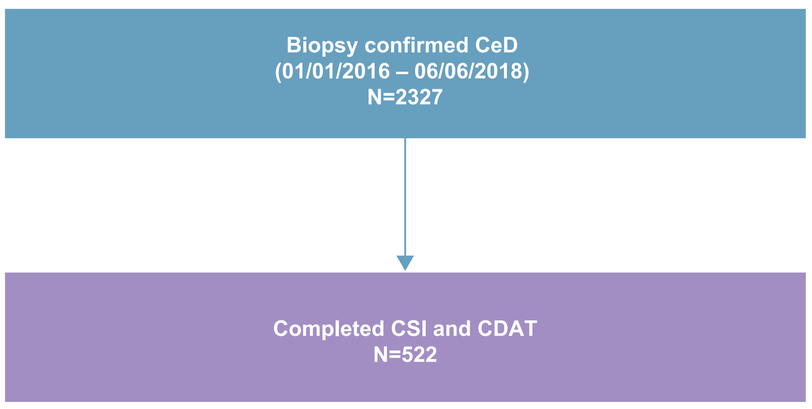
- iCureCeliac®, founded in 2016 by the Celiac Disease Foundation, is an online registry for patients to provide self-reported critical insights into living with CeD, including information on:

Diagnostic journey and current monitoring of CeD
- Tests to confirm diagnosis, reason for diagnosis (e.g. symptomatic)
- Number and type of healthcare professionals (HCPs) seen and diagnostic delay
- Current disease management and frequency of visits

Adherence to the GFD and treatment preferences
- Self rated "strict GFD" 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
- A patient-reported outcome (PRO) measure of quality of life provides a validated metric of the burden of CeD
  - Celiac Symptoms Index (CSI), Celiac Dietary Adherence Test (CDAT), Celiac Disease Quality of Life Measure (CD-QOL), SF-36, Patient-Reported Outcomes Measurement Information System (PROMIS) Gastrointestinal, PROMIS 29 Profile, and PROMIS Pediatric 25 Profile
- Impact on activities of daily living and social interactions
- Number of work/school days missed owing to CeD.

Figure 1. Study cohort



CDAT, Celiac Dietary Adherence Test; CeD, celiac disease; CSI, Celiac Symptoms Index

Results

- A high proportion of patients registered with the iCureCeliac registry were female (**Table 1**). **The registry may therefore be over-representative of female patients with CeD**.
- **The registry is geographically diverse** – it represents patients throughout the USA (**Table 1**).
- A total of **115 patients (22.1%) chose self-management only**.
- The primary reason for diagnosis was the **presence of symptoms (75.1%)**, followed by a request for screening by a HCP (30.9%). Other reasons included:
  - a family member with CeD (12.3%)
  - another autoimmune disease (12.3%)
  - a request for screening (9.4%).
- More than half of the patients (55.4%) had three or more HCP visits for gluten-related disorder prior to their CeD diagnosis (**Figure 2**).
- Only 24.1% of the patients had symptomatic control over their disease, i.e. low disease symptom burden, while about one third of patients still had high disease burden (CSI≥45) (**Table 3**).
- Half of patients (50.2%) had excellent GFD adherence based on CDAT score (CDAT≤12), with the majority (96.4%) of patients reporting that they "always" or "often" maintained a strict GFD in a single question in the CDAT.
  - There was a large discrepancy between self-reported and PRO measures of GFD adherence.

Table 1. Patient demographic and baseline characteristics

Patient demographics and baseline characteristics	N=521
Female, n (%) (n=521)	425 (81.6%)
Mean age when first diagnosed with gluten-related disorder, years (SD) (n=514)	31.3 (17.2)
Mean time since CeD diagnosis, months (SD) (n=519)	60.9 (84.2)
Mean age, years (SD) (n=521)	35.9 (17.3)
Age categories, n (%) (n=521)	
Less than 15 years	71 (13.6%)
15–40 years	238 (45.7%)
41–65 years	191 (36.7%)
Over 65 years	21 (4.0%)
Race and ethnicity, n (%) (n=514)	
White	486 (94.6%)
Hispanic	26 (5.1%)
Geographic region, n (%) (n=452)	
Northeast	121 (26.8%)
Midwest	141 (31.2%)
South	98 (21.7%)
West	92 (20.4%)

CeD, celiac disease; SD, standard deviation

Table 2. Specialty of HCPs managing the gluten-related disorder

Speciality of HCPs	N=521 n (%)
Self-managed	262 (50.3%)
Gastroenterologist	252 (48.4%)
Family Medicine Practitioner	139 (26.7%)
Pediatric Gastroenterologist	40 (7.7%)
Pediatrician	39 (7.5%)
Dietitian	33 (6.3%)
Internist	26 (5.0%)
Nutritionist	25 (4.8%)
Other HCP	22 (4.2%)
Endocrinologist	19 (3.7%)
Naturopath	11 (2.1%)
Chiropractor	10 (1.9%)
Rheumatologist	9 (1.7%)
Not managed	9 (1.7%)
Management is not required	8 (1.5%)
Pediatric Endocrinologist	4 (0.8%)

HCP, healthcare professional

Table 3. Symptom burden among those with sufficient or insufficient GFD adherence, based on CSI and CDAT scores

Celiac Symptom Index (CSI)	Overall (N=522)	Excellent adherence to GFD (CDAT≤12) (n=262)	Fair adherence to GFD (13≤CDAT≤16) (n=181)	Poor adherence to GFD (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%)

CDAT, Celiac Dietary Adherence Test; GFD, gluten-free diet; n/a, not applicable

- Among those with excellent adherence to a GFD (CDAT≤12), low disease symptomatic control (CSI≤30) was achieved in 41.2% of patients and high disease symptom burden (CSI≥45) persisted in 9.2% of patients (**Table 3**).
- The majority of those with poor GFD adherence (CDAT>16) experienced high disease symptom burden (63.3% with CSI≥45), and no one achieved low disease symptomatic control (CSI≤30) (**Table 3**).
- Quality of life was significantly higher in those with low disease symptom burden (mean [standard deviation]: 72.0 [12.0]) compared with either moderate disease symptom burden (61.0 [13.2]) (p<0.0001) or high disease symptom burden (54.0 [12.5]) (p<0.0001) (**Table 4**).

Table 4. Quality of life and annual work/school days missed by levels of 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)

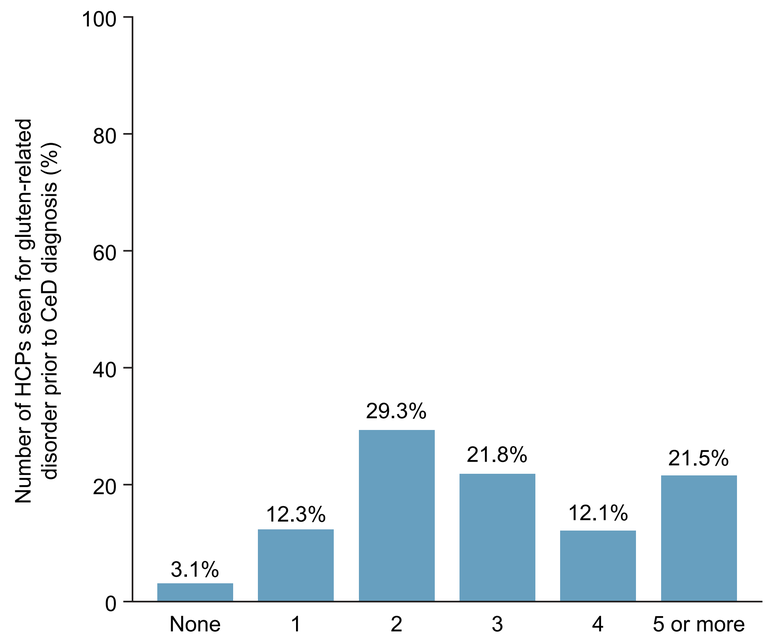
SD, standard deviation

Table 5. Annual work/school days missed by levels of disease symptom burden and adherence to GFD

Celiac Symptom Index (CSI)	Excellent adherence to GFD (CDAT≤12) (n=262)	Fair adherence to GFD (13≤CDAT≤16) (n=181)	Poor adherence to GFD (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)

CDAT, Celiac Dietary Adherence Test; GFD, gluten-free diet; n/a, not applicable

Figure 2. Number of HCPs seen for gluten-related disorder prior to CeD diagnosis



CeD, celiac disease; HCP, healthcare professional

- Patients with high disease symptom burden (CSI≥45) missed on average more than 5 weeks of work or school per year due to illness-associated gluten exposure. This was significantly more than the number of missed work or school days in patients with either moderate (31≤CSI≤44) (p=0.0003) or low disease symptom burden (CSI≥45) (p<0.0001) (**Table 4**).
- Even for patients with excellent GFD adherence (CDAT≤12), on average 3 weeks of work or school in a year were missed for those with high disease symptom burden (CSI≥45) (**Table 5**).
- Patients with poor adherence to GFD (CDAT>16) had more work or school absenteeism per year than those with excellent adherence to GFD (CDAT≤12) (p=0.0033) (**Table 5**).
- 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≤12); **62.1% of patients with CeD still had accidental exposure in the past 30 days.**

Study limitations

- Selection bias may exist as patients self-selected to report in the registry and complete the PRO measures.
- Diagnosis of CeD was not verified by clinicians.

Conclusions

- Self-perceived adherence to a GFD can be misleading as it almost doubles what is measured by a validated instrument.
- Half of the patients with CeD in this 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.
- The evidence suggests that adhering to a GFD is not universally effective at decreasing symptom burden and there is a significant unmet need for better treatment options.

References

1. Zingone F *et al. United European Gastroenterol J* 2015;3:182–9.
2. Ludvigsson JF *et al. Am J Gastroenterol* 2013;108:818–24.
3. Angeli G *et al. J Prev Med Hyg* 2012;53:20–3.
4. Tortora R *et al. Scand J Gastroenterol* 2016;51:1179–83.

Disclosures

KR, SW and DL are employees of Takeda Pharmaceutical International. JD was employed by Takeda Pharmaceutical International when this research was conducted. MG is the chief executive officer of the Celiac Disease Foundation and provided consultancy services for Takeda.

Acknowledgments

This study was sponsored by Takeda Pharmaceutical Company Ltd. Editorial assistance was provided by Oxford PharmaGenesis.

Presented at the 18th International Celiac Disease Symposium • 4–7 September 2019 • Paris, France

Cross-contact with gluten-containing school supplies may be reduced by **washing hands and work surfaces regularly.**

A Quantitative Analysis of Gluten Cross-Contact in Everyday School Supplies for Children with Celiac Disease

Vanessa M. Weisbrod[1], Jocelyn A. Silvester[2], Catherin Raber[1], Joyana McMahon[1], Shayna S. Coburn[1], Amy Damast[3], William Suslovic[1], Benny Kerzner[1]

[1] Children's National Health System, Washington, DC (USA) [3] Temple Sinai ECEP, Summit, NJ (USA)
[2] Boston Children's Hospital, Boston, MA (USA)

*Supported by grants from the Celiac Disease Foundation and Dr. Schar USA

Introduction

- A gluten-free (GF) diet is the current treatment for celiac disease (CD).
- Gluten is commonly found in schools, particularly in early childhood centers, art classes, and home economics classrooms.

Objectives

1. To quantify gluten transfer from common school supplies to GF foods that a child with CD may eat.
2. To assess the efficacy of washing techniques to remove gluten from a child's hands and classroom tables.

Methods

- Healthy children ages 2 to 18 without CD or another health condition necessitating gluten avoidance participated in five distinct experimental conditions simulating classroom activities using gluten-containing materials.

Methods Continued

- **Determination of Gluten Content:** All measurements made using R-Biopharm R7001 R5- ELISA Sandwich assay.
- **Scenarios Tested:** playdoh (n=30); home economics baking project (n=30); paper mâché (n=10); dry pasta in sensory table (n=10); and cooked pasta in sensory table (n=10).
- After each activity, the level of gluten was measured on separate slices of GF bread rubbed on participant hands and tables.
- Participants were randomly assigned one of three hand washing methods **(soap and water, water alone, or wet wipe).**
- Repeat gluten transfer measurements were taken from both the hands and tables.

Conclusions

- Cross-contact with gluten may occur more often with the use of some school supplies than others.
- Playdoh and dry pasta may not pose as high a risk as home economics baking activities, paper mâché projects, and cooked pasta in a sensory table.

Results

Table 1. Range of gluten levels detected on GF bread samples during each classroom activity.

Classroom Activity	No Gluten <5ppm		Gluten Detected 5-20 ppm		Gluten Detected >20ppm	
	N (%)	95% CI	N (%)	95% CI	N (%)	95% CI
Playdoh						
Transfer - Hands (n=30)	27 (90%)	72-97%	3 (10%)	3-28%	0 (0%)	0-14%
Transfer - Table (n=30)	24 (80%)	61-92%	4 (13%)	4-32%	2 (7%)	12-24%
Home Economics Baking Project						
Transfer - Hands (n=29)	0	0-15%	0	0-15%	29 (100%)	85-100%
Transfer -Table (n=30)	0	0-14%	0	0-14%	30 (100%)	86-100%
Paper Mâché						
Transfer from Hands (n=10)	0	0-34%	0	0-34%	10 (100%)	66-100%
Dry GC Pasta						
Transfer from Hands (n=10)	9 (90%)	54-99%	1 (10%)	0.5-46%	0 (0%)	0-34%
Cooked and Dyed GC Pasta						
Transfer from Hands (n=10)	0 (0%)	0-34%	1 (10%)	0.5-46%	9 (90%)	54-99%

Table 2. Range of gluten levels detected on the GF bread samples after washing

Classroom Activity	Gluten Detected <5ppm		Gluten Detected 5ppm-20ppm		Gluten Detected >20ppm	
	N (%)	95% CI	N (%)	95% CI	N (%)	95% CI
Playdoh						
(Hands) N (%)	30 (100%)	86-100%	0 (0%)	0-15%	0 (0%)	0-15%
Soap and Water	10		0		0	
Water Alone	10		0		0	
Wet Wipes	10		0		0	
(Table) N (%)	30 (100%)	86-100%	0 (0%)	0-15%	0 (0%)	0-15%
Soap and Water	10		0		0	
Water Alone	10		0		0	
Wet Wipes	10		0		0	
Home Economics Baking Project						
(Hands) N (%)	19 (63%)	44-79%	10 (33%)	18-53%	1 (3%)	0.2-20%
Soap and Water (N)	9 (90%)	54-99%	0 (0%)	0-34%	1 (10%)	0.5-46%
Water Alone (N)	7 (70%)	35-92%	3 (30%)	8-64%	0 (0%)	0-34%
Wet Wipes (N)	3 (30%)	8-64%	7 (70%)	35-92%	0 (0%)	0-34%
(Table) N (%)	8 (27%)	13-46%	13 (43%)	26-62%	9 (30%)	15-50%
Soap and Water	6 (60%)	27-86%	3 (30%)	8-64%	1 (10%)	0.5-46%
Water Alone	0 (0%)	0-34%	3 (30%)	8-64%	7 (70%)	35-92%
Wet Wipes	2 (20%)	4-56%	7 (70%)	35-92%	1 (10%)	0.5-46%

Children's National

Cross-contact with gluten may occur more often with the use of some school supplies than others.

A dedicated set of kitchen equipment and utensils may not be required to prevent gluten cross-contact.

A Real-life Assessment of Gluten Cross-Contact in a Shared Kitchen Environment

Vanessa M. Weisbrod[1], Jocelyn A. Silvester[2], Catherin Raber[1], Joyana McMahon[1], Shayna S. Coburn[1], Maureen Basye[1], Amy Damast[3], William Suslovic[1], Benny Kerzner[1]

[1] Children's National Health System, Washington, DC (USA)
[2] Boston Children's Hospital, Boston, MA (USA)
[3] Temple Sinai ECEP, Summit, NJ (USA)

*Supported by grants from the Celiac Disease Foundation and Dr. Schar USA

Introduction

- Recommendations from hospitals and advocacy groups for preventing cross-contact with gluten in a shared kitchen include using separate pots and pans, scrubbing shared utensils with soap and water, and employing a dedicated toaster.
- These recommendations are based on theory, not data.

Objectives

1. Evaluate if gluten is transferred from gluten-containing (GC) to gluten-free (GF) pasta, bread, and cupcakes prepared in a shared environment.
2. To determine if cross-contact can be prevented either by washing shared equipment or rinsing contaminated pasta.

Methods

- **Determination of Gluten Content:** All measurements made using R-Biopharm R7001 R5- ELISA Sandwich assay.

- **Experiment 1**: quantified gluten transfer to GF pasta that was cooked in water previously used for GC pasta (n=12). This was repeated after either washing the pots with soap and water (n=6) or rinsing the pots with water alone (n=6). As well, the level of gluten was measured on contaminated pasta that was rinsed with cold tap water for 30 seconds (n=6).

- **Experiment 2:** quantified level of gluten was measured on GF bread toasted in a shared rolling toaster (n=10) and a shared pop-up toaster (n=10).

- **Experiment 3:** quantified level of gluten was measured on GF cupcakes sliced with knives previously used to slice GC cupcakes (n=30).

Results

Preparation Method	Gluten Undetectable <5ppm	Gluten Detected 5ppm-20ppm	Gluten Detected >20ppm
	N (%)	N (%)	N (%)
Gluten-Free Pasta			
Cooked in shared water (n=12)	0	0	12 (100%)
Cooked in shared water, then rinsed for 30 seconds (n=6)	4 (67%)	2 (33%)	0
Shared pot washed with soap and water before cooking GF pasta (n=6)	6 (100%)	0	0
Shared pot rinsed with water before cooking GF pasta (n=6)	6 (100%)	0	0
Toaster			
GF bread toasted in shared rolling toaster (n=10)	8 (80%)	2 (20%)	0
GF bread toasted in shared Pop-Up Toaster (n=10)	10 (100%)	0	0
Cupcake			
GF cupcake sliced with shared knife (n=30)	2 (7%)	26 (86%)	2 (7%)
GF cupcake sliced with a washed knife (Table) N (%)	28 (93%)	2 (7%)	0 (0%)
Soap and Water	9	1	0
Water Alone	9	1	0
Wet Wipes	10	0	0

Conclusions

- Cooking GF pasta in water used to cook GC pasta and using a shared knife pose a considerable risk of gluten exposure.
- Employing **basic cleaning methods** offers sufficient gluten removal.
- A shared toaster produced little risk of gluten transfer, which may relieve anxiety for celiac patients and revise recommendations about the requirement to purchase a new toaster.
- Further studies are needed to develop evidence-based recommendations.

Children's National

Employing **basic cleaning methods to equipment and utensils** offers sufficient gluten removal.

MED ABOUT DATA

USE DATA. SAVE LIVES

Digital Health Hackathon

MAKING EARLY DIAGNOSIS OF CELIAC DISEASE POSSIBLE

Dr. Liat Kosovich, Celiac Association of Israel (Israel)
Marilyn G. Geller, Celiac Disease Foundation (United States)

THE CHALLENGE

EARLY DIAGNOSIS OF CELIAC DISEASE

Approximately 1 of 100 children and adults throughout Europe and the USA suffer from celiac disease (CeD).

Up to 80% of CeD cases remain undiagnosed.

Undiagnosed CeD may lead to serious health complications such as growth problems, infertility, anemia, osteoporosis and the development of other autoimmune disorders.

Our aim is to promote early diagnosis of CeD by using big data analysis.

METHODS

MED ABOUT DATA DIGITAL HEALTH HACKATHON

The Israeli NPO ii2020 lead by Dr. Erel Margalit partnered with members of the Israeli health eco-system to produce a hackathon focused on the theme of big data in digital health.

One of the challenges set for the event by Teva Pharmaceuticals, together with Celiac Association of Israel and the Celiac Disease Foundation, was to develop smart tools and algorithms that will enable an early diagnosis of celiac disease.

The aim of the CeD challenge was to yield novel information about CeD patients that would lead to a better diagnosis protocol of CeD than currently available, through the analysis of tens of thousands of patient records.

RESULTS

SMART TOOLS THAT ENABLE AN EARLY DIAGNOSIS

120 entrepreneurs, doctors and software developers participated at the hackathon. Out of 22 groups, 10 chose to compete in the CeD challenge.

The 'CeliACT' team won first place at the event for their innovative solution: a product that runs on all the medical records in the health provider's database and alerts the physician when patients with a high risk for CeD are found. The product is based on AI algorithms validated on 60,000 medical records (AUC~0.85).

The leader of the winning team, Shlomit Steinberg-Koch, has founded an innovative startup - 'Predicta Med', which provides a decision support platform for early detection of CeD.

CONCLUSIONS

Med About Data Hackathon was an innovative event, which has proven the ability of big data analysis to lead to better diagnosis protocols of CeD than currently available.

We are now working with 'Predicta Med' to transform their winning solution into a viable tool that will become the worldwide gold standard for CeD diagnosis.

Join us to make a change

office@celiac.org.il | +972-52-8822077

Presented at the 18th International Celiac Disease Symposium • September 5-7, 2019 • Paris, France