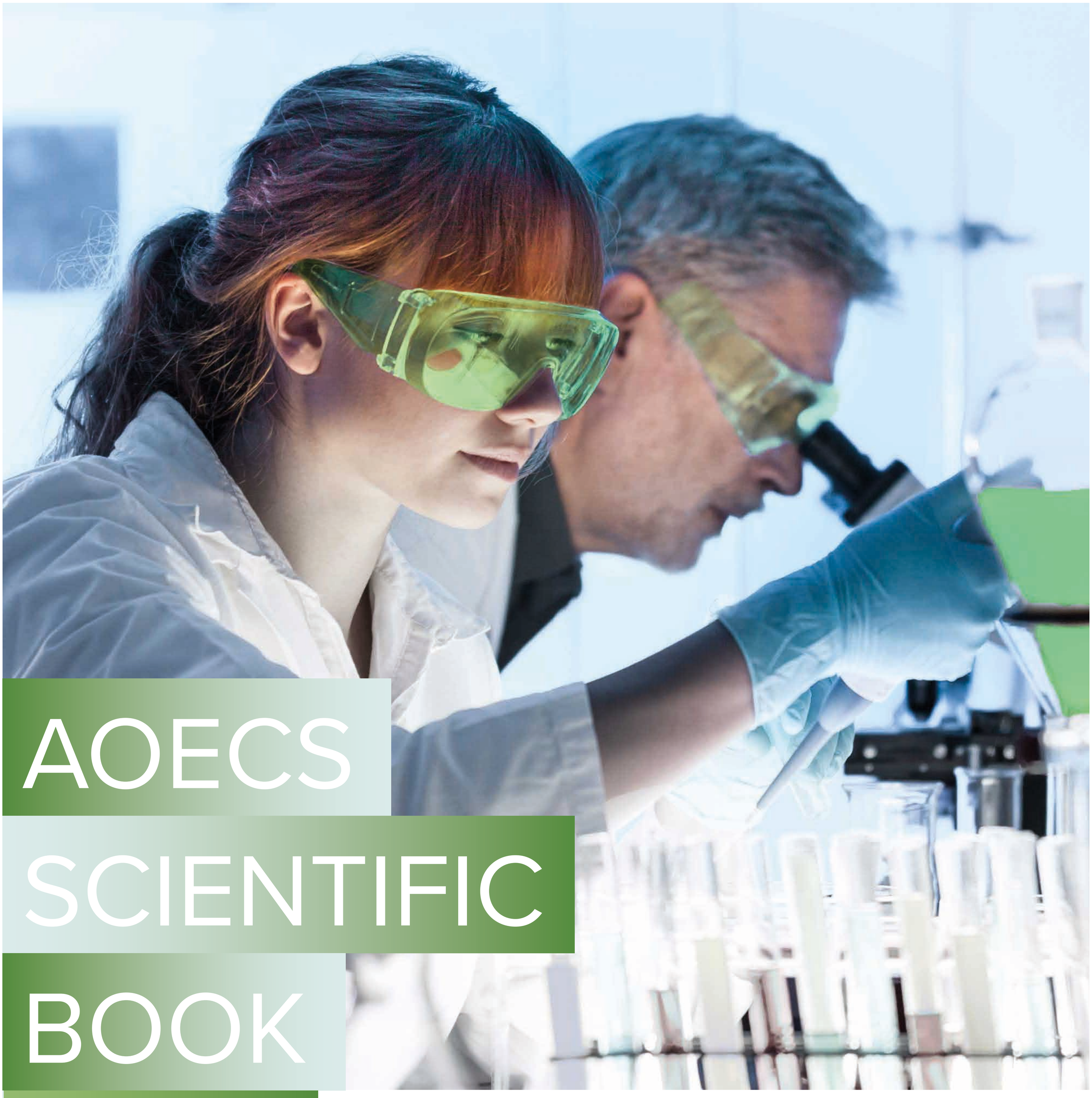
AOECS

Association of European Coeliac Societies



AOECS SCIENTIFIC BOOK 2024

Uniting and empowering coeliac societies in Europe and beyond

AOECS Scientific Book 2024

AOECS
Association of European Coeliac Societies

FOREWORD

Coeliac disease is a chronic, multiple-organ, autoimmune disease that affects genetically predisposed individuals when exposed to the ingestion of gluten.

Over the past 25 years, there has been an increasing prevalence of celiac disease, which affects about 1,3% of the population. Today, the only available treatment is the adherence to a strict and life-long gluten-free diet.

The Association of European Coeliac Societies (AOECS) together with its members is committed to work towards improving the lives of coeliacs and their relatives. We do so by promoting a reliable Food Safety Scheme for pre-packaged gluten-free food; enhancing Gluten-free Eating Out Schemes in different countries; raising awareness among policymakers and promoting sound research and innovation within the coeliacs and gluten-free ecosystems.

As part of these efforts, we are proud to offer this third collection of scientific posters to the public, which were displayed during the 36th AOECS General Assembly held in November 2024, in Madrid, Spain.

With this posters' exhibition and the subsequent e-book, AOECS aims to spread the word and incentivize research and innovation related to coeliac disease.

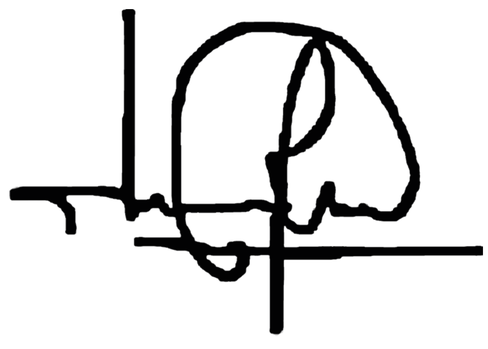
We want to acknowledge the work developed with the support of our member societies in different countries, as well as encourage researchers to continue working in this field.

For this third edition 2024, AOECS received 17 scientific abstract and scientific posters which we are delighted to make available to the public in this e-book. Here you will find a diverse range of topics related to basic scientific research and innovative topics such as:

- Multicentric studies, about investigation of body composition parameters in patients with celiac disease on a gluten-free diet,
- Development of new tools to improve diagnosis or evaluate symptoms,
- Rates of biopsy-confirmed celiac disease diagnosis and gluten-free diet adherence in Europe and the United States,
- Quality of life and adherence in different life moments (childhood and adulthood),
- The situation of the gluten-free offer in public hospitals and also about eating out in different countries.

All received posters have been submitted for an independent evaluation conducted by two experts in the field to provide feedback and insight to the authors.

We warmly thank these two experts, Carmen Ribes PhD and Izaskun Martín-Cabrejas PhD for their invaluable contribution to this project as well as to every author that has submitted their posters to this third edition 2024. Their contributions to increase awareness around coeliac disease and proposing innovative approaches are priceless, and we invite them to continue their passionate work in this field.



Veronica Rubio
Secretary General, AOECS

ACKNOWLEDGEMENT

COUNTRY & SUPPORTING COELIAC ORGANISATION	TITLE	AUTHORS
Italy - Page 7 Italian Coeliac Association (AIC)	**Celiac Disease and the Italian Catering Sector: A Survey**	Gianni Bientinesi, Susanna Neuhold, Michela Noli and Filomena Rotunno
Spain - Page 8 Spanish Coeliac Association (FACE)	**Guide To The Production Of Gluten-Free Craft Beers**	M.P. Fernández-Gil, S. Matias, J. Miranda, V Navarro, J. Esparta, O. Martínez, M. Bustamante, E. Simón
Spain - Page 9 Spanish Youth Coeliac Association (FACE Joven)	**Bridging academia and associations engagement: addressing coeliac disease challenges in early education by a Learning-Service project**	Martín-Cabrejas I, Marín M, Fernández-Cardero A, Morales D, Navarro-del Hierro J, Sánchez I, Herranz B, De Ávila MD, De Abreu C, Rodríguez M, Brieva V, van der Hofstadt M, Vega N, Ramírez J
Spain - Page 10 EU/Independent	**Quality of life in children with celiac disease in their first year on a gluten-free diet**	Perez-Junkera, G, Lasa, A, Delgado-Sanzonetti, L, Lecuona Serrano, A, Vázquez-Polo, M, Churruca, I, Navarro, V, Larretxi, I
Ukraine - Page 11 Ukranian Coeliac Association	**Characteristics of Gluten-Free Product Consumption and the Psycho-Emotional State of Individuals on a Gluten-Free Diet During the Full-Scale Invasion of Ukraine**	Feodrenko O, Naumova O, Donsova O
USA - Page 12 Independent	**Development of a novel celiac disease symptom tracker app**	Kirtana Sripathi, Marilyn Geller, Iraklis Kourtis, Daniel A. Leffler, Kimberly Skorupinski, Shrish Budree
Spain - Page 13 Celiac Disease & Gluten Sensitivity Association	**Is it safe to eat out when you are gluten free?**	Blanca Esteban
Ireland - Page 14 Coeliac Society of Ireland	**The Presence of Gluten Precautionary Allergen Labels on Dried Pulses and Dried Grain Packets**	Burrowes L
Belarus - Page 15 Harmony without gluten	**Hygienic assessment of the quality of nutrition of children with celiac disease in the Republic of Belarus**	Sycheuskaya N, Bashun N, Savanovich, Lipnitskaya E.

ACKNOWLEDGEMENT

COUNTRY & SUPPORTING COELIAC ORGANISATION	TITLE	AUTHORS
USA - Page 16 Independent (Takeda)	**Using patient insights to inform clinical study design: experiences from a US Patient Advisory Council**	Alyssa Halper, Jennifer A. Graf, Kimberly Skorupinski, Alyssa Vanderhoof1, Daniel A. Leffler
United Kingdom - Page 17 Coeliac UK	**Celiac Insider as a tool to improve Celiac Disease diagnosis**	A. Vandenberg, C. Kuey, B. den Drijver, C. Dalibert
Jordan - Page 18 Celiac Care Providers Society	**Adherence to the Gluten-Free Diet Role as a Mediating and Moderating of the Relationship between Food Insecurity and Health-Related Quality of Life in Adults with Celiac Disease: Cross-Sectional Study**	Nour Amin Elsahoryi, Mohammed Omar Ibrahim, Omar Amin Alhaj
USA/EU - Page 19 Celiac Disease Foundation	**Rates of biopsy-confirmed celiac disease diagnosis and gluten-free diet adherence in Europe and the United States: a real-world survey**	Hannah Knight, Niamh Harvey, Fatima Dawod, Rina Lukanova, Vanessa Weisbrod, Marcia Gailes, Marilyn Geller
Hungary - Page 20 Independent	**The added value of the cognition, dining, gastrointestinal problems, sleep and tiredness bolt-ons for the EQ-5D-5L in patients with coeliac disease**	M. Mercédesz Angyal, Mathieu F. Janssen, Peter L. Lakatos, Valentin Brodszky, and Fanni Rencz
Hungary - Page 21 Independent	**Investigation of body composition parameters in patients with celiac disease on a gluten-free diet. Prospective, multicenter, case-control study (ARCTIC study)**	Peresztegi Míra, Vereczkei Zsófia, Sipos Zoltán, Farkas Nelli, Máth Beáta, Lemes Klára, Lénárt Zsuzsanna, Papp Veronika, Dakó Eszter, Dakó Sarolta, Bajor Judit
Hungary - Page 22 Independent	**Hepatic steatosis and body composition in patients with celiac disease. Preliminary results of a prospective, multicenter, case-control study (ARCTIC study)**	Bajor, J, Peresztegi, M., Vereczkei, Z., Hagymási, K., Faluhelyi, N., Szekeres, G., Pásztor, G., Szirmay, B., Sipos, Z., Lemes, K., Papp, V. Lénárt, Z., Pár, G.
Spain - Page 23 Acecova	**Situation of the gluten free food available at public hospitals in Valencian community**	Palomares I., Escuriola B., Monfort M.C., van der Hofstadt M., Torada D.

EVALUATION PANEL

As previous years AOECS wanted to provide authors with additional feedback and words of encouragement from experts in research. In partnership with some independent experts from different fields about coeliac disease, the AOECS has worked closely with two experts that could evaluate the work received with particular attention to:

- Clarity and accessibility of the information
- Degree of Innovation
- The impact of the projects on the quality of life of coeliac patients

This professionals are working in the field of coeliac disease and other gluten mediated disorders from diferent perspectives. The high level of skills, knowledge, and expertise of the evaluation panel, makes its recommendations particularly valuable for the authors. All the authors have received a certificate of participation as well as a brief comment from the evaluation panel.

We want to warmly thank this year experts for their contribution to the AOECS posters evaluation panel, to encourage authors to continue with their research and innovation activity, with their support the impact of the contributions received is bigger and the feedback is more focused and detailed to encourage the authors to continue with their priceless research activity.

The scientific papers on display at the 36th Annual Conference in Madrid, Spain.

MEMBERS OF THE AOECS POSTER EVALUATION PANEL

Izaskun Martín-Cabrejas, PhD

Dr. Martín-Cabrejas is a professor and researcher at the Complutense University of Madrid (UCM) in the Faculty of Veterinary Medicine. She teaches across three different degree programs: Food Science and Technology, Veterinary Medicine, and Human Nutrition and Dietetics. Dr. Martín-Cabrejas is a nutritionist and food technologist, having completed her PhD in 2016. Her thesis focused on the search for food biopreservatives and the study of certain probiotic strains.

Currently, she conducts her research in the Department of Food Technology, specializing in food safety with a focus on microbiology. She is part of a collaborative project with several meat industry partners, where she characterizes pig microbiota and explores the use of sustainable technologies, such as pulsed light, to reduce the risk of foodborne pathogen contamination.

In addition, she coordinates a service-learning project that provides training in primary schools with Human Nutrition and Dietetics students to raise awareness about dietary restrictions for children with celiac disease. This social initiative, launched in 2020, allows her to stay engaged with various food restriction advocacy groups, many of which collaborate with her team.

Dr. Martín-Cabrejas began her tenure at UCM in 2021, initially in the Faculty of Medicine, where she taught Pediatric Nutrition as a full-time professor. In 2022, she obtained a full-time position in the Faculty of Veterinary Medicine. She now serves on the Dean's team as the Dean's Delegate for Guidance and Support in the Food Science and Technology degree program.

Additionally, she worked for almost six years at the Spanish Federation of Celiac Disease, where she developed the current "Eating Out" scheme, provided training to various sectors, including scientists, medical practitioners, quality departments in major restaurant chains, and food manufacturing companies, and wrote different among others.

Besides, she led the writing of several manuscripts for newly diagnosed individuals with celiac disease and a school guide on dietary restrictions to improve the inclusion of these groups. Dr. Martín-Cabrejas also served on the Board of Directors of the Association of European Celiac Societies for nearly three years, participating in the European License System working group, contributing to updates of the AOECS gluten-free standard, and advocating for patient rights at various European conferences and general assemblies.

Carmen Ribes-Koninckx, ESPGHAN

Carmen Ribes-Koninckx, Head of the Paediatric Gastroenterology Section at the Hospital Universitari i Politècnic La Fe. Coordinator of the Special Celiac Disease Interest Group of the European Society of Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN).

ESPGHAN is an international multidisciplinary society working to promote children's health from the point of view of gastroenterology, hepatology and nutrition.

As coordinator of the coeliac disease group from ESPGHAN, she is in charge of the different areas of work and of establishing strategies around coeliac disease, as well as promoting the development of clinical guidelines for diagnosis, treatment and follow-up of the pathology.

Dr. Ribes-Koninckx has focused her research in the area of coeliac disease for more than 20 years. In the last 10 years she has been the principal researcher or coordinator of more than 30 clinical trials related with coeliac disease, she have developed her research in the field of serological markers for coeliac disease, in genetics and also about environmental factors involved in the development of the disease.

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

Celiac Disease and the Italian Catering Sector: A Survey

Submitted by: Gianni Bientinesi [1], Susanna Neuhold [2], Michela Noli [2] and Filomena Rotunno [2]

[1] Business Intelligence Group (BIG) , [2] Associazione Italiana Celiachia (AIC),

Introduction

A survey among restaurants and hotels throughout Italy was conducted in 2022 by a company specialized in market studies and big data analysis appointed by the Italian Celiac Association (AIC).

The survey aimed to collect and benchmark the knowledge regarding Celiac Disease (CD), gluten-free diet (GFD) and the good manufacturing practices (GMPs) for the preparation and service of gluten-free food (GFF) comparing a sample of Eating Out gluten-free (EOGF) program accredited venues versus a sample of non-accredited venues.

The EOGF program is an AIC national scheme aimed at train and monitor venues versus a specific technical standard to guarantee safe GF meals for celiacs.

Method

The survey was conducted through interviews using the CATI (Computer-Assisted Telephone Interviewing) methodology on 2,400 non-accredited Italian restaurateurs and 400 accredited ones.

INTERVIEWS
Computer-Assisted Telephone Interviewing

2,400
with non-accredited Italian restaurateurs

400
with accredited ones

Results

Among Italian restaurateurs, only 22% have participated in specific training courses on CD or food intolerances and the 63% claims to have just a superficial knowledge of CD, while 100% of accredited venues undergoes a specific training on CD and GFD and have specific knowledge on GMPs for GFF. 68% of non-accredited venues do not use the “gluten-free” claim, independently if they offer meals for celiacs or not.

ITALIAN RESTAURANTS

GLUTEN FREE

68%
of non-accredited venues do not use the “gluten-free” claim

22% **italian restaurateurs have participated in specific training courses**

63% **have just a superficial knowledge**

ACCREDITED RESTAURANTS

100%
specific training & knowledge on CD, GFD and GMPs for GFF

11% of non-accredited restaurateurs would use any flour if it does not contain wheat, barley, etc. as ingredients, without checking if they could contain traces of gluten due to cross contact.

In the preparation of GFF, non-accredited restaurateurs are more inclined to prepare dishes separately, or stop traditional production, clean and restart, or serve only pre-packaged GFF (55%), while accredited venues are usually organized with dedicated production lines (74%). 42% of non-accredited venues do not prepare GFF.

ITALIAN RESTAURANTS’ GFF PRACTICES

55%
often prepare dishes separately or serve only pre-packaged GFF

42%
not serve celiacs

11%
use any flour without wheat, barley, etc., without checking for gluten cross-contact

ACCREDITED RESTAURANTS

74%
organized with dedicated production lines

Conclusion

Even if superficial, a high number of restaurateurs know about CD, which is still a positive fact compared to the past. The 42% who declare that they do not serve celiacs can also be seen as partially positive, as they want to serve celiacs only when they feel to be adequately prepared. Nevertheless, this means that only around half of the restaurants in Italy serve GFF.

Adherence to a scheme such as the Italian EOGF program seems to represent a significant element of difference in the safety guaranteed to the celiacs and can increase the number of restaurateurs able to serve celiacs safely.

Authors

1. Gianni Bientinesi, Business Intelligence Group (BIG)
2. Susanna Neuhold, Associazione Italiana Celiachia (AIC)
3. Michela Noli, Associazione Italiana Celiachia (AIC)
4. Filomena Rotunno, Associazione Italiana Celiachia (AIC)

Guide To The Production Of Gluten-Free Craft Beers

Submitted by: M.P. Fernández-Gil [1], S. Matias [2], J. Miranda [1,2], V Navarro [1,2,3], J. Esparta [2], O. Martínez [1,2,3], M. Bustamante [1,3], E. Simón [1,2,3]

[1] Gluten Analysis Laboratory of UPV/EHU, [2] Gluten3S research group, [3] Nutrition and Food Safety Research Group, Bioaraba Health Research Institute.

Introduction

Socialization often centers around food and drinks, creating challenges for those with celiac disease or gluten sensitivity. While drinking beer can be risky, the market for gluten-free beers is growing rapidly, with a projected annual growth rate of 13.72% from 2022 to 2027 (1). This growth mirrors the broader expansion of the craft beer market in Europe (2,3). Since gluten-free beers can be made from gluten-containing grains, producing them requires stringent safety processes.

This guide helps craft beer producers implement a self-control system to meet hygiene and safety standards for gluten-free beer.

Method

A comprehensive review of information at both national and international levels, including legal frameworks and scientific evidence, has been conducted. Based on this review, a practical, industry-focused guide tailored to the craft beer sector has been developed. The present guide follows on from a previous one, which was produced at national level and coordinated with the Basque Coeliac Association (EZE) (4).

Results

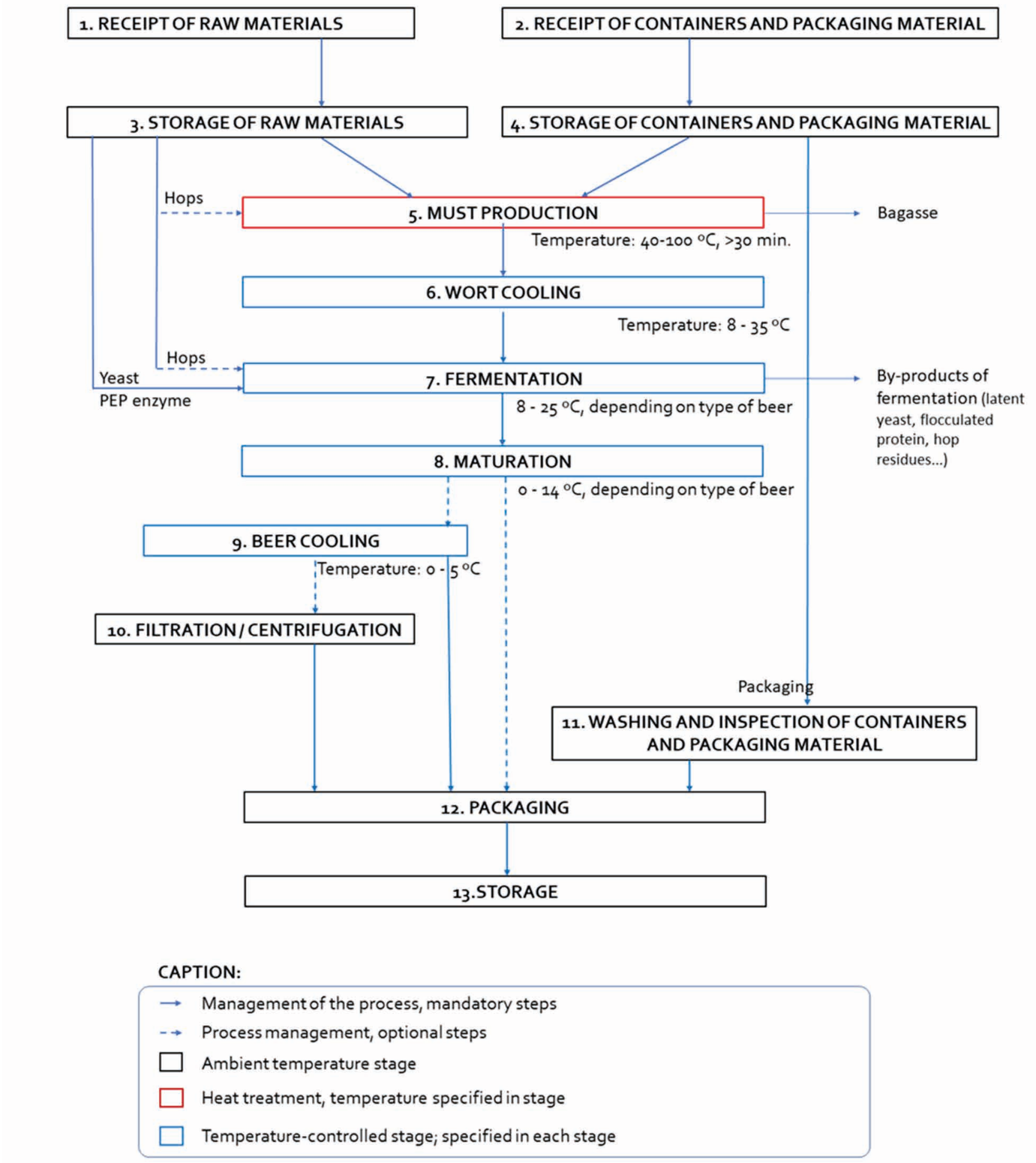
An English-language guide has been developed, primarily based on the Hazard Analysis and Critical Control Points system, and consists of five main sections along with a bibliography.

Chart 1

Index (1st page)

Chart 2

Flowchart of the production process



A key focus is on ensuring the safety of the final product by evaluating hazards associated with gluten-free beer production. It includes hazard management charts and outlines analytical control of the gluten-free brewing process.

Conclusion

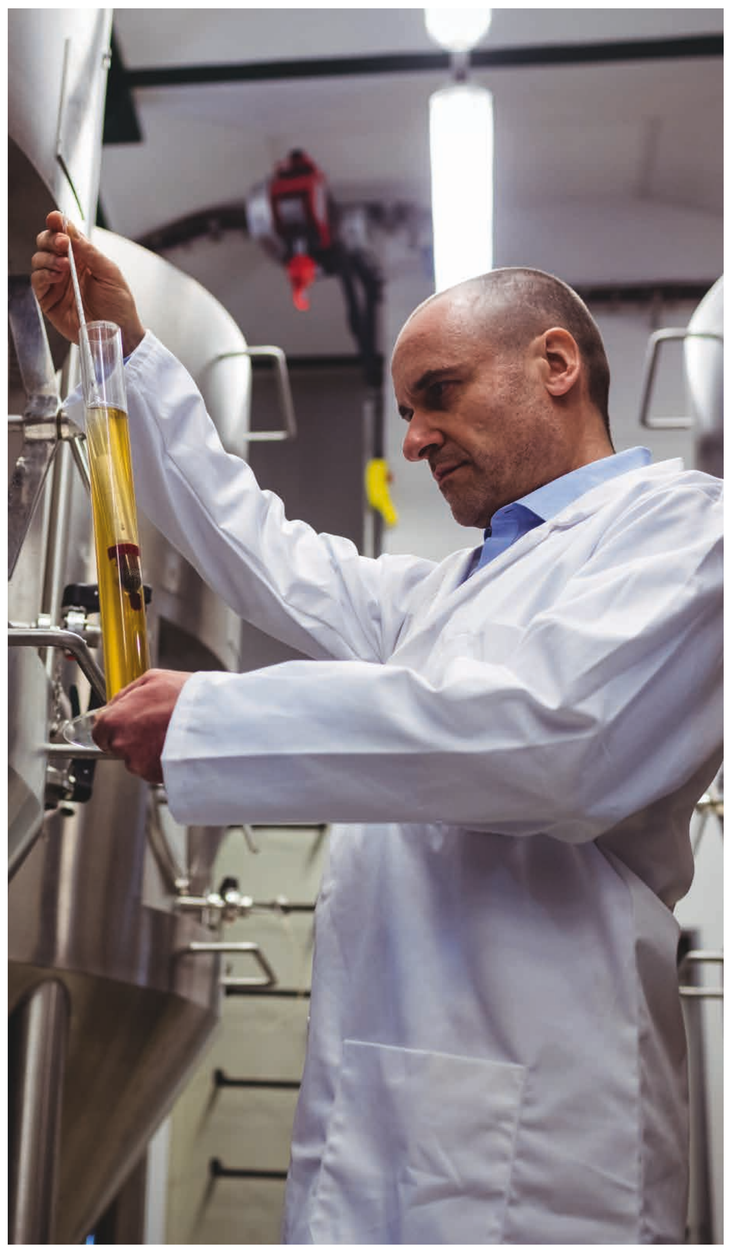
This guide, currently under consideration for endorsement by the AOECS, has the potential to become a key reference document for the European gluten-free craft beer industry.

References

1. Gluten-Free Beer Market Outlook, Size | 2022 - 27 | Industry Demand, Share [Internet]. www.mordorintelligence.com.
2. Informe Técnico de la Cerveza Artesana e Independiente en España, Cerveza Artesana e Independiente 2021 [Internet].
3. Craft beer market in Europe: Forecast and analysis – brewers journal Canada [Internet]. Brewersjournal.ca..
4. Guía para la producción de cervezas artesanas sin gluten – Asociación Celíacos Euskadi [Internet]. Celiacoseuskadi.org.

Acknowledgement

Silvia Matias is a researcher under contract to the Investigo programme, funded by the NextGenerationEU programme.



ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

Bridging academia and associations engagement: addressing coeliac disease challenges in early education by a Learning-Service project

Submitted by: FACE Joven; Martín-Cabrejas I [1], Marín M [1], Fernández-Cardero A [1], Morales D [1], Navarro-del Hierro J [1], Sánchez I [1], Herranz B [1], De Ávila MD [1], De Abreu C [2], Rodríguez M [2], Brieva V [2], van der Hofstadt M [3], Vega N [3], Ramírez J [4], Fernández-Hospital X [1]

[1] Food Technology Department, Veterinary Faculty, Complutense University of Madrid, UCM, [2] Federation of Spanish Coeliac Disease Associations, FACE, [3] Spanish Coeliac Disease Youth Group, FACE Joven, [4] Gluten Free Madrid, MSG

Introduction

Coeliac disease affects around 1% of the European population, with a higher incidence in children[1]. To address the challenges faced by coeliac students[2] in Spain, a service-learning project launched in 2020 involved the Complutense University of Madrid (UCM), the Federation of Coeliac Associations, and FACE Joven. The project aimed to enhance the quality of life for coeliac students by fostering awareness and inclusivity in schools.

Method

A survey was selected as the primary research tool, and its results were processed in two undergraduate thesis projects. Additionally, collaboration was established between the University and patient associations. Students from the Human Nutrition program developed an interactive workshop to educate primary school students about coeliac disease in an engaging way.

Project implementation

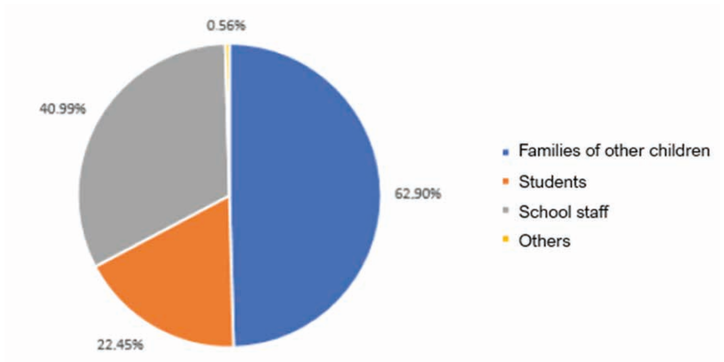
The project involved four university faculties, two primary schools, 10 university professors, 26 undergraduate students, and five patient associations. Through this collaboration, Human Nutrition students designed workshops that effectively engaged young children.

Results

More than 2,000 individuals responded to the survey, revealing that half of the coeliac students had faced difficulties in school due to their condition. Additionally, a quarter of these students reported experiencing rejection within the school environment. Over 500 children participated in the educational workshops, raising greater understanding of coeliac disease and dietary restrictions.

Chart 1

Groups from which coeliac students have experienced rejection.



Conclusion

The workshops successfully introduced elementary students to the concept of coeliac disease and emphasized the importance of acceptance and inclusion. This learning-service project has encouraged awareness among young students in Madrid about the daily challenges faced by their coeliac peers. Ongoing training in schools is advised to improve awareness and inclusion of children with coeliac disease

Picture 1a and 1b

Part of the service-learning staff during 23-24 edition at an elementary school (a); one of the workshops with children (b).

References

1. Grupo de trabajo del Protocolo para el diagnóstico precoz de la enfermedad celiaca (2018). Protocolo para el diagnóstico precoz de enfermedad celiaca. Ministerio de Sanidad; Servicios Sociales e Igualdad; SESCS.
2. Skjerning H, Mahony RO, Husby S et al. (2014). Health-related quality of life in children and adolescents with celiac disease: patient-driven data from focus group interviews. Qual Life Res 23, 1883–1894.

Quality of life in children with celiac disease in their first year on a gluten-free diet

Submitted by: Perez-Junkera, G[1,2], Lasa, A[1,2], Delgado-Sanzonetti, L[3], Lecuona Serrano, A[4], Vázquez-Polo, M[1,2], Churruca, I[1,2], Navarro, V[1,2], Larretxi, I[1,2]

[1]GLUTEN3S Research Group, University of the Basque Country, Vitoria-Gasteiz, Spain; [2]Bioaraba, Nutrición y Seguridad Alimentaria, [3]Vitoria-Gasteiz; Pediatric Gastroenterology, Hospital of Mondragón, Mondragón, Spain. [4]Pediatric Digestive, Hospital Zumárraga, Zumarraga, Spain.

Introduction

Although following a gluten-free diet (GFD) can have a positive impact on the quality of life (QoL) of people with celiac disease (CD) by reducing symptoms[1, 2], it can also have a negative impact due to social exclusion, lack of information and choice when eating out, risk of gluten cross-contamination or fear of social exclusion[3-7].

Given this scenario, it is necessary to consider to which the QoL of this population may be affected.

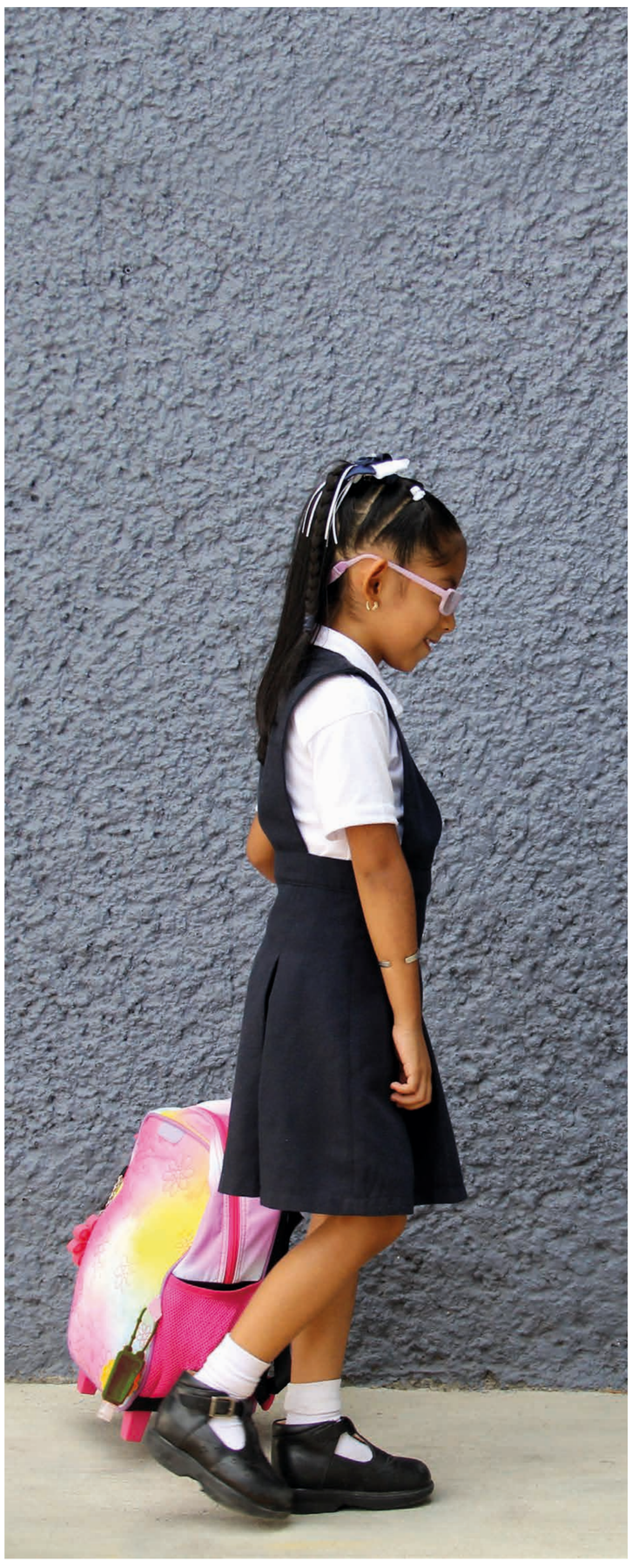
We aimed to analyse the evolution of QoL of newly diagnosed children with CD during their first year on a GFD.

Method

Recruitment: 46 participants with CD (35 girls and 11 boys; mean age 8,3 ± 3,3 years) were recruited from six hospitals in the Basque Country and the Celiac Association of Madrid.

Data collection: QoL data were collected using the CD-specific questionnaire (CD-DUX), which was administered at diagnosis (VT0) and three and twelve months after diagnosis (VT3 and VT12, respectively).

This instrument is based on 12 items divided into three subscales: "having CD", "communication" and "diet". A version of the CD-DUX was developed for children's parents/ carers and was also used in the present study to assess their perceptions of children's feelings about CD. Responses were scored from 1 to 5 for each answer, and the total score was then converted to a scale of 1 to 100: a score of 1-20 was considered very good, 21-40 good, 41-60 neutral, 61-80 poor, and 81 to 100 very poor.



Results

Overall scores of the participants and their parents/carers showed a poor QoL (children: 61'8 ± 16'5, 58 ± 19'3 and 60'4 ± 17'8; parents/ carers: 60 ± 13'8, 60'4 ± 15'1, 63'1 ± 15'2 at VT0, VT3 and VT12, respectively).

When the scores were grouped, the subscale "having CD" showed a slight decrease from VT0 to VT3 (p=0.036) in the case of children (Figure 1).

For both children and parents/ carers, the "communication" subscale was the lowest of the three subscales, but the results remained neutral over the year (Figure 1 and Figure 2).

Figure 1

Total score of children with CD for each subscale

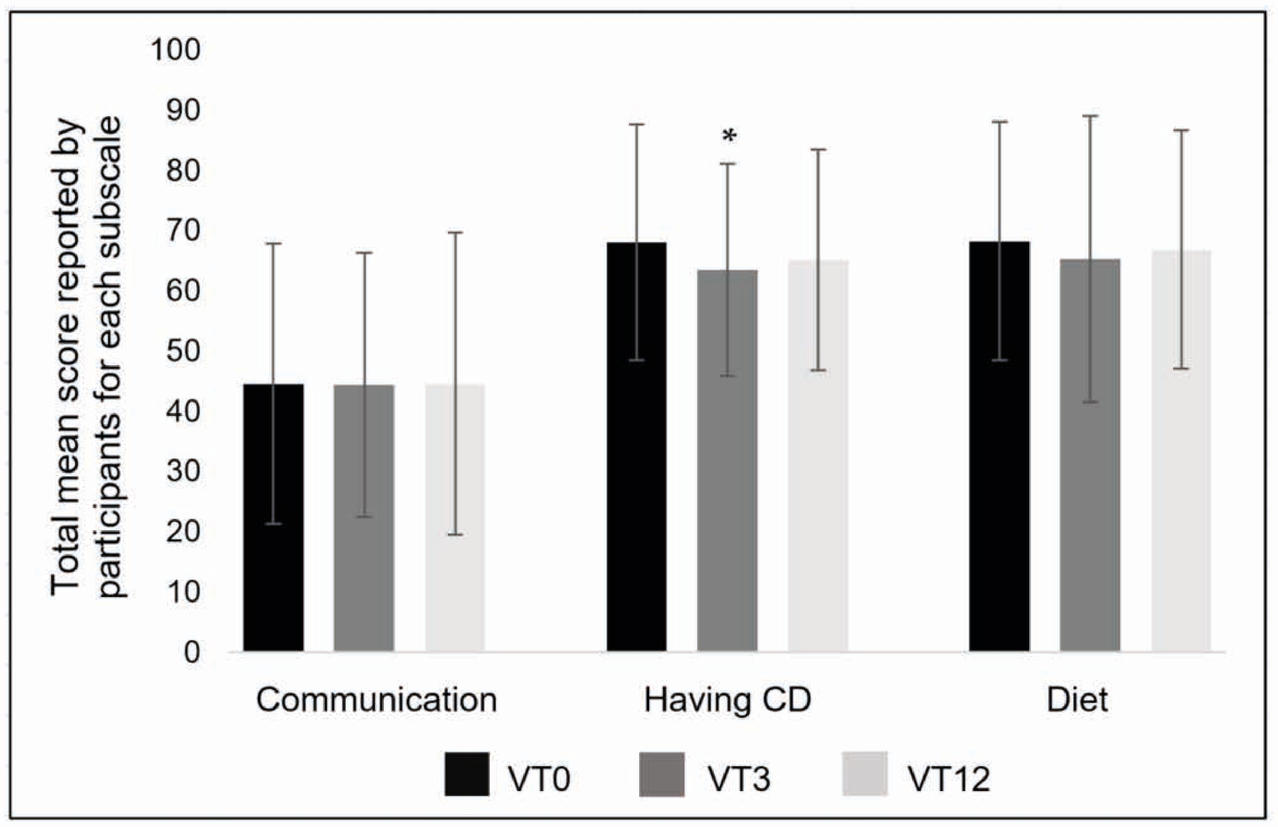
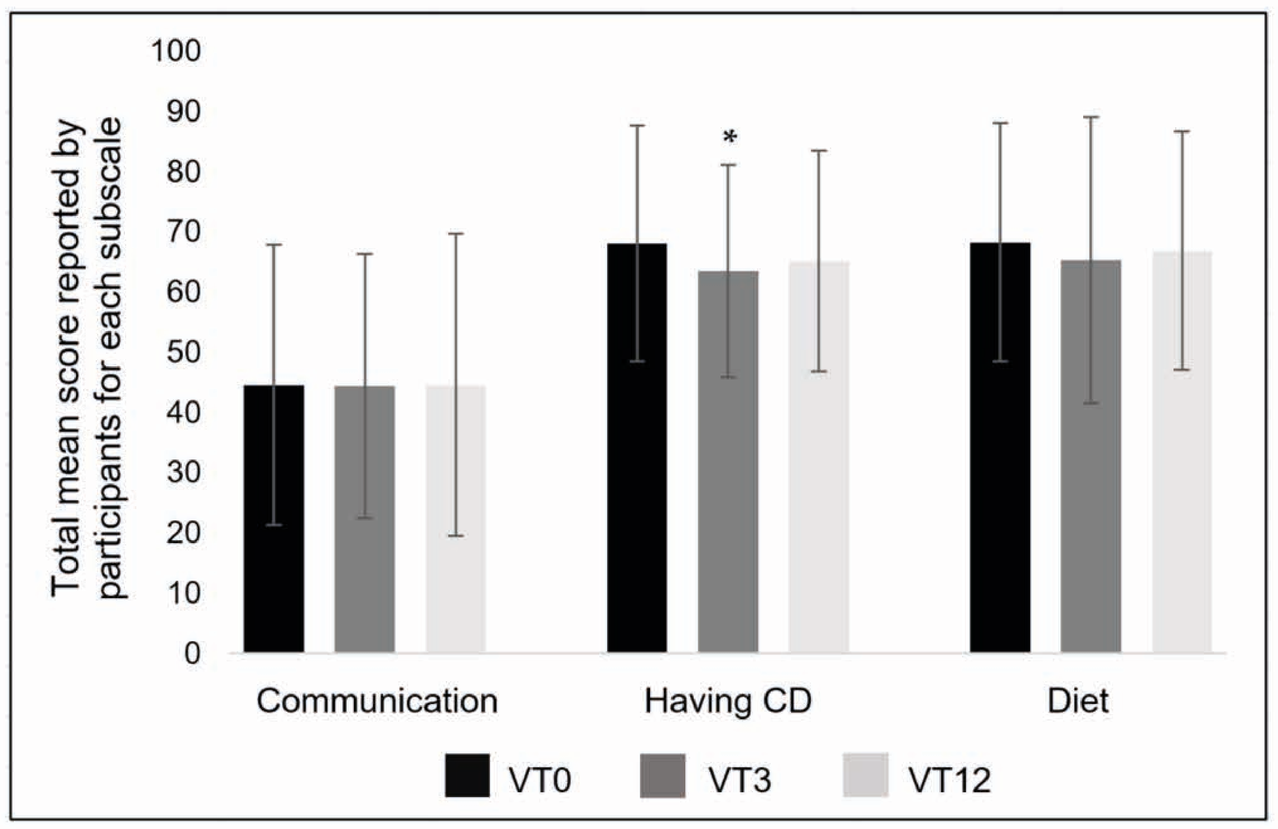


Figure 2

Total score of parent/carer's perceptions about CD for each subscale



Conclusion

Further efforts are needed to improve the QoL of children with CD. Social strategies could be adopted to increase society's knowledge about CD and GFD and thus improve the social inclusion of people with CD.

References

1. Wagner et al., 2008
2. Skjerning et al., 2017
3. Wolf et al., 2018
4. Vázquez-Polo et al., 2023
5. See et al., 2015
6. Singh et al., 2018
7. Zingone et al., 2015.

Acknowledgement

This research is part of the I+D+i PID2021 125695OA I00 project, funded by MCIN/ AEI /10.13039/501100011033/ and, as appropriate, by "ERDF A way of making Europe" by the European Union. Gesala Perez Junkera and Maialen Vázquez Polo are beneficiaries of pre-doctoral grants from the Basque Government and the University of the Basque Country (UPV/ EHU) respectively.

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

Characteristics of Gluten-Free Product Consumption and the Psycho-Emotional State of Individuals on a Gluten-Free Diet During the Full-Scale Invasion of Ukraine

Submitted by: Feodrenko O, Naumova O, Donsova O

All from the Ukrainian Celiac Society

Introduction

The Russian full-scale invasion of Ukraine has worsened the situation for people needing gluten-free products. Disruptions in logistics, shortages, and rising prices have negatively impacted the health and emotional state of individuals with celiac disease or gluten intolerance. This study aims to identify the peculiarities of gluten-free nutrition during the war, methods of obtaining it, and its effect on the well-being, activity, and mood of people with gluten-related disorders under invasion conditions.

Method

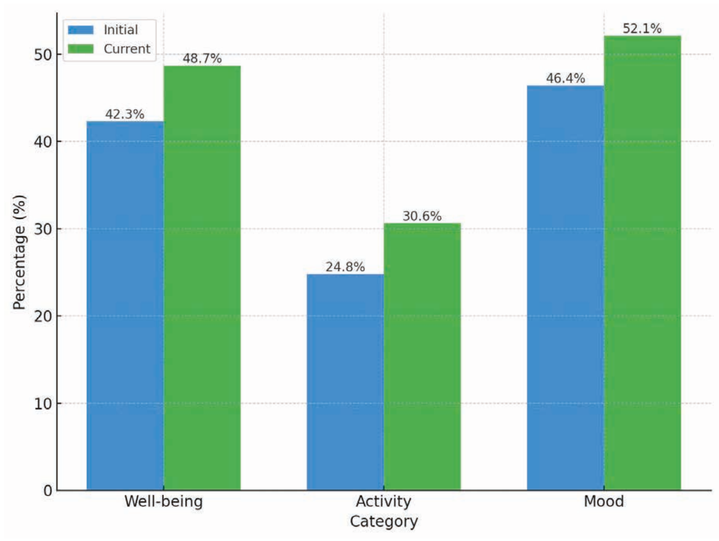
A survey of 468 individuals, aged 1 to 73, was conducted, with parents responding for children under 15. Most participants were members of the Ukrainian Celiac Society. The survey addressed the availability of gluten-free products, diet adherence, and psycho-emotional state

Results

Of the respondents, 81.8% stayed in Ukraine, including some under occupation. The main challenges were difficulty purchasing gluten-free products (47%), lack of funds (31.8%), and limited variety (25.9%). Fear of access to food was reported by 65% with 48.7% stating it was financially burdensome to afford these products. Some (40.2%) prioritized buying gluten-free items over other needs, while 7.1% couldn't afford them without aid, leading to diet violations.

Chart 1

Psycho-emotional State Before and After the Invasion



Most participants obtained gluten-free products via humanitarian aid (85.3%), online stores (61.1%), supermarkets (41.5%), and specialized shops (28.2%).

Key criteria for choosing products were quality (77.6%), price (57.9%), and taste (46.4%).

Stress significantly affected eating habits: 20.9% ate whatever was available in shelters, and 18.4% engaged in stress-eating without considering the type of food. Only 7.3% reported no change in their eating behavior. Diet violations were reported by 37.6%, while 39.1% adhered strictly.

Overall, the psycho-emotional state improved since the start of the invasion (Chart 1), with 48.7% reporting good well-being compared to 42.3% initially, and similar increases in activity (from 24.8% to 30.6%) and mood (46.4% till 52.1%).

Conclusion

The availability of gluten-free products is crucial to the well-being of those on a gluten-free diet. Humanitarian aid played a critical role in helping individuals cope during shortages. Since the start of the invasion, respondents' well-being, activity, and mood have significantly improved.

References

1. Tytarenko T, Vasiutynskyi V, Hubeladze I, Chunikhina S, Hromova H. War-Related Life-Making Landscapes: Ukrainian Context. J of Loss and Trauma. 2023;29(2):154-178. doi:10.1080/15325024.2023.2256219.
2. Beketova G, Soldatova O, Naumova O, Fedorenko O. Gluten-related disorders in children and adolescents. Clinical-diagnostic and psychological features. Prof edit. Ukraine: Kyiv; 2023. p. 70-99.

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

Development of a novel celiac disease symptom tracker app

Submitted by: Kirtana Sripathi[1], Marilyn Geller[2], Iraklis Kourtis[1], Daniel A. Leffler[1,3], Kimberly Skorupinski[1], Shrish Budree[1]

[1]Takeda Development Center Americas, Inc., Cambridge, MA, USA; [2]Celiac Disease Foundation, Woodland Hills, CA, USA; [3]Celiac Center, Beth Israel Deaconess Medical Center, Harvard Medical School Celiac Research Program, Boston, MA, USA

Introduction

- Patients with celiac disease (CeD) experience fluctuations in their CeD-related symptoms over time, which may be associated with inadvertent gluten exposure.
- The ability to track CeD symptoms is useful in real-world follow-up of patients; however, there are currently no freely available convenient tools to enable patients to track daily CeD symptoms longitudinally.
- Here, we present the development of a mobile application (app) designed by Takeda to help patients with CeD to monitor their symptoms.

Method

- The potential functions and content of the app were
- discussed with members of a Takeda-sponsored Patient Advisory Council (PAC), consisting of 10 adults with CeD, and with 10 CeD experts (from 3 research centers and Takeda Development Center Americas, Inc.).
- An app titled 'My Celiac' was then developed based on:
  - feedback received from the PAC and CeD experts
  - design elements and functionality that have been previously tested in patients with inflammatory bowel disease
  - gastrointestinal (GI) symptoms featured in the Celiac Disease Symptom Diary version 2.1© [1]
  - educational articles on CeD developed by a registered dietitian nutritionist with expertise in CeD (Beth Israel Deaconess Medical Center, Boston, MA, USA), according to the educational needs of patients with CeD.

Results

- Feedback received during the PAC discussion of potential app content included:
  - preference for a digital format (e.g. mobile app) over a paper version
  - suggested addition of non-GI CeD symptoms and an option to track the most bothersome non-GI symptoms
  - for patients who record severe symptoms, it was recommended that a call to action should be included to suggest that patients should contact their doctor to discuss their symptoms (note: the app will not provide medical advice to patients)
  - patient advisory groups (PAGs) and healthcare professionals (HCPs) were considered by patients to be a trusted source of information and patients recommended that the app be distributed by PAGs and HCPs (perhaps as part of a welcome pack for newly diagnosed patients)
  - suggested inclusion of a QR code to redirect patients to a PAG.
- Further recommendations from CeD experts included:
  - ensuring that the app addresses accessibility considerations (e.g. for color blindness)
  - using approaches to reduce subjectivity in assigning severity scores (e.g. the use of descriptions and a sliding scale rather than numbers).
- Key features of the My Celiac app include:
  - a severity rating for five key CeD-related GI symptoms (diarrhea, abdominal pain, bloating, nausea, constipation) over the previous 24 hours on a 5-point Likert scale from
  - 'no symptoms' (scored as '0' by the app) to 'very severe symptoms' (scored as '4' by the app) **(Figure 1)**
  - a visual summary of the patients' scores (in the form of a graph) for each symptom over the previous week and month **(Figure 2)**
  - the option for patients to provide demographic and medical information and share their symptom data with their gastroenterologist, dietitian, or other healthcare provider **(Figure 3)**
  - additional features to support patients in their CeD journey, including articles with information on CeD and gluten-free foods, patient stories, and information about ongoing clinical studies in CeD **(Figure 4)**
  - privacy notices and consent.
- In the future, the app has potential for the inclusion of other GI and non-GI CeD-related symptoms for patient symptom customizability and identification of symptom triggers.
- Takeda will not have visibility of data collected via the app.

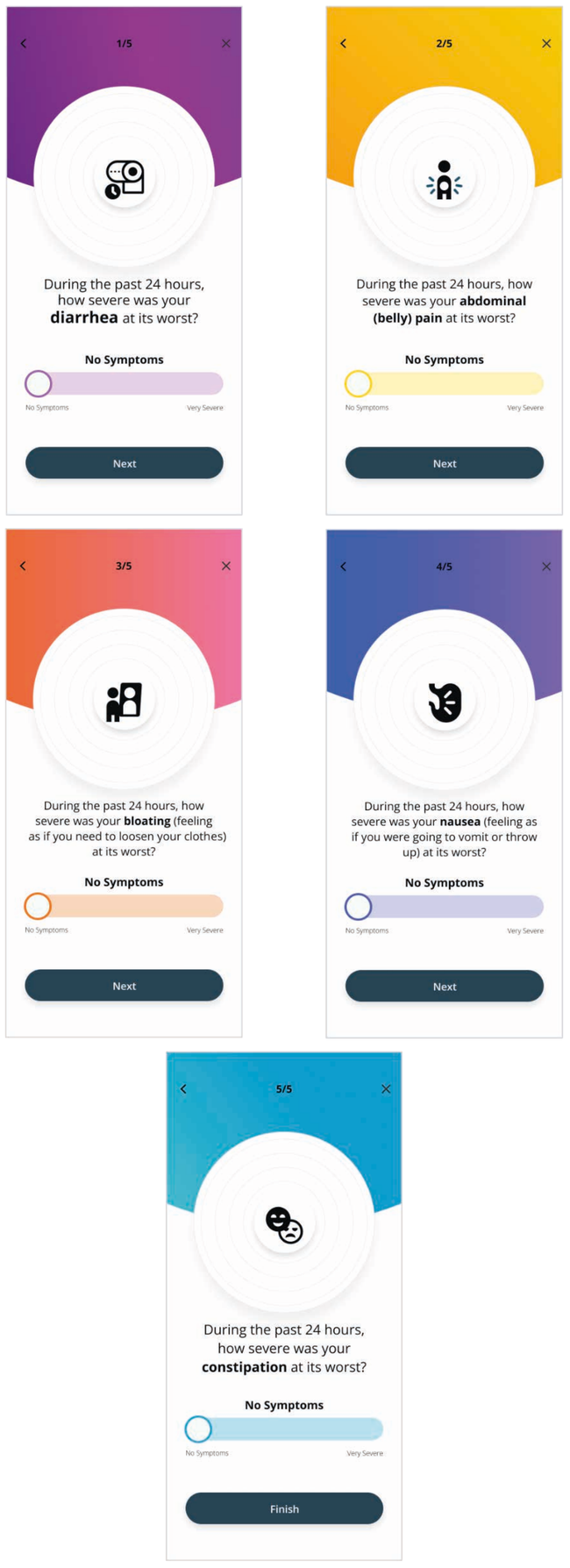
Key messages

- A novel mobile app (My Celiac) has been developed to enable patients to track their celiac disease (CeD) symptoms over time.
- Daily symptom monitoring by patients using this app may lead to improved disease management
- Other features in the app may improve patient understanding of CeD and allow clinical study eligibility assessment..

Scan the QR code to access the poster and any additional materials on your mobile device as well as forward yourself a link to it via email. If you do not have a QR reader, please enter https://tiny.one/U401738wdR in your browser. Copies of this poster obtained through the QR code are for personal use only and may not be reproduced without permission from the Association of European Coeliac Societies and the authors of this poster

Figure 1

Patients can use the My Celiac app to record the severity of five key CeD-related GI symptoms daily from 'no symptoms' to 'very severe symptoms'



CeD = celiac disease, PAC = Patient Advisory Council

Figure 2

The My Celiac app provides a visual summary of patients' symptom severity over the previous week and month

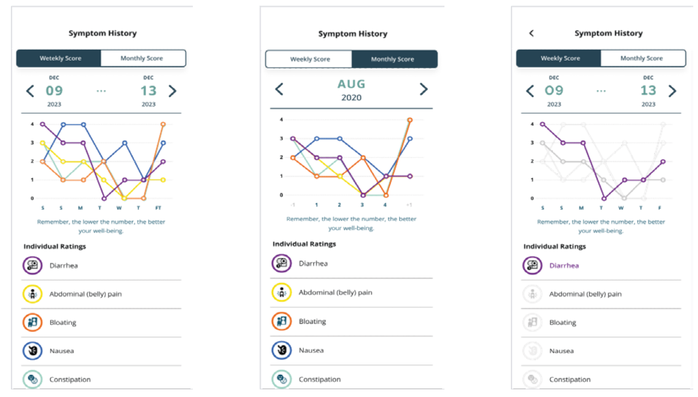


Figure 3

Patients can provide demographic and medical information in the My Celiac app

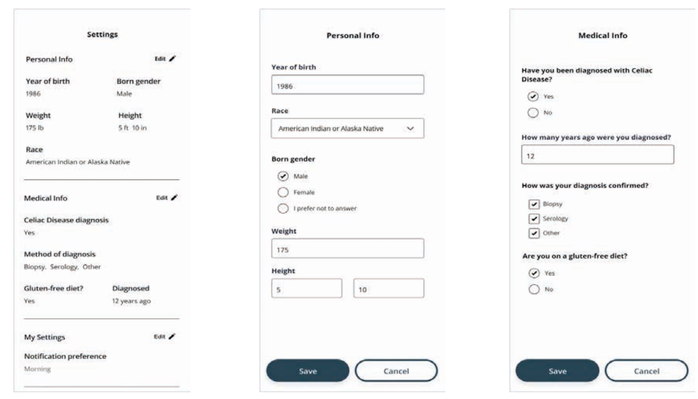
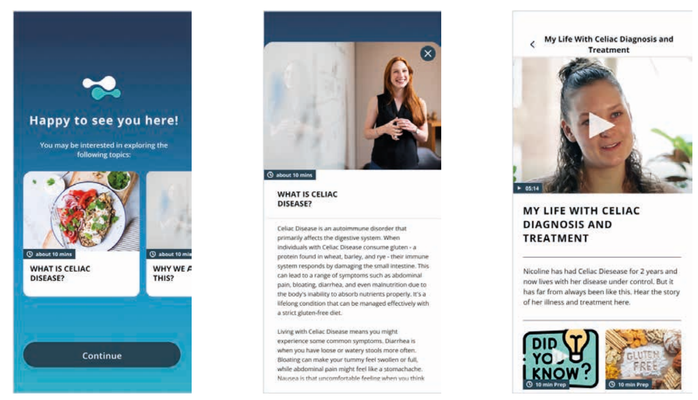


Figure 4

The My Celiac app includes educational materials with information on CeD and gluten-free foods, patient stories, and information about ongoing clinical studies



Limitations

The current PAC includes only 10 English-speaking adult patients living in the USA, and is therefore not representative of the global demographics of patients with CeD.

Conclusions

The My Celiac app is a novel tool that will allow patients to track their symptoms longitudinally, leading to improved disease management.

Furthermore, this app may improve patient education regarding CeD, and has the potential to be used to assess eligibility for CeD studies.

Next steps include usability testing for 4 weeks by members of the PAC, followed by collation of PAC feedback and formation of focus groups to discuss their experiences.

References

1. Patient Focused Medicines Development, 2024. Available from: https://patientfocusedmedicine.org/ (Accessed 19 September 2024).

Acknowledgements

The authors would like to thank Melinda Dennis (Beth Israel Deaconess Medical Center), Shawn Heiney and Nick Ommen (both Takeda Development Center Americas, Inc.) for their contributions to the development of the My Celiac app, and members of the PAC for their time and insights.

Funding statement

This study was sponsored by Takeda. Medical writing support was provided by Sally McTaggart, PhD, of Oxford PharmaGenesis, Oxford, UK and was funded by Takeda.

Disclosures

KS, IK, DAL, KS, and SB are employees and shareholders of Takeda. MG is an employee of the Celiac Disease Foundation, which receives financial support from Takeda.

Presented at 36th Association of European Coeliac Societies General Assembly Conference, November 14-17, 2024, Madrid, Spain
Corresponding author: kirtana.sripathi@takeda.com

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

Is it safe to eat out when you are gluten free?

Submitted by: Blanca Esteban. Celiac Disease & Gluten Sensitivity Association Madrid, Spain

Introduction

Almost all celiacs comment that they feel insecure when eating out, since they think that, in most restaurants, even if they offer gluten-free options, at the end they end up consuming some gluten.

The objective of the study was to study whether gluten really exists in the gluten-free options that are served to us in different restaurants.

Method

From June 2023 to January 2024, we anonymously purchased 21 samples offered as “gluten-free” in different types of restaurants, mainly fast food, but also American food and pizzerias (see Chart 1). Of course, they have all been restaurants where they prepare foods with and without gluten, since we know that this generates a lot of mistrust among celiacs.

The samples analyzed were pizzas, hamburgers, sandwiches, fries, nachos and tortilla chips.

The samples were analyzed at the Gluten Analysis Laboratory of the University of the Basque Country. The method used was the Elisa Sandwich R5.

Table 1

Types of restaurants

Restaurant	Samples
Burgers	13
Pizzerias	3
Italians	3
Others	2

Results

The laboratory did not detect gluten in any of the samples analyzed.

Conclusion/Discussion

Many times, the problem is not in eating in restaurants, but is in abusing of processed products at home, even if they are labeled “gluten-free” (they can contain up to 20 mg of gluten/kg). The gluten-free diet should be based on natural foods.

In our experience, errors occur more frequently at home, despite the insecurity that eating in restaurants generates for patients. Some of the establishments studied regularly receive complaints from celiac consumers about the lack of safety after episodes of discomfort that they attribute to possible contamination.

Our recommendation to patients is that they should always inform the establishment staff and ask as many times as necessary if the options they are being offered are really gluten-free, especially in those dishes that are available both with gluten and gluten-free.

References

1. Defensor del pueblo. Estudio sobre la situación de las personas con enfermedad celíaca en España [Internet]. Madrid: Defensor del Pueblo; 2017. 98 p. Available at: https://www.defensordelpueblo.es/wp-content/uploads/2017/04/Celiaquia_2017-1.pdf
2. Unión Europea. Reglamento de Ejecución (UE) No 828/2014 de la Comisión de 30 de julio de 2014 relativo a los requisitos para la transmisión de información a los consumidores sobre la ausencia o la presencia reducida de gluten en los alimentos. [Internet]. Available at: https://www.boe.es/doue/2014/228/L00005-00008.pdf

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

The Presence of Gluten Precautionary Allergen Labels on Dried Pulses and Dried Grain Packets

Submitted by: Burrowes L, Coeliac Society of Ireland

Introduction

Coeliac disease (CD) is an autoimmune condition triggered by ingesting gluten, a protein found in wheat, rye, and barley[1].

Precautionary allergen labels (PAL) serve as a communication tool employed by food manufacturers to alert consumers about potential allergen contamination risks[2].

Method

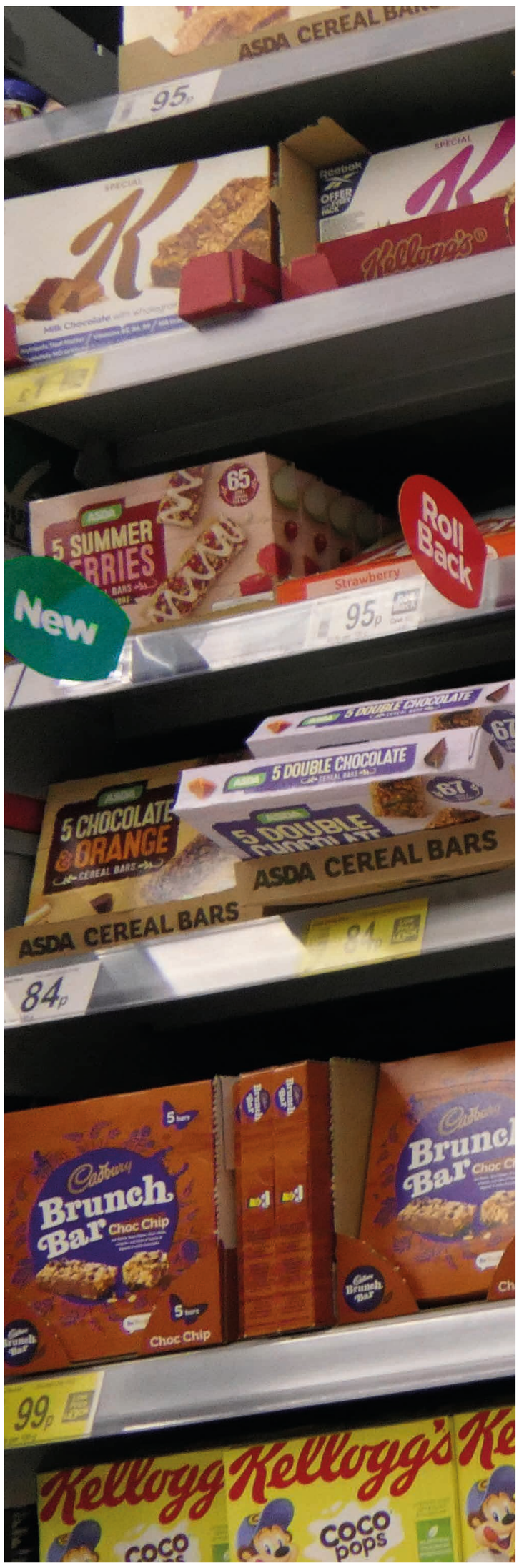
Five Supermarkets were chosen for data collection, representing the purchasing option for most Irish consumers.

Precautionary allergen labels were analyzed based on the inclusion of gluten, wheat, barley and rye warning statements.

Labelled Gluten Free Products were excluded from the analysis.

Analysis

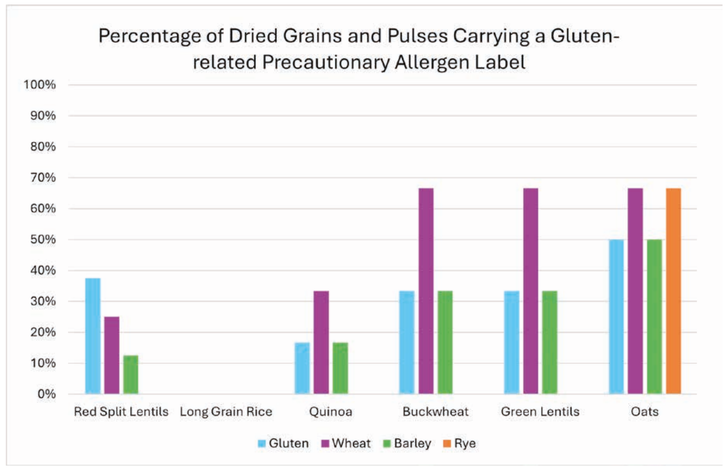
Data analysis was exported and cleaned on Microsoft Excel and data analysis was carried out using IBM SPSS.



Results

Table 1

PAL's seen across varying grains



Percentage of Dried Grains & Pulses Carrying a Gluten-related Precautionary Allergen Label

50% of Oats carried both gluten and barley precautionary allergen labels, two-thirds of Oat products carried precautionary allergen labels for wheat and rye.

No precautionary allergen labels on packaged long grain rice.

All other categories of dried pulses and grains carried gluten-related precautionary allergen labelling.

Conclusions

Oats exhibited the highest prevalence of PAL. This aligns with prior research, indicating that oats are often contaminated with gluten-containing grains during production[3].

Lentils, Buckwheat, and Quinoa also had a considerable quantity of products carrying a PAL, this agrees with a majority of research that indicates they were likely to come into contact with gluten[4].

The presence of PAL and the potential contamination of Naturally Gluten Free grains highlights the need for quality control methods and risk assessment.

Due to the lack of availability of GF products in some supermarkets, sometimes the only option for Coeliacs is the product containing the PAL. This poses a potential risk to those following a strict gluten-free diet.

References

1. Rubio-Tapia A, Hill ID, Kelly CP, Calderwood AH, Murray JA. ACG clinical guidelines: Diagnosis and management of celiac disease. American Journal of Gastroenterology [Internet]. 2013 May [cited 2024 Jan 5];108(5):656–76. Available from: https://journals.lww.com/ajg/fulltext/2013/05000/acg_clinical_guidelines__diagnosis_and_management.7.aspx
2. Precautionary Allergen Labeling: What Advice Is Available for Health Care Professionals, Allergists, and Allergic Consumers?La Vieille, Sébastien et al.The Journal of Allergy and Clinical Immunology: In Practice, Volume 11, Issue 4, 977 – 985
3. Thompson, T., & Keller, A. (2023). Gluten cross contact in oats: retrospective database analysis 2011 to 2023. Frontiers in nutrition, 10, 1284636. https://doi.org/10.3389/fnut.2023.1284636
4. Verma, A. K., Gatti, S., Galeazzi, T., Monachesi, C., Padella, L., Baldo, G. D., Annibali, R., Lionetti, E., & Catassi, C. (2017). Gluten Contamination in Naturally or Labeled Gluten-Free Products Marketed in Italy. Nutrients, 9(2), 115. https://doi.org/10.3390/nu902011

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

Hygienic assessment of the quality of nutrition of children with celiac disease in the Republic of Belarus

Submitted by: Sycheuskaya N.[1], Bashun N.[1], Savanovich I.[2], Lipnitskaya E.[3]

[1] Yanka Kupala State University of Grodno, [2] Belarusian State Medical University, [3] Harmony without gluten

Introduction

Organization of safe and high-quality nutrition for children with celiac disease in educational institutions and healthcare organizations is an important component in the system of protecting their health in the Republic of Belarus.

The aim of this study is to carry out a hygienic assessment of the quality of nutrition for children with celiac disease in the Republic of Belarus, focusing on compliance with the principles of gluten-free diets, ensuring safety and balanced nutrition in general education and pre-school institutions.

Methods

1. Analysis of food processing maps (technological maps of dishes and instructions) developed for children with celiac disease to ensure that the products meet hygiene standards and laboratory control for traces of gluten in finished foods, including checking ingredients and compliance with technological processes. The determination of the actual gliadin content in food products was carried out using the test system "Ridascreen Gliadin" produced by R-Biopharm, Germany (Method of performing measurements MVI.MN 4658-2013) by enzymoimmunoassay method.
2. Assessment of the sanitary and hygienic condition of educational institutions providing gluten-free food.

Results

Development of menu and technological maps. It was found that technological maps of dishes for children with celiac disease that offered in educational institutions meet the established requirements. Particular attention is given to the exclusion of gluten-containing products from the recipes, as well as the use of safe alternatives (for example, corn or rice flour [1,2]).

During the study, recipes and technology of dishes were developed for 11 dishes, namely, hot dishes: 1 - low-protein noodles with stewed vegetables, 2 - stewed stuffed tomatoes, 3 - buckwheat porridge with vegetables, 4 - vegetable casserole assorted, 5 - chicken meatballs with cheese, 6 - low-protein potato pancakes and 7 - rice balls; new soup: 8 - soup with meatballs and spinach; sweet dishes: 9 - gluten-free rice flour pancakes, 10 - beetroot mousse and 11 - gluten-free apple marshmallows. The main products used in the development of dishes were: apples, potatoes, poultry, tomatoes, rice flour, beetroot, onions, milk, vegetable oil, white cabbage, bell peppers, carrots, rice, buckwheat, sour cream, low-protein noodles, cheese and zucchini. All developed dishes have excellent organoleptic characteristics [3].

The laboratory studies of the developed dishes showed that the gliadin content in the presented samples is less than 10 mg/kg (10 ppm), which allows their use in gluten-free diet [4-6].

Assessment of nutritional balance: Studies have shown that the diet of children with celiac disease is, in most cases, balanced by major food groups. However, there is a lack of some important vitamins and minerals (e.g. iron, calcium, vitamin D [7-9]), which requires additional measures to replenish them.

Problems in ensuring food safety. Insufficient separation of food preparation areas and kitchen equipment can result in gluten ending up in the food. There are no violations in the educational institutions related to the lack of proper control over cross-contamination of products. When organizing meals in educational institutions, separate and marked equipment and kitchen utensils are used to prepare dishes and products, and careful hygiene of work surfaces where food is prepared is also carried out.

Information awareness. Most parents and educational institution staff noted the need to further increase awareness of the gluten-free diet, cooking features and hygiene standards.

Conclusion

The hygienic assessment of the quality of nutrition of children with celiac disease in the Republic of Belarus showed that there is a need to strengthen the monitoring of gluten-free diets in educational institutions. Although the developed technological maps comply with the standards, in a number of cases, problems with a lack of nutrients in the diet were found. It is necessary to continue working on raising the level of awareness of food service workers and parents of children with celiac disease, as well as to implement measures to improve the safety of cooking and replenish the deficiency of micronutrients.

References

1. Catassi C., Fabiani E., Iacono G., D'Agate C., Francavilla R., Biagi F., Volta U., Accomando S., Picarelli A., De Vitis I. et al. (2007). A prospective, double blind, placebo-controlled trial to establish a safe gluten threshold for patients with celiac disease. The American Journal of Clinical Nutrition, 85, pp. 160–166.
2. Itzlinger A, Branchi F, Elli L, Schumann M. (2018). Gluten-Free Diet in Celiac Disease-Forever and for All? Nutrients, 10 (1796), pp. 1–9.
3. Sycheuskaya, N., Bashun N. (2023). Analysis of gliadin content in developed dishes for children with celiac disease. Green economy in the function of solving global environmental problems: International scientific conference, Belgrade, p. 126.
4. Codex Standard 118-1979: Standard for foods for special dietary use for persons intolerant to gluten (2015). CCNFSDU.
5. Wieser H., Segura V., Ruiz-Carnicer Á., Sousa C., Comino I. (2021). Food Safety and Cross-Contamination of Gluten-Free Products: A Narrative Review. Nutrients, 13 (2244), pp.1–14.
6. Hollon J.R., Cureton P.A., Martin M.L., Puppa E.L., Fasano A. (2013). Trace gluten contamination may play a role in mucosal and clinical recovery in a subgroup of diet-adherent non-response celiac disease patients. BMC Gastroenterol., 13 (40), pp.1–9.
7. Grace-Farfaglia, P. (2015) Bones of Contention: Bone Mineral Density Recovery in Celiac Disease—A Systematic Review. Nutrients, 7, pp. 3347–3369.
8. Welstead, L. (2015). The Gluten-Free Diet in the 3rd Millennium: Rules, Risks and Opportunities. Diseases, 3, pp. 136–149.
9. Dickey, W., Ward M., Whittle C.R., Kelly M.T., Pentieva K., Horigan G., Patton S., McNulty H. et al. (2008). Homocysteine and related B-vitamin status in coeliac disease: Effects of gluten exclusion and histological recovery. Scandinavian Journal of Gastroenterology, 43 (6), pp. 682–688.

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

Using patient insights to inform clinical study design: experiences from a US Patient Advisory Council

Submitted by: Alyssa Halper[1], Jennifer A. Graf[1], Kimberly Skorupinski[1], Alyssa Vanderhoof[1], Daniel A. Leffler[1,2]*

[1]Takeda Development Center Americas, Inc., Cambridge, MA, USA; [2]Celiac Center, Beth Israel Deaconess Medical Center, Harvard Medical School Celiac Research Program, Boston, MA, USA
[*]At the time of the analysis

Introduction

- Collaboration between patients and the pharmaceutical industry is essential to ensure that patient needs, preferences and experiences are considered during the drug development process.[1,2]
  - Patient engagement enables patient-centric clinical study design, promotes health equity, builds trust and ultimately accelerates drug development.
- In 2020, Takeda sponsored the formation of a Patient Advisory Council (PAC) composed of adult patients with celiac disease (CeD) living in the USA.
- Here, we report how the PAC was initiated and run, and discuss insights provided by patients and how clinical study design has been influenced.

Method

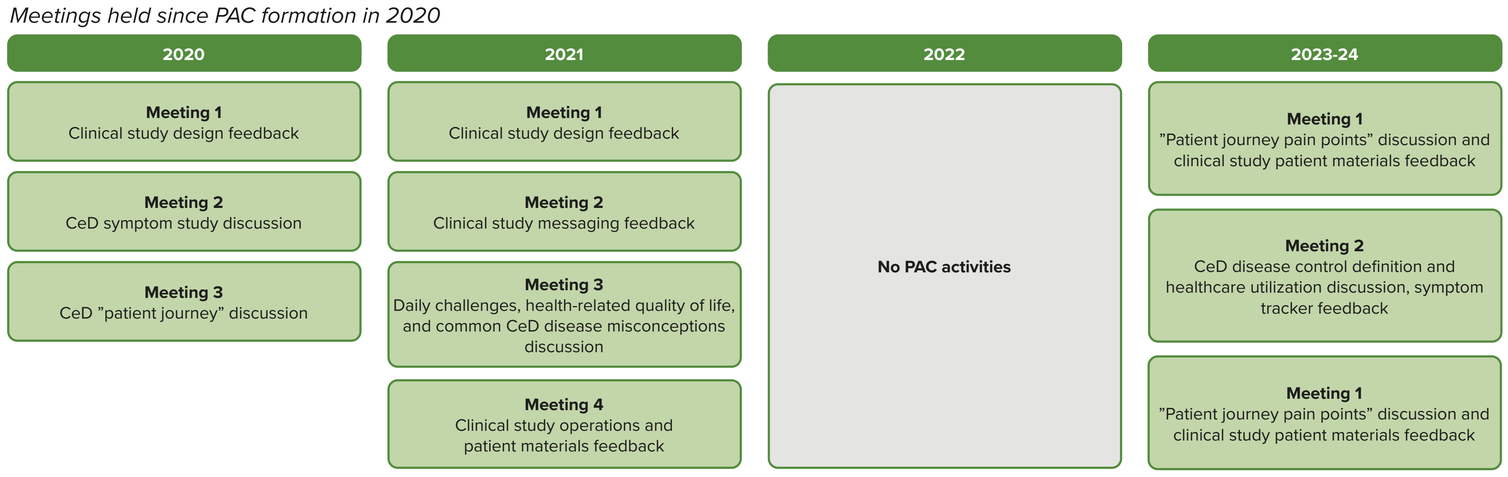
- Following an initial patient advisory board meeting in 2019, the PAC was formed in 2020.
  - PAC members (n = 10) were adult patients living with CeD in the USA.
  - Patients were identified through interactions with clinical treatment sites and patient organizations.
- In total, seven PAC meetings were held between 2020 and 2021 (Figure 1).
- PAC activities were paused in 2022, in part owing to the ongoing effects of the COVID-19 pandemic, and were resumed in 2023.
- At the point of re-initiation, six of the original PAC members continued to participate, and membership was broadened through further patient outreach.
  - To promote diversity, recruitment materials were prepared in both English and Spanish, and provision was made for bilingual PAC meetings.
- A further three PAC meetings have taken place since 2023 (Figure 1).
- Meetings were held in-person before the COVID-19 pandemic and virtually after the pandemic.

Results

- The current PAC is composed of 10 English-speaking adult patients with CeD, with demographic characteristics intended to be representative of the real-world US patient population (Figure 2).
- Meeting topics included the design, patient materials and results related to several clinical studies; the CeD 'patient journey'; the daily challenges and health-related quality of life of patients with CeD; common CeD disease misconceptions; definitions of CeD disease control; utilization of healthcare services; and the burden of clinical study participation (Figure 1).
- The key outcomes of discussions held across multiple meetings are summarized in Table 1.
- As a result of PAC discussions, several aspects of Takeda clinical study design have been made more patient-centric, including through:
  - the development of a 'Simulated Inadvertent Gluten Exposure' (SIGE) bar, intended to be more appetizing than a typical 'gluten slurry' (Figure 3)
  - modification of study visit schedules to improve convenience, for example by providing an option for home visits
  - development of study-related materials using language found to resonate with patients.

Figure 1

Meetings held since PAC formation in 2020



Overall insight: CeD symptoms have a large impact on patient HRQoL, and gluten-free diets do not provide sufficient control. Patients experience anxiety regarding gluten ingestion, either inadvertent or dureing clinical study participation.

CeD = celiac disease; HRQoL = health-related quality of life; PAC = Patient Advisory Council.

Key messages

- Through participation in a Takeda-sponsored Patient Advisory Council (PAC), individuals with celiac disease (CeD) have provided valuable insight into clinical study design, disease burden and the patient experience.
- Discussions have led to more patient-centric clinical study design, and have reinforced the urgency with which treatments for CeD should be developed.

Figure 2

Demographic characteristics of PAC members

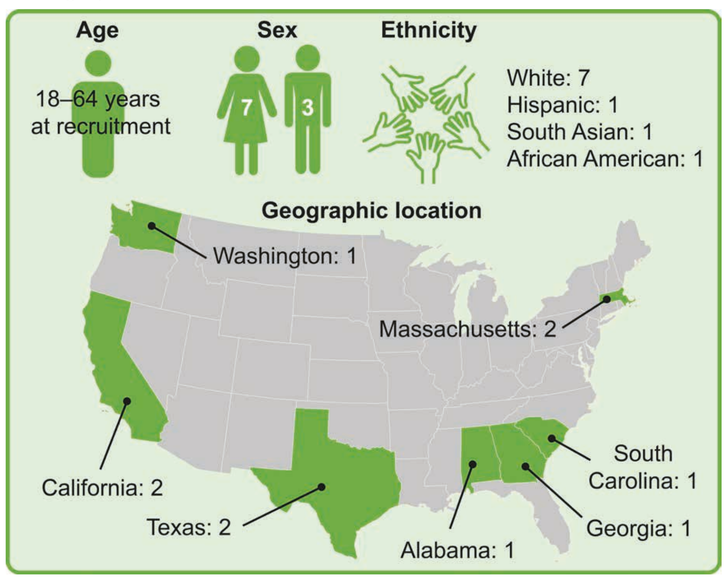


Figure 3

A Simulated Inadvertent Gluten Exposure (SIGE) bar

Ingredients
Vital wheat gluten (500 mg), tapioca syrup, rolled oats, almonds, brown rice crisps, organic semisweet chocolate chips, almond butter, cocoa butter, oat flour, glycerine, sunflower lecithin, sea salt, natural flavors

Table 1

Insights summary across PAC meetings

Theme	Insights
Hopes for a potential treatment	• Patients living with CeD desire a return to normalcy • Treatments should tackle the underlying causes of the disease, not just symptoms • Intestinal healing is an important aspect of treatment • Concerns included the possibility of forgetting a dose or leaving pills at home, and the requirement to add a pill to an existing burdensome comorbidity treatment regimen
Disease journey pain points	• Patients living with CeD desire a return to normalcy • Treatments should tackle the underlying causes of the disease, not just symptoms • Intestinal healing is an important aspect of treatment • Concerns included the possibility of forgetting a dose or leaving pills at home, and the requirement to add a pill to an existing burdensome comorbidity treatment regimen
Gluten challenge during clinical studies	• Hesitancy was expressed regarding participation in studies involving gluten challenge • It was felt that there was a lack of understanding among patients about gluten quantification and impact on symptoms – A mixture of words and visualizations to explain this was therefore suggested • An appetizing form of gluten challenge was requested, with a choice of flavors if possible
Optimizing the patient clinical study experience	• Flexibility in schedules was suggested, to make allowances for home life and varying symptoms • Home visits would be preferred for study check-ins • Customizable reminders and additional time to submit symptom diaries was requested
Definition of CeD disease control	• The terms 'managed' and 'unmanaged' better reflect the status of patients' CeD than 'controlled' and 'uncontrolled' • 'Mild', 'moderate' and 'severe' should be used to describe symptoms and the impact on daily life, but not the disease itself
Recruitment and retention in clinical studies	• Visual presentation of study design was suggested • Communication of study aims, the aims of treatment, possible impact of study participation on daily life, and safety information are all of high importance • PAC members suggested that study information should be shared through healthcare providers and community food programs, for individuals who are not involved in patient advocacy groups
Symptom tracking	• PAC members stated that the burden of symptoms goes beyond physical manifestations – Symptom tracking should include non-gastrointestinal symptoms and/or free-text entry • Digital formats were preferred over paper, and this may increase adherence to symptom reporting – If possible, patients should be able to use their own electronic devices • Information about symptom tracking could be distributed through healthcare providers and patient advocacy groups

CeD = celiac disease, PAC = Patient Advisory Council

Limitations

The current PAC includes only 10 English-speaking adult patients living in the USA, and is therefore not representative of the global demographics of patients with CeD.

Conclusions

- Insights have led to improvements in patient-centric design of Takeda-sponsored studies.
- Further efforts will be made to increase PAC diversity, with the possibilities of establishing one or more global PACs and/or PACs including pediatric patients and caregivers.
- Following PAC discussions, there are opportunities to work with the US Food and Drug Administration (FDA) to optimize the use of gluten in CeD clinical studies and with US health insurance companies to expand CeD coverage.

References

1. Patient Focused Medicines Development, 2024. Available from: https://patientfocusedmedicine.org/ (Accessed 19 September 2024).
2. Patient-Centered Outcomes Research Institute, 2024. Available from: https://www.pcori.org/ (Accessed 19 September 2024).

Acknowledgements

Patient Focused Medicines Development, 2024. Available from: https://patientfocusedmedicine.org/ (Accessed 19 September 2024).Patient-Centered Outcomes Research Institute, 2024. Available from: https://www.pcori.org/ (Accessed 19 September 2024).

Funding statement

Medical writing support was provided by Stephen Sweet, PhD, of Oxford PharmaGenesis, Oxford, UK, and was funded by Takeda

Disclosures

AH, JAG,* DAL, KS and AV are employees of and shareholders of Takeda.
*At the time of the analysis.

Presented at 36th Association of European Coeliac Societies General Assembly Conference, November 14-17, 2024, Madrid, Spain
Corresponding author: daniel.leffler@takeda.com

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

Celiac Insider as a tool to improve Celiac Disease diagnosis

Submitted by: A. Vandenberg[1,2], C. Kuey[1,3], B. den Drijver[1,4], C. Dalibert[1,5]

[1] Thermo Fisher Scientific, ImmunoDiagnostics Division. [2] Spain, [3] United Kingdom, [4] The Netherlands, [5] France.

Introduction

Diagnosing Celiac Disease (CeD) is challenging for healthcare professionals (HCPs) as CeD has diverse symptoms that can overlap with other gastrointestinal diseases. Also, time to diagnosis is long. Meaning patients suffer a long journey before getting diagnosed. To address these challenges, we have created an online platform: Celiac Insider (www.celiacinsider.com), a website providing comprehensive information about CeD. Aimed at patients and HCPs, it includes resources to support individuals getting the right diagnosis, and their patient journey. Celiac Insider is also committed to supporting HCPs in delivering the best possible care to their patients. Celiac Insider aims to create a community where patients can access reliable information, find support, and ultimately lead fulfilling lives while managing their condition.

Method

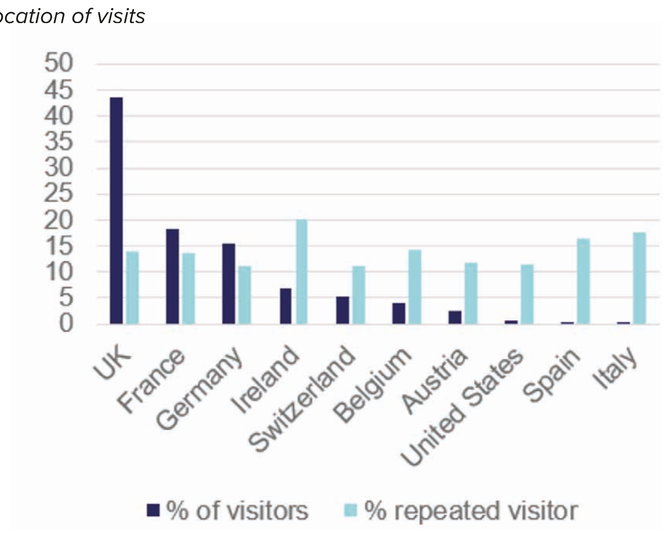
Developed by Thermo Fisher Scientific, CeliacInsider became available in English in November 2022. Website was promoted via Search Engine Marketing (SEM) and influencer campaigns. French and German versions went live on May 2024.

Timescale of the Data

The data presented here is collected until the activation of the websites until 30th of October 2024.

Chart 1

Location of visits



Origin of visiors from 12 May - 22 October, 2024.

Chart 2

Main search terms

1. glutenunverträglichkeit	15,3%
2. celiac	5,3%
3. gluten intolerance	3,6%
4. maladie coeliaque	2,9%
5. celiac disease	2,8%
6. maladie du gluten	2,8%
7. zöliakie	2,7%
8. Qu'est-ce que la maladie coeliaque	2,4%

What visitors searched most until 30th of October.

Results

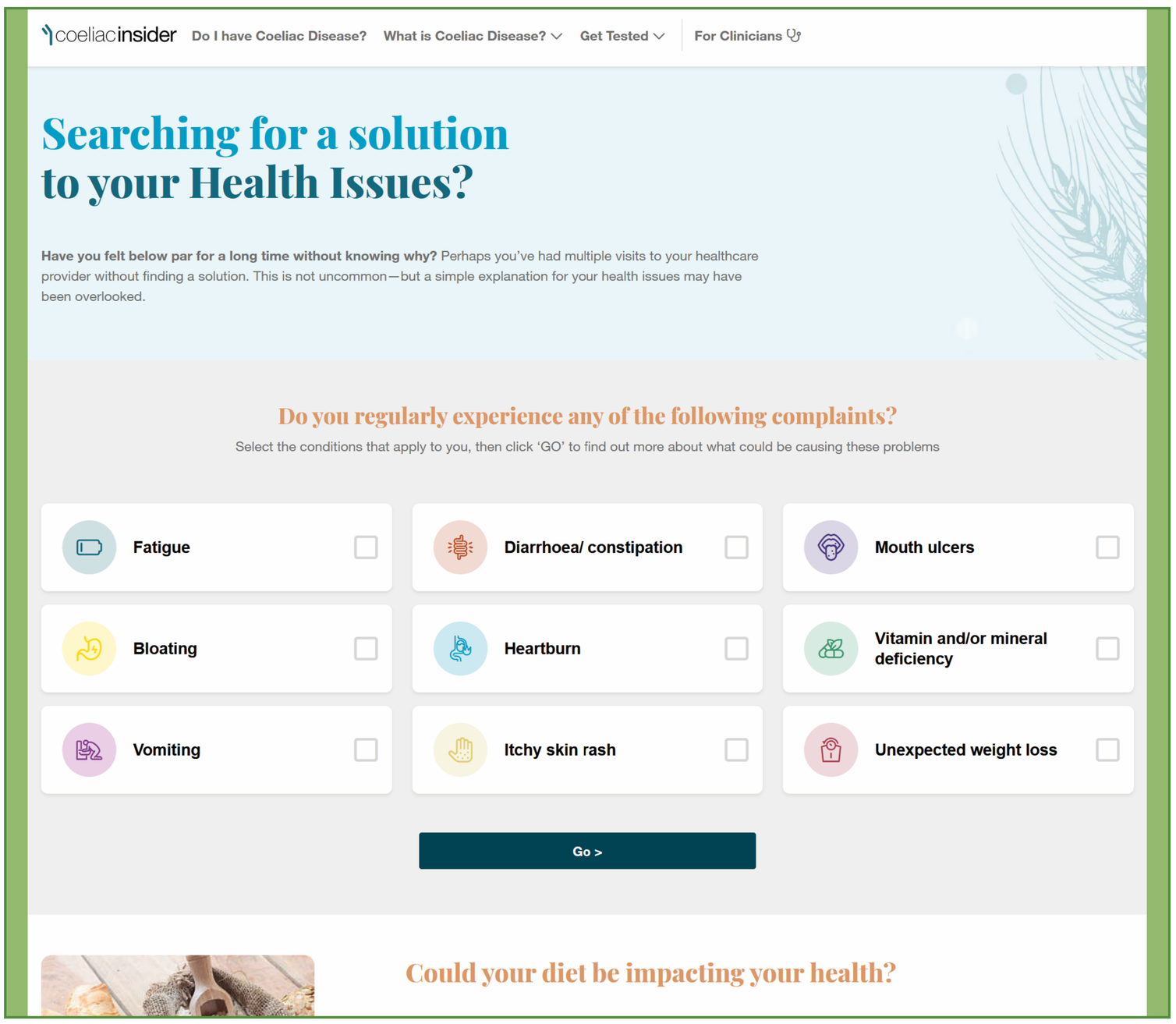
Currently all sites received **138,556** unique visits (12 May- 30 Oct 2024) from more than 100 different countries. Average time spent on the page was **1 minute 39 seconds**.

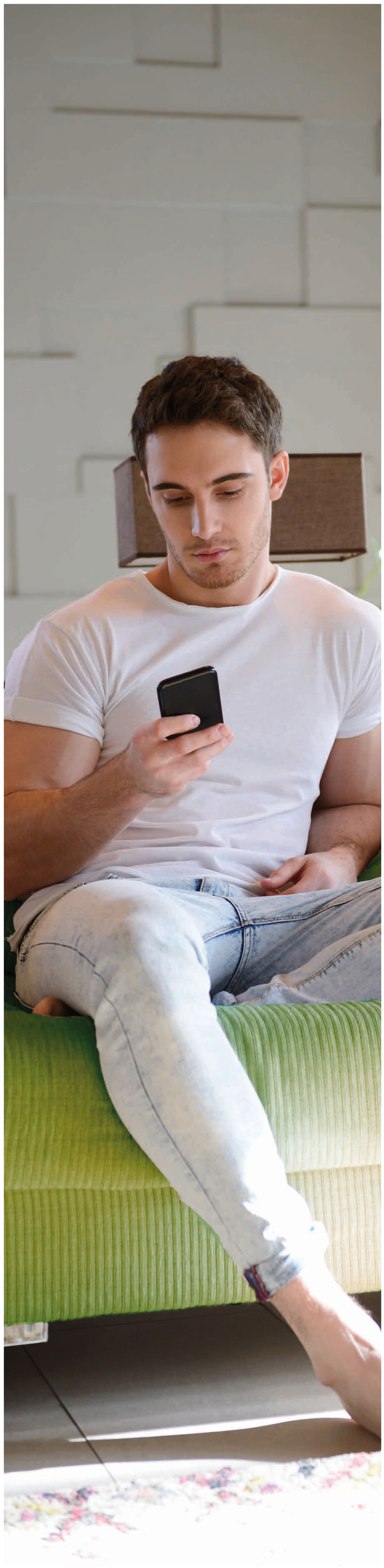
Scan for the website

Conclusions

- ~160,000 visits were made to all websites: UK, FR, GER.
- In 2 years, UK website had ~158,000 tracked unique visitors.
- In just about 6 months, the French Speaking website has ~35,000 tracked unique visitors, German Speaking website has ~72,000 tracked unique visitors.
- CeliacInsider's aim to contribute to the diagnostic journey of the patient and quality of life for those living with CeD through education and empowerment is continuing to grow across Europe.

Trademark/Licensing





ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

Adherence to the Gluten-Free Diet Role as a Mediating and Moderating of the Relationship between Food Insecurity and Health-Related Quality of Life in Adults with Celiac Disease: Cross-Sectional Study

Submitted by: Celiac Care Providers Society, Jordan

Introduction

Celiac disease (CD) is an autoimmune disorder triggered by gluten, damaging the small intestine and leading to nutrient malabsorption. The only treatment is lifelong adherence to a gluten-free diet (GFD), which is challenging due to the limited availability and high cost of gluten-free foods, especially in Jordan. Food insecurity (FI) further complicates adherence to GFD, negatively affecting CD patients' health-related quality of life (HRQoL). This study explores the relationship between FI, HRQoL, and GFD adherence among adults with CD.

Method

This cross-sectional study, conducted in Jordan from January to June 2023, surveyed 1,162 adults with celiac disease (CD) using a self-reported online questionnaire. The survey covered demographics, health-related quality of life (HRQoL), adherence to a gluten-free diet (GFD), and food insecurity. Data were analyzed using SPSS, with multiple regression to explore predictors of HRQoL and the moderation and mediation effects of GFD adherence on the relationship between food insecurity and HRQoL.

Analysis

Data were analyzed using SPSS version 25, with continuous data summarized by mean and standard deviation, and categorical data by frequencies and percentages. Pearson correlation was used to examine relationships between FI, GFD adherence, and HRQoL. Multiple linear regression identified HRQoL predictors. Mediation analysis, following Hayes' guidelines, tested the mediating role of GFD adherence using five steps, with bias-corrected 95% confidence intervals (CIs) via 1,000 bootstrap samples to assess significance. Full mediation was indicated if the beta weight reduced and the p-value became nonsignificant. Moderation analysis tested whether GFD adherence moderated the relationship between FI and HRQoL.

Table 1

Characteristics of the study participants (n = 1162)

Variable	Categories	*N* (%)
Age *	28.52 ± 8.48	
Gender	Male	321 (27.6)
	Female	841 (72.4)
Marital status	Single without spouse	703 (60.5)
	Married	459 (39.5)
Monthly income (JOD) **	<500	672 (57.8)
	500–700	292 (25.1)
	>700	198 (17.0)
Education level	Secondary school or lower	635 (54.6)
	Undergraduate degree	479 (41.2)
	Postgraduate degree	48 (4.1)
Body Mass Index *	20.16 ± 2.3	
	Normal	270 (23.2)
	Overweight	832 (71.6)
	Obese	60 (5.2)

* Continuous variable, the data represented as mean ± SD. JOD—Jordanian Dinar. ** The average monthly wage in Jordan was JOD 535 in 2000 and increased to JOD 691 in 2021.

Figure 1

Food Insecurity Categories

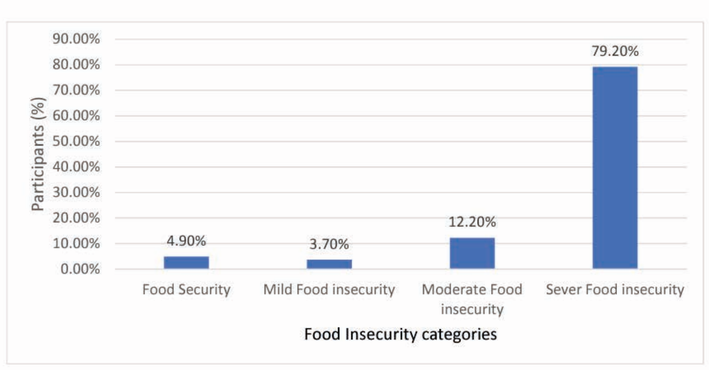


Figure 2

Adherence level to the gluten-free diet (GFD) in patients with Celiac Disease (CD)

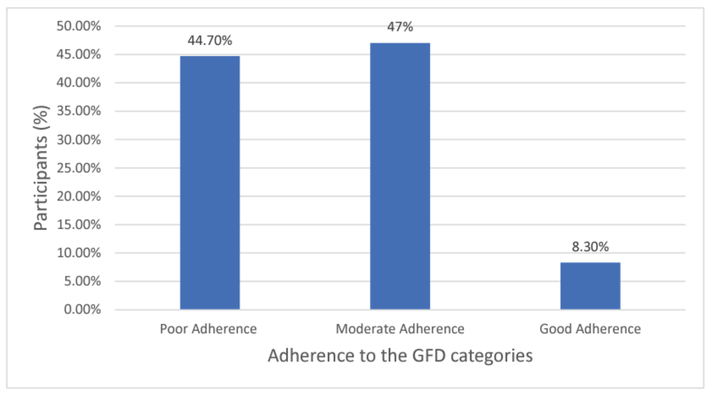


Figure 3

Health-related quality of life (HRQoL) percentage in adults with Celiac Disease (CD)

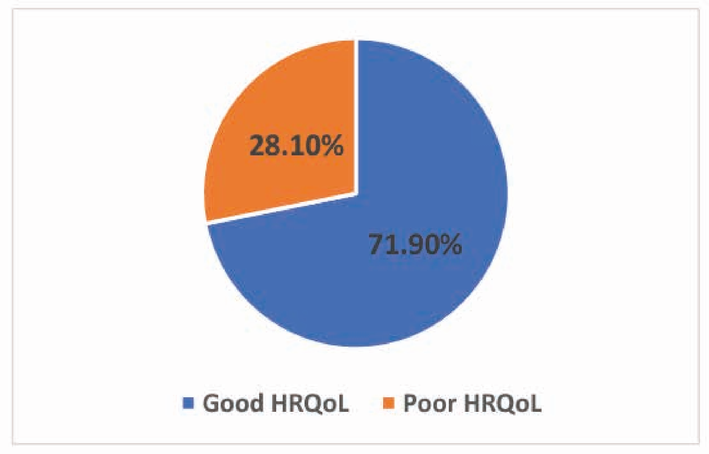


Table 2

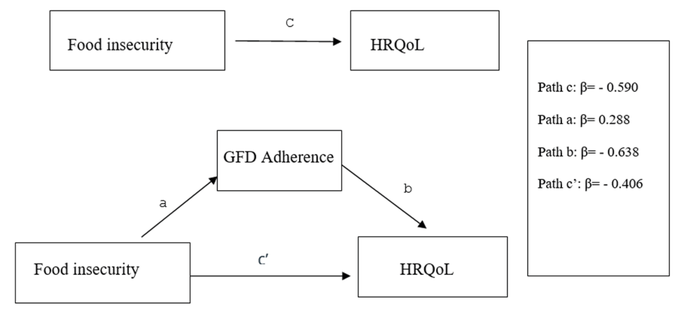
Results from PROCESS macro testing GFD adherence mediation model.

Effect [a], Variable	R^2	F	β	*p*-Value
Direct effect of mediator (GFD adherence on HRQoL)	0.213	62.56	−0.638	≤0.0001
Direct effect of the predictor (FI) on mediator (GFD adherence)	0.246	94.15	0.288	≤0.0001
Total effect of predictor (FI) on HRQoL	0.178	28.97	−0.509	≤0.0001
Direct effect of predictor (FI) on HRQoL with inclusion of the mediator (GFD adherence t)	0.213	62.56	−0.406	≤0.0001
	β	**95% CL**		***p*-Value**
Indirect predictor (Food insecurity) on HRQoL	−0.184	−0.236	−0.134	≤0.0001

[a] Adjusted for gender, marital status, and monthly income. FI—Food Insecurity; GFD—Gluten-Free Diet; HRQoL—Health-Related Quality of Life.

Figure 4

Conceptual framework of the potential mediating effect of adherence to the GFD on the relationship between FI and HRQoL in adults with Celiac Disease (CD). Analysis was adjusted for gender, marital status, and monthly income.



Results

The study included 1,162 celiac disease (CD) patients, with 72.4% being female and 71.6% classified as overweight. Most participants reported severe food insecurity (FI), with low adherence to a gluten-free diet (GFD). Two-thirds of participants experienced poor health-related quality of life (HRQoL). Pearson correlations revealed a moderate positive relationship between FI and GFD adherence (24% shared variance), and significant negative correlations between FI, GFD adherence, and HRQoL. Regression analysis found that gender, marital status, and income significantly influenced HRQoL, with females and married individuals reporting lower HRQoL scores.

Conclusion

In conclusion, there is a complex relationship between food insecurity (FI) and health-related quality of life (HRQoL) in patients with celiac disease (CD), influenced by factors such as gender, marital status, and income. FI negatively impacts HRQoL, and adherence to a gluten-free diet (GFD) is crucial for improving CD management and mitigating these effects. However, GFD adherence does not alter the direct relationship between FI and HRQoL. Future interventions should address FI and promote GFD adherence, while future studies should involve more diverse populations to increase generalizability.

Authors

1. Nour Amin Elsahoryi, University of Petra
2. Mohammed Omar Ibrahim, Mutah University
3. Omar Amin Alhaj, University of Petra

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

Rates of biopsy-confirmed celiac disease diagnosis and gluten-free diet adherence in Europe and the United States: a real-world survey

Submitted by: Hannah Knight[1] Niamh Harvey[1], Fatima Dawod[1], Rina Lukanova[1], Vanessa Weisbrod[2], Marcia Gailes[2], Marilyn Geller[2]

[1] Adelphi Real World, Bollington, United Kingdom, [2] Celiac Disease Foundation, Woodlands Hills, CA, United States of America.

Introduction

Guidelines recommend that celiac disease (CeD) in adults is confirmed by biopsy[1-2] and managed with a gluten-free diet (GFD).

However, existing data on biopsy-confirmed (BC) diagnosis rates and GFD-adherence across countries are limited.

We aimed to identify differences in rates of biopsy-confirmed diagnosis of CeD and GFD-adherence across Germany, Italy, Spain, and the United States (US).

Method

Data were drawn from the Adelphi Real World CeD Disease Specific Programme (DSP)™, a cross-sectional survey with retrospective data collection of physicians and their patients with CeD, conducted in Germany, Italy, Spain, and the US between July 2021 and January 2022. The DSP methodology has been previously published and validated[3-5].

Gastroenterologists (GIs) and primary care physicians (PCPs) were recruited to complete patient record forms for their next eight consecutively consulting adult CeD patients who were symptomatic in the last 12 months.

GIs and PCPs reported demographics, diagnostic tests used, and GFD-adherence immediately after diagnosis for their patients.

The same patients were invited to complete a voluntary patient self-completion form which captured consultation history and awareness of CeD prior to diagnosis.

Analysis

Patients were grouped according to their diagnosis: BC or non-biopsy-confirmed (NBC).

Analyses were descriptive.

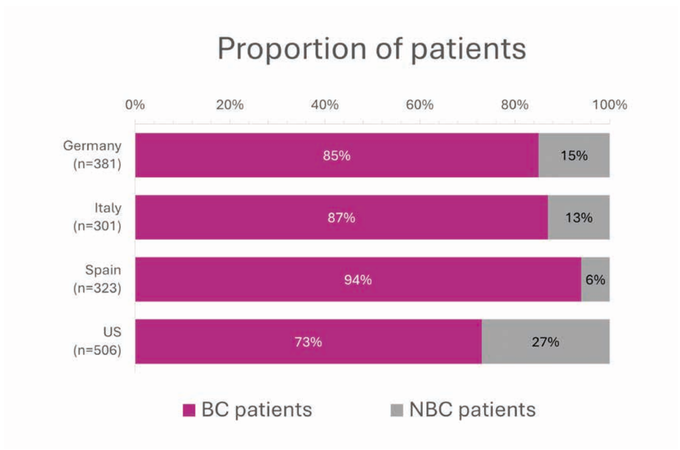
Results

Analyses included data from 262 GIs and PCPs and 1,511 patients from Germany (n=381), Italy (n=301), Spain (n=323), and the US (n=506).

BC diagnosis rates were 85% of patients (Germany), 87% (Italy), 94% (Spain), and 73% (US), with the remainder NBC (Figure 1).

Figure 1

Patient diagnosis by country



BC, Biopsy-confirmed; NBC, Non-biopsy confirmed; US, United States

Overall, patients had a mean [standard deviation; SD] age of 37.4 [13.1] years. Patient age split by countries and cohort is shown in Table 1.

The proportion of female patients was 60–87% across the countries and BC/NBC cohorts, except for NBC patients in Germany of which 38% were female (Table 1).

Mean [SD] BMI ranged from 21.8 [2.6] in Italy to 27.3 [4.8] in the US, most patients were White (92%), and 46–74% of patients were in full-time work (Table 1).

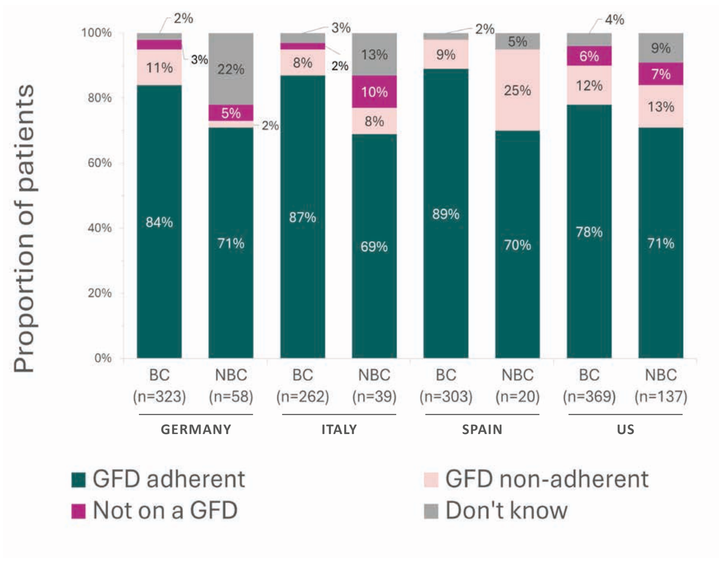
On average, patients had been diagnosed with CeD for more than 2 years regardless of the use of a biopsy. Average disease duration was notably short in the US (median {IQR} 2.1 {0.9-4.4} years for BC; 2.3 {0.8-5.3} years for NBC patients; Table 1).

Across all countries, GFD-adherence was 78–89% among BC patients and 69–71% among NBC patients (Figure 2).

GFD-adherence was unknown for between 2–4% of BC patients, compared to 5–22% of NBC patients (Figure 2).

Figure 2

Physician-reported gluten-free diet adherence immediately after diagnosis.



BC, Biopsy-confirmed; GFD, Gluten-free diet; NBC, Non-biopsy confirmed; US, United States. 'Gluten-free diet adherent' combines response options: 'On a strict gluten-free diet with no gluten uptake' and 'On a gluten-free diet, but likely to have inadvertent gluten uptake.' 'Gluten-free diet non-adherent' combines response options: 'On a gluten-free diet, but likely to have advertent gluten uptake occasionally' and 'On a gluten-free diet, but likely to have advertent gluten uptake most of the time.'

Conclusion

We found that not all patients had a BC diagnosis of CeD, notably in the US.

Across countries, 69–71% of NBC patients were GFD-adherent, compared to 78–89% of BC patients.

GFD status was unknown mainly in NBC patients, suggesting less engagement in condition management.

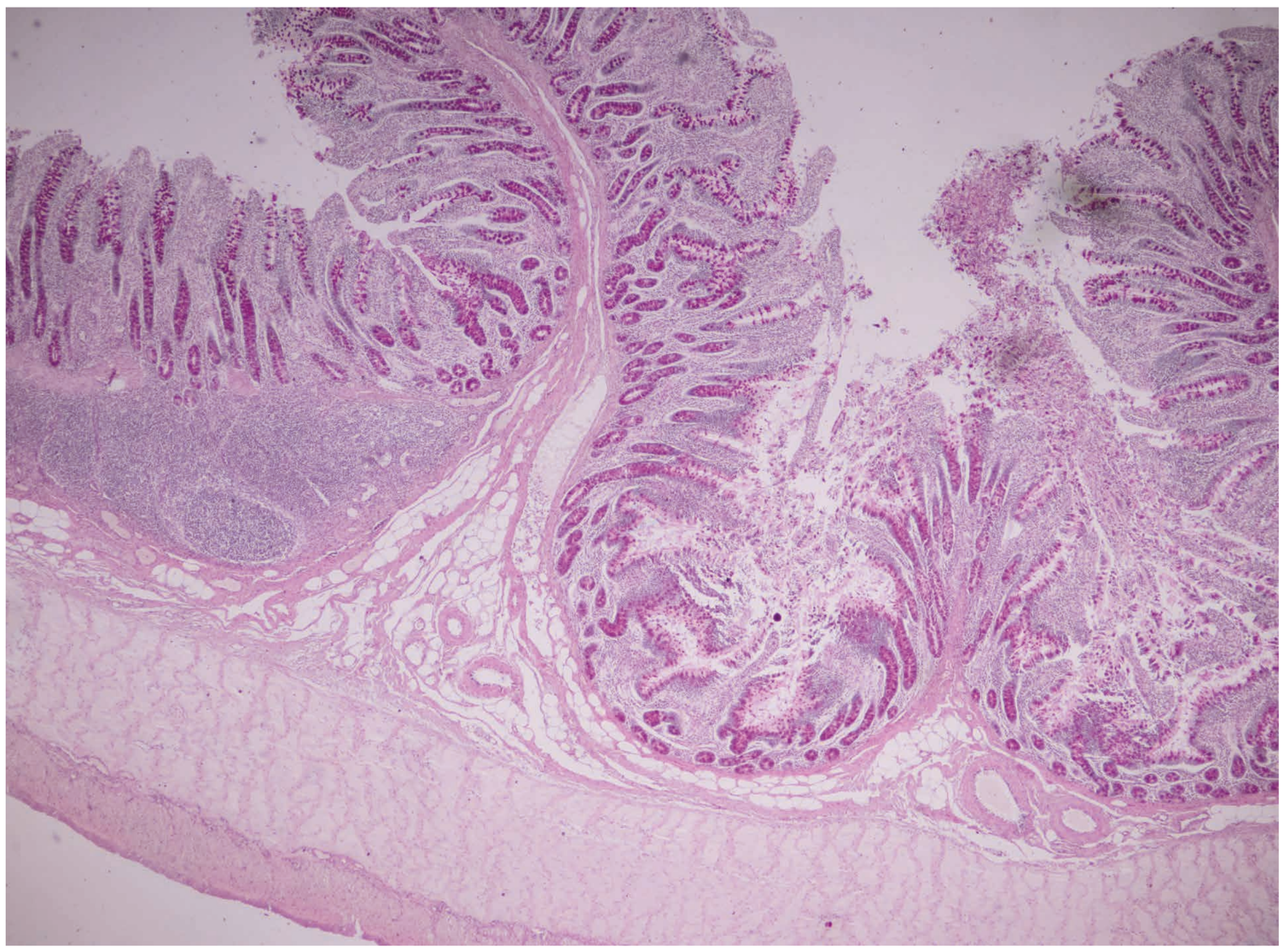
Further analysis is needed to investigate the association of BC diagnosis with GFD-adherence and ultimately optimal disease control, alongside understanding reasons for using/not using biopsy for diagnosing CeD.

Table 1

Patient demographics and characteristics

	Germany		Italy		Spain		US	
	BC	NBC	BC	NBC	BC	NBC	BC	NBC
n	**323**	**58**	**262**	**39**	**303**	**20**	**369**	**137**
Age, *mean [SD]*	34.5 [11.0]	35.2 [10.9]	38.2 [13.4]	36.0 [14.0]	38.6 [13.4]	34.8 [12.7]	38.0 [14.2]	40.4 [13.0]
Female, *n (%)*	195 (60)	22 (38)	157 (60)	34 (87)	195 (64)	15 (75)	227 (62)	87 (64)
BMI, *mean [SD]*	23.1 [2.9]	23.2 [2.9]	23.1 [3.7]	21.8 [2.6]	23.4 [3.3]	23.2 [3.1]	25.0 [4.6]	27.3 [4.8]
Ethnicity, White, *n (%)*	310 (96)	52 (90)	248 (95)	35 (90)	288 (95)	20 (100)	307 (83)	124 (91)
Working full-time, *n (%)*	205 (63)	42 (72)	161 (61)	18 (46)	144 (48)	12 (60)	210 (57)	102 (74)
Disease duration, Years, *median [IQR]*	2.1 [0.9–4.0]	3.9 [0.9–12.1]	3.5 [1.2–8.6]	6.6 [1.5–10.7]	3.5 [1.8–6.7]	3.1 [0.5–8.5]	2.1 [0.9–4.4]	2.3 [0.8–5.3]

Patients with known data. BC, Biopsy-confirmed; BMI, Body mass index; IQR, Inter-quartile range; NBC, Non-biopsy confirmed; SD, Standard deviation; US, United States



References

1. Rubio-Tapia A, et al., Am J Gastroenterol. 2023;118(1): 59-76.
2. Raiteri A, et al., World J Gastroenterol. 2022;28(1): 154-175.
3. Anderson P, et al., Cur Med Res Opin. 2008;24(11): 3063-72.
4. Babineaux SM, et al., BMJ Open. 2016;6(8): e010352.
5. Higgins V, et al., Diabetes Metab Syndr Obes. 2016;1(9): 371-380.

Disclosures

HK, NH, FD & RL are employees of Adelphi Real World.

VB, MG & MG are employees of the Celiac Disease Foundation.

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

The added value of the cognition, dining, gastrointestinal problems, sleep and tiredness bolt-ons for the EQ-5D-5L in patients with coeliac disease

Submitted by: M. Mercédesz Angyal[1,2], Mathieu F. Janssen[3], Peter L. Lakatos[4,5], Valentin Brodszky[2], and Fanni Rencz[2]

[1] Károly Rácz Doctoral School of Clinical Medicine, Semmelweis University, Budapest, Hungary, [2] Department of Health Policy, Corvinus University of Budapest, Budapest, Hungary, email: fanni.rencz@uni-corvinus.hu, [3] Section Medical Psychology and Psychotherapy, Department of Psychiatry, Erasmus MC, Rotterdam, The Netherlands, [4] McGill University Health Centre, Montreal General Hospital, Canada, [5] Department of Internal Medicine and Oncology, Semmelweis University, Budapest, Hungary

Introduction

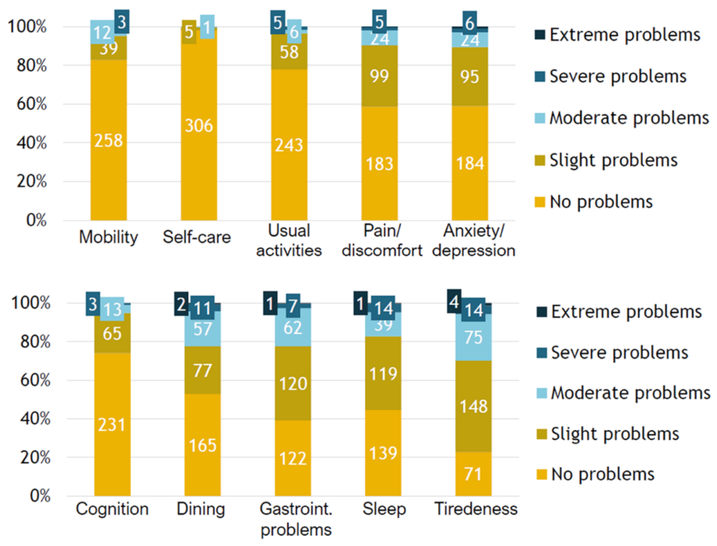
The EQ-5D is one of the most commonly used generic preference-based health-related quality of life measures in the world, which is recommended by the health technology assessment guidelines in more than 20 countries, including Hungary. However, multiple studies suggest that the EQ-5D may overestimate health-related quality of life (HRQoL) in patients with coeliac disease (CD). We aimed to develop and psychometrically test potentially relevant bolt-on dimensions to improve the measurement performance of the EQ-5D-5L in CD patients.

Methods

The development and selection of bolt-ons were informed by a literature review on HRQoL in CD, expert and patient input. A cross-sectional online survey was conducted amongst 312 adult CD patients. Respondents completed the EQ-5D-5L, two condition-specific bolt-ons newly-developed for the present study [dining (DI) and gastrointestinal problems (GI)] and three existing bolt-ons [cognition (CO), sleep (SL) and tiredness (TI)], alogside with the Gastrointestinal Symptom Rating Scale (GSRS) and the Satisfaction with Life Scale (SWLS). The following psychometric properties were tested: ceiling, informativity, convergent and known-group validity, and dimensionality (confirmatory factor analysis).

Results

Figure 1. Responses on five EQ-5D-5L dimensions and five bolt-ons



Adding the TI, SL, GI, DI and CO individual bolt-ons reduced the ceiling of the EQ-5D-5L (39%) to 17%, 23%, 24%, 26% and 37%, respectively. GI excelled with strong convergent validity with the Gastrointestinal Symptom Rating Scale total score (rs=0.71) and improved the discriminatory power for all known-groups. GI was the only bolt-on loading on a different factor from the five core dimensions, whereas the other four bolt-ons loaded onto the same 'psychosocial health' factor as the EQ-5D-5L anxiety/ depression dimension. The addition of bolt-ons to the EQ-5D-5L improved the explained variance of EQ VAS and SWLS scores, as indicated by adjusted R2. Specifically, two bolt-ons (GI and CO) improved the explained variance in EQ VAS from 0.411 to 0.440, while three bolt-ons (DI, GI and SL) improved the explained variance in SWLS from 0.193 to 0.206.

Table 2. The explanatory power of EQ-5D-5L and bolt-ons on EQ VAS and SWLS

Selection of domains	EQ VAS		Selection of domains	SWLS	
	Adjusted R^2	ΣΔ Adjusted R^2		Adjusted R^2	ΣΔ Adjusted R^2
EQ-5D-5L domains					
Mobility (MO)	0.1587	-	Mobility (MO)	0.0345	-
Self-care (SC)	0.0886	-	Self-care (SC)	0.0044	-
Usual activities (UA)	0.3039	-	Usual activities (UA)	0.1101	-
Pain/discomfort (PD)	0.3012	-	Pain/discomfort (PD)	0.1156	-
Anxiety/depression (AD)	0.1826	-	Anxiety/depression (AD)	0.1399	-
Bolt-on domains					
Gastrointestinal problems (GI)	0.1787	-	Gastrointestinal problems (GI)	0.0954	-
Cognition (CO)	0.1958	-	Cognition (CO)	0.0950	-
Sleep (SL)	0.1085	-	Sleep (SL)	0.0718	-
Tiredeness (TI)	0.1617	-	Tiredeness (TI)	0.1029	-
Dining (DI)	0.0652	-	Dining (DI)	0.0802	-
EQ-5D-5L(+bolt-on) domains					
MO+SC+UA+PD+AD	0.4109	-	MO+SC+UA+PD+AD	0.1934	-
MO+SC+UA+PD+AD+CO	0.4293	0.0184	MO+SC+UA+PD+AD+DI	0.2039	0.0105
MO+SC+UA+PD+AD+CO+GI	0.4402	0.0109	MO+SC+UA+PD+AD+DI+SL	0.2052	0.0013
			MO+SC+UA+PD+AD+DI+SL+GI	0,2057	0.0005

Table 3. Discriminatory power for GSRS tertiles, self-perceived health, and symptomatic and asymptomatic patient groups

Health and quality of life	Mean (SD) EQ-5D-5L+bolt-on LSS (0-100)			ANOVA F	RE (95%CI), ref: previous row
Health status	**Poor-fair**	**Good**	**Very good-excellent**		
n	75	141	96	-	-
EQ-5D-5L	17.6 (14.25)	6.81 (7.45)	2.45 (4.04)	63.94	-
EQ-5D-5L+GI	20.83 (13.44)	9.31 (7.69)	3.56 (4.87)	82.85	1.30 (1.14-1.49)
Gastrointerstinal symptoms (GSRS tertiles)	**<21**	**22-30**	**30+**		
n	111	99	102	-	-
EQ-5D-5L	3.24 (5.59)	6.97 (6.84)	14.36 (13.94)	37.68	-
EQ-5D-5L+GI	3.75 (5.36)	9.43 (7.16)	18.30 (13.05)	69.18	1.84 (1.56-2.23)
Symptomatic	**No symptoms**		**At least one symptom**		
n	90		222	-	-
EQ-5D-5L	3.00 (7.10)		10.11 (10.99)	32.23	-
EQ-5D-5L+GI	3.56 (6.45)		13.04 (11.11)	57.59	1.79 (1.49-2.44)

Table 4. Spearman's correlation coefficients between EQ-5D-5L, bolt-ons, EQ VAS and GSRS

Variables	EQ-5D-5L					Bolt-ons					EQ VAS	GSRS total score
	MO	SC	UA	PD	AD	DI	GI	CO	SL	TI		
SC	0.285	-										
UA	0.429	0.300	-									
PD	0.365	0.240	0.499	-								
AD	0.159	0.174	0.273	0.407	-							
DI	0.163	0.098	0.333	0.283	0.271	-						
GP	0.200	0.103	0.357	0.508	0.372	0.383	-					
CO	0.165	-0.016	0.391	0.374	0.365	0.326	0.369	-				
SL	0.202	0.087	0.269	0.335	0.294	0.245	0.309	0.314	-			
TI	0.313	0.136	0.390	0.465	0.425	0.355	0.403	0.399	0.376	-		
EQ VAS	-0.329	-0.193	-0.424	-0.542	-0.317	-0.229	-0.504	-0.347	-0.262	-0.388	-	
GSRS total score	0.222	0.139	0.376	0.534	0.344	0.359	0.712	0.331	0.364	0.492	-0.462	-

Table 1. Ceiling and informativity of EQ-5D-5L and bolt-ons

	Ceiling		Ceiling in EQ-5D-5L + bolt-ons		Informativity of EQ-5D-5L + bolt-ons	
	n	%	n	%	Sh. index H'	Sh. index J'
EQ-5D-5L						
Mobility (MO)	258	82.7%	121	38.8%	3.71	0.32
Self-care (SC)	306	98.1%				
Usual activities (UA)	243	77.9%				
Pain/discomfort (PD)	183	58.7%				
Anxiety/depression (AD)	184	59.0%				
(EQ-5D-5L +) Bolt-ons						
Dining (DI)	165	52.9%	82	26.3%	4.95	0.36
Gastrointestinal problems (GI)	122	39.1%	75	24.0%	4.84	0.35
Cognition (CO)	231	74.0%	114	36.5%	4.33	0.31
Sleep (SL)	139	44.6%	72	23.1%	4.94	0.35
Tiredness (TI)	71	22.8%	53	17.0%	4.88	0.35
EQ-5D-5L + all bolt-ons			23	7.4%	7.28	0.31

Conclusion

The DI, GI, SL and TI bolt-ons, especially the GI, enhance the validity of EQ-5D-5L in patients with CD, suggesting their value in capturing important HRQoL aspects potentially missed by the five core dimensions. These bolt-ons can be used in sensitivity analyses supporting health technology assessments and subsequent resource allocation decisions.

Funding sources

F.R.'s work was supported by the János Bolyai Research Scholarship of the Hungarian Academy of Sciences (BO/00304/21) and the New National Excellence Program of the Ministry for Innovation and Technology from the source of the National Research, Development and Innovation Fund (ÚNKP-23-5-CORVINUS-5). Project no. 2023-2.1.2-KDP-2023-00016 has been implemented with the support provided by the Ministry of Culture and Innovation of Hungary from the National Research, Development and Innovation Fund, financed under the KDP-2023 funding scheme for M.M.A.'s work.

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

Investigation of body composition parameters in patients with celiac disease on a gluten-free diet. Prospective, multicenter, case-control study (ARCTIC study)

Submitted by: Peresztegi Míra, Vereczkei Zsófia, Sipos Zoltán, Farkas Nelli, Máth Beáta, Lemes Klára, Lénárt Zsuzsanna, Papp Veronika, Dakó Eszter, Dakó Sarolta, Bajor Judit

Introduction

Body composition parameters in patients with celiac disease differ from the normal population, and in some cases, they do not completely normalize even with a gluten-free diet.

Despite weight gain on the diet, the change in body composition is generally unfavorable (less increase in fat-free body mass, significantly higher increase in fat content).

One reason for this is improved absorption, but the high calorie, sugar, and fat content of the gluten-free diet can also lead to undesirable weight gain and unfavorable metabolic changes (dyslipidemia, fatty liver, insulin resistance) without dietary control.

Aim

Clarification of the cardiovascular and metabolic effects of celiac disease, and the gluten-free diet (GFD) used for its treatment.

Method

In our prospective multicenter, case-control study (ARCTIC study), we examined body composition parameters and blood lipid levels of patients with celiac disease who had been on a gluten-free diet for at least 1 year and compared them to those of healthy control individuals.

Patients from three university centers with celiac disease participated in the study.

Body composition analysis was performed using an Inbody 770 device, measuring the following parameters: body mass index (BMI), waist-hip ratio, Inbody score, Skeletal muscle mass (SMM), Percent body fat (PBF), Visceral fat area (VFA). Blood lipids including total cholesterol, LDL, and triglyceride levels were measured. Abdominal ultrasound was performed to assess the degree of hepatic steatosis.

Fischer's exact test and Chi-Square test were used for categorical variables, and the Welch Two Sample t-test was used to assess continuous variables. A *p*-value less than 0.05 is considered statistically significant.

Patient enrollment

Patients of 3 clinical centers. On a GFD for min. 1 year. Positive serology and histology. No severe comorbidities.

Data collection

Measurements questionnaires, abdominal US, laboratory testing.

Statistical analysis

SPSS: Welch Two Sample t-test, Fischer's exact test.

Results

97 patients with celiac disease (78 female, 19 male) and 47 (40 female, 7 male) control individuals were included.

The mean age of patients with celiac disease (36.2 years) was slightly higher than that of controls (32.5 years), but the difference was not significant.

The mean waist and hip circumference were higher in patients with celiac disease but did not reach the significance threshold (p=0.051 and p=0.10).

Among the body composition parameters, higher mean BMI, Skeletal muscle mass, Percent body fat, Visceral fat area, and lower Inbody score were observed, but the differences were not significant (p=0.31, 0.16, 0.72, 0.39, 0.62).

Based on BMI, 9.3% of celiac patients were underweight, 54.7% had normal weight, 18.5% were overweight, and 17.5% were obese. These proportions for controls were: 8.5%, 66%, 19%, 6.5%.

The mean total cholesterol level was lower in patients with celiac disease (p=0.043), while the mean triglyceride level was higher (p=0.85).

We found significantly more cases of hepatic steatosis in celiac patients than in controls (p=0.012). Among them, 83% met the Metabolic Dysfunction–Associated Liver Disease (MASLD) criteria, while 60% of controls with hepatic steatosis did.

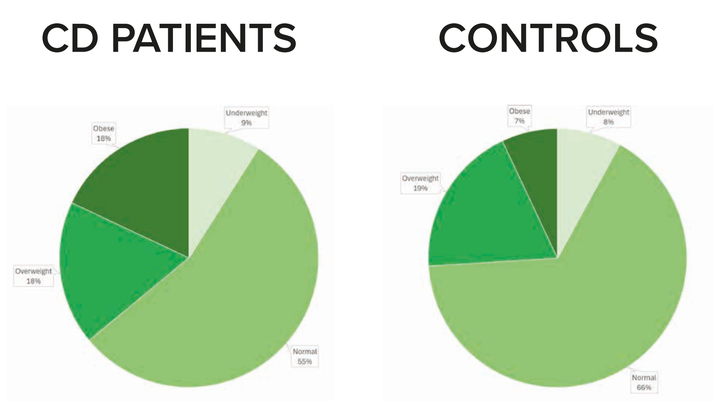
Table 1

Body composition parameters

	CD PATIENTS	CONTROLS	*p*-value
Skeletal muscle mass	27,3 +/- 7,1 kg	25,8 +/- 5,2 kg	*0,167*
Percent body fat	27,5 +/- 9,4%	26,9 +/- 9%	*0,729*
Visceral fat area	88,9 +/- 49,7 cm^2	81,6 +/- 47,6 cm^2	*0,393*
BMI	24,12 +/- 6,26	23,3 +/- 4,3	*0,319*
InBody Score	72,9 +/- 7,5	73,6 +/- 7,5	*0,624*
Waist-hip ratio	0,84 +/- 0,1	0,82 +/- 0,1	*0,380*

Figure 1

Body Mass Index (BMI) categories



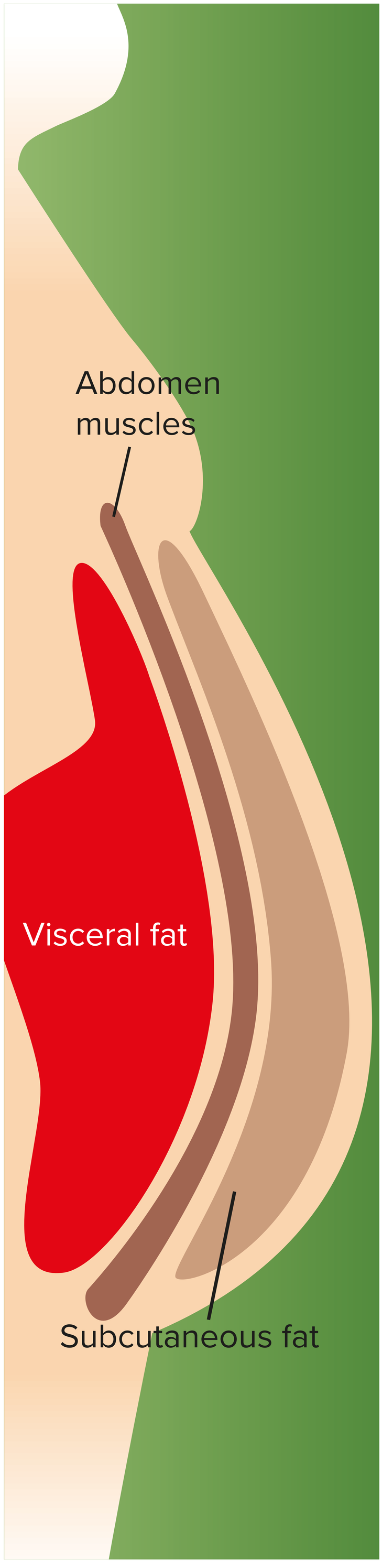
Conclusion

- The body composition parameters of celiac patients on a gluten-free diet are less favorable compared to control cases, albeit not significantly.
- Our data suggest that for most of these patients, the problem is not caused by malabsorption and malnutrition.
- Preventing cardiovascular and metabolic complications poses a new challenge in patient care.

Acknowledgements

The project is non-industry funded. Study and center costs are covered by the University of Pécs Medical School and the National Research, Development, and Innovation Office (grant FK142942 to JB). This study is also supported by the ÚNKP-23-3 New National Excellence Program of the Ministry for Culture and Innovation from the source of the National Research, Development and Innovation Fund (grant ÚNKP-23-3-II-PTE-1855) to ZV, PTE-KITEP-2024-433 to MP.

All authors have declared no conflict of interest.



Hepatic steatosis and body composition in patients with celiac disease. Preliminary results of a prospective, multicenter, case-control study (ARCTIC study)

Submitted by: Bajor, J.[1], Peresztegi, M.[2], Vereczkei, Z.[3], Hagymási, K.[4], Faluhelyi, N.[5], Szekeres, G.[5], Pásztor, G.[6], Szirmay, B.[7], Sipos, Z.[3], Lemes, K.[8], Papp, V.[4] Lénárt, Z.[8], Pár, G.[1]

[1] University of Pécs, Medical School, First Department of Medicine, Division of Gastroenterology, Pécs, Hungary, [2] Medical School, University of Pécs, Pécs, Hungary, [3]Institute for Translational Medicine, Medical School, University of Pécs, Pécs, Hungary, [4] Department of Surgery, Transplantation and Gastroenterology, Semmelweis University, Faculty of Medicine, Budapest, Hungary, [5] Department of Radiology, Medical School, University of Pécs, Pécs, Hungary, [6] Department of Radiology, University of Szeged, Albert Szent-Györgyi Medical School, Szeged, Hungary, [7] Department of Laboratory Medicine, Medical School, University of Pécs, Pécs, Hungary, [8] Department of Medicine, University of Szeged, Albert Szent-Györgyi Medical School, Szeged, Hungary

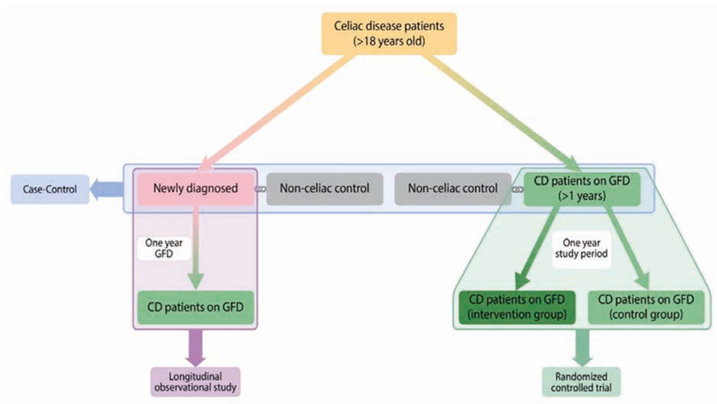
Introduction

According to literature data, the occurrence of hepatic steatosis is more common in patients with celiac disease than in the general population. The reasons behind this include malabsorption, proinflammatory processes, as well as weight gain and unfavorable metabolic changes on a gluten-free diet.

In our prospective multicenter, case-control study (ARCTIC study) (Figure 1), we examined the occurrence of hepatic steatosis determined by ultrasound (US), body composition parameters, and blood lipid levels in patients with celiac disease who had been on a gluten-free diet for at least 1 year. We investigated the proportion of celiac patients with and without steatosis, and compared the data of celiac patients with and without steatosis.

Method

Patients from three university centers with celiac disease participated in the study. Body composition analysis was performed using an InBody 770 device, measuring parameters such as BMI, waist-hip ratio, Inbody score, skeletal muscle mass (SMM), percent body fat (PBF), and visceral fat area (VFA). Blood lipids including total cholesterol, LDL, and triglyceride levels were measured. Hepatic steatosis was assessed by US using the Hamaguchi score and the NAFLD-LFS score. If either score was positive, the patient was classified into the steatosis group. Fischer's exact test was used for categorical variables, and Welch Two Sample t-test was used to assess continuous variables. A p-value less than 0.05 was considered statistically significant.



Results

97 patients with celiac disease and 47 control individuals were included. Hepatic steatosis was described in 13.8% of control subjects and 36% of celiac patients (p=0.012). In celiac patients, steatosis developed in 31% with normal BMI. The occurrence of hepatic steatosis in celiac patients showed a significant association with BMI (p<0.001), waist circumference (p<0.001), hip circumference (p<0.001), PBF (p=0.037), VFA (p=0.006), and triglyceride levels (p=0.006). However, there was no significant difference in waist-hip ratio (p=0.56), SMM (p=0.164), InBody score (p=0.31), LDL (p=0.80), and total cholesterol level (p=0.73).

The adherence to a gluten-free diet did not influence hepatic steatosis (p=0.60).

Among celiac disease patients with hepatic steatosis, 83% met the Metabolic Dysfunction–Associated Liver Disease (MASLD) criteria (vs controll patients 60%). Overweight or obesity (BMI over 25) detected in 30% of patients (vs controll patients 19%). 30 % of celiac patients with steatosis developed at normal BMI. 62% of celiac patients have at least one cardiovascular risk factor (obesity, hypertension, carbohydrate metabolism disorder, dyslipidaemia) most of theses were detected by the study (Table 1,2).

Table 1

Parameters	Celiac patients (n=97) (mean±SD)	Control group (n=47) (mean±SD)	*p*-value
Female/male ratio	4,1	6,6	*0,492*
Age (years)	36,24 (18-76)	32,55 (18-55)	*0,091*
Waist-hip ratio (cm)	0,83 (066-1,15)	0,82 (0,65,1,27)	*0,380*
Skeletal muscle mass (kg)	27.28 (15.1-48.1	25.82 (18-41.3)	*0,167*
Percent body fat (%)	27.5 (8.3-48.9)	26.9 (9.4-52.6)	*0,729*
Visceral fat area (cm3)	88.9 (18-218.7)	81.5 (21.7-256.4)	*0,393*
InBody score (points)	72.8 (57-92)	73.5 (45-92)	*0.624*
LDL-cholesterol (mmol/l)	2.77 (1.07-4.7)	2.96 (1.68-4.56)	*0,171*
Total cholesterol (mmol/l)	4.65 (2.8-7.5)	4.98 (3.4-7.2)	*0,043**
Triglycerides (mmol/l)	4.98 (3.4-7.2)	0.98 (0.38-2.62)	*0,856*
BMI (kg/m2)	24.12 (14.8-44)	23.27 (17.6-41.2)	*0,319*
CRP (mmol/l)	2.98 (0.2-36.5)	2.16 (0.2-9.7)	*0,156*
Occurence of steatosis (%)	36.08	13.80	*0,012**

Table 2

Parameters	Celiac patients without steatosis (n=62) (median, range)	Celiac patients with steatosis (n=62) (median, range)	*p*-value
Female/male ratio	5.25	2.86	*0.253*
Adequate diet adherence (%)	87	86	*0.601*
tTG pozitivity (%)	13	11	*0.999*
Waist circumference (cm)	76.2 (50-109)	88 (62-122)	*<0.001**
Hip circumference (cm)	91.29 (72-116)	104.34 (85-136)	*<0.001**
Sceletal muscle mass (kg)	26.5 (15,1-48,1)	28.67 (18,7-46,7)	*0,164*
Percent body fat (%)	25.92 (8.3-47.7)	30.29 (9.7-48.9)	*0,037*
Visceral fat area (cm3)	77.47 (19.7-197.2)	109.15 (18-218.7)	*0,006**
InBody score (points)	73.5 (58-91)	71.8 (57-92)	*0.316*
LDL-cholesterol (mmol/l)	2.78 (1.07-4.7)	2.74 (1.32-4.3)	*0.806*
Total cholesterol (mmol/l)	4.67 (2.8-7.5)	4.6 (3.1-6.0)	*0.733*
Triglycerides (mml/l)	0.84 (0.3-2.62)	1.27 (0.41-4.29)	*0.006**
BMI (kg/m2)	22.06 (14.8-34.3)	27.75 (17-44)	*<0.001**
CRP (mg/l)	2.98 (0.2-36.5)	2.99 (0.6-6.7)	*0.969*

Conclusion

The occurrence of hepatic steatosis is substantial in celiac patients on a gluten-free diet, even in those with normal BMI. Increased attention should be paid to its examination and monitoring during care, weight control, dietary and lifestyle counseling, as well as timely recognition and prevention of cardiovascular and metabolic diseases.

Acknowledgements

The project is non-industry funded. Study and center costs are covered by the University of Pécs Medical School and the National Research, Development, and Innovation Office (grant FK142942 to JB). This study is also supported by the ÚNKP-23-3 New National Excellence Program of the Ministry for Culture and Innovation from the source of the National Research, Development and Innovation Fund (grant ÚNKP-23-3-II-PTE-1855 to ZV and PTE-KITEP-2024-433 to MP.

All authors have declared no conflict of interest.

ABSTRACT OF ORIGINAL RESEARCH ON COELIAC DISEASE

Situation of the gluten free food available at public hospitals in Valencian Community (Spain)

Submitted by: Palomares I., Escuriola B., Monfort M.C., van der Hofstadt M., Torada D.

ACECOVA (Association of people affected by coeliac disease in Valencian Community)

Introduction

Patients with coeliac disease face lots of problems when eating out, especially when they can't choose the location. This problem is also a reality when coeliac patients need to visit or stay at hospitals. Authorities ought to guarantee gluten free food at healthcare facilities, especially for public ones.

Furthermore, in the Valencian Community there are two laws related to gluten free food offered in public centers. One of them obliges to have food which fill all users' nutritional necessities of public catering. The other one specifically obliges to have gluten free food in public centers' catering and vending machines.

Method

Our association technicians has elaborated a Google Forms survey to reach valuable information about this situation. Surveyed people are patients with coeliac disease, or their close relatives when the patients are minors. Moreover, hospitals workers with close relation with the disease (patients or close relatives of them) are also included in the survey. People are accepted as respondents only if they also have visited a public healthcare facility in 2023 or 2024 at Valencian Community (Spain).

Survey has been shared with association's members (via email) and through social media platforms (Instagram, Facebook and Twitter).

Chart 1

Process flowchart

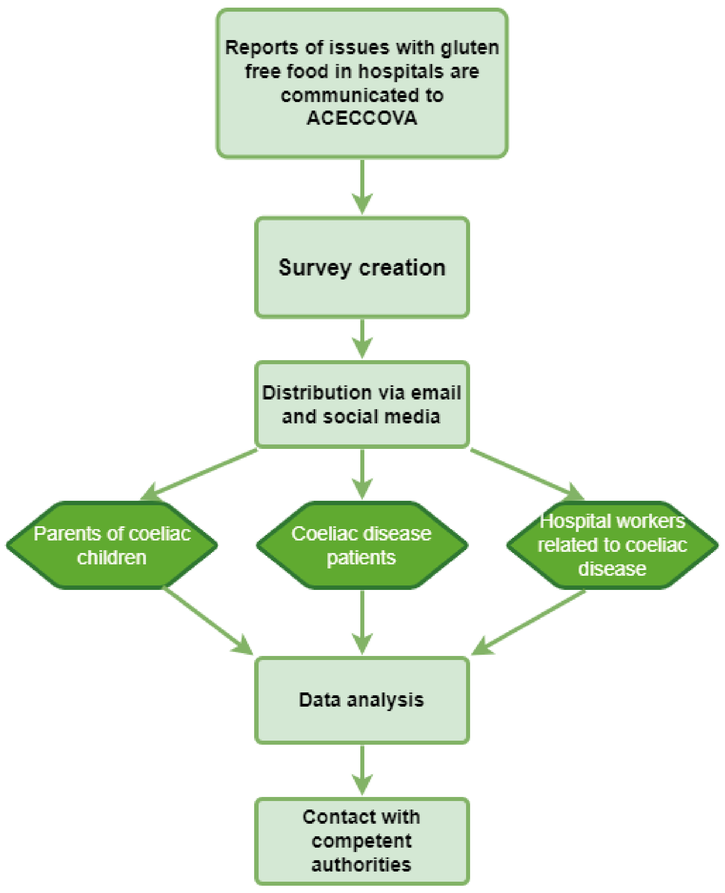


Diagram with the most important parts of the process followed.

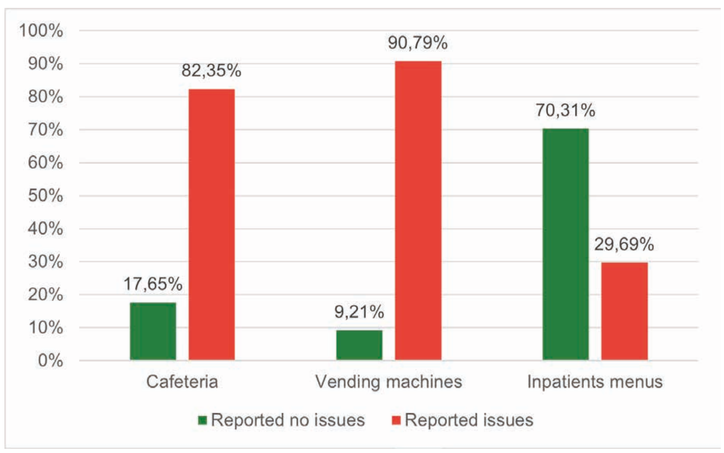
The survey includes three food-related aspects in hospitals. One of them being the health center cafeteria, if there's one; another being the items sold at vending machines, and, finally, the menus served directly to inpatients. 169 responses to the survey have been analyzed. Afterwards, analyzed information is presented to competent authorities.

Results

The availability of gluten free products in public hospitals is concerningly lacking. The survey results point out that only 18% of participants reported no issues when eating at hospital cafeterias. The results about vending machines are even worse, only 9% of the surveyed people didn't report issues.

Chart 2

Reported issues



Reported issues for the three food-related aspects analyzed in public hospital. The red bars indicate the percentage of participants who report any kind of issue related to gluten and food.

On top of that, vending machines are a focal point because they're the only option when cafés are closed or in services such as the emergency areas. For both, cafeterias and vending machines, the most reported issue is lacking gluten free food. Another important issue in vending machine is the unavailability of ingredient information. Patients reported that they can't read it when products are inside the machine.

Concerning patients who stay at hospital, 30% of them face problems with gluten free food during their stay. Out of all the surveyed patients, five of them were offered food with gluten, endangering their health.

Discussion - Conclusion

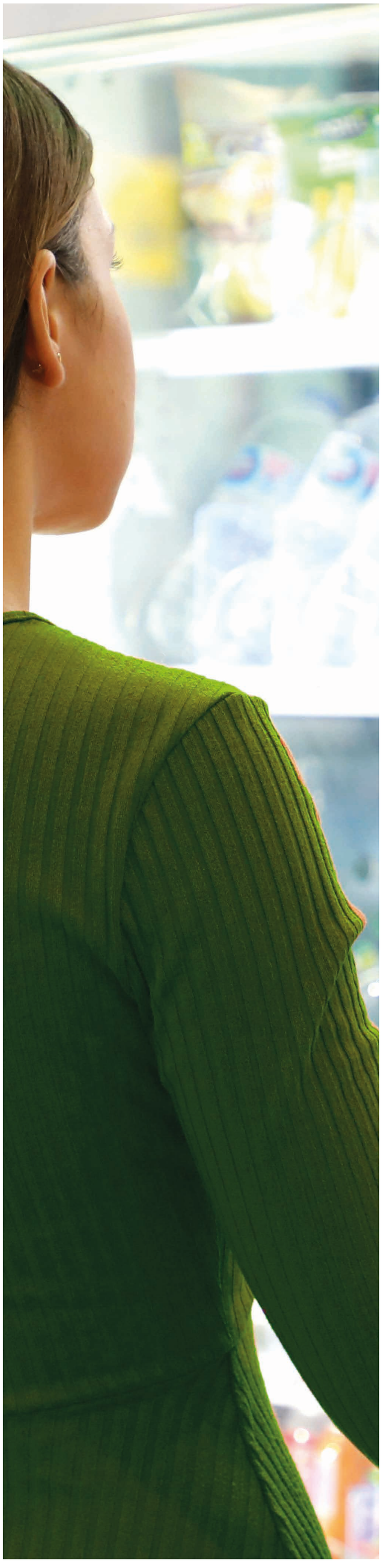
New measures are required to avoid hazards to coeliac disease patient's health. More studies are needed to know specific situations and necessities, as well as data for other territories. The information collected can be used to do advocacy and promote a higher implication from authorities.

ACECOVA has used these results to instigate more effective actions and specific studies in public hospitals. Moreover, the survey has helped to convene a meeting with the Health Care Managing Director.

In the meeting, he has committed to send the study, as well as a letter to every health department manager. On top of that, a revision three months later of the public hospital situation in this matter has been established.

Furthermore, at this meeting other important topics about coeliac disease and public health have been discussed, e.g. gluten free food in blood donations.

On a related note, ACECOVA has used the same survey's structure to study the state of gluten free food availability at universities.



CONTACT

If you have any questions regarding the content in this brochure, please contact us at **helpdesk@aoecs.org**, or visit our webpage **www.aoecs.org**

AOECS
Association of European Coeliac Societies

This brochure was created in Jan. 2025 by the Association of European Coeliac Societies (AOECS). The AOECS is an international non-profit association, registered in Belgium. Registered number: BE0460502154. Registered Office: 4, Rue de la Presse, B-1000 Brussels, Belgium